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1. Introduction

The objective of WP4 “Quality of life and validation report” phase is: Recruit older adults who will use the technology over a period of time for evaluating its impact on older adults’ QoL, and for clinically validating the technology.

The main activities in the tasks are:

1. Pilot Specification and Recruitment Methodology. Describe the environment where vINCI will be deployed and the behaviours/biomarkers that will be monitored. Select individuals to be participants of the pilots, as well as members of a control group wherever applicable.
2. Baseline for Wellbeing Metrics and Quantitative Observational Models. Measure the general wellbeing and QoL of older adults before the application and use of technology (as an on-going longitudinal study focusing on the task of producing wellbeing “scores”). The wellbeing of older adults will be assessed at different granularities for the purposes of proactive autonomous reporting.
3. Assistive Care Clinical Validation. This task aims to ensure that the impact of technology is well measured and evaluated, so we'll apply technology for a period of time and measure participants’ QoL again, to capture any differences in the pre-technology and post-technology intervention scores. Identify the areas that have changed.

2. Pilots, Quality of Life, and Validation

The validation study of vINCI technology implies:

A. Acceptability Testing (3 consecutive tests)

B. Clinical Testing.

- A. Acceptability Testing: users will test each device (Smart Tablet-ST, Smart Insole-SI, Smart Watch-SW and Smart Camera-SC) over 7 days in three different and successive steps (Test I and Test III – Romania, Test II – Cyprus); during this delay technological adaptations were possible.
- B. Clinical Testing: Clinical validation of vINCI Technology (test-retest: WHOQOL-BREF & IPAQ).
 - duration: 7 days
 - Romania clinical pilot site: 30 users Experimental Group and 30 subjects Control Group.

The user tested all vINCI technology over 7 days delay in different steps (Acceptability & Clinical Testing), so each device was tested during 28 days in total.

2.1 Romania NIGG Pilot

The aim of the vINCI project was to develop a self-health care instrument designed for independent use by older people in order to enable early identification of modifiable health risk factors and also allow lifestyle adjustment without medical intervention unless deemed necessary. This kind of health care is prophylactic, known as primary prevention, therefore we employed a strict and carefully chosen set of eligibility criteria for selecting participants. The target population for the vINCI project were older people without major disabilities or health problems.

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

Before starting the Acceptability Study, it was made a descriptive model of the patient, by assessing the needs of the subjects involved. The objective was to identify the user needs with regard to independently using the vINCI technology for assessing their daily physical activities, location, well-being and general health status as well as the potential benefits of vINCI technology for supporting medical and informal care. Two different but similar User Needs questionnaires were handed over to a sample of patients and to a sample of carers for self-completion.

The User Needs Questionnaires for Patients were completed by a total number of 62 subjects after they had signed the Informed Consent. All consecutive patients 65 years of age and older admitted to NIGG - Geriatrics and Gerontology Inpatients and Outpatients Departments on referral from general practitioners or other specialist for various chronic or subacute conditions were considered for inclusion and evaluated against exclusion criteria after signing the Informed Consent. In order to ensure consistency throughout the Validation Study, we defined the same target population by using the same exclusion criteria applied to vINCI technology Test Study sample. The User Needs Questionnaires for Carers were completed by a total number of 62 subjects after they had signed the Informed Consent. The carers sample included medical doctors and nurses working at the NIGG - Geriatrics and Gerontology Inpatients and Outpatients Departments.

The Acceptability Study I and III were conducted at NIGG “Ana Aslan”.

Test I included a total number of 20 users, each device was tested by 5 users who completed Acceptability Questionnaire. After Acceptability Study I the devices were technologically adapted to the users’ feedback and underwent Acceptability Study II in Cyprus. Again, the devices were technologically adapted to the users’ feedback and the entire vINCI platform was then tested during Acceptability Study III in Romania.

Test III included a total number of 20 users who tested entire vINCI technology and completed Acceptability Questionnaire.

The Clinical Validation study included a total number of 60 participants (an additional 30 subjects to the initial plan). The Clinical Validation Study is a randomized clinical study. Two groups of equal numbers of subjects were selected, 30 patients for experimental group and 30 patients for control group.

2.1.1 Methodology

Participants and study design

All consecutive patients 65 years of age and older admitted to the “Ana Aslan” Institute of Gerontology and Geriatrics on the geriatric ward on referral from general practitioners or other specialist for various chronic or subacute conditions were considered for inclusion in the Clinical Validation Study and then evaluated against exclusion criteria. In the first 3 days from the hospital admittance all patients were screened for study inclusion against eligibility criteria until the sample target number was reached. Two groups of equal numbers of subjects were selected, 30 patients each, one experimental and one control group.

The inclusion criteria were older people 65 years of age and older living independently in their communities.

The exclusion criteria were:

- acute medical condition,
- surgery in the last 3 months,
- major neurocognitive disorder (Mini-Mental State Examination, MMSE ≤ 20),
- moderate and severe depression (Geriatric Depression Scale – Short Form GDS-SF > 10),
- existing disability (ADL - needs human help in one or more basic activities of daily living),
- heart failure functional class NYHA III-IV,
- angina pectoris,
- uncontrolled high blood pressure (> 160 mmHg systolic),
- heart arrhythmias (on electrocardiogram) that could interfere with functionality,
- peripheral arterial disease,
- frailty syndrome (PRISMA 7 ≥ 3 “yes” answers),
- risk of falls (Tinetti Tool Score < 24),
- conditions that might limit mobility (e.g. Parkinson’s disease, severe arthritis, stroke sequela),
- visual impairment (best corrected visual acuity of worse than either 20/40 or 20/60),
- subjects not living in the catchment area (Bucharest).

Exclusion criteria were documented by medical examination, anamnesis and from patients’ medical charts and documented medical history. Prior to study initialization, all seniors signed the Informed Consent form. The persons who do not sign the Informed Consent were excluded. All potential participants filled in a Digital Skills Questionnaire (DSQ) to evaluate their computer and technological literacy. Seniors who scored low on the DSQ were excluded from inclusion in the study group. Inclusion and exclusion criteria were applied to both experimental and control groups.

At inclusion, each participant received a study number in a sealed envelope, in the order of inclusion. Two equal sets of 30 randomly generated numbers (from 1 to 60) were designated to identify participants in the experimental and control groups. After inclusion, the envelopes were opened and participants were distributed to the experimental and control groups according to their study number. Participants in the experimental group received the vINCI devices for testing over a period of 7 days while participants in the control group received only usual care, not used vINCI technology. At the beginning of day 1, each experimental group participant received instructions on how to use each device and filled in the WHOQOL-BREF and IPAQ questionnaires on the smart tablet. Technical support was available to the patients if it was needed. At the beginning of day 1, each control group participant received the WHOQOL-BREF and IPAQ questionnaires in printed form for self-completion. After 7 days,

on the 8th day of the study, participants in both experimental and control groups filled in the follow-up WHOQOL-BREF and IPAQ questionnaires, only participants of experimental group filled in the Satisfaction Questionnaire on the smart tablet.

2.1.2 Acceptability of vINCI technology

2.1.2.1 Acceptability testing

Testing Strategy

The Acceptability Study had 2 parts (Figure 2.1):

- Acceptability Test of individual smart devices (SD): Test I - Romania and Test II – Cyprus,
- Test III - Acceptability Test of the entire vINCI Platform – Romania.

After each test the devices (Smart Watch, Smart Insole, Smart Tablet, Smart Camera) were technologically revision based on users' feedback and preferences.

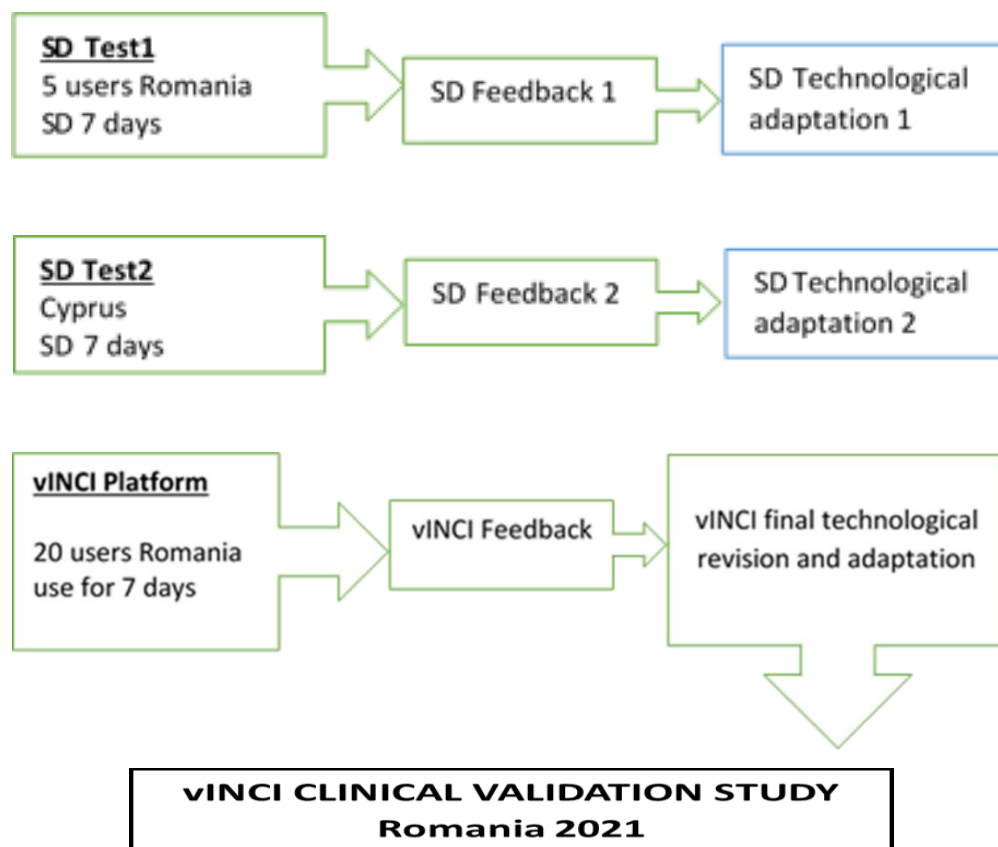


Figure 2.1 "The vINCI Pilot Study" - NIGG Romania

Recruitment and sampling

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 were considered

for inclusion in the Acceptability Study and then evaluated against exclusion criteria. In the first 3 days of hospital admittance all patients were screened for study inclusion against inclusion and exclusion criteria and for computer digital skills until the sample target number was reached.

The Acceptability Test I was conducted during January - March at the NIGG “Ana Aslan”. A total number of 20 users tested each device and completed the Acceptability Questionnaire. Each device (Smart Watch, Smart Insole, Smart Tablet, Smart Camera) was tested by 5 users. After Acceptability Test I the devices were technologically adapted to the users’ feedback and underwent Acceptability Test II in Cyprus. Again, the devices were technologically adapted to users’ feedback and the entire vINCI platform was then tested during the Acceptability Test III in Romania.

The Acceptability Test III was conducted during August - October at the NIGG “Ana Aslan”. A total number of 20 users tested the entire vINCI platform and completed the Acceptability Questionnaire. The initial Project Plan specified a number of 10 users for Acceptability Test III but, in order to increase the reliability of the results, we decided to add another 10 users to the sample.

The eligibility criteria used were the same as for the Clinical Validation Study which took place in the next phase of the project.

The inclusion criteria

- age \geq 65 years,
- presence of digital skills,
- signed Informed Consent,
- preserved basic functional independence,
- adequate compliance with study protocol.

All potential participants filled in the Digital Skills Questionnaire (DSQ) to evaluate their computer and technological literacy. Seniors who scored low on the DSQ were excluded.

Prior to study initialization, all seniors signed the Informed Consent form. The participants who did not sign the Informed Consent were excluded.

The exclusion criteria

- acute medical condition,
- surgery in the last 3 months,
- major neurocognitive disorder (Mini-Mental State Examination, MMSE \leq 20),
- moderate and severe depression (Geriatric Depression Scale – Short Form GDS-SF $>$ 10),
- existing disability (ADL - needs human help in one or more basic activities of daily living),
- heart failure functional class NYHA III-IV,

- angina pectoris,
- uncontrolled high blood pressure (>160 mmHg systolic),
- heart arrhythmias that could interfere with functionality,
- peripheral arterial disease,
- frailty syndrome (PRISMA 7 \geq 3 “yes” answers)
- risk of falls (Tinetti Tool Score < 24),
- conditions that might limit mobility (e.g. Parkinson’s disease, severe arthritis, stroke sequela),
- visual impairment (best corrected visual acuity of worse than either 20/40 or 20/60),
- subjects not living in the catchment area (Bucharest).

Exclusion criteria were documented by medical examination, anamnesis and from patients’ medical charts and documented medical history.

Participants who did not fully comply with vINCI instructions or did not appropriately use vINCI devices, were excluded from the Acceptability Study.

2.1.2.2 Acceptability Study - Test I

We adapted and discussed the need for further modifications of the Smart Shoes, which were transformed into Smart Insoles for ease of use and adaptability. Several further technical changes of the Smart Insoles were also requested. The Smart Cameras were installed in a specifically designated room and several technical adjustments were performed. The research team members received instructions on how to use each device during a series of meetings and workshops.

None of the smart devices were fully functional. The devices were tested without data transmission and processing.

Smart Watch (SW), Smart Insole (SI) and Smart Camera (SC) was tested by the users for a period of 7 days, the Smart Tablet (ST) for 2 days.

The users received detailed verbal and written instructions about how to use the device. At the end of the testing period all users filled in the semi-structures Acceptability Questionnaire.

The Smart Camera was installed in a dedicated room at the NIGG “Ana Aslan”, similar to the other geriatrics ward rooms.

Results

All users found the instructions on how to use the device clear for all devices (Figure 2.2).



Figure 2.2 Acceptability Test I - Feedback for “The instructions on how to use the device”.

One user found the Smart Watch was uncomfortable on the wrist. One user had a neutral opinion about the Smart Tablet. All other users found the smart devices comfortable when using them (Figure 2.3).

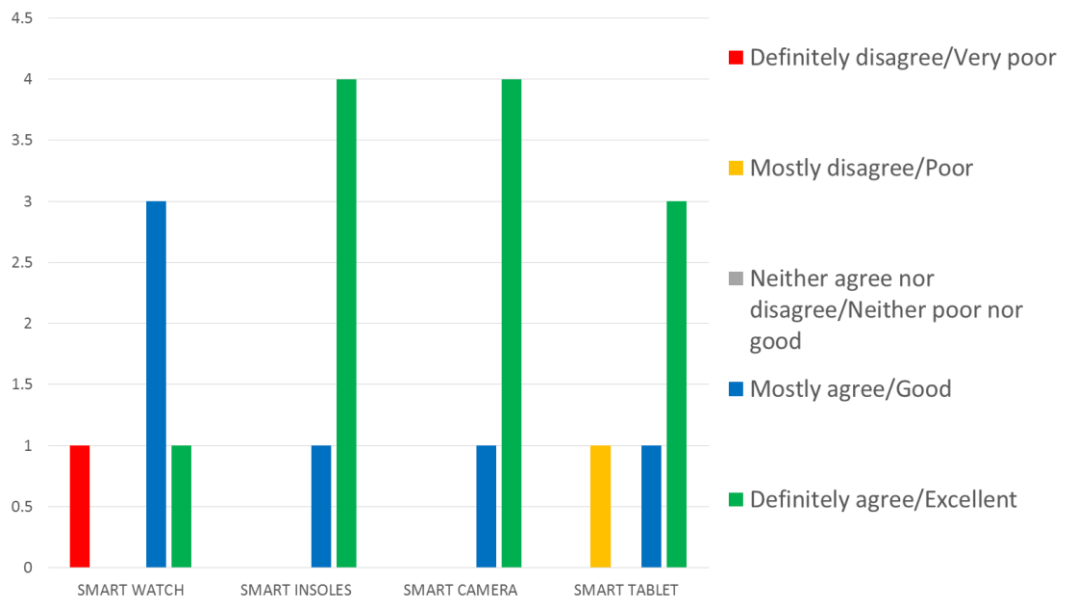


Figure 2.3 Acceptability Test I - Feedback for “The device was comfortable”.

Regarding the ease of use of the smart device, 2 users “Mostly disagreed” with the ease of use of the ST, while 3 of the users “Definitely agreed”. The majority of the users (4 out of 5) considered the SI very easy to use. The ease of use of the SW and SC received neutral feedback from the majority of the users (Figure 2.4).

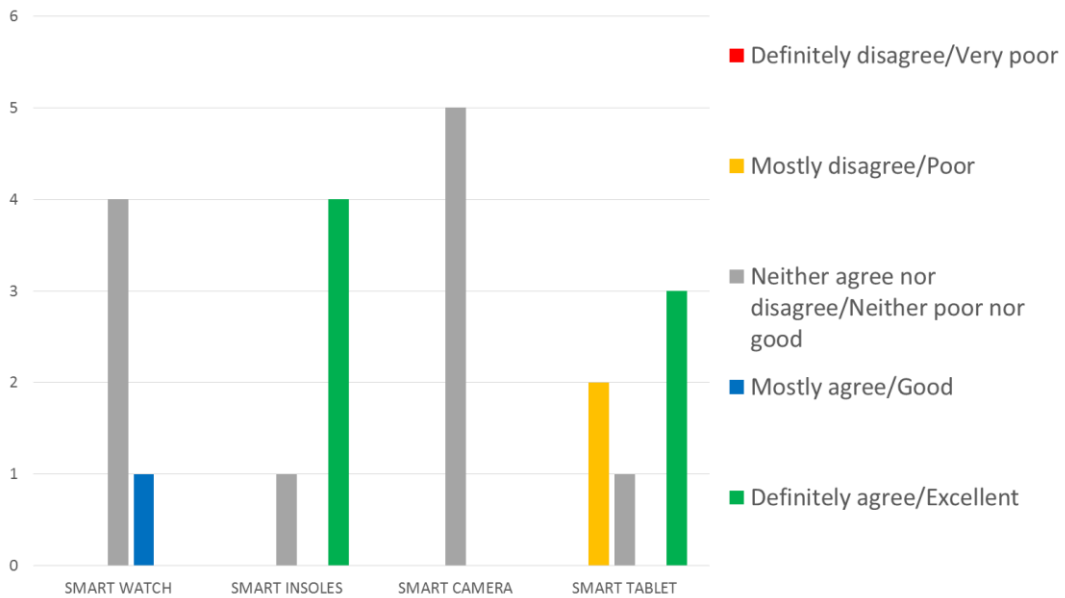


Figure 2.4 Acceptability Test I - Feedback for “The device was easy to use”.

All users had a neutral opinion of the usefulness of the smart devices (Figure 2.5).

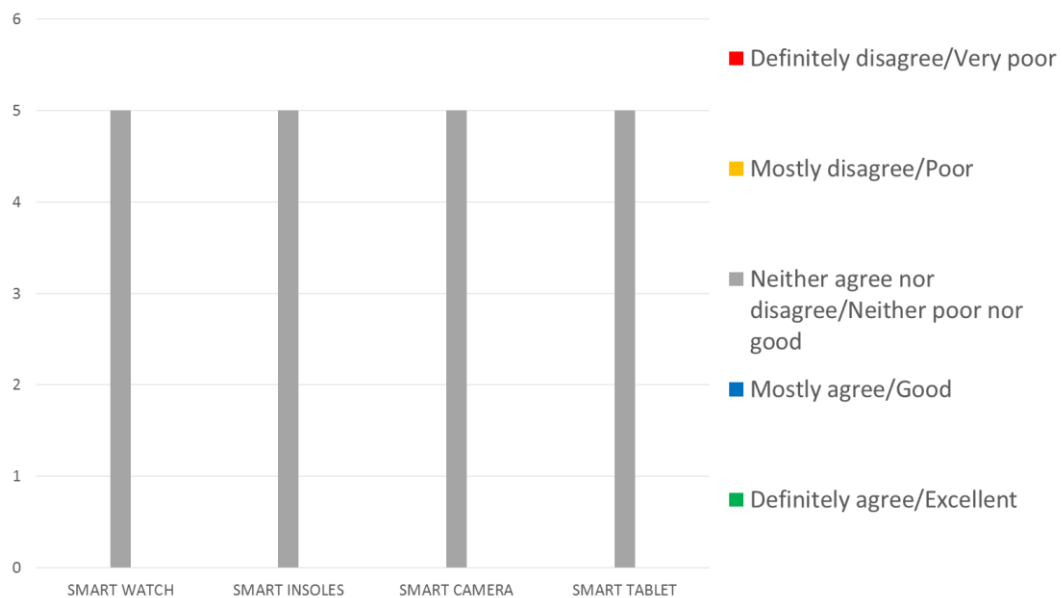


Figure 2.5 Acceptability Test I - Feedback for “The device was useful”.

The overall rating of the smart devices was positive: 2 users rated the SW “Good” and “Excellent”, 4 users rated the SI “Good”, 2 users rated the SC “Good” and 4 users rated the ST “Good” and “Excellent” (Figure 2.6).

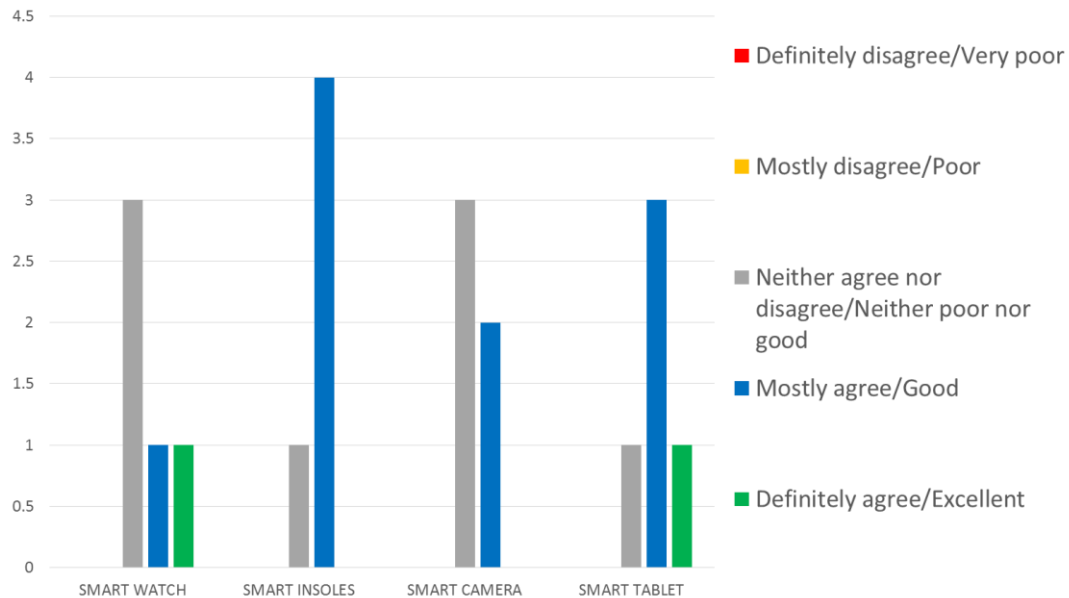


Figure 2.6 Acceptability Test I - Feedback for “How would you rate the device”.

The open-ended questions of the Acceptability Questionnaire received the following answers:

Smart Watch

- because of its big dimensions and rigidity of the fastening system it creates discomfort for the patient.

Smart Insole

- it does not provide sufficient fastening on the shoe, it easily detaches from the side fixed to the shoe, probably if it would increase the fastening surface, the problem would be solved.
- it would be necessary to reposition the fastening bar because sometimes it comes in contact with the ankle causing discomfort to the patient.

Smart Tablet

- the screen is not sensitive enough to touch, requiring a too strong touch which generates errors.

Smart Camera

- by not using it directly, patients could not provide feedback for this device.

Research Team Feedback:

- the Smart Insoles could be attached only to the shoe which is a problem for patients who have hospital footwear (slippers).
- the Smart Insoles register steps even when the device is not functioning.

- the Smart Camera covers only 2 of 3 beds which makes it difficult using the device for all available patients, implicitly increasing the testing period.
- the question about the utility from the acceptability questionnaire does not have relevance for any of the devices.

2.1.2.3 Acceptability Study - Test III

After the devices were adapted by the technological partners according to the feedback provided, we tested the entire vINCI platform on a total number of 20 users.

The recruitment, inclusion and testing processes were the same as for the Acceptability Test I.

Results

The majority of the users found the instruction clear (19/20) (Figure 2.7).

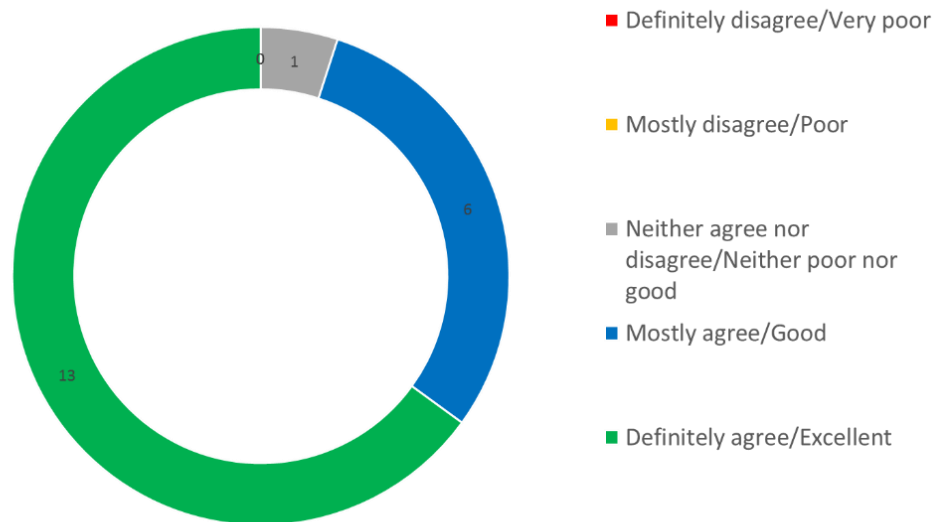


Figure 2.7 Acceptability Test III - Feedback for “The instructions on how to use the vINCI platform”.

The majority of the users thought that the vINCI platform was easy to use, while only one user disagreed with (Figure 2.8).

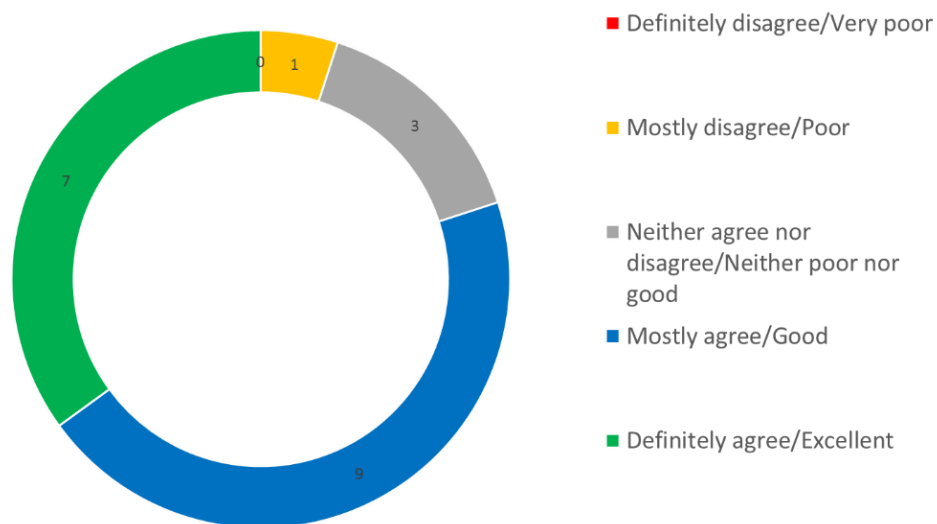


Figure 2.8 Acceptability Test III - Feedback for “The vINCI platform was easy to use”.

However, the majority of the users opted for “Neither agree nor disagree” answer when asked if they found the vINCI platform useful, the same result as at the first testing (Figure 2.9).

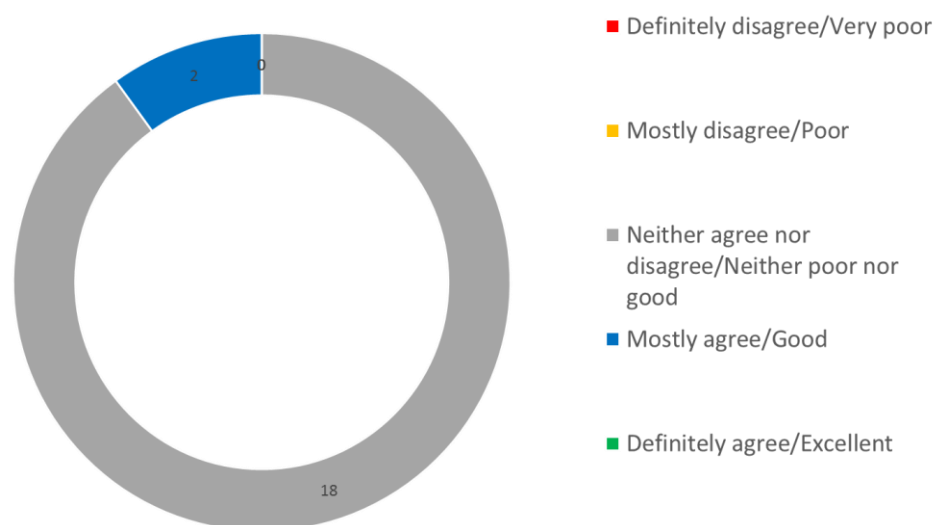


Figure 2.9 Acceptability Test III - Feedback for “The vINCI platform was useful”.

Out of the 20 participants, 8 rated the vINCI platform “Good” or “Excellent” and none “Very Poor” nor “Poor” (Figure 2.10).

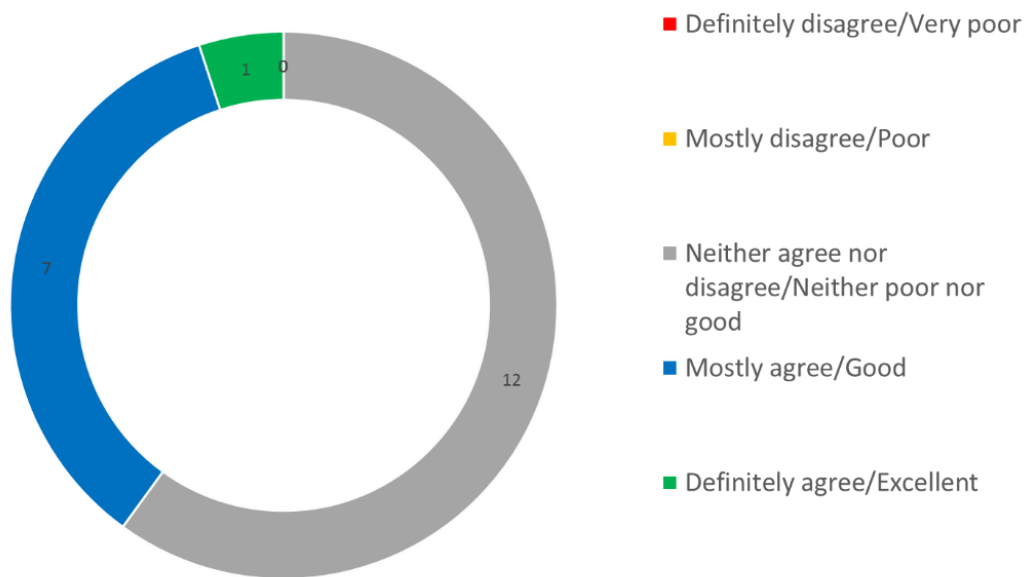


Figure 2.10 Acceptability Study III - Feedback for “How would you rate the vINCI platform”.

The open-ended part of the Acceptability Questionnaire received the following answers: “It looks nice and it feels comfortable. I was enjoying the communication with the doctor.” “It is safe and easy to use.”, “It’s trustworthy and safe. I don’t like the black colour of the watch and insoles.”, “It was fun to be a part of this project. The insoles are not very comfortable, it slips out.”, “It would make me feel safe.”, “The watch strap is not comfortable. It’s difficult to change the insoles batteries.”, “It takes too long to use the tablet.”, “I think I would constantly worry about running out of batteries.”, “I don’t like the camera, I feel like it’s watching me.”, “It’s not working like it was explained to me.”, “It’s very useful, it helps me take better care of myself and I can be in touch with the doctor.”, “It could be useful when you understand how it works”. “Charging them is an additional worry.”, “I wouldn’t use the camera in my personal space.”

Conclusions of Acceptability Study

- The majority of the users found the instructions on how to use the vINCI platform and devices clear and easy to understand.
- The majority of the users thought the vINCI platform and devices were easy to use.
- The majority of the users felt neutral about the vINCI devices being useful.
- Only 40% of the users rated the vINCI platform “Good” or “Excellent”.

2.1.3 Data collection

2.1.3.1 Quality of life assessment (WHOQOL-BREF)

Background

The quality of life (QOL) questionnaire is the language version of the World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF). We have a legal agreement between us and World Health Organization (WHO), granting us a licence to use the Licensed Materials subject to their terms and conditions. WHO grants this licence to us based on the representation and warranties we made in the licence request we submitted through WHO's online platform. We received from them all three versions that we requested for WHOQOL-BREF: Romanian, Slovenian and Cypriot versions.

The WHOQOL-BREF comprises 26 items (questions), 24 of these items are divided into four domains: Physical, Psychological, Social, and Environment (Table 2.1). Two individual items assess the perception of overall QOL and general health. All items are rated on a 5-point scale, with higher scores indicate higher QOL.

Table 2.1 WHOQOL-BREF - domains and items

| Domain | ID | Items |
|----------------------|-----|----------------------------|
| Physical Health | Q3 | Physical pain |
| | Q4 | Dependence medication |
| | Q10 | Energy |
| | Q15 | Mobility |
| | Q16 | Sleep and rest |
| | Q17 | Activities of daily living |
| | Q18 | Working capacity |
| Psychological Health | Q5 | Life enjoyment |
| | Q6 | Meaningfulness of life |
| | Q7 | Concentration |
| | Q11 | Body appearance |
| | Q19 | Self-esteem |
| | Q26 | Negative feelings |
| Social Relationships | Q20 | Personal relationship |
| | Q21 | Sexual activity |
| | Q22 | Social support |
| Environment | Q8 | Safety |
| | Q9 | Physical environment |
| | Q12 | Financial resources |
| | Q13 | Daily information |
| | Q14 | Leisure |

Q23 Home environment

Q24 Access to health care

Q25 Transport

In order to achieve vINCI project's objectives we have to manage the WHOQOL-BREF 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 published WHOQOL-BREF 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 (Silva et al., 2014; vINCI, 2019).

An QOL ≥ 60 cut-off point moderately sensitive for recognizing individuals with good / satisfactory QOL and a QOL < 60 cut-off optimum negative predictive value for screening older adults whose QoL was poor / unsatisfactory (vINCI, 2019).

In our studies 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.

2.1.3.2 Physical activity assessment (IPAQ-SF)

Background

Physical activity (PA) is an important component of a healthy lifestyle and it influences the health and wellness of individuals (WHO, 2018). The importance of physical activities in terms of enhancing health and reducing the risk of chronic diseases has been widely documented. According to Ainsworth (2009), many different methods are available for assessing physical activity, including objective (such as accelerometers, heart rate monitors) and subjective (such as questionnaires, observation) measurements.

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, and (d) transport-related physical activity. The IPAQ is available in short and long versions and can be either self-administered or telephone / interview administered. Latest versions of IPAQ instruments are available from www.ipaq.ki.se.

The IPAQ short form (IPAQ-SF), used in the present study, asks about three

specific types of activity undertaken in the four domains introduced above. The items in the IPAQ-SF 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.

There are three categorical levels of physical activity scoring to classify populations through the IPAQ: 'low', 'moderate' and 'high'. Criteria set for each of the levels consider each question asked on the IPAQ-SF (IPAQ, 2005; Craig, et al. 2003).

The 'high' category describes high levels of physical activity participation: either >1500 MET-minutes/week (consisting of vigorous activity on at least three days), or >3000 MET-minutes/week (consisting of any combination of activities across seven days). This provides a higher threshold of measures of total physical activity and is useful to examine population variation.

The 'moderate' category defines an individual to be participating in some activity, more than those in the 'low' category (600 to 1499 MET-minutes/week).

Those in the 'low' category do not engage in at least half an hour moderate-intensity physical activity most days (0 to 599 MET-minutes/week). Individuals in the 'low' category do not meet any criteria from the high or moderate categories, and are not participating in any regular physical activity.

MET minutes represent the amount of energy expended carrying out physical activity. A MET is a multiple of your estimated resting energy expenditure. One MET is what you expend when you are at rest. Therefore 2 METS is twice what you expend at rest. To get a continuous variable score from the IPAQ (MET-minutes/week) we will consider walking to be 3.3 METS, moderate physical activity to be 4 METS and vigorous physical activity to be 8 METS.

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. 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.

For each IPAQ Category, vINCI provides the following recommendations (vINCI, 2019):

- 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.

2.1.4 Data analysis and processing - WHOQoL

Data analysis was performed using IBM SPSS Statistics 24. Descriptive statistics were reported for the socio-demographic variables by mean \pm standard deviation or proportion, as appropriate.

In the first step, we used the SPSS syntax file (WHOQOL Group, 1996) that automatically checks, recodes data and computes domain scores for scales in the range 4-20. Then, we used a SPSS syntax file developed by the vINCI team to calculate the domain scores for scale in the range 0-100.

After these actions, we analyzed the data from the samples both at the level of the items and at the level of each WHOQOL-BREF domain.

At the level of the items, descriptive statistics were calculated and reported (e.g., mean, standard deviation, median) and the Shapiro-Wilk normality test was performed.

At the level of the domains, descriptive statistics were calculated and reported. Construct validity was evaluated by domain-to-domain correlations and by correlating item Q1 (Overall QOL) and item Q2 (General health) with the four domains in the WHOQOL-BREF using Pearson correlation coefficient.

Then, independent-sample t-tests were performed to compare the scores of each domain for socio-demographic variables (gender, age, education, marital status, and health status) and to identify differences between different groups

of patients across domains. Thus, we determined the patient profile in each sample considered.

Finally, paired-samples t-test were conducted to compare the scores of the domains for different sample pairs, as appropriate.

2.1.5 Results

2.1.5.1 Results - the control sample (day 1 and day 8)

Sample characteristics

Data were collected for the same participants on both the first day and the eighth day. The control sample (day 1 and day 8) consisted of 30 participants with a mean age of 72.5 years (SD= \pm 6.09; range of 65–85). The sample comprised equal numbers of men and women. The majority had secondary education (76.7%) and more than half (56.7%) of the participants were married. More information on socio-demographic characteristics of participants is shown in Table 2.2.

Table 2.2 Participant characteristics

| Control sample, N=30, day 1 and day 8 | |
|---------------------------------------|-----------------|
| Sex, <i>n</i> (%) | |
| Male | 15 (50.0) |
| Female | 15 (50.0) |
| Age | |
| Mean (SD) | 72.50 (6.09) |
| Range | 65–85 |
| Marital status, <i>n</i> (%) | |
| Single | 1 (3.3) |
| Married | 17 (56.7) |
| Divorced | 2 (6.7) |
| Living as married | 1 (3.3) |
| Widowed | 9 (30.0) |
| Education, <i>n</i> (%) | |
| Primary school | 0 (0.0) |
| Secondary school | 23 (76.7) |
| Tertiary / Higher education | 7 (23.3) |
| Health status, <i>n</i> (%) | |

| | |
|-----------|-----------|
| Healthy | 10 (33.3) |
| Unhealthy | 20 (66.7) |

Item-level analysis

In the control sample (day 1) the overall mean of the 24 items was 3.76 and the average correlation was .15. Items Q23 (*home environment*), Q24 (*access to health care*), Q13 (*daily information*), Q20 (*personal relationship*), and Q26 (*negative feeling*) were the five highest scoring items. On the other hand, Q4 (*dependence medication*) and Q16 (*sleep and rest*) scored lowest among the 24 items (see, Table 2.3).

Table 2.3 Items: summary statistics (control sample, day 1, N=30)

| Items | Mean | Std. Dev. | Median | Skewness | Kurtosis |
|------------------|------|-----------|--------|----------|----------|
| Q1 | 4.13 | .507 | 4.00 | .266 | .945 |
| Q2 | 3.57 | .858 | 4.00 | -.396 | -.359 |
| Q3 ^{a)} | 3.23 | 1.104 | 3.00 | -.168 | -.397 |
| Q4 ^{a)} | 2.77 | 1.135 | 3.00 | .645 | .100 |
| Q5 | 3.87 | .776 | 4.00 | -.707 | .797 |
| Q6 | 3.90 | .712 | 4.00 | -.467 | .673 |
| Q7 | 3.57 | .728 | 4.00 | -.247 | .010 |
| Q8 | 3.70 | .702 | 4.00 | .499 | -.781 |
| Q9 | 4.07 | .691 | 4.00 | -.087 | -.770 |
| Q10 | 3.70 | .952 | 4.00 | -.108 | -.886 |
| Q11 | 3.87 | .937 | 4.00 | -1.066 | 1.867 |
| Q12 | 4.00 | .788 | 4.00 | -.453 | -.034 |
| Q13 | 4.17 | .699 | 4.00 | -.240 | -.831 |
| Q14 | 3.83 | .874 | 4.00 | -.319 | -.474 |
| Q15 | 3.47 | 1.167 | 4.00 | -.054 | -1.475 |
| Q16 | 3.00 | 1.174 | 3.00 | -.137 | -.573 |
| Q17 | 3.87 | .730 | 4.00 | -.355 | .293 |
| Q18 | 3.67 | .758 | 4.00 | -.358 | .116 |
| Q19 | 3.97 | .718 | 4.00 | -.548 | .830 |
| Q20 | 4.17 | .699 | 4.00 | .409 | .591 |
| Q21 | 3.37 | .964 | 3.00 | -.335 | .030 |
| Q22 | 3.73 | .640 | 4.00 | -.556 | .864 |
| Q23 | 4.43 | .679 | 5.00 | -.805 | -.402 |
| Q24 | 4.20 | .847 | 4.00 | -1.139 | 1.275 |

| | | | | | |
|-------------------|------|------|------|-------|-------|
| Q25 | 3.47 | .629 | 3.00 | .133 | -.104 |
| Q26 ^{a)} | 4.17 | .834 | 4.00 | -.715 | -.083 |

^{a)} Q3, Q4 and Q26 have been reversed coded.

The mean scores \pm SD for the other two questions Q1 and Q2, scored on a 5-point Likert scale and scored from 1 to 5 (ranged from very poor to very good and very dissatisfied to very satisfied, respectively), were 4.13 ± 0.51 and 3.57 ± 0.89 , respectively (Table 2.3). These questions should be evaluated separately and are not included in a domain, as per the WHOQOL-BREF manual (WHOQOL Group, 1998; WHO, 1998).

Also, we calculated the coefficients of skewness and kurtosis (Table 2.3). The acceptable range is -1.00 to 1.00. Three items were outside this range (for skewness and/or kurtosis). For example, item Q11 (*body appearance*) had a skewness and a kurtosis coefficient of -1.066 and 1.382, respectively, and item Q15 (*mobility*) a kurtosis coefficient of -1.475.

The Shapiro-Wilk test showed a significant result at the item level ($p < 0.05$), which indicates that data were non-normal distributed.

In the control sample (day 8) the overall mean of the 24 items was 3.84 and the average correlation was .21. Items Q23 (*home environment*), Q20 (*personal relationship*), Q13 (*daily information*), and Q24 (*access to health care*) were the four highest scoring items. On the other hand, Q4 (*dependence medication*) and Q16 (*sleep and rest*) scored lowest among the 24 items (see, Table 2.4).

Table 2.4 Items: summary statistics (control sample, day 8, N=30)

| Items | Mean | Std. Dev. | Median | Skewness | Kurtosis |
|------------------|------|-----------|--------|----------|----------|
| Q1 | 4.20 | .551 | 4.00 | .106 | .097 |
| Q2 | 3.90 | .845 | 4.00 | -.904 | .813 |
| Q3 ^{a)} | 3.30 | 1.088 | 3.00 | .038 | -.649 |
| Q4 ^{a)} | 2.77 | 1.194 | 2.00 | .484 | -.789 |
| Q5 | 4.07 | .691 | 4.00 | -.758 | 1.753 |
| Q6 | 4.07 | .740 | 4.00 | -.108 | -1.085 |
| Q7 | 3.63 | .669 | 4.00 | -.155 | .090 |
| Q8 | 3.77 | .626 | 4.00 | .201 | -.453 |
| Q9 | 4.17 | .699 | 4.00 | -.240 | -.831 |
| Q10 | 3.97 | .928 | 4.00 | -.763 | .018 |
| Q11 | 3.77 | 1.073 | 4.00 | -.756 | .137 |
| Q12 | 3.93 | .640 | 4.00 | -.793 | 2.283 |
| Q13 | 4.23 | .626 | 4.00 | -.201 | -.453 |
| Q14 | 3.83 | .699 | 4.00 | -.409 | .591 |

| | | | | | |
|-------------------|------|-------|------|--------|-------|
| Q15 | 3.77 | .971 | 4.00 | -.462 | -.609 |
| Q16 | 3.20 | 1.215 | 3.00 | -.287 | -.829 |
| Q17 | 3.70 | .988 | 4.00 | -.487 | -.655 |
| Q18 | 3.70 | .915 | 4.00 | -.497 | -.362 |
| Q19 | 4.07 | .583 | 4.00 | .003 | .229 |
| Q20 | 4.30 | .750 | 4.00 | -1.094 | 1.621 |
| Q21 | 3.63 | .765 | 4.00 | -.236 | -.043 |
| Q22 | 3.83 | .834 | 4.00 | -.050 | -.785 |
| Q23 | 4.53 | .571 | 5.00 | -.732 | -.429 |
| Q24 | 4.23 | .858 | 4.00 | -1.889 | 5.892 |
| Q25 | 3.67 | .547 | 4.00 | -.050 | -.699 |
| Q26 ^{a)} | 4.10 | .759 | 4.00 | -1.187 | 2.497 |

^{a)} Q3, Q4 and Q26 have been reversed coded.

The mean scores \pm SD for the other two questions Q1 and Q2, scored on a 5-point Likert scale and scored from 1 to 5 (ranged from very poor to very good and very dissatisfied to very satisfied, respectively), were 4.20 ± 0.55 and 3.90 ± 0.84 , respectively (Table 2.4).

Five items were outside of the acceptable range (for skewness and/or kurtosis). For example, item Q20 (*sexual activity*) had a skewness and a kurtosis coefficient of -1.094 and 1.621, respectively, and item Q5 (*life enjoyment*) a kurtosis coefficient of 1.753 (Table 2.4). The Shapiro-Wilk test showed a significant result at the item level ($p < 0.05$), which indicates that data were non-normal distributed.

Figure 2.11 shows the average of the items on day 1 and day 8. A paired-samples t-test was conducted to compare the items scores for day 1 and day 8. There was no significant difference in scores for day 1 and day 8 (the results are not shown).

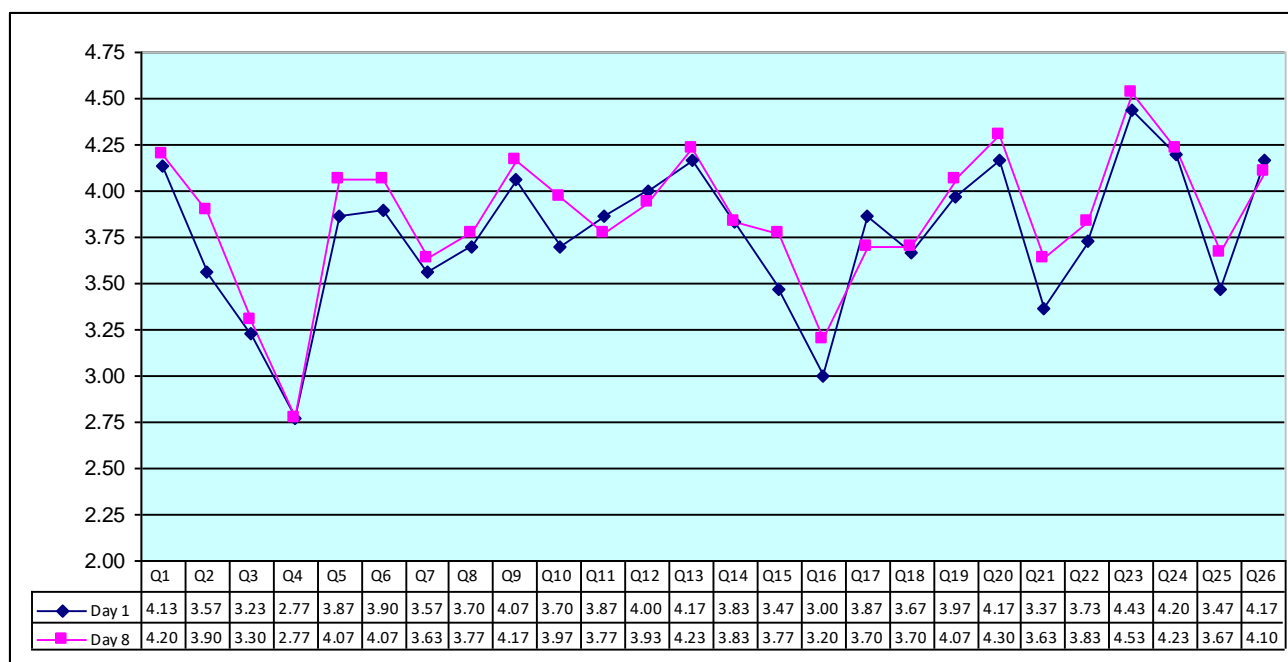


Figure 2.11 The mean scores of the 26 items in WHOQOL-BREF scale (control sample, day 1 and day 8, N=30)

Domain-level analysis

The mean scores \pm SD for the four domains of the WHOQOL-BREF, physical, psychological, social, and environmental domains in the transformed scores of 0-100 are showed in Table 2.5 (day 1) and Table 2.6 (day 8), respectively. Comparing the four domains, environmental domain was the highest with a mean score of 74.58 (day 1) and 76.12 (day 8), while the physical domain was the lowest (59.64 and 62.15, respectively).

Table 2.5 Domains: summary statistics (transformed scores 0-100; control sample, day 1, N=30)

| Domain | Mean (SD) | Median | Minimum | Maximum | Skewness | Kurtosis |
|---------------|---------------|--------|---------|---------|----------|----------|
| Physical | 59.64 (16.78) | 62.50 | 32.14 | 96.43 | .228 | -.557 |
| Psychological | 72.22 (11.34) | 72.92 | 54.17 | 91.67 | -.080 | -.977 |
| Social | 68.89 (9.00) | 66.67 | 50.00 | 91.67 | .127 | .917 |
| Environment | 74.58 (11.00) | 75.00 | 53.13 | 93.75 | -.125 | -.865 |

Table 2.6 Domains: summary statistics (transformed scores 0-100; control sample, day 8, N=30)

| Domain | Mean (SD) | Median | Minimum | Maximum | Skewness | Kurtosis |
|---------------|------------------|--------|---------|---------|----------|----------|
| Physical | 62.15 (18.98) | 64.29 | 17.86 | 96.83 | -.428 | -.063 |
| Psychological | 73.75 (11.69) | 75.00 | 50.00 | 100.00 | .079 | -.211 |

| | | | | | | |
|-------------|------------------|-------|-------|--------|--------|-------|
| Social | 73.06 (12.70) | 75.00 | 50.00 | 100.00 | .235 | -.068 |
| Environment | 76.12 (10.13) | 78.12 | 43.75 | 93.75 | -1.166 | 2.231 |

An QOL ≥ 60 cut-off point moderately sensitive for recognizing patients with good / satisfactory QOL and a QOL < 60 cut-off optimum negative predictive value for screening patients whose QoL was poor / unsatisfactory (VINCI, 2019). A total score below 60 points signals impaired QOL (social domain in day 1) and a score of at least 60 points identifies patients with a good QOL (all other domains on day 1 and day 8).

The relationship between the four domains, overall QOL and general health was investigated using Pearson product-moment correlation coefficient. Results are shown in Table 2.7 (day 1) and Table 2.8 (day 8).

In the control sample (day 1), the Pearson correlation coefficient showed a high positive correlation between the physical and psychological domains, with high levels of physical domain associated with higher levels of psychological domain ($r=.65$, $p<.01$).

Overall QOL (Q1) was positive interrelated with all the four domains, but significantly only with the psychological domain (moderate, $r=.39$, $p<.05$).

The four domains and general health (Q2) were significantly and positively interrelated with moderate to high relationships, ranged from .43 ($p<.05$) to .58 ($p<.01$), except for environment domain (Table 2.7).

Table 2.7 Pearson correlations of the four QOL domains, overall QOL and general health (day 1)

| | Physical | Psychological | Social | Environment | Overall QOL | General health |
|---------------------|----------|---------------|--------|-------------|-------------|----------------|
| Physical | 1. | .650** | .329 | .279 | .292 | .582** |
| Psychological | | 1. | .262 | .138 | .391* | .522** |
| Social | | | 1. | .064 | .310 | .426* |
| Environment | | | | 1. | .338 | .265 |
| Overall QOL (Q1) | | | | | 1. | .533** |
| General health (Q2) | | | | | | 1. |

* $p<0.05$; ** $p<0.01$

There was a high positive correlation between the overall QOL and general health ($r=.53$, $p<.01$).

In the control sample (day 8), the Pearson correlation coefficient showed a significantly high positive correlation between the physical and psychological domains ($r=.69$, $p<.01$), between the psychological and social domains ($r=.52$, $p<.01$) and between the psychological and environment domains ($r=.50$, $p<.01$).

Also, there was a significantly moderate positive correlation between the physical and social domains ($r=.48$, $p<.01$).

The four domains and overall QOL (Q1) were significantly and positively interrelated with moderate to high relationships, ranged from $.42$ ($p<.05$) to $.57$ ($p<.01$), except for physical domain (Table 2.8).

Table 2.8 Pearson correlations of the four QOL domains, overall QOL and general health (day 8)

| | Physical | Psychological | Social | Environment | Overall QOL | General health |
|---------------------|----------|---------------|--------|-------------|-------------|----------------|
| Physical | 1. | .686** | .484** | .295 | .101 | .573** |
| Psychological | | 1. | .519** | .498** | .521** | .208 |
| Social | | | 1. | .344 | .575** | .398* |
| Environment | | | | 1. | .425* | .218 |
| Overall QOL (Q1) | | | | | 1. | -.081 |
| General health (Q2) | | | | | | 1. |

* $p<0.05$; ** $p<0.01$

General health (Q2) was positive interrelated with all the four domains, but significantly only with the physical domain (high, $r=.57$, $p<.01$) and social domain (moderate, $r=.40$, $p<.05$).

2.1.5.2 Patients profile (WHOQOL-BREF)

In the control sample, separated for day 1 and day 8, were performed independent-sample t-tests to identify differences between the different groups of patients regarding to domains. Results are shown in Table 2.9.

Table 2.9 Results of the WHOQOL-BREF domains by the different demographic variables (day 1, day 8)

| | | | Physical health | Psychological health | Social relationships | Environment domain |
|--------------------------|----------------|-------|----------------------|----------------------|----------------------|----------------------|
| Gender (15+15) | | | | | | |
| Day 1 | Male | M(SD) | 60.24 (18.35) | 74.17 (12.81) | 69.44 (7.50) | 74.17 (11.78) |
| | Female | M(SD) | 59.05 (15.68) | 70.28 (9.69) | 68.33 (10.54) | 75.00 (10.56) |
| | <i>p-value</i> | | .850 | .357 | .742 | .840 |
| Day 8 | Male | M(SD) | 63.57 (19.38) | 77.78 (11.96) | 75.00 (11.36) | 78.33 (8.64) |
| | Female | M(SD) | 60.71 (19.14) | 69.72 (10.26) | 71.11 (14.04) | 73.96 (11.31) |
| | <i>p-value</i> | | .688 | .058 | .411 | .244 |
| Age group (14+16) | | | | | | |
| Day 1 | 65-70 | M(SD) | 66.07 (16.62) | 75.59 (9.51) | 70.83 (8.49) | 75.45 (10.09) |
| | 71-85 | M(SD) | 54.02 (15.26) | 69.27 (12.25) | 67.18 (9.36) | 73.83 (12.01) |

| | | | | | | |
|-------------------------------|-----------------------|-------|----------------------|----------------------|----------------------|----------------------|
| | <i>p-value</i> | | 0.048 | 0.130 | 0.276 | 0.695 |
| Day 8 | 65-70 | M(SD) | 72.19 (15.67) | 79.46 (9.02) | 77.98 (12.91) | 76.12 (11.67) |
| | 71-85 | M(SD) | 53.35 (17.52) | 68.75 (11.69) | 68.75 (11.18) | 76.17 (8.97) |
| | <i>p-value</i> | | .005 | .010 | .045 | .988 |
| Education (23+7) | | | | | | |
| Day 1 | secondary | M(SD) | 61.65 (17.20) | 73.91 (11.03) | 69.93 (9.65) | 74.59 (10.50) |
| | tertiar/higher | M(SD) | 53.06 (14.50) | 66.67 (11.28) | 65.48 (5.75) | 74.55 (13.43) |
| | <i>p-value</i> | | .243 | .141 | .259 | .994 |
| Day 8 | secondary | M(SD) | 64.75 (17.24) | 74.82 (12.01) | 73.19 (12.30) | 76.77 (10.14) |
| | tertiar/higher | M(SD) | 53.57 (23.24) | 70.24 (10.60) | 72.62 (15.00) | 74.11 (10.63) |
| | <i>p-value</i> | | .177 | .373 | .919 | .553 |
| Marital status (18+12) | | | | | | |
| Day 1 | married | M(SD) | 56.75 (16.47) | 71.53 (12.15) | 67.59 (8.52) | 74.31 (12.16) |
| | widowed | M(SD) | 63.99 (16.99) | 73.26 (10.43) | 70.83 (9.73) | 75.00 (9.61) |
| | <i>p-value</i> | | .254 | .689 | .343 | .869 |
| Day 8 | married | M(SD) | 59.72 (18.93) | 74.54 (12.03) | 70.83 (13.48) | 77.60 (8.72) |
| | widowed | M(SD) | 65.77(19.29) | 72.57 (11.58) | 76.39 (11.14) | 73.96 (12.02) |
| | <i>p-value</i> | | .402 | .660 | .247 | .343 |
| Health status (10+20) | | | | | | |
| Day 1 | healthy | M(SD) | 64.29 (8.07) | 72.50 (10.79) | 70.83 (10.58) | 80.00 (8.23) |
| | unhealthy | M(SD) | 57.32 (19.54) | 72.08 (11.87) | 67.92 (8.23) | 71.87 (11.39) |
| | <i>p-value</i> | | .292 | .926 | .413 | .055 |
| Day 8 | healthy | M(SD) | 68.93 (11.55) | 76.67 (7.14) | 75.00 (17.12) | 80.62 (6.39) |
| | unhealthy | M(SD) | 58.75 (21.22) | 72.29 (13.33) | 72.08 (10.21) | 73.90 (11.03) |
| | <i>p-value</i> | | .170 | .252 | .562 | .087 |

In the control sample (day 1), the results showed that there were no statistically significant differences (p -value>.05) between the different groups of participants in terms of QOL in each of the WHOQOL-BREF domains, except for physical domain in relation to the age groups. There was difference in scores for age group ≤ 70 years ($M=66.07$, $SD=16.62$) and age group > 70 years ($M=54.02$, $SD=15.26$, $t(28)=2.071$, $p=.048$), as shown in Figure 2.12. The magnitude of the differences in the means was large ($\eta^2=.133$). Expressed as a percentage, 13,3% of variance in physical domain is explained by age.

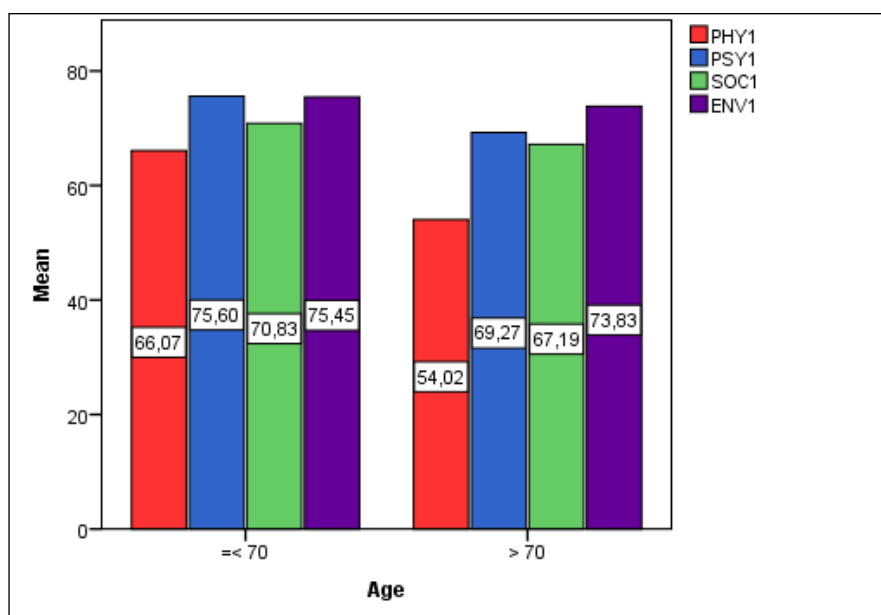


Figure 2.12 Differences among domains (control sample, day 1, N=30)

However, as shown in Table 2.9, male patients had a higher level of QOL in the physical, psychological, and social domains, while female patients had a slightly higher level in the environmental domain. Also, non-unmarried patients, healthy patients and patients with secondary education have a higher level of QOL in all four domains.

In the control sample (day 8), the results showed that there were no statistically significant differences (p -value>.05) between the different groups of participants in terms of QOL in each of the WHOQOL-BREF domains, except for physical, psychological, and social domains in relation to the age groups.

In the physical domain there was difference in scores for age group ≤ 70 years ($M=72.19$, $SD=15.67$) and age group > 70 years ($M=53.35$, $SD=17.52$, $t(28)=3.086$, $p=.005$), as shown in Figure 2.13. The magnitude of the differences in the means was large ($\eta^2=.254$). Expressed as a percentage, 25.4% of variance in physical domain is explained by age.

In the psychological domain there was difference in scores for age group ≤ 70 years ($M=79.46$, $SD=9.02$) and age group > 70 years ($M=68.75$, $SD=11.69$, $t(28)=2.780$, $p=.010$). The magnitude of the differences in the means was large ($\eta^2=.216$). Expressed as a percentage, 21.6% of variance in psychological domain is explained by age.

In the social domain there was difference in scores for age group ≤ 70 years ($M=77.98$, $SD=12.91$) and age group > 70 years ($M=68.75$, $SD=11.18$, $t(28)=2.098$, $p=.045$). The magnitude of the differences in the means was large ($\eta^2=.136$). Expressed as a percentage, 13.6% of variance in social domain is explained by age.

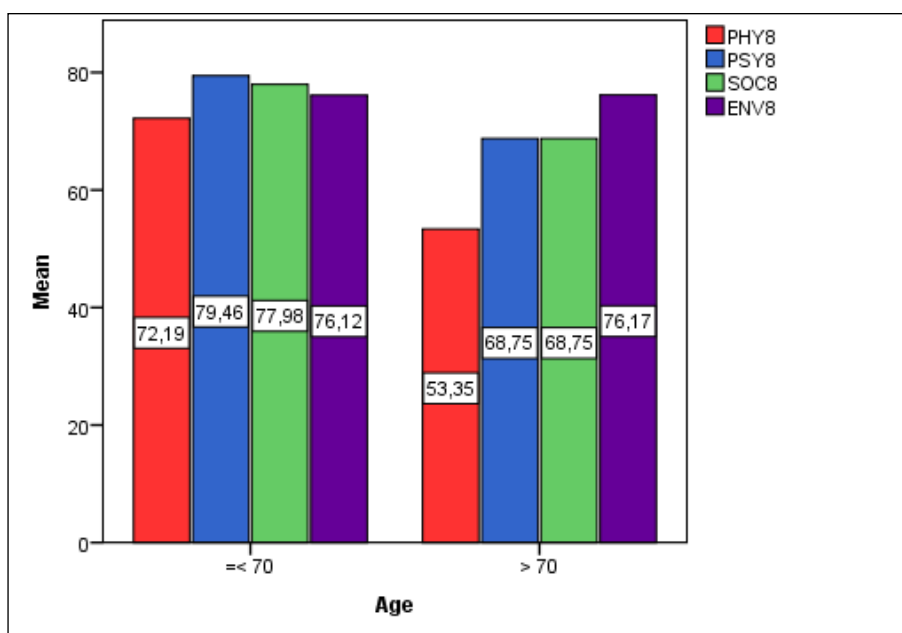


Figure 2.13 Differences among domains (control sample, day 8, N=30)

However, as shown in Table 2.9, healthy male patients with secondary education had a higher level of QOL in all four domains. Also, married patients had a higher level of QOL in the psychological and environment domains, while unmarried patients had a higher level of QOL in the physical and social domains.

Finally, a paired-samples t-test was conducted to compare the scores of the domains for day 1 and day 8. The results showed that there were no statistically significant differences ($p\text{-value} > .05$) in the scores for participants between day 1 and day 8 regarding QOL in each of the WHOQOL-BREF domains, except for the social domain (Table 2.10).

Table 2.10 The results of comparing the scores of each domain on day 1 and day 8 (N=30)

| | | Physical health | Psychological health | Social relationships | Environment domain |
|--------------|----------------|----------------------|----------------------|----------------------|----------------------|
| Day 1 | M(SD) | 59.64 (16.78) | 72.22 (11.34) | 68.89 (9.00) | 74.58 (11.00) |
| Day 8 | M(SD) | 62.15 (18.98) | 73.75 (11.69) | 73.06 (12.70) | 76.12 (10.13) |
| | t(28) | -1.165 | -0.917 | -2.055 | -1.005 |
| | <i>p-value</i> | .254 | .366 | .049 | .323 |

However, as shown in Table 2.10, scores were higher on day 8 than scores on day 1 in all four domains.

2.1.5.3 Results - the experimental sample (day 1 and day 8)

Sample characteristics

Data were collected for the same participants on both the first day and the eighth day. The experimental sample (day 1 and day 8) consisted of 30

participants with a mean age of 71.40 years (SD= \pm 5.92; range of 65–85). The sample comprised equal numbers of men and women, 63.3% of the participants had secondary education and 63.3% of the participants were married. More information on socio-demographic characteristics of participants is shown in Table 2.11.

Table 2.11 Participant characteristics

| Experimental sample, N=30, day 1 and day 8 | |
|--|-----------------|
| Age | |
| Mean (SD) | 71.40 (5.92) |
| Range | 65–85 |
| Sex, <i>n</i> (%) | |
| Male | 15 (50.0) |
| Female | 15 (50.0) |
| Marital status, <i>n</i> (%) | |
| Single | 0 (0.0) |
| Married | 19 (63.3) |
| Divorced | 3 (10.0) |
| Living as married | 1 (3.3) |
| Widowed | 7 (23.3) |
| Education, <i>n</i> (%) | |
| Primary school | 2 (6.7) |
| Secondary school | 19 (63.3) |
| Tertiary / Higher education | 9 (30.0) |
| Health status, <i>n</i> (%) | |
| Healthy | 7 (23.3) |
| Unhealthy | 23 (76.7) |

Item-level analysis

According to the WHOQOL Manual (WHO, 1998), where more than 20% of data are missing from an assessment, the assessment should be discarded. Where up to two items are missing, the mean of other items in the domain is substituted. Where more than two items are missing from the domain, the domain score should not be calculated (with the exception of domain 3, where the domain should only be calculated if < 1 item is missing).

In the experimental sample (day 1) the overall mean of the 24 items was 3.84 and the average correlation was .23. Items Q24 (*access to health care*) and Q13 (*daily information*) were the highest scoring items. On the other hand, Q4 (*dependence medication*) and Q3 (*physical pain*) scored lowest among the 24 items (see, Table 2.12).

Table 2.12 Items: summary statistics (experimental sample, day 1, N=30)

| Items | Mean | Std. Dev. | Median | Skewness | Kurtosis |
|-------------------|------|-----------|--------|----------|----------|
| Q1 | 3.97 | .718 | 4.00 | -.548 | .830 |
| Q2 | 3.53 | .900 | 4.00 | -.411 | -.565 |
| Q3 ^{a)} | 3.33 | 1.061 | 3.00 | .007 | -.477 |
| Q4 ^{a)} | 2.60 | 1.133 | 2.00 | .574 | -.408 |
| Q5 | 3.73 | .691 | 4.00 | -.261 | .269 |
| Q6 | 3.97 | .765 | 4.00 | -.438 | .155 |
| Q7 | 3.60 | .675 | 3.50 | .693 | -.517 |
| Q8 | 3.73 | .691 | 4.00 | -.261 | .269 |
| Q9 | 4.17 | .747 | 4.00 | -.286 | -1.095 |
| Q10 | 3.70 | .988 | 4.00 | -.487 | .414 |
| Q11 | 4.10 | .995 | 4.00 | -1.563 | 2.723 |
| Q12 | 4.13 | .819 | 4.00 | -.259 | -1.457 |
| Q13 | 4.50 | .572 | 5.00 | -.591 | -.620 |
| Q14 | 4.13 | .819 | 4.00 | -.259 | -1.457 |
| Q15 | 3.70 | 1.055 | 4.00 | -.287 | -1.068 |
| Q16 | 3.50 | .974 | 4.00 | -.240 | -.890 |
| Q17 | 3.83 | 1.020 | 4.00 | -.480 | -.798 |
| Q18 | 3.80 | .997 | 4.00 | -.466 | -.711 |
| Q19 | 4.03 | .890 | 4.00 | -.697 | -.049 |
| Q20 | 4.17 | .834 | 4.00 | -.715 | -.083 |
| Q21 | 3.50 | .938 | 4.00 | -.672 | .551 |
| Q22 | 3.87 | .860 | 4.00 | -.774 | .424 |
| Q23 | 4.50 | .731 | 5.00 | -1.702 | 3.475 |
| Q24 | 4.07 | .907 | 4.00 | -1.325 | 3.082 |
| Q25 | 3.53 | .776 | 4.00 | -.830 | 2.762 |
| Q26 ^{a)} | 3.97 | .718 | 4.00 | -.763 | .018 |

^{a)} Q3, Q4 and Q26 have been reversed coded.

The mean scores \pm SD for the other two questions Q1 and Q2, scored on a 5-point Likert scale and scored from 1 to 5 (ranged from very poor to very good and very dissatisfied to very satisfied, respectively), were 3.97 ± 0.72 and 3.53 ± 0.90 , respectively (Table 2.12). These questions should be evaluated separately and are not included in a domain, as per the WHOQOL-BREF manual (WHOQOL Group, 1998; WHO, 1998).

Figure 2.14 shows the average of the items on day 1 and day 8. A paired-samples t-test was conducted to compare the items scores for day 1 and day 8. There was no significant difference in scores for day 1 and day 8 (the results are no shown).

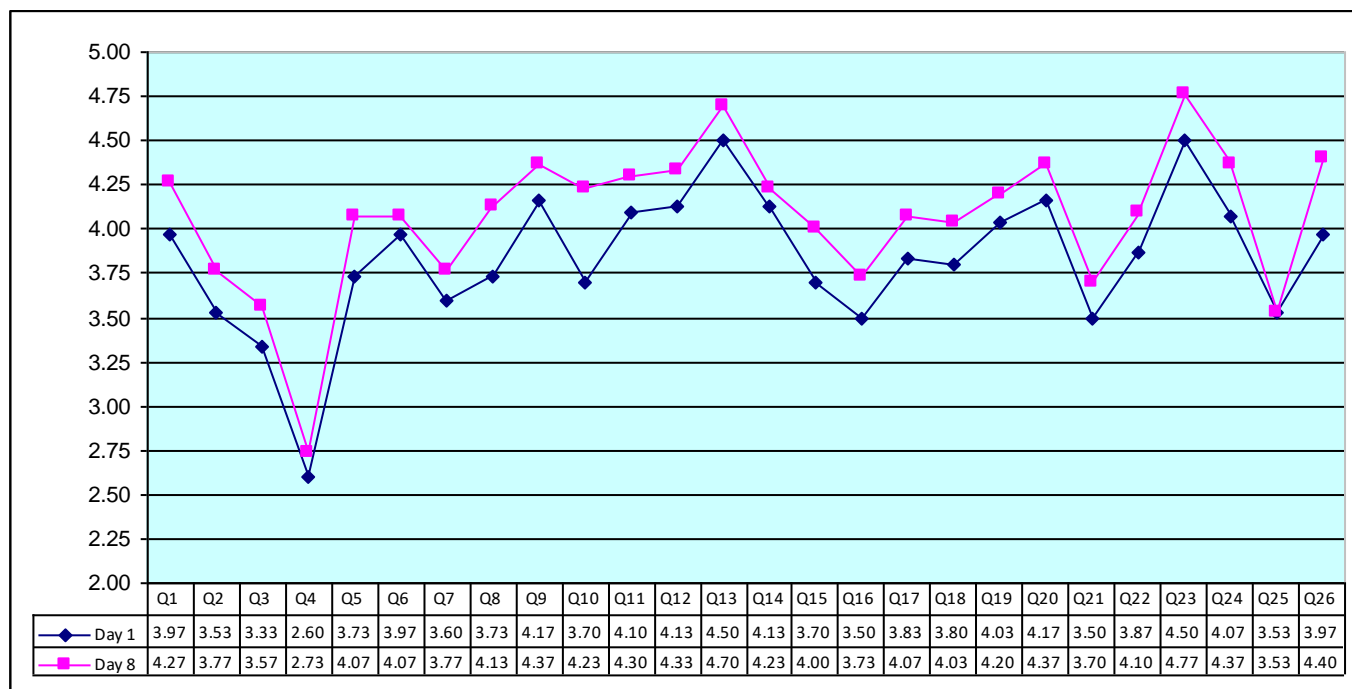


Figure 2.14 The mean scores of the 26 items in scale (experimental sample, day 1 and day 8, N=30)

Domain-level analysis

The mean scores \pm SD for the four domains of the WHOQOL-BREF, physical, psychological, social, and environmental domains in the transformed scores of 0-100 are showed in Table 2.13 (day 1) and Table 2.14 (day 8), respectively. Comparing the four domains, environmental domain was the highest with a mean score of 82.60 (day 8) and 77.40 (day 1), while the physical domain was the lowest (62.38 in day 1 and 69.17 in day 8).

Table 2.13 Domains: summary statistics (transformed scores 0-100; experimental sample, day 1, N=30)

| Domain | Mean (SD) | Median | Minimum | Maximum | Skewness | Kurtosis |
|---------------|---------------|--------|---------|---------|----------|----------|
| Physical | 62.38 (18.78) | 60.71 | 17.86 | 96.43 | .035 | -.074 |
| Psychological | 72.50 (13.16) | 70.83 | 41.67 | 95.83 | -.339 | .603 |
| Social | 71.11 (15.43) | 75.00 | 33.33 | 100.00 | -.475 | .132 |
| Environment | 77.40 (9.97) | 78.13 | 53.13 | 93.75 | -.154 | .236 |

Table 2.14 Domains: summary statistics (transformed scores 0-100; experimental sample, day 8, N=30)

| Domain | Mean (SD) | Median | Minimum | Maximum | Skewness | Kurtosis |
|---------------|---------------|--------|---------|---------|----------|----------|
| Physical | 69.17 (20.26) | 69.64 | 21.43 | 100.00 | -.335 | -.444 |
| Psychological | 78.33 (12.64) | 79.17 | 45.83 | 100.00 | -.487 | .220 |
| Social | 76.39 (12.96) | 75.00 | 50.00 | 100.00 | -.179 | -.211 |
| Environment | 82.60 (9.42) | 79.69 | 65.63 | 100.00 | .079 | -1.188 |

A score of at least 60 points identifies patients with a good QOL (all the domains on day 1 and day 8).

The relationship between the four domains, overall QOL and general health was investigated using Pearson product-moment correlation coefficient. Results are shown in Table 2.15 (day 1) and Table 2.16 (day 8).

In the experimental sample (day 1), the Pearson correlation coefficient showed a significantly and high positive correlation between the four QOL domains, ranged from .53 ($p<.01$) to .62 ($p<.01$), except for the correlation between physical and social domains.

The four domains and overall QOL (Q1) were significantly and positively interrelated with moderate to high relationships, ranged from .39 ($p<.05$) to .61 ($p<.01$), except for physical domain (Table 2.15).

General health (Q2) was significantly and high positive interrelated with all the four domains, ranged from .56 ($p<.01$) to .69 ($p<.01$).

Table 2.15 Pearson correlations of the four QOL domains, overall QOL and general health (day 1)

| | Physical | Psychological | Social | Environment | Overall QOL | General health |
|---------------------|----------|---------------|--------|-------------|-------------|----------------|
| Physical | 1. | .564** | .342 | .558** | .059 | .558** |
| Psychological | | 1. | .528** | .564** | .386* | .675** |
| Social | | | 1. | .623** | .558** | .693** |
| Environment | | | | 1. | .613** | .681** |
| Overall QOL (Q1) | | | | | 1. | .402* |
| General health (Q2) | | | | | | 1. |

* $p<0.05$; ** $p<0.01$

There was a significantly and moderate positive correlation between the overall QOL and general health ($r=.40$, $p<.01$).

In the experimental sample (day 8), the Pearson correlation coefficient showed a significantly and positive correlation between the four QOL domains, ranged from moderate .48 ($p<.01$) to high .68 ($p<.01$), except for the correlation between physical and social domains.

The four domains and overall QOL (Q1) were significantly and positively interrelated with moderate to high relationships, ranged from .37 ($p < .05$) to .61 ($p < .01$), except for environment domain (Table 2.16).

General health (Q2) was significantly and positively interrelated with the four domains with moderate to high relationships, ranged from .43 ($p < .05$) to .71 ($p < .01$), except for environment domain.

Table 2.16 Correlations of the four QOL domains, overall QOL and general health (experimental sample, day 8)

| | Physical | Psychological | Social | Environment | Overall QOL | General health |
|---------------------|----------|---------------|--------|-------------|-------------|----------------|
| Physical | 1. | .632** | .349 | .477** | .428** | .429* |
| Psychological | | 1. | .592** | .685** | .615** | .709** |
| Social | | | 1. | .477** | .370* | .574** |
| Environment | | | | 1. | .296 | .295 |
| Overall QOL (Q1) | | | | | 1. | .548** |
| General health (Q2) | | | | | | 1. |

* $p < 0.05$; ** $p < 0.01$

There was a significantly and high positive correlation between the overall QOL and general health ($r = .55$, $p < .01$).

2.1.5.4 Patients profile (WHOQOL-BREF)

In each experimental sample (day 1 and day 8, respectively) were performed independent-sample t-tests to compare the scores of each domain for socio-demographic variables (gender, age, education, marital status, and health status). Results are shown in Table 2.17.

Table 2.17 The WHOQOL-BREF domains by the demographic variables (experimental sample, day 1, day 8)

| | | | Physical health | Psychological health | Social relationships | Environment domain |
|--------------------------|----------------|-------|----------------------|----------------------|----------------------|----------------------|
| Gender (15+15) | | | | | | |
| Day 1 | Male | M(SD) | 70.00 (17.85) | 78.61 (9.69) | 73.33 (14.50) | 79.37 (8.90) |
| | Female | M(SD) | 54.76 (16.95) | 66.39 (13.59) | 68.89 (16.51) | 75.42 (10.88) |
| | <i>p-value</i> | | .023 | .008 | .440 | .285 |
| Day 8 | Male | M(SD) | 77.62 (17.52) | 82.22 (10.96) | 78.33 (14.36) | 82.92 (8.98) |
| | Female | M(SD) | 60.71 (19.75) | 74.44 (13.35) | 74.44 (11.56) | 82.29 (10.14) |
| | <i>p-value</i> | | .019 | .092 | .421 | .859 |
| Age group (17+13) | | | | | | |
| | 65-70 | M(SD) | 61.55 (17.20) | 76.72 (11.70) | 69.61 (13.80) | 77.57 (10.02) |

| | | | | | | |
|-------------------------------|-----------------------|-------|----------------------|----------------------|----------------------|----------------------|
| Day 1 | 71-85 | M(SD) | 63.46 (21.34) | 66.99 (13.33) | 73.08 (17.73) | 77.16 (10.32) |
| | <i>p-value</i> | | .788 | .043 | .551 | .913 |
| | 65-70 | M(SD) | 69.96 (19.77) | 82.60 (10.44) | 78.92 (11.83) | 82.72 (9.89) |
| Day 8 | 71-85 | M(SD) | 68.13 (21.65) | 72.76 (13.46) | 73.08 (14.09) | 82.45 (9.16) |
| | <i>p-value</i> | | .814 | .032 | .227 | .940 |
| Education (21+9) | | | | | | |
| | secondary | M(SD) | 57.99 (17.31) | 72.62 (12.54) | 71.43 (14.08) | 77.08 (9.29) |
| Day 1 | tertiar/higher | M(SD) | 72.62 (18.98) | 72.22 (15.31) | 70.37 (19.14) | 78.12 (12.00) |
| | <i>p-value</i> | | .049 | .941 | .867 | .798 |
| | secondary | M(SD) | 65.99 (18.85) | 78.57 (11.81) | 76.19 (10.63) | 82.74 (9.09) |
| Day 8 | tertiar/higher | M(SD) | 76.59 (22.59) | 77.78 (15.17) | 76.85 (18.05) | 82.29 (10.71) |
| | <i>p-value</i> | | .194 | .878 | .920 | .908 |
| Marital status (19+11) | | | | | | |
| | married | M(SD) | 62.03 (20.93) | 73.90 (12.87) | 69.74 (16.00) | 76.64 (9.85) |
| Day 1 | widowed | M(SD) | 62.99 (15.26) | 70.08 (13.92) | 73.48 (14.82) | 78.69 (10.53) |
| | <i>p-value</i> | | .896 | .452 | .531 | .597 |
| | married | M(SD) | 67.67 (22.57) | 78.07 (12.94) | 77.63 (13.34) | 80.76 (9.04) |
| Day 8 | widowed | M(SD) | 71.75 (16.17) | 78.79 (12.70) | 74.24 (12.61) | 85.79 (9.62) |
| | <i>p-value</i> | | .603 | .884 | .500 | .162 |
| Health status (7+23) | | | | | | |
| | healthy | M(SD) | 76.53 (18.77) | 76.19 (10.12) | 79.76 (17.25) | 83.48 (9.15) |
| Day 1 | unhealthy | M(SD) | 58.07 (16.90) | 71.38 (13.95) | 68.48 (14.20) | 75.54 (9.64) |
| | <i>p-value</i> | | .020 | .406 | .091 | .064 |
| | healthy | M(SD) | 83.67 (14.70) | 80.95 (13.58) | 82.14 (18.90) | 87.50 (8.46) |
| Day 8 | unhealthy | M(SD) | 64.75 (19.86) | 77.54 (12.55) | 74.64 (10.50) | 81.11 (9.35) |
| | <i>p-value</i> | | .028 | .541 | .348 | .118 |

In the experimental sample (day 1), the results showed that there were statistically significant differences (p -value<.05) between the different groups of participants regarding of QOL in each of the WHOQOL-BREF domains.

There was difference in scores for males (M=70.00, SD=17.85) and females (M=54.76, SD=16.95, $t(28)=2.398$, $p=.023$) in physical (PHY1) domain. Also, there was difference in scores for male (M=78.61, SD=9.69) and females (M=66.39, SD=13.59, $t(28)=2.836$, $p=.008$) in psychological (PSY1) domain. Male patients had higher scores than women in these domains.

In the psychological domain (PSY1) there was difference in scores for age group ≤ 70 years (M=76.72, SD=11.70) and age group > 70 years (M=66.99,

SD=13.33, $t(28)=2.125$, $p=.043$). Patients in age group ≤ 70 years had higher scores than patients in age group > 70 years in psychological domain.

There was difference in scores for patients with primary and secondary education ($M=57.99$, $SD=17.31$) and patients with tertiary education ($M=72.62$, $SD=18.98$, $t(28) = -2.062$, $p=.048$) in physical domain (PHY1). Patients with primary and secondary education had lower scores than patients with tertiary / higher education in this domain.

There was difference in scores for healthy patients ($M=76.53$, $SD=18.77$) and unhealthy patients ($M=58.07$, $SD=16.90$, $t(28)=2.469$, $p=.020$) in physical domain (PHY1). Healthy patients had higher scores than unhealthy patients in this domain.

It should be noted that, in each case, we calculated the effect size statistics using the information provided in the SPSS output (SPSS does not provide eta squared values for the t tests). The effect size statistics provide an indication of the magnitude of the differences between the groups considered (not only if the difference occurred by chance). The guidelines for interpreting this value are .01=small effect, .06=moderate effect, .14=large effect. In this study, the magnitude of the difference in the means was large (eta squared \geq .14).

In all other cases there was no significant difference in scores (see Table 2.17).

In the experimental sample (day 8), the results showed that there were statistically significant differences (p -value $<.05$) between the different groups of participants regarding of QOL in each of the WHOQOL-BREF domains.

There was difference in scores for males ($M=77.62$, $SD=17.52$) and females ($M=60.71$, $SD=19.75$, $t(28)=2.480$, $p=.019$) in physical (PHY8) domain. Male patients had higher scores than women in this domain.

In the psychological domain (PSY8) there was difference in scores for age group ≤ 70 years ($M=82.60$, $SD=10.44$) and age group > 70 years ($M=72.76$, $SD=13.46$, $t(28)=2.258$, $p=.032$). Patients in age group ≤ 70 years had higher scores than patients in age group > 70 years in psychological domain.

There was difference in scores for healthy patients ($M=83.67$, $SD=14.70$) and unhealthy patients ($M=64.75$, $SD=19.86$, $t(28)=2.322$, $p=.0280$) in physical domain (PHY1). Healthy patients had higher scores than unhealthy patients in this domain.

In this study, the magnitude of the difference in the means was large (eta squared \geq .14).

In all other cases there was no significant difference in scores (see Table 2.17).

Figures 2.15 and 2.16 show the cases in which statistically significant differences (p -value $<.05$) were identified between the different groups of participants regarding of QOL in each of the WHOQOL-BREF domains, day 1 and day 8.

Experimental sample

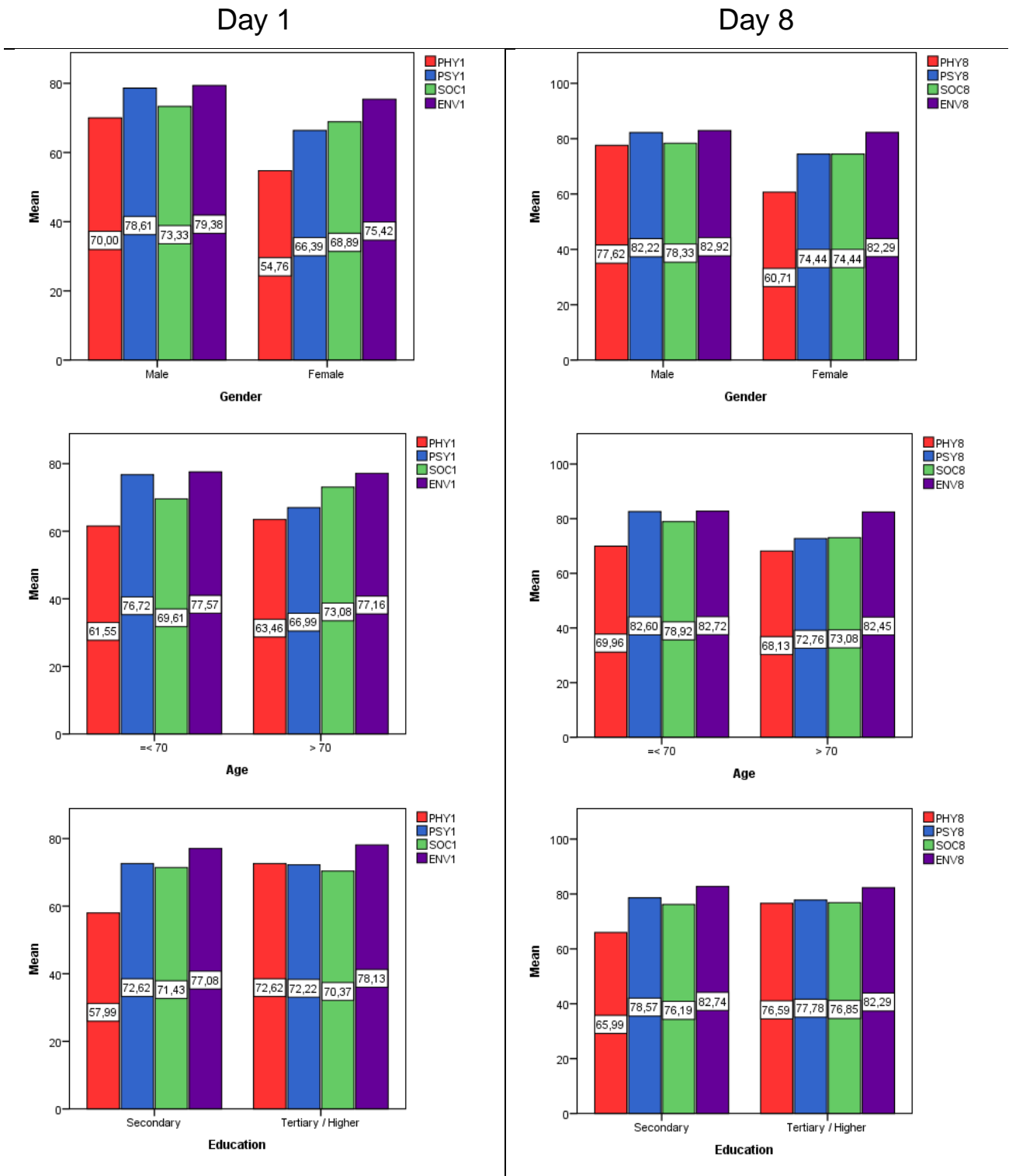


Figure 2.15 The mean scores of the 26 items in scale (experimental sample, day 1 and day 8, N=30)

Experimental sample

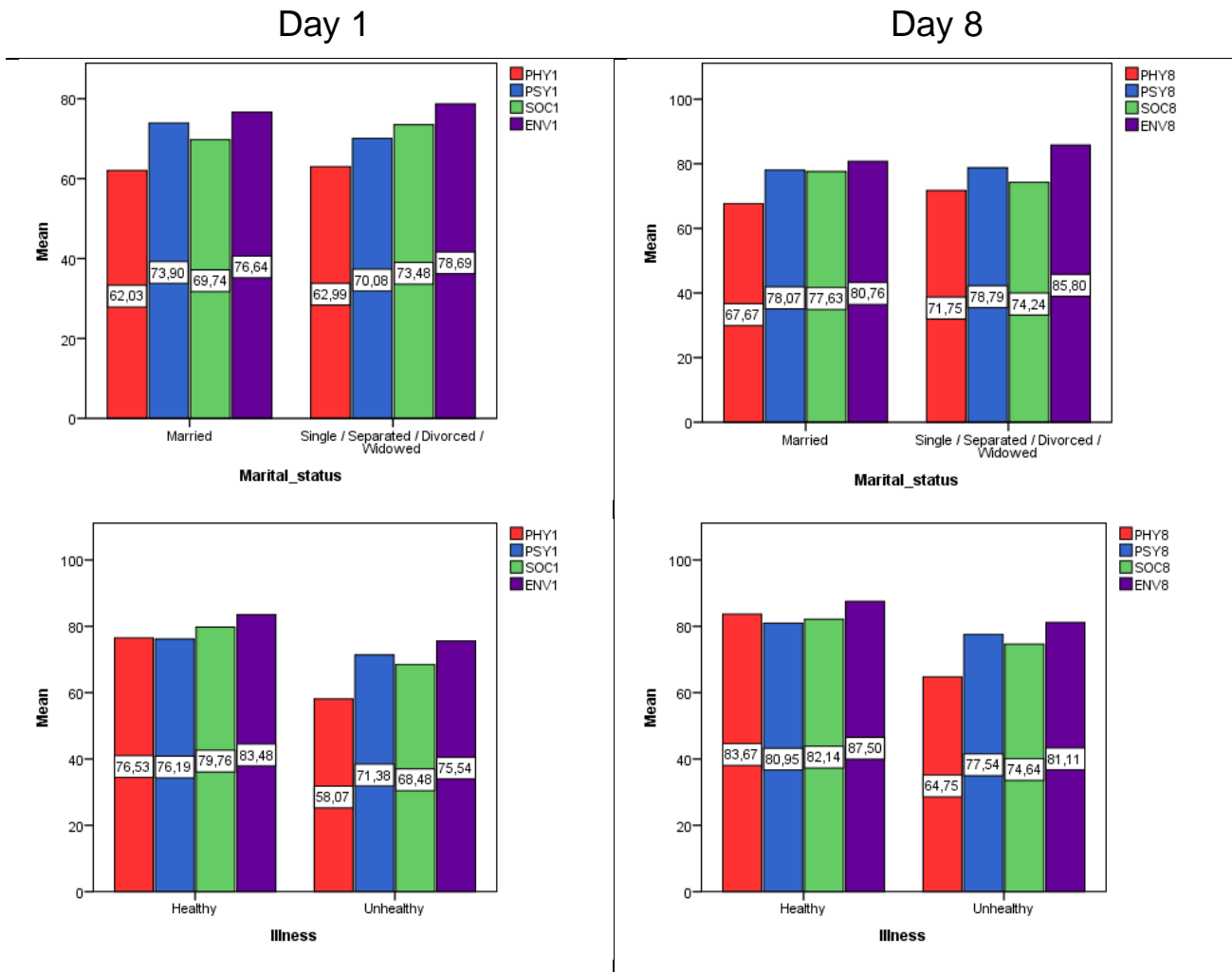


Figure 2.16 The mean scores of the 26 items in scale (experimental sample, day 1 and day 8, N=30)

2.1.6 Data analysis and processing - IPAQ

The instructions of the November 2005 version of the Guidelines for data processing and analysis of the IPAQ short form were used for data cleaning and processing prior to computing the algorithms (IPAQ, 2005), as follows:

Rule 1 (excerpt from IPAQ, 2005): if data are missing for time or days then that case is removed from analysis.

Data processing rules 2, 3, and 4 deals first with excluding outlier data, then secondly, with recoding minimum values and then finally dealing with high values. These rules will ensure that highly active people remain classified as 'high', while decreasing the chances that less active individuals are misclassified and coded as 'high'.

Rule 2: Maximum values for excluding outliers.

This rule is to exclude data which are unreasonably high; these data are to be considered outliers and thus are excluded from analysis. All cases in which the sum total of all Walking, Moderate and Vigorous time variables is greater than 960 minutes (16 hours) should be excluded from the analysis. This assumes that on average an individual of 8 hours per day is spent sleeping.

The 'days' variables can take the range 0-7 days, or 8, 9 (don't know or refused); values greater than 9 should not be allowed and those cases excluded from analysis.

Rule 3: Minimum values for duration of activity.

Only values of 10 or more minutes of activity should be included in the calculation of summary scores. The rationale being that the scientific evidence indicates that episodes or bouts of at least 10 minutes are required to achieve health benefits. Responses of less than 10 minutes and their associated days should be re-coded to 'zero'.

Rule 4: Truncation of data rules.

This rule attempts to normalize the distribution of levels of activity which are usually skewed in national or large population data sets. In IPAQ short - it is recommended that all Walking, Moderate and Vigorous time variables exceeding '3 hours' or '180 minutes' are truncated (that is re-coded) to be equal to '180 minutes' in a new variable. This rule permits a maximum of 21 hours of activity in a week to be reported for each category (3 hours * 7 days).

Rule 5: Calculating MET-minute/week scores.

Median values and interquartile ranges can be computed for walking (W), moderate intensity activities (M), vigorous-intensity activities (V) and a combined total physical activity score. All continuous scores are expressed in MET-minutes/week as defined below.

The following values to be used for the analysis of IPAQ data: Walking = 3.3 METs, Moderate PA = 4.0 METs and Vigorous PA = 8.0 METs. Using these values, four continuous scores are defined:

Walking MET-minutes/week = 3.3 * walking minutes * walking days

Moderate MET-minutes/week = 4.0 * moderate-intensity activity minutes * moderate days

Vigorous MET-minutes/week = 8.0 * vigorous-intensity activity minutes * vigorous-intensity days

Total physical activity MET-minutes/week = sum of Walking + Moderate + Vigorous MET-minutes/week scores.

Rule 6: Calculating total days for presenting categorical data on moderate and high levels.

Presenting IPAQ data using categorical variables requires the total number of 'days' on which all physical activity was undertaken to be assessed. This is difficult because frequency in 'days' is asked separately for walking, moderate-intensity and vigorous intensity activities. The IPAQ instrument does not record if different types of activity are undertaken on the same day.

The procedures were implemented using a spreadsheet available online [Cheng, 2016]. Additionally, the verification of the correctness of the results and some statistical analyses were performed using IBM SPSS Statistics v24.

2.1.6.1 Results - the control sample (day 1 and day 8)

This study used the same Romanian control sample of patients (day 1 and day 8, N=30) from whom data were collected for the WHOQOL-BREF instrument. In Table 2.18, Table 2.19 and Table 2.20 are shown the IPAQ-SF final results.

In the control sample (day 1), of the 30 patients, 33.3% had a "High" IPAQ category, 53.5% had a "Moderate" IPAQ category, and 13.3% had a "Low" IPAQ category. The median value of Total physical activity (MET-min / week) was 1801.50.

Table 2.18 IPAQ-SF MET-min/week and Categorical Scores (control sample, day 1, N=30)

| No. | MET-MINUTES PER WEEK | | | | PHYSICAL ACTIVITY CATEGORY | |
|-----|----------------------|----------|-------|-------|----------------------------|---------------------|
| | Vigorous | Moderate | Walk | Total | Category | Category (Recorded) |
| 1 | 960 | 5040 | 3564 | 9564 | High | 3 |
| 2 | 0 | 0 | 1386 | 1386 | Moderate | 2 |
| 3 | 480 | 560 | 4158 | 5198 | High | 3 |
| 4 | 0 | 300 | 346.5 | 647 | Moderate | 2 |
| 5 | 0 | 840 | 2772 | 3612 | High | 3 |
| 6 | 0 | 960 | 396 | 1356 | Moderate | 2 |
| 7 | 240 | 840 | 3465 | 4545 | High | 3 |
| 8 | 0 | 960 | 1584 | 2544 | Moderate | 2 |
| 9 | 0 | 0 | 247.5 | 248 | Low | 1 |
| 10 | 0 | 400 | 1386 | 1786 | Moderate | 2 |
| 11 | 0 | 420 | 462 | 882 | Moderate | 2 |
| 12 | 0 | 80 | 346.5 | 427 | Low | 1 |
| 13 | 0 | 420 | 693 | 1113 | Moderate | 2 |
| 14 | 0 | 0 | 1386 | 1386 | Moderate | 2 |

| | | | | | | |
|----|-----|------|--------|------|----------|---|
| 15 | 0 | 2160 | 4158 | 6318 | High | 3 |
| 16 | 0 | 1440 | 4158 | 5598 | High | 3 |
| 17 | 0 | 0 | 594 | 594 | Low | 1 |
| 18 | 0 | 2880 | 462 | 3342 | High | 3 |
| 19 | 0 | 0 | 495 | 495 | Moderate | 2 |
| 20 | 0 | 300 | 2079 | 2379 | Moderate | 2 |
| 21 | 0 | 200 | 1617 | 1817 | Moderate | 2 |
| 22 | 0 | 480 | 693 | 1173 | Moderate | 2 |
| 23 | 480 | 400 | 1782 | 2662 | Moderate | 2 |
| 24 | 0 | 0 | 330 | 330 | Low | 1 |
| 25 | 0 | 1440 | 2772 | 4212 | High | 3 |
| 26 | 0 | 240 | 1485 | 1725 | Moderate | 2 |
| 27 | 600 | 840 | 1039.5 | 2480 | High | 3 |
| 28 | 0 | 0 | 1386 | 1386 | Moderate | 2 |
| 29 | 0 | 0 | 2079 | 2079 | Moderate | 2 |
| 30 | 480 | 1680 | 1386 | 3546 | High | 3 |

In the control sample (day 8), of the 30 patients, 43.3% had a "High" IPAQ category, 50.0% had a "Moderate" IPAQ category, and 6.7% had a "Low" IPAQ category. The median value of Total physical activity (MET-min / week) was 2029.50.

Table 2.19 IPAQ-SF MET-min/week and Categorical Scores (control sample, day 8, N=30)

| No. | MET-MINUTES PER WEEK | | | | PHYSICAL ACTIVITY CATEGORY | |
|-----|----------------------|----------|-------|-------|----------------------------|---------------------|
| | Vigorous | Moderate | Walk | Total | Category | Category (Recorded) |
| 1 | 0 | 2400 | 2970 | 5370 | High | 3 |
| 2 | 0 | 0 | 1386 | 1386 | Moderate | 2 |
| 3 | 0 | 560 | 4158 | 4718 | High | 3 |
| 4 | 0 | 420 | 693 | 1113 | Moderate | 2 |
| 5 | 0 | 840 | 2772 | 3612 | High | 3 |
| 6 | 0 | 600 | 171.6 | 772 | Moderate | 2 |
| 7 | 0 | 840 | 3465 | 4305 | High | 3 |
| 8 | 0 | 960 | 2772 | 3732 | High | 3 |
| 9 | 0 | 120 | 66 | 186 | Low | 1 |
| 10 | 0 | 400 | 1386 | 1786 | Moderate | 2 |
| 11 | 0 | 420 | 462 | 882 | Moderate | 2 |
| 12 | 0 | 120 | 346.5 | 467 | Low | 1 |

| | | | | | | |
|----|------|------|--------|------|----------|---|
| 13 | 0 | 180 | 693 | 873 | Moderate | 2 |
| 14 | 0 | 3600 | 693 | 4293 | High | 3 |
| 15 | 0 | 2160 | 2970 | 5130 | High | 3 |
| 16 | 2400 | 1440 | 2772 | 6612 | High | 3 |
| 17 | 0 | 0 | 990 | 990 | Moderate | 2 |
| 18 | 0 | 2800 | 1386 | 4186 | High | 3 |
| 19 | 0 | 240 | 693 | 933 | Moderate | 2 |
| 20 | 0 | 300 | 2079 | 2379 | Moderate | 2 |
| 21 | 120 | 200 | 1617 | 1937 | Moderate | 2 |
| 22 | 120 | 600 | 693 | 1413 | Moderate | 2 |
| 23 | 480 | 560 | 2772 | 3812 | High | 3 |
| 24 | 0 | 0 | 2079 | 2079 | Moderate | 2 |
| 25 | 0 | 1200 | 2772 | 3972 | High | 3 |
| 26 | 0 | 300 | 1485 | 1785 | Moderate | 2 |
| 27 | 400 | 200 | 1085.7 | 1686 | High | 3 |
| 28 | 0 | 0 | 1980 | 1980 | Moderate | 2 |
| 29 | 0 | 600 | 2079 | 2679 | Moderate | 2 |
| 30 | 480 | 1680 | 1386 | 3546 | High | 3 |

Table 2.20 IPAQ-SF MET-min/week and continuous scores (control sample. day 1 and day 8)

| | Day 1 | | | Day 8 | | |
|--|---------|-------------|---------|---------|-------------|---------|
| | Median | Percentiles | | Median | Percentiles | |
| | | 25 | 75 | | 25 | 75 |
| Vigorous (MET-minutes/week) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Moderate (MET-minutes/week) | 410.00 | 0.00 | 960.00 | 490.00 | 195.00 | 1020.00 |
| Walking (MET-minutes/week) | 1386.00 | 486.75 | 2252.25 | 1435.50 | 693.00 | 2772.00 |
| Total physical activity (MET-min/week) | 1801.50 | 1055.25 | 3562.50 | 2029.50 | 1082.25 | 4025.50 |

2.1.6.2 Results - the experimental sample (day 1 and day 8)

This study used the same Romanian experimental sample of patients (day 1 and day 8, N=30) from whom data were collected for the WHOQOL-BREF instrument. In Table 2.21, Table 2.22 and Table 2.23 are shown the IPAQ-SF final results.

In the experimental sample (day 1), of the 30 patients, 63.3% had a "High" IPAQ category, 33.4% had a "Moderate" IPAQ category, and 3.3% had a "Low" IPAQ category. The median value of Total physical activity (MET-min / week) was 3066.50.

Table 2.21 IPAQ-SF MET-min/week and Categorical Scores (experimental sample, day 1, N=30)

| No. | MET-MINUTES PER WEEK | | | | PHYSICAL ACTIVITY CATEGORY | |
|-----|----------------------|----------|--------|-------|----------------------------|---------------------|
| | Vigorous | Moderate | Walk | Total | Category | Category (Recorded) |
| 1 | 0 | 0 | 2079 | 2079 | Moderate | 2 |
| 2 | 0 | 4200 | 693 | 4893 | High | 3 |
| 3 | 0 | 2520 | 2079 | 4599 | High | 3 |
| 4 | 0 | 1680 | 1386 | 3066 | High | 3 |
| 5 | 1440 | 480 | 165 | 2085 | High | 3 |
| 6 | 1200 | 840 | 2772 | 4812 | High | 3 |
| 7 | 0 | 420 | 198 | 618 | Moderate | 2 |
| 8 | 0 | 5040 | 1584 | 6624 | High | 3 |
| 9 | 0 | 480 | 2772 | 3252 | High | 3 |
| 10 | 160 | 2400 | 792 | 3352 | High | 3 |
| 11 | 0 | 1440 | 1485 | 2925 | Moderate | 2 |
| 12 | 0 | 280 | 1039.5 | 1320 | Moderate | 2 |
| 13 | 0 | 4320 | 1386 | 5706 | High | 3 |
| 14 | 0 | 1440 | 2772 | 4212 | High | 3 |
| 15 | 0 | 2520 | 4158 | 6678 | High | 3 |
| 16 | 720 | 840 | 4158 | 5718 | High | 3 |
| 17 | 0 | 400 | 1386 | 1786 | Moderate | 2 |
| 18 | 0 | 1440 | 2772 | 4212 | High | 3 |
| 19 | 240 | 840 | 2079 | 3159 | High | 3 |
| 20 | 0 | 1680 | 1386 | 3066 | High | 3 |
| 21 | 1440 | 2520 | 3465 | 7425 | High | 3 |
| 22 | 160 | 200 | 693 | 1053 | Moderate | 2 |
| 23 | 0 | 280 | 3465 | 3745 | High | 3 |
| 24 | 240 | 840 | 1039.5 | 2120 | Moderate | 2 |
| 25 | 0 | 0 | 264 | 264 | Low | 1 |
| 26 | 0 | 1080 | 854.7 | 1935 | Moderate | 2 |
| 27 | 0 | 240 | 1386 | 1626 | Moderate | 2 |
| 28 | 400 | 240 | 990 | 1630 | High | 3 |
| 29 | 240 | 120 | 396 | 756 | Moderate | 2 |
| 30 | 240 | 560 | 990 | 1790 | High | 3 |

In the experimental sample (day 8), of the 30 patients, 66.7% had a "High" IPAQ category, 33.4% had a "Moderate" IPAQ category, and 0.0% had a "Low" IPAQ

category. The median value of Total physical activity (MET-min / week) was 3304.50.

Table 2.22 IPAQ-SF MET-min/week and Categorical Scores (experimental sample, day 8, N=30)

| No. | MET-MINUTES PER WEEK | | | | PHYSICAL ACTIVITY CATEGORY | |
|-----|----------------------|----------|-------|-------|----------------------------|---------------------|
| | Vigorous | Moderate | Walk | Total | Category | Category (Recorded) |
| 1 | 0 | 0 | 1782 | 1782 | Moderate | 2 |
| 2 | 0 | 3600 | 1386 | 4986 | High | 3 |
| 3 | 0 | 2520 | 2079 | 4599 | High | 3 |
| 4 | 0 | 1680 | 1386 | 3066 | High | 3 |
| 5 | 0 | 900 | 594 | 1494 | Moderate | 2 |
| 6 | 1200 | 840 | 4158 | 6198 | High | 3 |
| 7 | 0 | 420 | 577.5 | 998 | Moderate | 2 |
| 8 | 0 | 0 | 2376 | 2376 | Moderate | 2 |
| 9 | 0 | 720 | 3696 | 4416 | High | 3 |
| 10 | 400 | 2880 | 1782 | 5062 | High | 3 |
| 11 | 80 | 1440 | 2475 | 3995 | High | 3 |
| 12 | 0 | 280 | 1485 | 1765 | Moderate | 2 |
| 13 | 0 | 5040 | 2772 | 7812 | High | 3 |
| 14 | 0 | 1680 | 2772 | 4452 | High | 3 |
| 15 | 0 | 2520 | 4158 | 6678 | High | 3 |
| 16 | 720 | 2400 | 4158 | 7278 | High | 3 |
| 17 | 0 | 600 | 4158 | 4758 | High | 3 |
| 18 | 240 | 3360 | 3465 | 7065 | High | 3 |
| 19 | 240 | 840 | 2079 | 3159 | High | 3 |
| 20 | 0 | 1680 | 1650 | 3330 | High | 3 |
| 21 | 1080 | 2000 | 3465 | 6545 | High | 3 |
| 22 | 160 | 200 | 1155 | 1515 | Moderate | 2 |
| 23 | 0 | 400 | 2970 | 3370 | High | 3 |
| 24 | 240 | 840 | 1386 | 2466 | High | 3 |
| 25 | 160 | 300 | 2079 | 2539 | Moderate | 2 |
| 26 | 0 | 1600 | 924 | 2524 | Moderate | 2 |
| 27 | 0 | 240 | 1485 | 1725 | Moderate | 2 |
| 28 | 480 | 720 | 2079 | 3279 | High | 3 |
| 29 | 240 | 200 | 693 | 1133 | Moderate | 2 |

Table 2.23 IPAQ-SF MET-min/week and continuous scores (experimental sample. day 1 and day 8)

| | Day 1 | | | Day 8 | | |
|--|---------|-------------|---------|---------|-------------|---------|
| | Median | Percentiles | | Median | Percentiles | |
| | | 25 | 75 | | 25 | 75 |
| Vigorous (MET-minutes/week) | 0.00 | 0.00 | 240.00 | 0.00 | 0.00 | 240.00 |
| Moderate (MET-minutes/week) | 840.00 | 280.00 | 1860.00 | 840.00 | 375.00 | 2100.00 |
| Walking (MET-minutes/week) | 1386.00 | 839.03 | 2772.00 | 2079.00 | 1386.00 | 3093.75 |
| Total physical activity (MET-min/week) | 3066.00 | 1747.00 | 4652.25 | 3304.50 | 2227.50 | 5005.00 |

2.1.7 Satisfaction with vINCI technology

2.1.7.1 Process of measuring user satisfaction

Measuring user satisfaction is of great importance to any future improvements of the vINCI technologies. The process of measuring user satisfaction is performed in three stages. In the first stage, the users from the target group have access to the services and technologies developed within the vINCI project. The testing of these technologies and services is carried out under medical supervision, within the Institute of Geriatrics and Gerontology "Ana Aslan" (NIGG) for Romania and UNRF for Cyprus. Users, independently or with NIGG / UNRF support, mainly use the vINCI mobile application together with intelligent devices for monitoring bio-medical parameters. Here we refer especially to the smart insoles and to the monitoring technologies based on smart watches developed both within the project (CMD Smart watch) and taken over from other companies (FITBIT). The obtained results are corroborated with the results obtained from completing the questionnaires regarding the quality of life or measuring the level of physical activity, thus obtaining a score that indicates the evolution of the monitored parameters.

During the second phase, users are invited to complete a user satisfaction survey that provides valuable insight into the real experience of users interacting with the vINCI services and technologies. In the final phase, the survey responses will be evaluated and the degree of acceptance of the technology will be studied. Users' opinions on aspects that may be improved will be gathered.

2.1.7.2 vINCI Satisfaction Questionnaire Results Analysis

In order to measure the degree of user satisfaction regarding the use of vINCI technology and services, one questionnaire, divided into two parts, was developed (in line with the objectives of vINCI project) as follows:

- Part I – Demographic, Frequency of using the vINCI application;
- Part II – Interaction with all vINCI devices.

Part I - Demographic, Frequency of using the vINCI application

This section provides the results of the first part of the satisfaction questionnaires. The next sub-sections provide and analyse the results collected about demographic and frequency of using the vINCI application.

Demographic data

This study provides researchers with demographic data that help them better understand the impact of vINCI technology on both age and gender. Tables 2.24 and 2.25 provide demographic information about 30 elderly from NIGG pilot and another 30 elderly from Romania, participants in the satisfaction measuring surveys.

Table 2.24 Gender of elderly who participated in satisfaction measuring surveys

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|--------------|-----------|---------|---------------|--------------------|
| Valid Female | 37 | 61,7 | 61,7 | 61,7 |
| Male | 23 | 38,3 | 38,3 | 100,0 |
| Total | 60 | 100,0 | 100,0 | |

Table 2.25 Studies of elderly who participated in satisfaction measuring surveys

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|------------------------|-----------|---------|---------------|--------------------|
| Valid Higher education | 18 | 30,0 | 30,0 | 30,0 |
| Other | 5 | 8,3 | 8,3 | 38,3 |
| Secondary education | 37 | 61,7 | 61,7 | 100,0 |
| Total | 60 | 100,0 | 100,0 | |

Table 2.26 presents information regarding the answers provided by the elderly to statement I-1: “Frequency of use of vINCI application” from the feedback questionnaire on the satisfaction of using the vINCI application.

Table 2.26 Answers of elderly to question I-1: “Frequency of use of vINCI application”

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|----------------------|-----------|---------|---------------|--------------------|
| Valid daily | 40 | 66,7 | 66,7 | 66,7 |
| monthly | 9 | 15,0 | 15,0 | 81,7 |
| several times a year | 1 | 1,7 | 1,7 | 83,3 |
| weekly | 10 | 16,7 | 16,7 | 100,0 |
| Total | 60 | 100,0 | 100,0 | |

Part II – Interaction with all vINCI devices

Next, we will analyze the users' answers regarding the frequency of use of the vINCI application, as well as the distribution of the answers according to gender. Participants have the opportunity to indicate on a scale from 1 to 5, how often they use the vINCI application. The proposed scale measure has the following significance:

- *1 - means daily*: study participants use Vinci app daily. The impact of these users is high;
- *2 - weekly*: study participants use the vINCI application once or several times a week;
- *3 - monthly*: study participants use the vINCI application once or several times a month;
- *4 – several times a year*: study participants use the vINCI application once or several times a year.
- *5 - never*: Users do not use the vINCI application.

Table 2.27 presents information regarding the answers provided by the elderly to the statement II-1: “It is easy to learn how to work with the vINCI application”.

Table 2.27 Answers of elderly to II-1: “It is easy to learn how to work with the vINCI application”

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|-----------|-----------|---------|---------------|--------------------|
| Valid 2,0 | 2 | 3,3 | 3,3 | 3,3 |
| 3,0 | 6 | 10,0 | 10,0 | 13,3 |
| 4,0 | 38 | 63,3 | 63,3 | 76,7 |
| 5,0 | 14 | 23,3 | 23,3 | 100,0 |
| Total | 60 | 100,0 | 100,0 | |

Table 2.28 presents information regarding the answers provided by the elderly to the statement II-2: “The vINCI application is easy to use”.

Table 2.28 Answers of elderly to II-2: “The vINCI application is easy to use”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 3 | 5,0 | 5,0 | 5,0 |
| | 3,0 | 6 | 10,0 | 10,0 | 15,0 |
| | 4,0 | 35 | 58,3 | 58,3 | 73,3 |
| | 5,0 | 16 | 26,7 | 26,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.29 presents information regarding the answers provided by the elderly to the statement II-3: “Using the vINCI app, I am better informed about my health”.

Table 2.29 Answers of elderly to II-3: “Using the vINCI app, I am better informed about my health”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 1 | 1,7 | 1,7 | 1,7 |
| | 3,0 | 13 | 21,7 | 21,7 | 23,3 |
| | 4,0 | 34 | 56,7 | 56,7 | 80,0 |
| | 5,0 | 12 | 20,0 | 20,0 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.30 presents information regarding the answers provided by the elderly to the statement II-4: “My security level has improved using the vINCI application”.

Table 2.30 Answers of elderly to II-4: “My security level has improved using the vINCI application”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 5 | 8,3 | 8,3 | 8,3 |
| | 3,0 | 19 | 31,7 | 31,7 | 40,0 |
| | 4,0 | 35 | 58,3 | 58,3 | 98,3 |
| | 5,0 | 1 | 1,7 | 1,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.31 presents information regarding the answers provided by the elderly to the statement II-5: “The vINCI application helps me to obtain relevant quality of life data”.

Table 2.31 Answers of elderly to II-5: “The vINCI application helps me to obtain relevant quality of life data”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 3 | 5,0 | 5,0 | 5,0 |
| | 2,0 | 1 | 1,7 | 1,7 | 6,7 |
| | 3,0 | 10 | 16,7 | 16,7 | 23,3 |
| | 4,0 | 36 | 60,0 | 60,0 | 83,3 |
| | 5,0 | 10 | 16,7 | 16,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.32 presents information regarding the answers provided by the elderly to the statement II-6: “The vINCI application gives me the opportunity to more easily communicate data about my physical condition / quality of life”.

Table 2.32 Answers of elderly to II-6: “The vINCI application gives me the opportunity to more easily communicate data about my physical condition / quality of life”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 3,0 | 8 | 13,3 | 13,3 | 16,7 |
| | 4,0 | 42 | 70,0 | 70,0 | 86,7 |
| | 5,0 | 8 | 13,3 | 13,3 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.33 presents information regarding the answers provided by the elderly to the statement II-7: “The system interface is pleasant and intuitive”.

Table 2.33 Answers of elderly to II-7: “The system interface is pleasant and intuitive”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 3,0 | 7 | 11,7 | 11,7 | 15,0 |
| | 4,0 | 41 | 68,3 | 68,3 | 83,3 |
| | 5,0 | 10 | 16,7 | 16,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.34 presents information regarding the answers provided by the elderly to the statement II-8: “The results provided by the application are easy to access and understand”.

Table 2.34 Answers of elderly to II-8: “The results provided by the application are easy to access and understand”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 3,0 | 15 | 25,0 | 25,0 | 28,3 |
| | 4,0 | 39 | 65,0 | 65,0 | 93,3 |
| | 5,0 | 4 | 6,7 | 6,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.35 presents information regarding the answers provided by the elderly to the statement II-9: “I think I could improve my health using the vINCI app”.

Table 2.35 Answers of elderly to II-9: “I think I could improve my health using the vINCI app”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 2,0 | 1 | 1,7 | 1,7 | 5,0 |
| | 3,0 | 12 | 20,0 | 20,0 | 25,0 |
| | 4,0 | 38 | 63,3 | 63,3 | 88,3 |
| | 5,0 | 7 | 11,7 | 11,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.36 presents information regarding the answers provided by the elderly to the statement II-10: “The information provided by the vINCI application is complete and useful”.

Table 2.36 Answers of elderly to II-10: “The information provided by the vINCI application is complete and useful”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 1 | 1,7 | 1,7 | 1,7 |
| | 3,0 | 16 | 26,7 | 26,7 | 28,3 |
| | 4,0 | 42 | 70,0 | 70,0 | 98,3 |
| | 5,0 | 1 | 1,7 | 1,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.37 presents information regarding the answers provided by the elderly to the statement II-11: “The daily monitoring performed through the vINCI application does not interfere with my personal data”.

Table 2.37 Answers of elderly to II-11: “The daily monitoring performed through the vINCI application does not interfere with my personal data”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 1 | 1,7 | 1,7 | 1,7 |
| | 3,0 | 3 | 5,0 | 5,0 | 6,7 |
| | 4,0 | 39 | 65,0 | 65,0 | 71,7 |
| | 5,0 | 17 | 28,3 | 28,3 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.38 presents information regarding the answers provided by the elderly to the statement II-12: “The vINCI application has improved the quality of medical services received”.

Table 2.38 Answers of elderly to II-12: “The vINCI application has improved the quality of medical services received”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 2,0 | 2 | 3,3 | 3,3 | 6,7 |
| | 3,0 | 10 | 16,7 | 16,7 | 23,3 |
| | 4,0 | 37 | 61,7 | 61,7 | 85,0 |
| | 5,0 | 9 | 15,0 | 15,0 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.39 presents information regarding the answers provided by the elderly to the statement II-13: “The interaction with the vINCI application is clear and easy to understand”.

Table 2.39 Answers of elderly to II-13: “The interaction with the vINCI application is clear and easy to understand”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 1 | 1,7 | 1,7 | 1,7 |
| | 3,0 | 7 | 11,7 | 11,7 | 13,3 |
| | 4,0 | 39 | 65,0 | 65,0 | 78,3 |
| | 5,0 | 13 | 21,7 | 21,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.40 presents information regarding the answers provided by the elderly to the statement II-14: “The organization of the information on the screen of the devices running the vINCI application is clear and intuitive”.

Table 2.40 Answers of elderly to II-14: “The organization of the information on the screen of the devices running the vINCI application is clear and intuitive”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 3,0 | 11 | 18,3 | 18,3 | 18,3 |
| | 4,0 | 42 | 70,0 | 70,0 | 88,3 |
| | 5,0 | 7 | 11,7 | 11,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.41 presents information regarding the answers provided by the elderly to the statement II-15: “The vINCI application is very useful for me in my daily life”.

Table 2.41 Answers of elderly to II-15: “The vINCI application is very useful for me in my daily life”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 1,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 2,0 | 3 | 5,0 | 5,0 | 8,3 |
| | 3,0 | 16 | 26,7 | 26,7 | 35,0 |
| | 4,0 | 31 | 51,7 | 51,7 | 86,7 |
| | 5,0 | 8 | 13,3 | 13,3 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.42 presents information regarding the answers provided by the elderly to the statement II-16: “Using the vINCI application is very exciting”.

Table 2.42 Answers of elderly to II-16: “Using the vINCI application is very exciting”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 4 | 6,7 | 6,7 | 6,7 |
| | 3,0 | 16 | 26,7 | 26,7 | 33,3 |
| | 4,0 | 34 | 56,7 | 56,7 | 90,0 |
| | 5,0 | 6 | 10,0 | 10,0 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.43 presents information regarding the answers provided by the elderly to the statement II-17: “I like to interact with the vINCI application interface”.

Table 2.43 Answers of elderly to II-17: “I like to interact with the vINCI application interface”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 4 | 6,7 | 6,7 | 6,7 |
| | 3,0 | 9 | 15,0 | 15,0 | 21,7 |
| | 4,0 | 42 | 70,0 | 70,0 | 91,7 |
| | 5,0 | 5 | 8,3 | 8,3 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.44 presents information regarding the answers provided by the elderly to the statement II-18: “I use the vINCI application with confidence”.

Table 2.44 Answers of elderly to II-18: “I use the vINCI application with confidence”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 3 | 5,0 | 5,0 | 5,0 |
| | 3,0 | 8 | 13,3 | 13,3 | 18,3 |
| | 4,0 | 42 | 70,0 | 70,0 | 88,3 |
| | 5,0 | 7 | 11,7 | 11,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.45 presents information regarding the answers provided by the elderly to the statement II-19: “Overall, I am satisfied with how to use the vINCI application”.

Table 2.45 Answers of elderly to II-19: “Overall, I am satisfied with how to use the vINCI application”

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|-------|-----------|---------|---------------|--------------------|
| Valid | 2,0 | 2 | 3,3 | 3,3 | 3,3 |
| | 3,0 | 7 | 11,7 | 11,7 | 15,0 |
| | 4,0 | 44 | 73,3 | 73,3 | 88,3 |
| | 5,0 | 7 | 11,7 | 11,7 | 100,0 |
| | Total | 60 | 100,0 | 100,0 | |

Table 2.46 presents the Descriptive Statistics about the satisfaction of the elderly from Romania with vINCI technology.

Table 2.46 Descriptive Statistics about the satisfaction of the elderly from Romania with vINCI technology

| | N | Minimum | Maximum | Mean | Std. Deviation |
|--------------------|----|---------|---------|--------------|----------------|
| Q1 | 60 | 2,0 | 5,0 | 4,067 | ,6856 |
| Q2 | 60 | 2,0 | 5,0 | 4,067 | ,7561 |
| Q3 | 60 | 1,0 | 5,0 | 3,933 | ,7561 |
| Q4 | 60 | 2,0 | 5,0 | 3,533 | ,6756 |
| Q5 | 60 | 1,0 | 5,0 | 3,817 | ,9112 |
| Q6 | 60 | 1,0 | 5,0 | 3,900 | ,7524 |
| Q7 | 60 | 1,0 | 5,0 | 3,950 | ,7686 |
| Q8 | 60 | 2,0 | 5,0 | 3,750 | ,6277 |
| Q9 | 60 | 1,0 | 5,0 | 3,783 | ,8045 |
| Q10 | 60 | 2,0 | 5,0 | 3,717 | ,5237 |
| Q11 | 60 | 2,0 | 5,0 | 4,200 | ,6051 |
| Q12 | 60 | 1,0 | 5,0 | 3,817 | ,8535 |
| Q13 | 60 | 2,0 | 5,0 | 4,067 | ,6342 |
| Q14 | 60 | 3,0 | 5,0 | 3,933 | ,5482 |
| Q15 | 60 | 1,0 | 5,0 | 3,667 | ,8957 |
| Q16 | 60 | 2,0 | 5,0 | 3,700 | ,7433 |
| Q17 | 60 | 2,0 | 5,0 | 3,800 | ,6840 |
| Q18 | 60 | 2,0 | 5,0 | 3,883 | ,6662 |
| Q19 | 60 | 2,0 | 5,0 | 3,933 | ,6069 |
| Valid N (listwise) | 60 | | | | |

2.1.8 Conclusion on NIGG Pilot

This study involved two different groups from the Romanian pilot with similarly demographic data:

Experimental Group (30 users): mean age 71.4 years,

- equal numbers of men and women (15 & 15),
- the majority had secondary education (63.3%),
- more than half (63.3%) were married.

Control Group (30 participants): mean age 72.5 years,

- equal numbers of men and women (15 & 15),
- the majority had secondary education (76.7%),
- more than half (56.7%) were married.
- Data were collected for the same participants on both the first day and the eighth day.
 - At the beginning of day 1, each experimental group participant received instructions on how to use each device and filled in the WHOQOL-BREF and IPAQ questionnaires on the smart tablet. Technical support was available to the patients if it was needed.
 - At the beginning of day 1, each control group participant received the WHOQOL-BREF and IPAQ questionnaires in printed form for self-completion.
 - After 7 days, on the 8th day of the study, participants in both experimental and control groups filled in the follow-up WHOQOL-BREF and IPAQ questionnaires, only participants of experimental group filled in the Satisfaction Questionnaire on the Smart Tablet.
- The recruitment process of the subjects in order to participate in the vINCI experiment went smoothly, the patients admitted to the "Ana Aslan" NIGG clinics showing a high interest in the use of smart devices and in completing the experiment.
- The recruited patients went through the experimental process until the end being involved in all stages of development.
- The experiment consisted of the simultaneous measurement of three smart devices (Smart insole, Smart Watch and Fitbit) for a period of 7 days. Additionally during a 30-minute per day, 5 days, each subject walked with the researcher psychologist, with purpose to achieve a synchronization of the three types of measurements and validation of the transmitted data. This had secondary benefits:
 - Due to the existence of a limitation of patient mobility during hospitalization, this measurement process was attractive and tender for the subjects.
 - The daily walk, for 30 minutes together with a member of the team of psychologists was associated with mood improvement, according to the questionnaires applied, but also the spontaneous reports of the subjects.
- During the experiment, the subjects wore a Smart Watch, which was used in parallel with a Fitbit through which the daily measurement of some parameters was performed to validate the transmitted data. The use of Fitbit raised particular interest by providing easily accessible additional information.
- Subjects were open and motivated to wear the vINCI devices to obtain specific information about a range of biophysiological measurements.

- In the experimental group, the results showed that there were statistically significant differences between day 1 and day 8 regarding Quality of Life (QOL) in each of the WHOQOL-BREF domains: Physical, Psychological, Social, and Environment. Finally, in the control group, the results showed that there were no statistically significant differences in the scores for participants between day 1 and day 8 regarding QOL in each of the WHOQOL-BREF domains, except for the social domain.
- In the experimental group (day 8), of the 30 patients, 66.7% had a "High" IPAQ category and the median value of Total physical activity (MET-min/ week) was 3304.50, the "high" category describes high levels of physical activity participation. In the control sample (day 8), of the 30 patients, 50.0% had a "Moderate" IPAQ category and the median value of Total physical activity (MET-min/ week) was 2029.50.
- Walking might have been increased because of the use of vINCI technology and the feedback regarding their quality of life and physical exercise status.
- The vINCI devices were easy to use by the subjects, as they had no difficulty in wearing them and keeping them in function.
- *There was also a motivating effect on continuing and walking at home and adopting healthy habits.*

2.2 Cyprus Pilot

2.2.1 Phase 1: Acceptability of vINCI technology

2.2.1.1 Objective

The purpose of phase 1 pilot in Cyprus was the use of vINCI devices by older people and understand their level of acceptability of this technology (Constantinou et al., 2021).

2.2.1.2 Methodology

The methodology used for piloting the vINCI project in Cyprus for acceptability purposes is that of mixed research methods whereby participants used the technology for a period of seven days and then completed questionnaires with closed and open questions, which led to short interviews. According to Bryman (2006), a mixed research method is used for many reasons, namely triangulation, complementarity, development, initiation and expansion. In this study, a mixed method was used for triangulation (corroboration), complementarity (elaboration) and expansion (exploration in more depth).

2.2.1.3 The instrument

The instrument for measuring acceptability was designed to reflect vINCI technology and consisted of 15 likert-scale statements (five statements per device). The statements were: 1) The instructions of how to use this device were clear, 2) Using the device was comfortable, 3) Using the device was easy, 4) Using the device was useful, and 5) Overall, I am satisfied with this device. These statements were answered on the basis of a likert-scale, such as “strongly disagree”, “disagree”, “neither agree nor disagree”, “agree”, “strongly agree”. Internal consistency of the closed questionnaire was calculated by using the Cronbach’s alpha coefficient (α). Cronbach’s alpha reliability coefficient normally ranges between 0 and 1. The closer Cronbach’s alpha coefficient is to 1.0 the greater the internal consistency of the questionnaire. An α of 0.6-0.7 indicates an acceptable level of reliability, and 0.8 or greater a very good level (Gliem and Gliem 2003). Analysis of our data showed that the value of Cronbach’s alpha coefficient for internal consistency for the 15-items acceptability questionnaire was 0.735, which indicated an acceptable level of reliability. This shows that the questionnaire reliably measured acceptability of the vINCI technology.

For each device there were two open questions asking participants to reflect on what was good about the device and on any suggestions for improvement. However, these were not fixed questions but were open enough to allow space for more questions by the researcher turning them eventually into short interviews.

2.2.1.4 Sampling, recruitment and procedure

The convenient and purposive sample methods were used to recruit 20 participants for this pilot study. The sample was convenient because older adults were found in a convenient place, that of a Day Centre in Strovolos, Nicosia. Sampling was also purposive in the sense that the participants had to have specific characteristics, such as being 65 or older and being active in the community, and they were recruited for a specific purpose, that of using technology for some period and providing feedback. Whenever it was not feasible to recruit participants from the Day Centre, participants were recruited from local community.

The procedure of phase 1 pilot is shown in Figure 2.17. That is, each device was used separately for a period of seven days and then participants were asked to complete the acceptability questionnaires. Participants' comments were sent to the developers of vINCI technology for any technological adaptation.

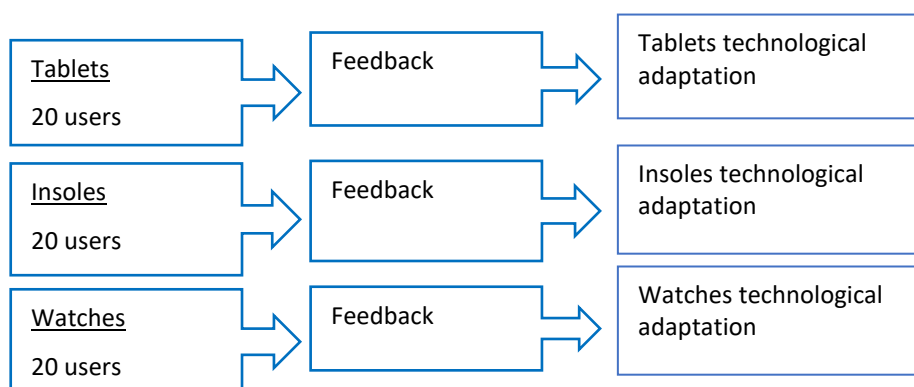


Figure 2.17 Process of acceptability pilot

2.2.1.5 Analysis

The analysis of data was done through the SPSS (Statistical Package for the Social Sciences), whereby means were calculated and statistically compared. Qualitative comments were coded inductively and analyzed on the basis of the General Inductive Approach (Thomas, 2006). Thomas (2006, p.242) described the process of inductive coding as follows: “label the segments of texts to create categories → reduce overlap and redundancy among categories → create a model incorporating most important categories”. Because the qualitative data generated were largely for triangulation, complementarity and expansion we did not aim to develop a model but an interpretive explanation which would reflect the purpose of employing a mixed research methodology.

2.2.1.6 Results

Tablets

Tablets would host the vINCI app and participants were given the opportunity to complete WHOQOL-BREF (Quality of Life) and IPAQ (Physical exercise)

questionnaires, and were explained how the information inserted would be processed along with other information from the insoles and watches in order to receive feedback about their biopsychosocial condition. Out of a maximum score of 5, participants scored clarity of instruction with 4.85, comfort of device with 4.80, ease of use with 4.55, usefulness with 4.65, and they overall scored tablets with 4.55. These scores show that participants had a positive experience.

Qualitative comments indicated that the use of tablets was very well-received by the participants. Because the use was very straight forward, participants did not have any elaborated comments to make. They liked the instructions, that the questions were clear and the questionnaires short. They did not raise any issues or made any suggestions for the device itself. This is possibly because many of the participants were already familiar with tablets and had positive prior experience. However, some of the participants clarified that they would not like a tablet to tell them what to do. They would prefer the app giving them options, based on the information from the questionnaires, the insoles and watches, to choose from so that intervention would reflect their needs at the time.

Insoles

Participants were provided with the insoles, which they should use for seven days and during their daily routine. Therefore, they started using the insoles at the Day Centre because they had visited the Centre for an activity they wanted to do (e. g. dancing lessons, signing, computer lessons etc.). When their commitment at the Centre ended, they continued wearing it at their home and anywhere else they went for other activities, such as going to a supermarket, visiting friends and relatives, driving a car and so forth. When the 7-days period lapsed, the participants returned the insoles and were asked to provide feedback. They scored the insole as follows: clarity of instructions received 4.75, comfort of device 4.55, ease of use 4.75, usefulness 4.55, and overall evaluation 4.30.

Unlike the tablets, participants provided more elaborated feedback on the insoles. The feedback from the participants was generally positive. Participants found the insoles to be very thin and that they did not feel them in their shoe. The general feeling was comfort. They found the instructions clear, the insoles easy to use and useful for what they will be doing in the end. Participants clarified that they understood that the use of the insoles will be for their own good and they would be happy to use them permanently. Interestingly, all participants explained that using such a device which would make the specific measures and provide feedback to the users about the next steps and actions to be taken would give a context of safety and would enhance their confidence in daily living independently. Participants also clarified that the insoles would not cause them to feel different and that it would not be a context of stigmatisation. On the other hand, the participants identified an area which needed to be considered for improving the device. The main issue was that the

dock did not stick well to the shoe. This was because the dock with the tab inserted became heavy and it got off easily.

Watches

The use of arm watches was similar as the use of insoles in the sense that participants were provided with the devices, which they used for seven days in their daily life. Participants' experience with watches was also positive as the scores were: clarity of instructions: 4.85, comfort of device: 4.40, ease of use: 4.45, usefulness: 4.45, overall evaluation: 4.40.

Participants wrote very positive comments on the watches. They explained that the watch was easy to wear, it could safely stay on their wrist without them worrying if it could go off, it was light enough and they often forgot that they were wearing it. They did not have any negative comments on the device itself and they clarified that they would not feel stigmatised while wearing the device possibly because of their familiarity with watches in general or with smart watches.

Comparing scores across the three devices

Table 2.47 shows the scores for each device per question. Comparing these scores in graph from Figure 2.18 indicates that the devices have been scored similarly. This suggests that the vINCI devices gave a relatively consistent experience and were accepted in a similar way.

Table 2.47 Scores on devices per question.

| Items | Tablets (T) | Insoles (I) | Watches (W) |
|-------|-------------|-------------|-------------|
| Q1 | 4.85 | 4.75 | 4.85 |
| Q2 | 4.80 | 4.55 | 4.40 |
| Q3 | 4.55 | 4.75 | 4.45 |
| Q4 | 4.65 | 4.55 | 4.45 |
| Q5 | 4.55 | 4.30 | 4.40 |

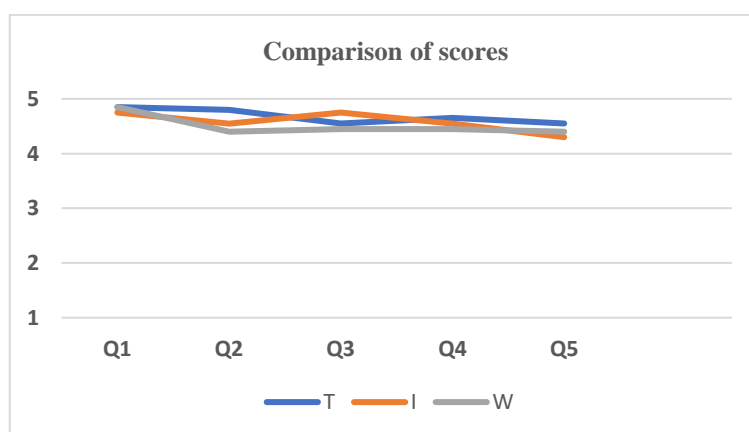


Figure 2.18 Graph: Comparison of scores among the devices

Although all three devices were scored positively, it was imperative to check if there were any statistically significant differences in terms of how the scoring per question on one device influenced the scoring on other devices. The results from all five questions showed no important differences, as the statistical testing revealed no statistical significance (see Table 2.48). This means that the information about the devices as well as the devices themselves were understood as being of similar clarity, comfort, ease to use, usefulness, and importance.

Table 2.48 Statistical comparison of how the devices were scored per question

| Items | sig. (2-sided) | sig. (1-sided) |
|--------|----------------|----------------|
| T1, I1 | 0.140 | 0.140 |
| I1, W1 | 0.140 | 0.140 |
| T1, W1 | 0.404 | 0.404 |
| T2, I2 | 0.617 | 0.396 |
| I2, W2 | 1.000 | 0.535 |
| T2, W2 | 0.347 | 0.292 |
| T3, I3 | 1.000 | 0.604 |
| I3, W3 | 1.000 | 0.604 |
| T3, W3 | 0.92 | 0.80 |
| T4, I4 | 0.374 | 0.272 |
| I4, W4 | 0.90 | 0.78 |
| T4, W4 | 0.374 | 0.272 |
| T5, I5 | 0.157 | 0.119 |
| I5, W5 | 0.161 | 0.137 |
| T5, W5 | 0.67 | 0.465 |

Statistical significance <0.05

2.2.1.7 Acceptability of vINCI technology

Integrating the scores and the qualitative comments as per the purpose of a mixed research method, acceptability of the vINCI technology has been affected by a number of parameters which are shown in Figure 2.19. These parameters are clarity of instruction use and purpose of the device, how comfortable the devices are on the human body and to the senses, how easy they are to use, how useful they are for older adults and their health or life, the devices give a sense of safety for the future, and older adults have control over the decision making with regard to corrective actions required following processing of information from the WHOQOL and the IPAQ questionnaires, as well as, the insoles and the watches. Moreover, older adults appreciated that the vINCI technology was familiar as it was employing devices used in daily life (i.e. tablets, watches, very thin unnoticeable insoles) and the technology would

cause them to continue their life as normal as before with the potential of improvement.

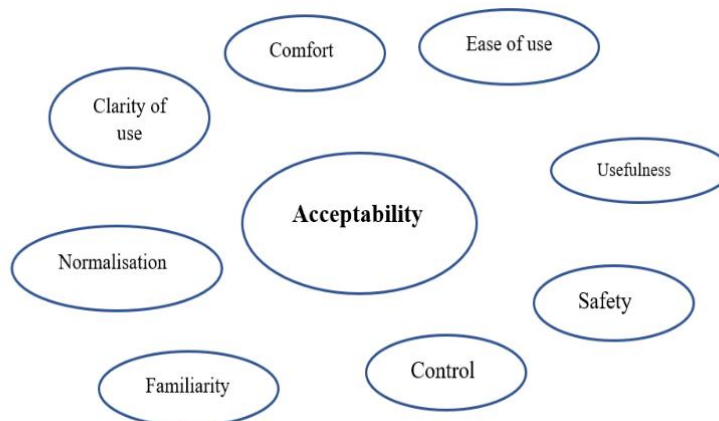


Figure 2.19 Parameters affecting acceptability of vINCI technology

2.2.2 Phase 2: Quality of life (WHOQOL-BREF)

Participants and study design

The 20 participants phase 2 were selected through a convenient sampling at a Day Centre in Strovolos, Nicosia. The sample was convenient because the participants were conveniently found in a place they usually visit for leisure activities and socialisation. In some cases, participants were recruited from the community as the Day Centre could not recruit the required number. They were selected on the basis of age (65 or older) and health status (absent of a limiting health condition that would not allow them to use the vINCI technology). Exclusion criteria on the basis of medical conditions were the same as the ones used in Romania, outlined on pages 5 and 6 in this report. Participants completed the WHOQoL-BREF and IPAQ questionnaires for quality of life and physical exercise via interviews before the use of technology. After using vINCI technology for two weeks, they completed the same questionnaires again via interviews.

Sample characteristics

Data were collected for the same participants before and after the use of vINCI. The sample consisted of 20 participants with a mean age of 73.6 years (SD=±5.29; range of 65–83). More than half (55.0%) were female and majority were married (70.0%). More information on socio-demographic characteristics of participants is shown in Table 2.49.

Table 2.49 Participant characteristics

| Cyprus sample, N=20 | |
|---------------------|-----------|
| Sex, <i>n</i> (%) | |
| Male | 9 (45.0) |
| Female | 11 (55.0) |

| | |
|------------------------------|-------------|
| Age | |
| Mean (SD) | 73.6 (5.29) |
| Range | 65–83 |
| 65 - 70 years | 6 (30.0) |
| 71 -75 years | 6 (30.0) |
| > 76 years | 8 (40.0) |
| Marital status, <i>n</i> (%) | |
| Married | 14 (70.0) |
| Living as married | 1 (5.0) |
| Divorced | 1 (5.0) |
| Widowed | 4 (20.0) |
| Education, <i>n</i> (%) | |
| Primary school | 6 (30.0) |
| Secondary school | 7 (35.0) |
| Tertiary school | 7 (35.0) |

2.2.2.1 Results

Data analysis was performed separately for data collected before and after using vINCI. Therefore, the results are presented separately: study 1 - before the use of vINCI, study 2 - after the use of vINCI. Finally, the results obtained by the same patients at the two different times are compared.

2.2.2.2 Study 1 - before the use of vINCI

Item-level analysis

According to the WHOQOL Manual (WHO, 1998), where more than 20% of data are missing from an assessment, the assessment should be discarded. Where up to two items are missing, the mean of other items in the domain is substituted. Where more than two items are missing from the domain, the domain score should not be calculated (with the exception of domain 3, where the domain should only be calculated if < 1 item is missing).

There are no data missing, with the exception of the Q21 item (*sexual activity*) where 35% of data are missing. No univariate outliers were found; all z-scores were $>+3.29$ or <-3.29 ($p<.001$, two-tailed test), according to conventional criteria (e.g., Tabachnick & Fidell, 2013).

The overall mean of the 24 items was 3.20. Items Q3 (*physical pain*), Q4 (*dependence medication*), Q15 (*mobility*), and Q12 (*financial resources*) were the four highest scoring items. On the other hand, Q20 (*personal relationship*) and Q19 (*self-esteem*) scored lowest among the 24 items (see, Table 2.50).

The mean scores \pm SD for the other two questions Q1 (*overall QOL*) and Q2 (*general health*), scored on a 5-point Likert scale and scored from 1 to 5 (ranged from very poor to very good and very dissatisfied to very satisfied, respectively), were 3.30 ± 0.66 and 3.30 ± 0.66 , respectively. These questions should be evaluated separately and are not included in a domain, as per the WHOQOL-BREF manual (WHOQOL Group, 1998; WHO, 1998).

Table 2.50 Items: summary statistics (before the use of vINCI, N=20)

| Items | Mean | Std. Dev. | Median |
|-------------------|------|-----------|--------|
| Q1 | 3.30 | .657 | 3.00 |
| Q2 | 3.30 | .657 | 3.00 |
| Q3 ^{a)} | 3.80 | .768 | 4.00 |
| Q4 ^{a)} | 3.80 | .833 | 4.00 |
| Q5 | 3.10 | .641 | 3.00 |
| Q6 | 3.30 | .733 | 3.00 |
| Q7 | 3.45 | .686 | 4.00 |
| Q8 | 3.45 | .605 | 3.50 |
| Q9 | 3.35 | .671 | 3.00 |
| Q10 | 3.20 | .696 | 3.00 |
| Q11 | 3.05 | .686 | 3.00 |
| Q12 | 3.50 | .688 | 4.00 |
| Q13 | 3.45 | .686 | 3.00 |
| Q14 | 3.30 | .657 | 3.00 |
| Q15 | 3.55 | .686 | 4.00 |
| Q16 | 2.95 | .759 | 3.00 |
| Q17 | 3.05 | .759 | 3.00 |
| Q18 | 2.75 | .967 | 3.00 |
| Q19 | 2.60 | .821 | 2.50 |
| Q20 | 2.50 | .946 | 2.00 |
| Q21 | 2.77 | .725 | 3.00 |
| Q22 | 2.85 | .933 | 3.00 |
| Q23 | 3.30 | .733 | 3.00 |
| Q24 | 3.45 | .686 | 4.00 |
| Q25 | 3.30 | .571 | 3.00 |
| Q26 ^{a)} | 3.05 | .510 | 3.00 |

^{a)} Q3, Q4 and Q26 have been reversed coded.

Domain-level analysis

The mean scores \pm SD for the four domains of the WHOQOL-BREF, physical, psychological, social, and environmental domains in the transformed scores of 0-100 are showed in Table 2.51. Comparing the four domains, environmental domain was the highest with a mean score of 59.69, while the social domain was the lowest (43.59).

Table 2.51 Domains: summary statistics (transformed scores 0-100; before the use of vINCI, N=20)

| Domain | Mean (SD) | Median | Minimum | Maximum |
|---------------|---------------|--------|---------|---------|
| Physical | 57.50 (15.06) | 50.00 | 39.29 | 89.29 |
| Psychological | 52.29 (12.64) | 52.08 | 29.17 | 79.17 |
| Social | 43.59 (13.67) | 41.67 | 25.00 | 75.00 |
| Environment | 59.69 (12.78) | 59.37 | 37.50 | 84.38 |

An QOL \geq 60 cut-off point moderately sensitive for recognizing patients with good / satisfactory QOL and a QOL $<$ 60 cut-off optimum negative predictive value for screening patients whose QoL was poor / unsatisfactory (vINCI, 2019). A total score below 60 points signals impaired QOL (all domains).

The relationship between the four domains, overall QOL and general health was investigated using Pearson product-moment correlation coefficient. Results are shown in Table 2.52.

The Pearson correlation coefficient showed a moderately high positive correlation between the social and environment domains, and high levels between the other domains.

The four domains and overall QOL (Q1) were significantly and positively interrelated with moderate to high relationships, ranged from .58 ($p < .05$) to .65 ($p < .01$).

The four domains and general health (Q2) were significantly and positively interrelated with high relationships, ranged from .63 ($p < .05$) to .81 ($p < .01$).

Table 2.52 Pearson correlations of the four QOL domains, overall QOL and general health (before the use of vINCI, N=20)

| | Physical | Psychological | Social | Environment | Overall QOL | General health |
|---------------------|----------|---------------|--------|-------------|-------------|----------------|
| Physical | 1. | .831** | .740** | .833** | .654** | .768** |
| Psychological | | 1. | .693** | .822** | .652** | .811** |
| Social | | | 1. | .585* | .585* | .748** |
| Environment | | | | 1. | .615** | .635** |
| Overall QOL (Q1) | | | | | 1. | .512* |
| General health (Q2) | | | | | | 1. |

* $p < 0.05$; ** $p < 0.01$

There was a significantly moderate positive correlation between the overall QOL and general health ($r=.51$, $p<.05$).

2.2.2.3 Study 2 - after the use of vINCI

Item-level analysis

There are no data missing, with the exception of the Q21 item (*sexual activity*) where 40% of data are missing. No univariate outliers were found; all z-scores were $>+3.29$ or <-3.29 ($p<.001$, two-tailed test), according to conventional criteria (e.g., Tabachnick & Fidell, 2013).

The overall mean of the 24 items was 3.37. Items Q3 (*physical pain*), Q4 (*dependence medication*), Q6 (*meaningfulness of life*), and Q10 (*energy*) were the four highest scoring items. On the other hand, Q21 (*sexual activity*), Q19 (*self-esteem*), and Q18 (*working capacity*) scored lowest among the 24 items (see, Table 2.53).

Table 2.53 Items: summary statistics (after the use of vINCI sample, N=20)

| Items | Mean | Std. Dev. | Median |
|------------------|------|-----------|--------|
| Q1 | 3.50 | .607 | 3.00 |
| Q2 | 3.35 | .587 | 3.00 |
| Q3 ^{a)} | 3.90 | .718 | 4.00 |
| Q4 ^{a)} | 3.85 | .813 | 4.00 |
| Q5 | 3.45 | .605 | 3.50 |
| Q6 | 3.75 | .550 | 4.00 |
| Q7 | 3.55 | .605 | 4.00 |
| Q8 | 3.50 | .513 | 3.50 |
| Q9 | 3.35 | .671 | 3.00 |
| Q10 | 3.70 | .571 | 4.00 |
| Q11 | 3.10 | .641 | 3.00 |
| Q12 | 3.55 | .605 | 4.00 |
| Q13 | 3.40 | .754 | 3.00 |
| Q14 | 3.30 | .657 | 3.00 |
| Q15 | 3.55 | .605 | 3.50 |
| Q16 | 3.00 | .725 | 3.00 |
| Q17 | 3.50 | .607 | 3.00 |
| Q18 | 2.90 | .912 | 3.00 |
| Q19 | 2.85 | .671 | 3.00 |
| Q20 | 3.25 | .639 | 3.00 |

| | | | |
|-------------------|------|------|------|
| Q21 | 2.79 | .699 | 3.00 |
| Q22 | 3.05 | .759 | 3.00 |
| Q23 | 3.30 | .733 | 3.00 |
| Q24 | 3.45 | .686 | 4.00 |
| Q25 | 3.30 | .571 | 3.00 |
| Q26 ^{a)} | 3.60 | .503 | 4.00 |

^{a)} Q3, Q4 and Q26 have been reversed coded.

The mean scores \pm SD for the other two questions Q1 (*overall QOL*) and Q2 (*general health*), scored on a 5-point Likert scale and scored from 1 to 5 (ranged from very poor to very good and very dissatisfied to very satisfied, respectively), were 3.50 ± 0.61 and 3.35 ± 0.59 , respectively.

Domain-level analysis

The mean scores \pm SD for the four domains of the WHOQOL-BREF, physical, psychological, social, and environmental domains in the transformed scores of 0-100 are showed in Table 2.54. Comparing the four domains, physical domain was the highest with a mean score of 62.14, while the social domain was the lowest (49.40).

Table 2.54 Domains: summary statistics (transformed scores 0-100; after the use of vINCI, N=20)

| Domain | Mean (SD) | Median | Minimum | Maximum |
|---------------|---------------|--------|---------|---------|
| Physical | 62.14 (12.87) | 57.14 | 46.43 | 89.29 |
| Psychological | 59.58 (11.16) | 58.33 | 33.33 | 79.17 |
| Social | 49.40 (11.07) | 50.00 | 33.33 | 75.00 |
| Environment | 59.84 (12.51) | 59.37 | 40.63 | 84.38 |

An QOL ≥ 60 cut-off point moderately sensitive for recognizing patients with good / satisfactory QOL and a QOL < 60 cut-off optimum negative predictive value for screening patients whose QoL was poor / unsatisfactory (vINCI, 2019). A total score below 60 points signals impaired QOL (all domains, with the exception of the physical domain).

The relationship between the four domains, overall QOL and general health was investigated using Pearson product-moment correlation coefficient. Results are shown in Table 2.55.

The Pearson correlation coefficient showed a moderately high positive correlation between the social and environment domains, and high levels between the other domains.

The four domains and overall QOL (Q1) were significantly and positively interrelated with moderate to high relationships, ranged from .55 ($p < .05$) to .68 ($p < .01$), with except of the environment domain (Table 2.55).

Table 2.55 Correlations of the four QOL domains, overall QOL and general health (after the use of vINCI)

| | Physical | Psychological | Social | Environment | Overall QOL | General health |
|---------------------|----------|---------------|--------|-------------|-------------|----------------|
| Physical | 1. | .696** | .719** | .809** | .626** | .801** |
| Psychological | | 1. | .688** | .634** | .551* | .566** |
| Social | | | 1. | .569* | .679** | .653* |
| Environment | | | | 1. | .422 | .648** |
| Overall QOL (Q1) | | | | | 1. | .517* |
| General health (Q2) | | | | | | 1. |

* p<0.05; ** p<0.01

General health (Q2) was high positive interrelated with all the four domains, ranged from .57 (p<.01) to .80 (p<.01).

There was a significantly moderate positive correlation between the overall QOL and general health (r=.52, p<.05).

Comparison of results from study 1 and study 2

The graph from Figure 2.20 shows the average of the items on WHOQOL-BREF before the use of vINCI (study 1) and after the use of vINCI (study 2). A paired-samples t-test was conducted to compare the items scores for study 1 and study 2. There were significant differences in the scores of seven items (Q1, Q5, Q10, Q17, Q19, Q20, Q26) between study 1 and study 2.

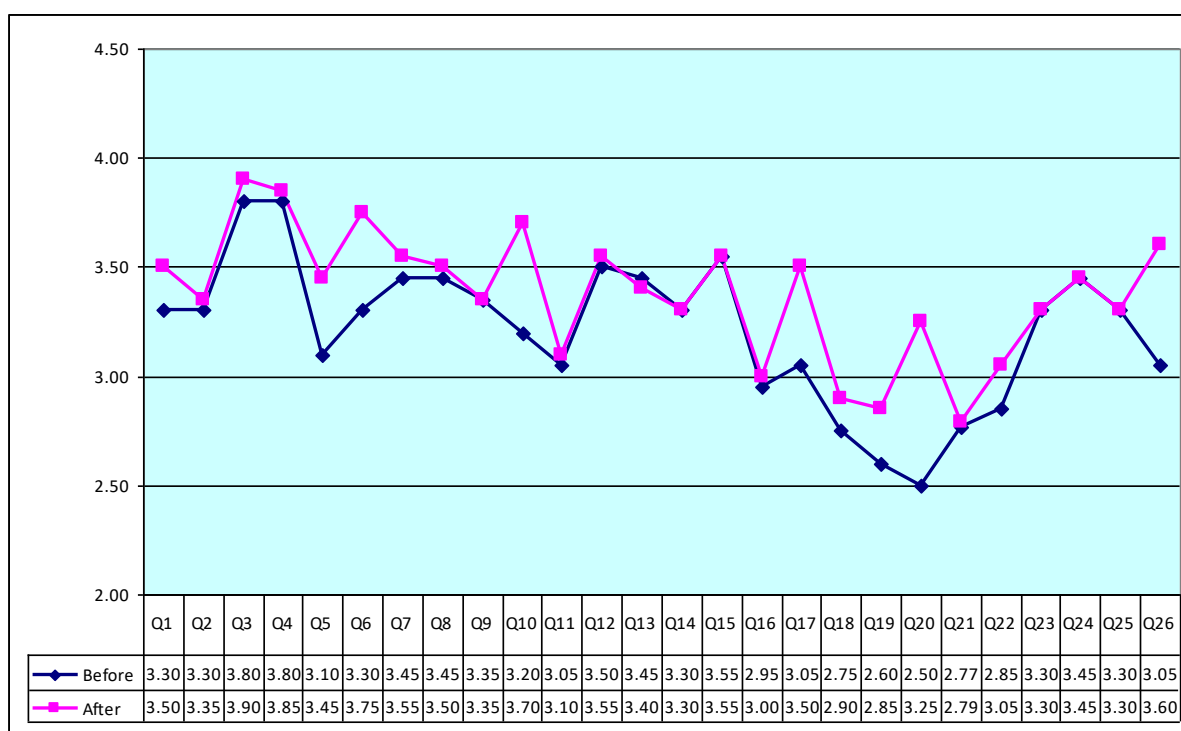


Figure 2.20 Graph: The mean scores of the 26 items in WHOQOL-BREF scale (before and after the use of vINCI, N=20)

Finally, a paired-samples t-test was conducted to compare the scores of the domains for study 1 and study 2. The results showed that there were statistically significant differences ($p < .05$) in the scores for participants regarding QOL in each of the WHOQOL-BREF domains, with except of the environment domain (Table 2.56).

Table 2.56 The results of comparing the scores of each domain (N=20)

| | | Physical health | Psychological health | Social relationships | Environment domain |
|--------------------------------|----------------|----------------------|----------------------|----------------------|----------------------|
| Before the use of vINCI | M(SD) | 57.50 (15.06) | 52.29 (12.64) | 43.59 (13.67) | 59.69 (12.78) |
| After the use of vINCI | M(SD) | 62.14 (12.87) | 59.58 (11.16) | 49.36 (11.52) | 59.84 (12.51) |
| | t(19) | -3.901 | -4.837 | t(12)=-3.323 | -1.000 |
| | <i>p-value</i> | .001 | .000 | .006 | .330 |

However, as shown in Table 2.56, scores were higher in study 2 (after the use of vINCI) than scores in study 1 (before the use of vINCI) in all four domains.

It seems that the feedback participants received through vINCI encouraged them to increase their physical engagement and, more importantly, their social interactions, which has helped their psychological wellbeing.

2.2.3 Phase 2: Physical activity (IPAQ-SF)

Participants and study design

The process of collecting data through the IPAQ questionnaire is the same as the one used for the WHOQoL-BREF which is described under section "Participants and research design".

Results - before and after the use of vINCI

This analysis used the same sample of patients (before and after the use of vINCI, N=20) from whom data were collected for the WHOQOL-BREF instrument. In Table 2.57 and Table 2.58 are shown the IPAQ-SF final results.

In study 1 (before the use of vINCI), of the 20 patients, 15.0% had a "Moderate" IPAQ category, and 85.0% had a "Low" IPAQ category (Table 2.57). The median value of Total physical activity (MET-min / week) was 421.50.

Table 2.57 IPAQ-SF MET-min/week and Categorical Scores (before the use of vINCI, N=20)

| No. | MET-MINUTES PER WEEK | | | | PHYSICAL ACTIVITY CATEGORY | |
|-----|----------------------|----------|------|-------|----------------------------|---------------------|
| | Vigorous | Moderate | Walk | Total | Category | Category (Recorded) |
| 1 | 960 | 240 | 594 | 1794 | Moderate | 2 |

| | | | | | | |
|----|-----|-----|-------|------|----------|---|
| 2 | 480 | 160 | 264 | 904 | Moderate | 2 |
| 3 | 0 | 160 | 33 | 193 | Low | 1 |
| 4 | 320 | 160 | 66 | 546 | Low | 1 |
| 5 | 0 | 160 | 264 | 424 | Low | 1 |
| 6 | 0 | 160 | 148.5 | 309 | Low | 1 |
| 7 | 240 | 160 | 33 | 433 | Low | 1 |
| 8 | 80 | 160 | 99 | 339 | Low | 1 |
| 9 | 0 | 80 | 148.5 | 229 | Low | 1 |
| 10 | 160 | 80 | 198 | 438 | Low | 1 |
| 11 | 0 | 120 | 132 | 252 | Low | 1 |
| 12 | 160 | 240 | 198 | 598 | Low | 1 |
| 13 | 160 | 160 | 99 | 419 | Low | 1 |
| 14 | 160 | 160 | 198 | 518 | Low | 1 |
| 15 | 0 | 80 | 132 | 212 | Low | 1 |
| 16 | 0 | 120 | 198 | 318 | Low | 1 |
| 17 | 0 | 160 | 99 | 259 | Low | 1 |
| 18 | 160 | 160 | 198 | 518 | Low | 1 |
| 19 | 0 | 160 | 132 | 292 | Low | 1 |
| 20 | 480 | 480 | 396 | 1356 | Moderate | 2 |

In study 2 (after the use of vINCI), of the 20 patients, 25.0% had a "Moderate" IPAQ category, and 75.0% had a "Low" IPAQ category (Table 2.58). The median value of Total physical activity (MET-min / week) was 431.00 (Table 2.59).

Table 2.58 IPAQ-SF MET-min/week and Categorical Scores (after the use of vINCI, N=20)

| No. | MET-MINUTES PER WEEK | | | | PHYSICAL ACTIVITY CATEGORY | |
|-----|----------------------|----------|-------|-------|----------------------------|---------------------|
| | Vigorous | Moderate | Walk | Total | Category | Category (Recorded) |
| 1 | 960 | 240 | 594 | 1794 | Moderate | 2 |
| 2 | 0 | 160 | 264 | 424 | Low | 1 |
| 3 | 0 | 240 | 198 | 438 | Low | 1 |
| 4 | 320 | 160 | 99 | 579 | Low | 1 |
| 5 | 0 | 120 | 264 | 384 | Low | 1 |
| 6 | 0 | 200 | 99 | 299 | Low | 1 |
| 7 | 200 | 160 | 99 | 459 | Low | 1 |
| 8 | 80 | 200 | 198 | 478 | Low | 1 |
| 9 | 0 | 80 | 247.5 | 328 | Low | 1 |

| | | | | | | |
|----|-----|-----|-----|------|----------|---|
| 10 | 160 | 80 | 297 | 537 | Low | 1 |
| 11 | 0 | 120 | 132 | 252 | Low | 1 |
| 12 | 160 | 240 | 264 | 664 | Moderate | 2 |
| 13 | 160 | 160 | 99 | 419 | Low | 1 |
| 14 | 160 | 240 | 297 | 697 | Moderate | 2 |
| 15 | 0 | 80 | 132 | 212 | Low | 1 |
| 16 | 0 | 120 | 297 | 417 | Low | 1 |
| 17 | 0 | 160 | 198 | 358 | Low | 1 |
| 18 | 160 | 240 | 297 | 697 | Moderate | 2 |
| 19 | 0 | 0 | 297 | 297 | Low | 1 |
| 20 | 480 | 480 | 396 | 1356 | Moderate | 2 |

Table 2.59 IPAQ-SF MET-min/week and continuous scores (Cyprus sample, N=20)

| | Before the use of vINCI | | | After the use of vINCI | | |
|--|-------------------------|-------------|--------|------------------------|-------------|--------|
| | Median | Percentiles | | Median | Percentiles | |
| | | 25 | 75 | | 25 | 75 |
| Vigorous (MET-minutes/week) | 120.00 | 0.00 | 220.00 | 40.00 | 0.00 | 160.00 |
| Moderate (MET-minutes/week) | 160.00 | 130.00 | 160.00 | 160.00 | 120.00 | 240.00 |
| Walking (MET-minutes/week) | 148.50 | 99.00 | 198.00 | 255.75 | 132.00 | 297.00 |
| Total physical activity (MET-min/week) | 421.50 | 267.25 | 539.00 | 431.00 | 335.13 | 642.75 |

The findings from the completion of the IPAQ questionnaires are interesting in the sense that vigorous exercise fell, moderate exercise did not change significantly and walking increased. It is possible that decreasing the amount of vigorous activity and not substantially changing moderate activity had to do the heat in Cyprus during the time (summer) that the pilot was taking place. Walking might have been increased because of the use of vINCI technology and the feedback regarding their quality of life and physical exercise status.

2.2.4 Satisfaction with vINCI technology

As per Table 2.60, all participants advised that they used vINCI on a daily basis (item S). Overall, they were satisfied with the use of vINCI with an average score of 4 out of 5 (item S19). Most items received an average score of or near 4, with the exemption of items S3 (score: 2.95), S4 (score: 2.95), S6 (score: 3.0) and S12 (score: 2.9). S3 was about participants' feeling that they are better informed about their health and S4 about how their feeling of security developed because of vINCI. S6 asked about the ease to communicate data about participants' condition and quality of life, and S12 focused on participants' thoughts about how vINCI had improved the quality of medical services received. Considering that participants were generally satisfied with vINCI, and that quite a few domains and areas in both QoL and IPAQ questionnaires were improved during the period of using vINCI, it is likely that the lower score on

S3,4,6 and 12 resulted from using the technology for only two weeks. Using the technology over a larger period of time when participants would have the opportunity to immerse themselves into the functionalities of vINCI would possibly improve participants' satisfaction even further.

Table 2.60 Satisfaction scores

| Items | N | Mean |
|-------|----|--------|
| S | 20 | 1.0000 |
| S1 | 20 | 3.9500 |
| S2 | 20 | 3.9000 |
| S3 | 20 | 2.9500 |
| S4 | 20 | 2.9500 |
| S5 | 20 | 3.6000 |
| S6 | 20 | 3.0000 |
| S7 | 20 | 3.9500 |
| S8 | 20 | 3.9500 |
| S9 | 20 | 3.9500 |
| S10 | 20 | 3.8500 |
| S11 | 20 | 4.0000 |
| S12 | 20 | 2.9000 |
| S13 | 20 | 4.0500 |
| S14 | 20 | 4.0000 |
| S15 | 20 | 4.0500 |
| S16 | 20 | 3.9000 |
| S17 | 20 | 3.9500 |
| S18 | 20 | 4.0000 |
| S19 | 20 | 4.0000 |

2.2.5 Qualitative Interviews

Methodology and interview guide

The purpose of in-depth interviews was to gain greater insights from the users of vINCI but also from family members (spouses). The users were one man and one woman who participated in the quality of life and physical exercise pilot. The interviews lasted about 30 minutes and took place at the participants' place. The researcher was taking notes during the interviews. The coding and

analysis were based on Thomas' General Inductive Approach as described earlier in this report and resulted in constructing themes which derived from participants' narrated experience with the vINCI technology. The interview guide was short and aimed to capture what the participants liked, what they did not like, how vINCI helped them, whether they would like to use it again and why. The guide was semi-structured in order to leave room for more questions that could derive from the discussion.

Results

From the coding and analysis of the interviews, four themes derived, namely: Enjoyable interaction, Connection, Purpose, and Sense of control.

Enjoyable interaction

Both users enjoyed using the vINCI technology as the insoles and watches were easily wearable and the interface of the vINCI app was easy to understand, use and navigate through. They explained that they used the technology for a few hours per day for two weeks and they completed the relevant questionnaires via the app and on paper. One user said "This is so easy, no complexities, no busy interface, simple and clear". The spouses also used it sometimes and they advised that they had enjoyed the interaction with the technology too.

Connection

"It became part of me", one user explained. The other user also said that he would like to continue using the technology. That was really interesting because these two users had only used the technology for two weeks and it would be imperative to understand why they developed a sense of connection with vINCI. With further discussion, it became apparent that the main reason why these two users developed a sense of connection with vINCI was their familiarity with the devices employed and that the technology in general was not intrusive. More specifically, both users clarified that the technology was so familiar because they have been used to wearing a watch for almost all their life, the insole was so thin that it did not feel like they had anything in their shoe, and the app was easy to use like they have used other apps on their phone. Therefore, it did not feel that they were using something alien to them. One spouse said that most of the time she did not notice that the husband was using it.

At the same time, both users expressed their concerns for having to charge three devices in order to keep the technology functional and usable.

Purpose

Both spouses sounded enthusiastic because their partner had something different to focus on which aimed to help with their health and quality of life. In addition, one user explained "this is like a game, I know my score and then I have a new target, it keeps me interested and motivated". Such understanding shows that vINCI provided users with a purpose and a goal to achieve. That is,

achieve a higher score in the QoL and IPAQ questionnaires and being praised for their actions.

Sense of control

Finally, vINCI could potentially help users develop a sense of control. This did not derive directly from the participants' experience but the users explained that using the technology over a large period of time would help them better control their health and quality of life, increase their physical activity, social participation and psychological wellbeing. Both spouses advised that they would like to use the technology because it could give them a clearer and immediate direction regarding where they should go about their general wellbeing. More specifically, one spouse said "I have something praising me and reminding all the time, which is good".

2.2.6 Conclusion on Cyprus pilot

The pilot study of vINCI technology in Cyprus showed that vINCI is a useful and effective means for older people which they have embraced and helped them engage with their quality of life and physical exercise, improving a few important areas such as social relations, daily activities, meaning in life, negative thoughts, psychological wellbeing etc. The pilot also indicated that more domains and items in both QoL and IPAQ could potentially improve with the use of vINCI by more participants over a larger period.

In summary, participants liked vINCI and worked with it effectively, and the use of vINCI improved the following:

Quality of Life

- Physical, Psychological, and Social relationships,
- General quality of life, enjoying life, daily energy, performing daily activities, satisfaction with self, personal relationships, and negative thoughts.

Physical exercise

- Walking.

Overall, participants were satisfied with the use of vINCI with a score of 4 out of 5. Qualitative data revealed that the users and their spouses appreciated vINCI because the technology was enjoyable to use, was familiar, gave them a purpose, and a sense of control.

2.3 Italy Pilot

Besides the qualitative interviews described above, partners of the vINCI consortium tried to have the vINCI mobile app tested by as many users as possible, even if in an informal and unstructured way. For this reason, each partner tried to involve older adults selected among personal connections, to invite them to have a look and quickly test the app functionalities.

This section briefly reports about the outcomes obtained from these qualitative tests.

Italian users

Data were collected for 2 participants with a mean age of 83 years (range of 77–89). The sample comprised equal numbers of men and women. The information on socio-demographic characteristics of participants is shown in Table 2.61.

Table 2.61 Participant characteristics

| N=2 | |
|-------------------|--------|
| Sex, <i>n</i> (%) | |
| Male | 1 (50) |
| Female | 1 (50) |
| Age | |
| Mean (SD) | 83 |
| Range | 77–89 |

The participants responded to vINCI App User - Feedback Questionnaire, that contains the following questions:

- Q1 - The instructions on how to use the vINCI app were clear.
- Q2 - The completion of the WHO-QoL and IPAQ questionnaires in the vINCI app was easy.
- Q3 - Font type, colour, and size, as well as the general interface, facilitated interaction with the app and the completion of the questionnaires.
- Q4 - The feedback I received from the vINCI app regarding my quality of life was useful.
- Q5 - Considering the use of the vINCI app, how would you evaluate it?
- Q6 - Considering your experience with the vINCI app, please describe what was good and what you think should change.

The results are presented in the following figures.

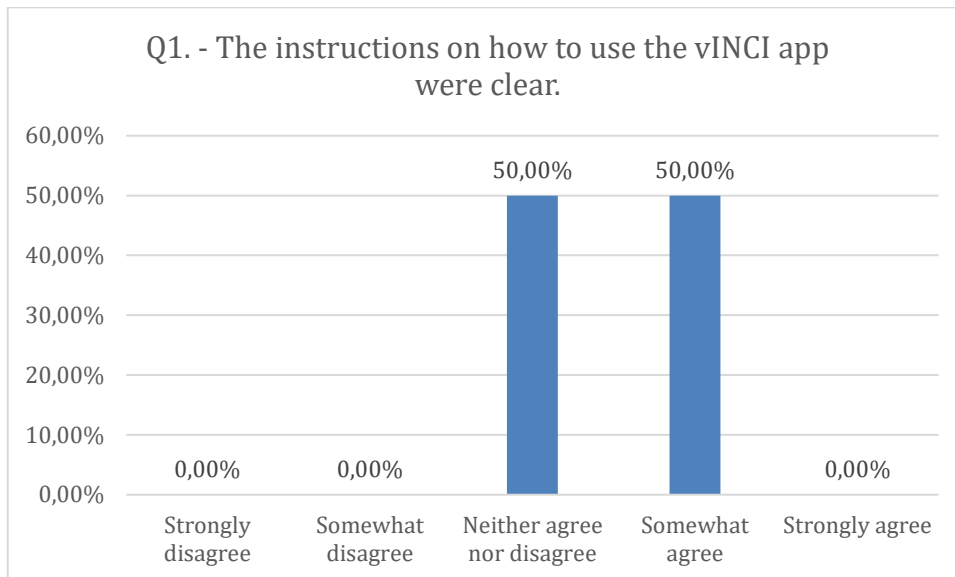


Figure 2.21 Q1. - The instructions on how to use the vINCI app were clear.

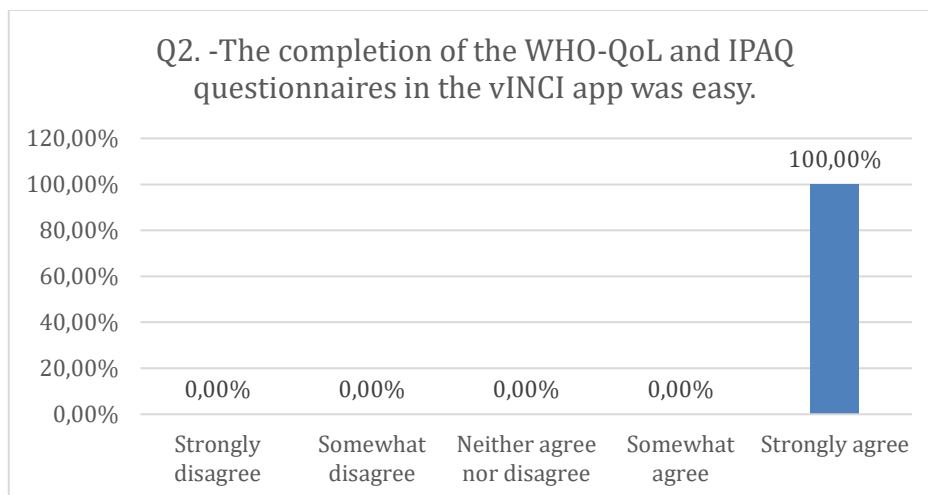


Figure 2.22 Q2 - The completion of the WHO-QoL and IPAQ questionnaires in the vINCI app was easy.

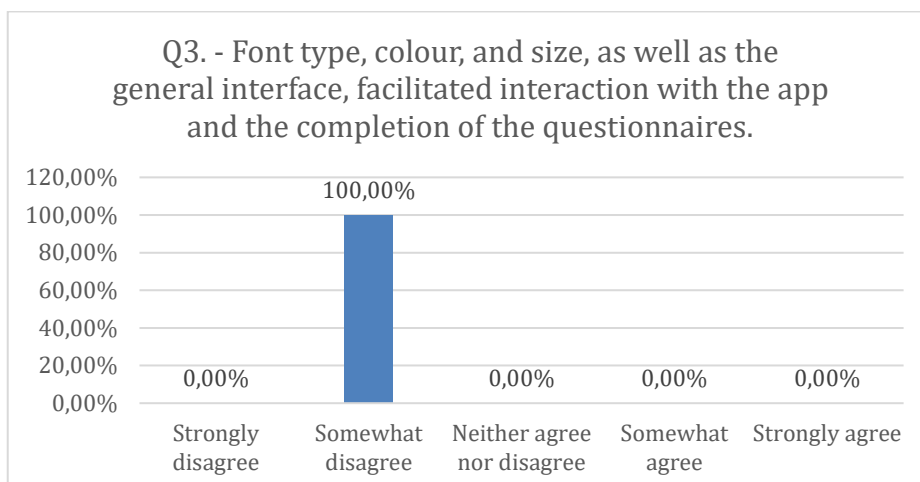


Figure 2.23 Q3. - Font type, colour, and size, as well as the general interface, facilitated interaction with the app and the completion of the questionnaires.

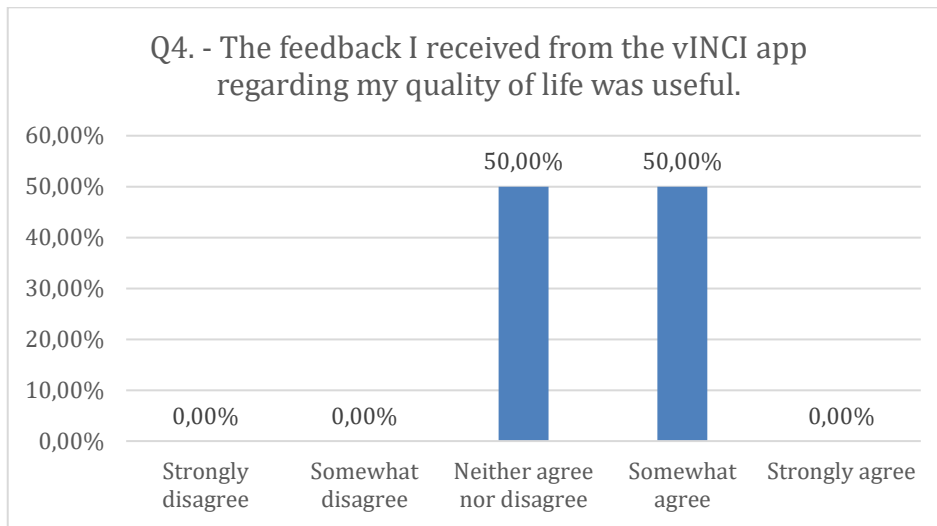


Figure 2.24 Q4. - The feedback I received from the vINCI app regarding my quality of life was useful.

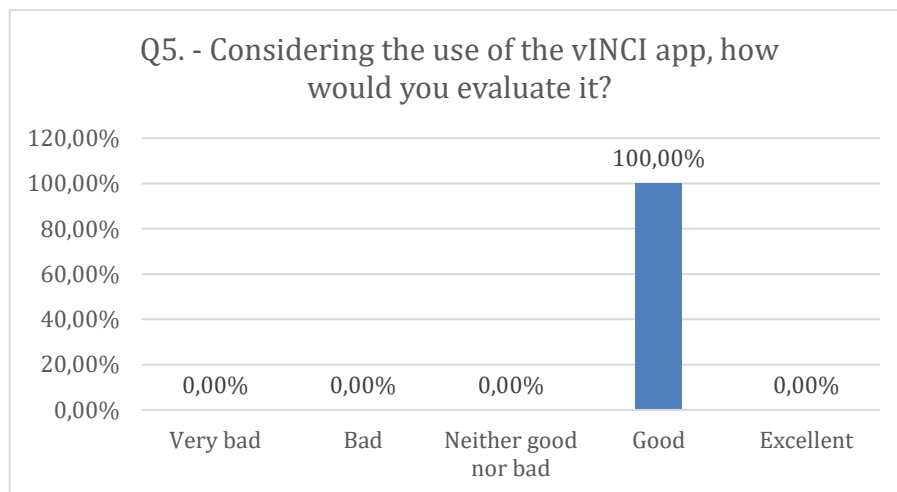


Figure 2.25 Q5. - Considering the use of the vINCI app, how would you evaluate it?

The following comments were freely provided by the test users, regarding question “Q6 - Considering your experience with the vINCI app, please describe what was good and what you think should change”.

Female:

- About Q.3, fonts used in the text of the questions of questionnaires should be bigger; it appears there is some room in the app page to enlarge the font dimension;
- In the QoL questionnaire, the question about sexual habits was weird as the user is a widow; maybe it should be made possible to skip this question, if the user doesn't want to answer it;
- The colors used in the graphical interface are nice;
- It is not clear why the button related to the smart insole has been called “scan screen”: it is not easy-to-understand that to use the insole one's has to push that button.

Male:

- The app seems friendly and easy to use; colors are nice and icons are quite easy to understand.
- Bigger fonts should be used in the textual labels, especially for the questionnaires. Even some buttons should be bigger, sometimes it is not easy to activate them with my trembling fingers.
- It would be interesting to see the “cognitive games” section; I think it would be funny to play some games that are good for my brain!
- Even if I have not used the app for a long time, from the description and explanations I received, I think it could be a good tool to help improving one’s health status. In my case it would be very good to have these automatic reminders because I usually forget about things!

2.4 Slovenia CTR Pilot

In Slovenia, 3 different users were testing the application. Application was installed on their phones. We gave them basic instructions, how to use the application and solve questionnaires. They were all able to find and solve questionnaires and gave feedback about their feelings. One of the users was also using Fitbit watch for the duration of the pilot.

The most important goal of the Slovenian Pilot was testing of Slovenian localization of the vINCI mobile application.

Results of the questionnaires are presented in Table 2.62.

Table 2.62 Results of the questionnaires

| | Result(points) |
|--------------------------|----------------|
| IPA Questionnaire | |
| Male 1 | 1942 |
| | 2848 |
| Male 2 | 3510 |
| Female 1 | 891 |
| | |
| WHOQOL_Bref | |
| Male 1 | 52 |
| | 46 |
| | 48 |
| Male 2 | 62 |
| Female 1 | 61 |
| | |
| Feelings | |
| Male 1 | 3 |
| | 4 |
| Male 2 | 5 |
| Female 1 | 5 |
| | 4 |

Slovenian users

Data were collected for 3 participants. The sample consisted of 2 men (66,67%) and 1 woman (33,33%). The information on socio-demographic characteristics of participants is shown in Table 2.63.

Table 2.63 Participant characteristics

| N=3 | |
|-------------------|-----------|
| Sex, <i>n</i> (%) | |
| Male | 2 (66,67) |
| Female | 1 (33,33) |

The participants responded to vINCI App User - Feedback Questionnaire, that contains the following questions:

- Q1 - The instructions on how to use the vINCI app were clear.
- Q2 - The completion of the WHO-QoL and IPAQ questionnaires in the vINCI app was easy.
- Q3 - Font type, colour, and size, as well as the general interface, facilitated interaction with the app and the completion of the questionnaires.
- Q4 - The feedback I received from the vINCI app regarding my quality of life was useful.
- Q5 - Considering the use of the vINCI app, how would you evaluate it?
- Q6 - Considering your experience with the vINCI app, please describe what was good and what you think should change.

The results are presented in the following figures.

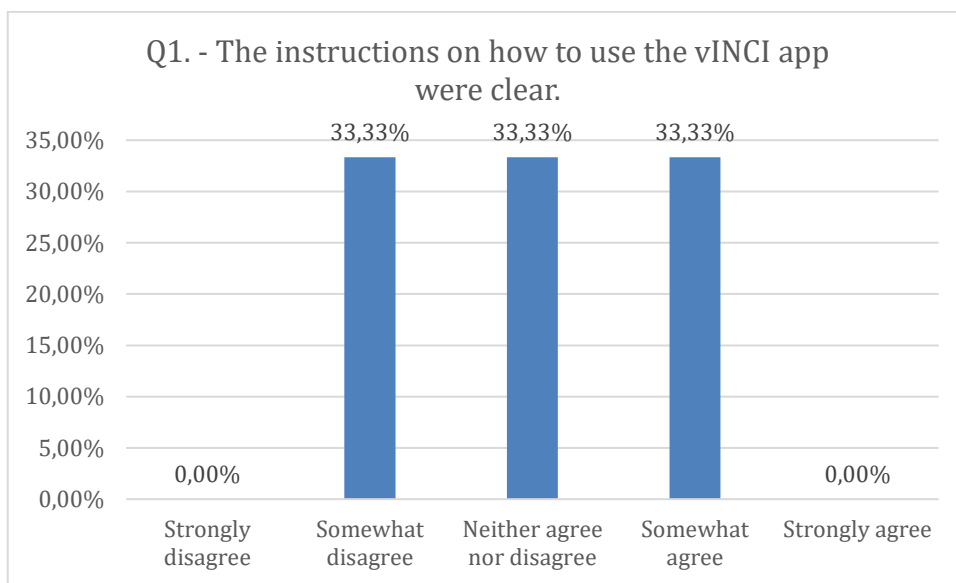


Figure 2.26 Q1. - The instructions on how to use the vINCI app were clear.

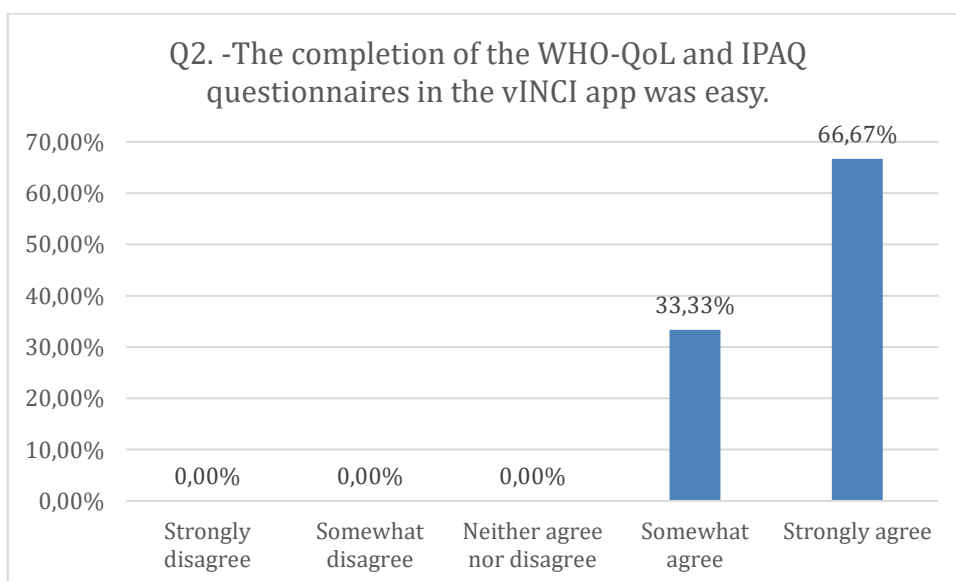


Figure 2.27 Q2 - The completion of the WHO-QoL and IPAQ questionnaires in the vINCI app was easy.

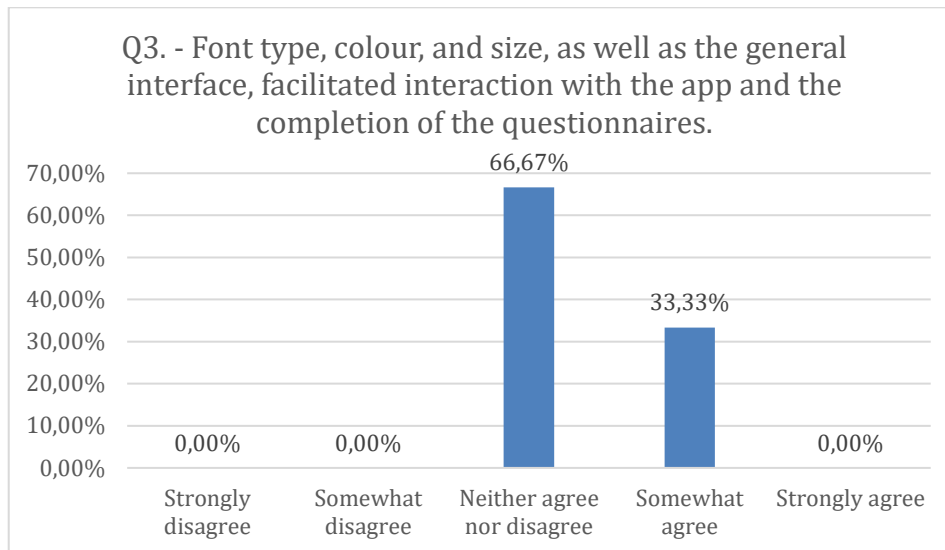


Figure 2.28 Q3. - Font type, colour, and size, as well as the general interface, facilitated interaction with the app and the completion of the questionnaires.

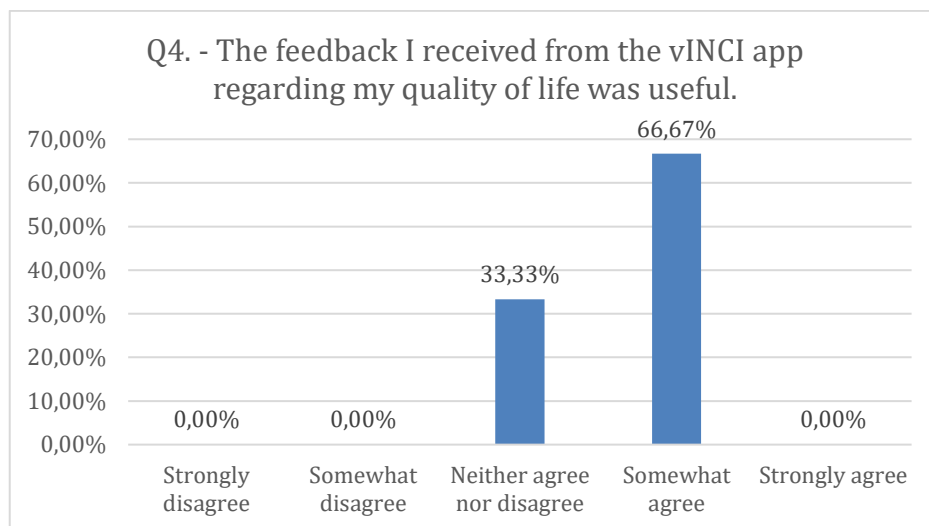


Figure 2.29 Q4. - The feedback I received from the vINCI app regarding my quality of life was useful.

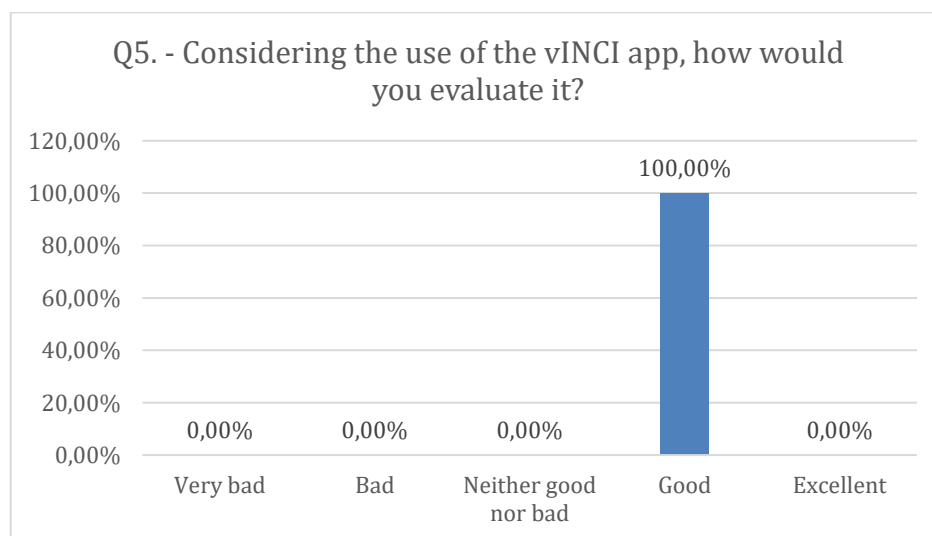


Figure 2.30 Q5. - Considering the use of the vINCI app, how would you evaluate it?

Female user was also using Fitbit watch during the pilot. She recorded between 1500 and 2000 steps every day. She agreed the device helped her get motivation to be more active during these days. Very interesting feature was also controlling her heart rate in real time.

We have received some positive and some negative comments about the application.

Positive:

- Motivation for staying active
- Easy to contact and invite friends to events
- Very useful for monitoring and sending alerts about health also to family members
- Localization of vINCI mobile application to Slovenian locale is excellent as there were no complains related to not understanding of using application and no complains related to filling questionnaires.

Problems and suggestions:

- Some questions in questionnaires are too long and complicated with too many possible answers, older people will have trouble solving them. Questionnaires could maybe be solved just by selecting some icons, not buttons with long text.
- Questionnaires are too long and at the end of questionnaire, customer forget what it was at the beginning.
- Some interactive cognitive games could be added for people, that have trouble moving around, so they can play against each other.

2.5 Romania CMD Pilot

CMD Pilot – Observations and conclusions

Because of pandemic situation and in order to reach a minimum number of users, for its vINCI pilot project, CMD decided to work with two caregiving centers and individuals/ potential users outside caregiving centers. One of the centers, Caminul Cajal, is a public caregiving institution and the other center, Senior Residence Ciofliceni, is a privately owned caregiving center. The two centers have a total of 35 senior residents, but only about 21 of them were still active. The rest were mainly staying in bed and needed permanent care. The elders outside caregiving centers were active and entirely independent of 3rd party care.

All respondents had ages between 65 and 95 years old: 2 persons between 65 and 75, 16 between 75 and 85 and 3 between 85 and 95.

Thus, data were collected for 21 participants. The sample consisted of 3 men (86%) and 18 women (14%) with a mean age of 81 years (range of 65–95). Regarding the education 10 of participants had secondary education (48%), 8 had higher education (38%) and 3 had primary education. More information on socio-demographic characteristics of participants is shown in Table 2.64.

Table 2.64 Participant characteristics

| N=21 | |
|------------------------------|---------|
| Sex, <i>n</i> (%) | |
| Male | 3 (86) |
| Female | 18 (14) |
| Age | |
| Mean | 81 |
| Range | 65–95 |
| Marital status, <i>n</i> (%) | |
| Single | 0 (0) |
| Married | 5 (24) |
| Divorced | 4 (19) |
| Living as married | 0 (0) |
| Widowed | 12 (57) |
| Education, <i>n</i> (%) | |
| Primary school | 3 (14) |
| Secondary school | 10 (48) |
| Tertiary / Higher education | 8 (38) |

Considering that the life expectancy in Romania for men is below 80 year, it is understandable that in the selected group of people most of them are women and also most of them are widowed:

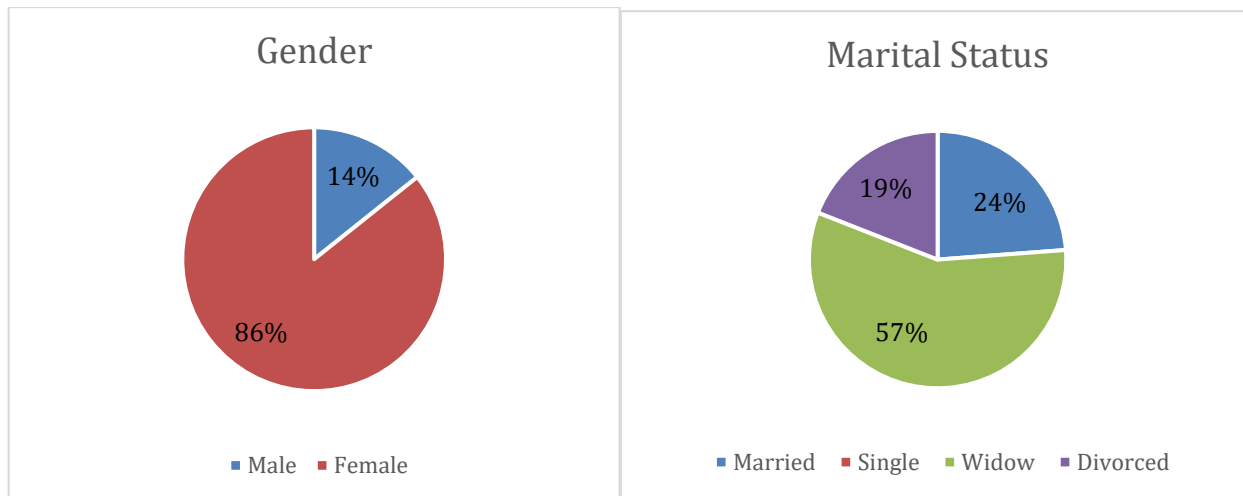


Figure 2.31 CMD Pilot: Gender and Marital Status of respondents

All of the people in the selected group have a form of education, but only one third of them have a higher education.

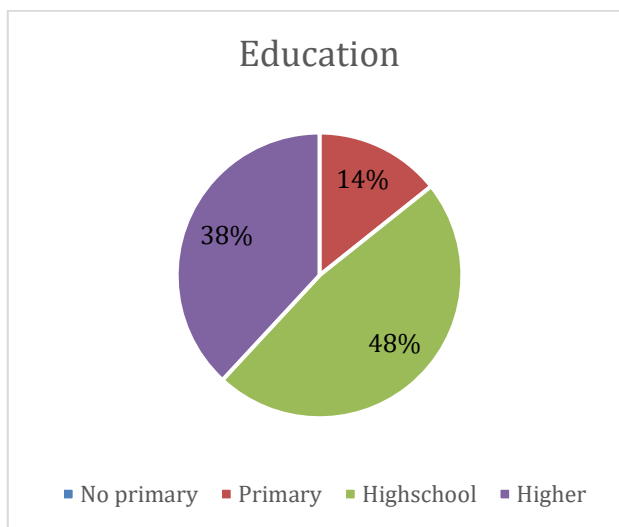


Figure 2.32 CMD Pilot: Education of respondents

It is also important to mention that the older adults in the selected group are still active persons (the non-movable residents or those with a form of dementia were not included in the pilot, because they would certainly not be able to make use of the vINCI product). As it can be seen in the graph below, more than half of the respondents undertake a form of physical activity or social interaction and about one third of them have a less active life (with a monthly frequency).

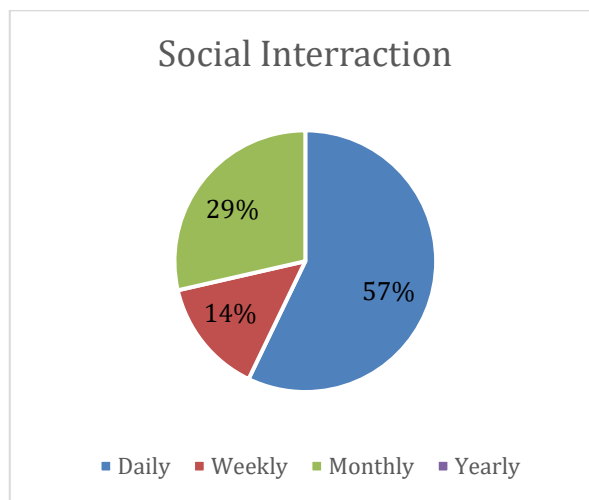


Figure 2.33 CMD Pilot: Social interaction of respondents

In this real-live pilot undertaking, one of the first important observations was that the majority of the elders in the caregiving centers are not regular users of technology and almost none of “smart” technology – less than one third of the selected group owns a smartphone. The others are also using a mobile phone device, but regular ones (not smart-phones). Still, even less are actually using social networks – only 10% of the group. Therefore there are not used and probably not open to the idea of interacting with friends or other individuals with the help of an app.

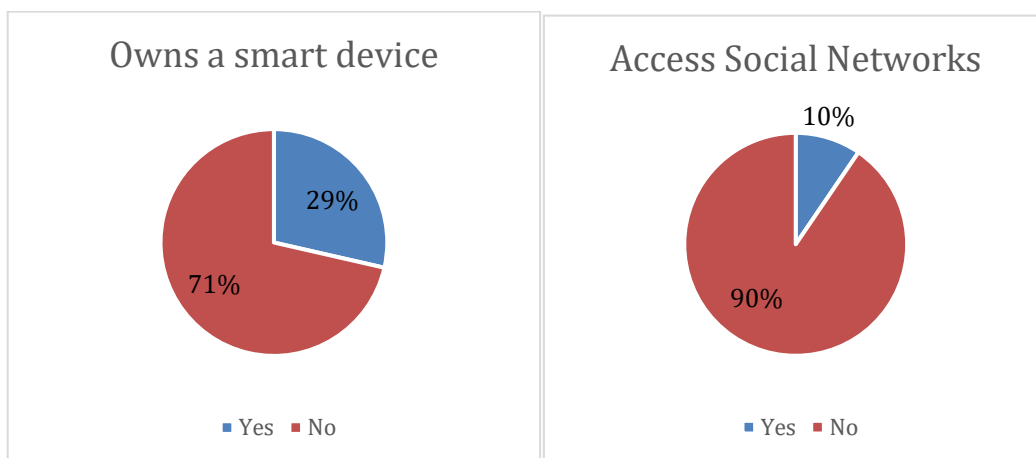


Figure 2.34 CMD Pilot: Respondents that own a smart device and that Access Social Networks

That’s why an important number of elders refused to use the technology. In total approximately 10 people accepted to wear a device and look at the app, but the rest actually refused it and said that they are simply not interested. Our understanding is also that that some might be afraid of being tracked or affected in some way by the technology.

As a result, we could quickly draw the conclusion that the Vinci app has limited applicability for potential users living within a caregiving center and we don’t perceive it segment of high interest. Nevertheless, the interest from the caregiving center management and medical personnel was significantly higher,

as they are actively interesting in being able to monitor their patients' health status and also to simplify the monitoring process (with the help of technology). Therefore, a solution with a centralized monitoring dashboard for a higher number of users was a product of interest for the caregiving center and CMD perceives it as an important commercial segment.

Looking more into details at the persons that agreed to use the vINCI app and devices, there are some general observations, as well as some detail feedback on the vINCI app functionality, like the following:

- The users are not able to install and prepare the app and devices for use on their own. They need third party support for installing accounts and everything else and additionally they need a personal training on the features/functionality of the devices and the vINCI app.
- The in-app questionnaires have to be updated, as some of the respondents expressed frustration from some questions like those related to their current sexual life.
- Again, related to questionnaires, the users sometimes to have longer period of inactivity than 24 hours in a week, but the option to introduce a higher number was not available

Once the user understood the functions of vINCI app and had all equipment installed, it had a general neutral or good opinion about the app, its usability and usefulness – as it can be seen in the graphs below. Still it is important to keep in mind that from the total number of selected people, only about half of them responded to the questions related to the app. Therefore, considered at the larger group level, less than one third of the older adults agree that an app like vINCI would be user friendly and helpful.

At the “Feedback questionnaire on the satisfaction of using the vINCI application” have responded 15 participants and the Romania CMD Pilot results are presented as follows.

Pilot results:

II-1: “It is easy to learn how to work with the vINCI application.”

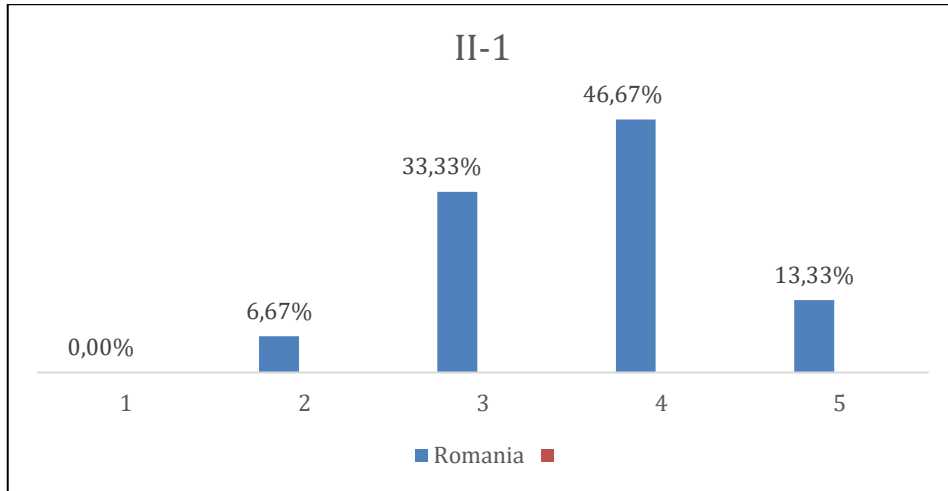


Figure 2.35 II-1: “It is easy to learn how to work with the vINCI application.”

II-2: “The vINCI application is easy to use”

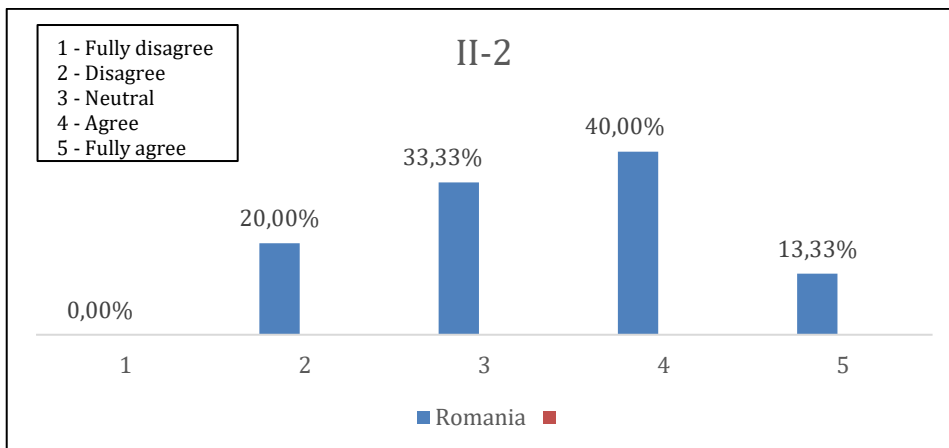


Figure 2.36 II-2: “The vINCI application is easy to use”

II-3: “Using the vINCI app, I am better informed about my health”

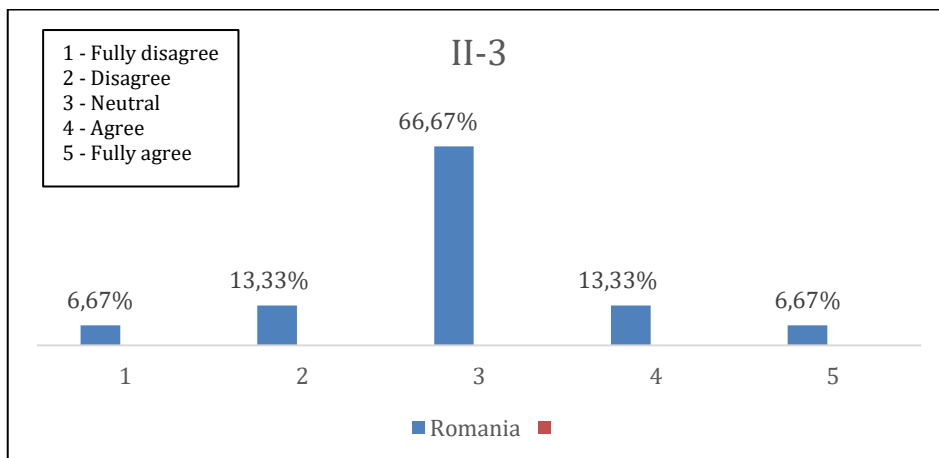


Figure 2.37 II-3: “Using the vINCI app, I am better informed about my health”

II-4: “My security level has improved using the vINCI application”

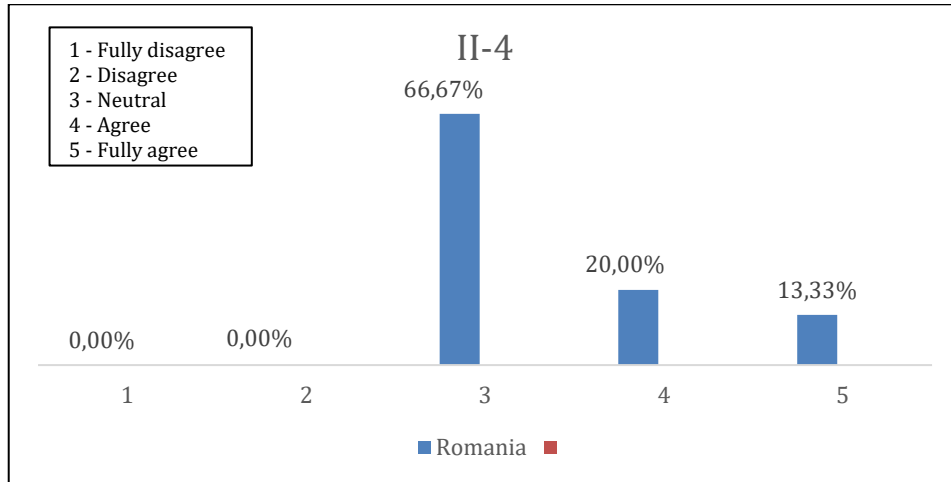


Figure 2.38 II-4: “My security level has improved using the vINCI application”

II-5: “The vINCI application helps me to obtain relevant quality of life data”

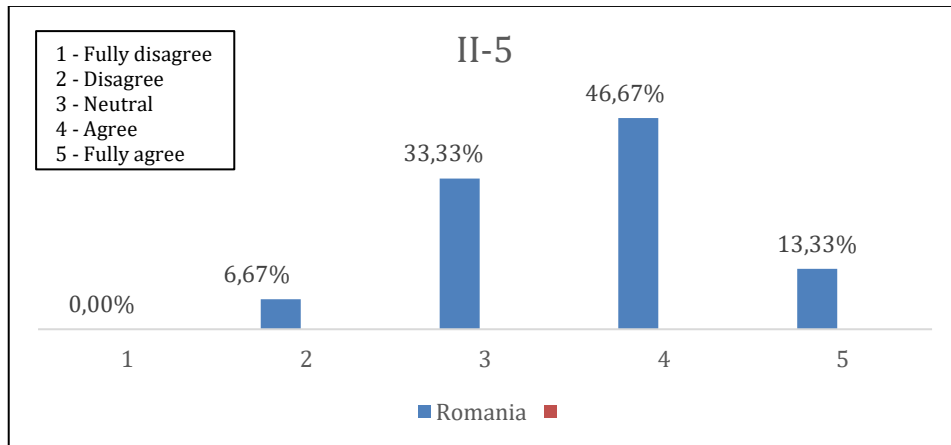


Figure 2.39 II-5: “The vINCI application helps me to obtain relevant quality of life data”

II-6: “The vINCI application gives me the opportunity to more easily communicate data about my physical condition / quality of life”

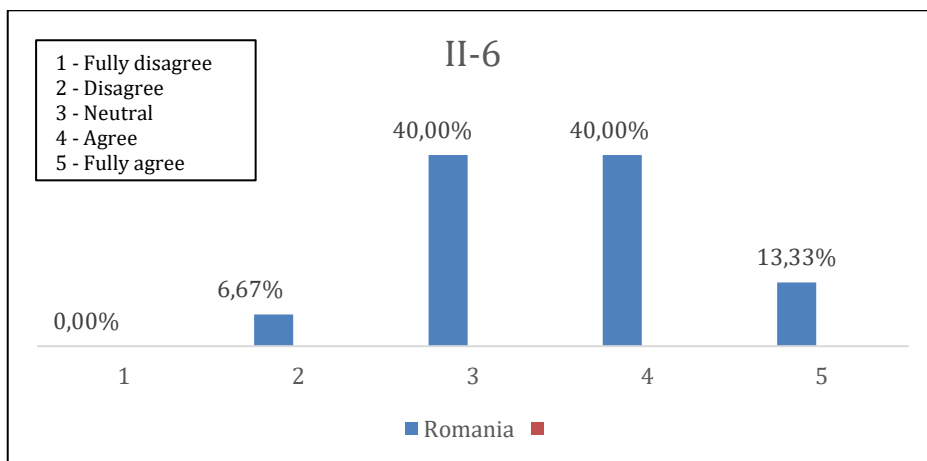


Figure 2.40 II-6: “The vINCI application gives me the opportunity to more easily communicate data about my physical condition / quality of life”

II-7: “The system interface is pleasant and intuitive”

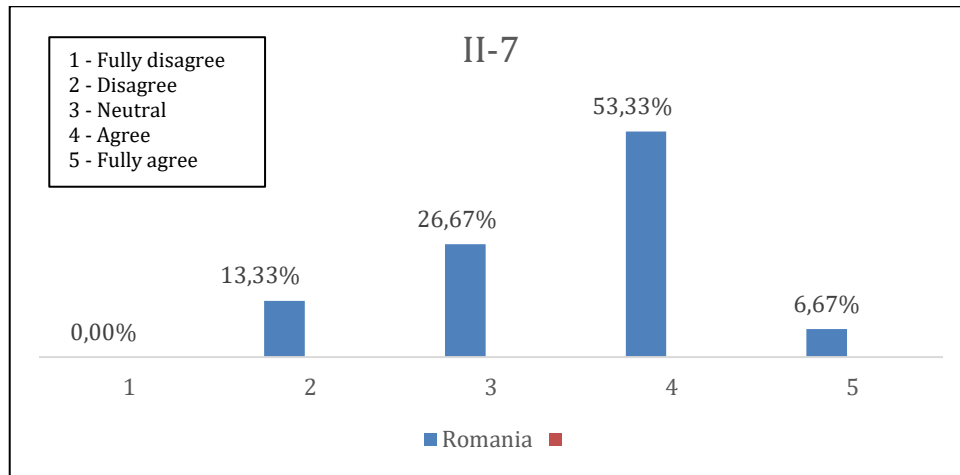


Figure 2.41 II-7: “The system interface is pleasant and intuitive”

II-8: “The results provided by the application are easy to access and understand”

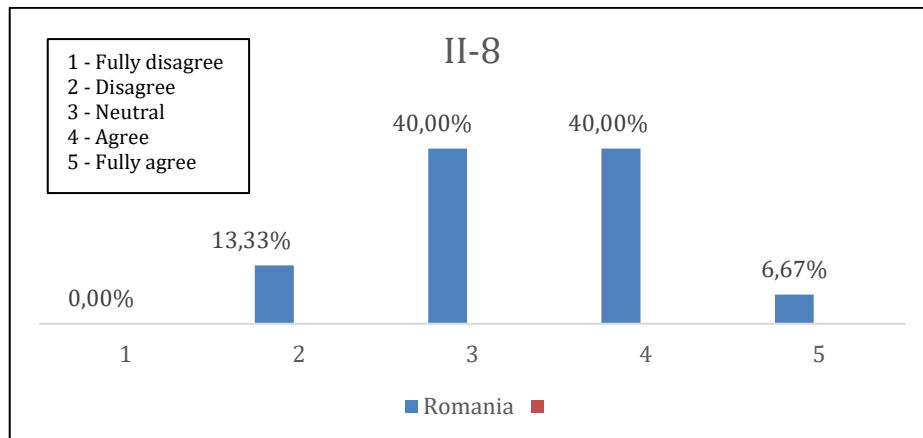


Figure 2.42 II-8: “The results provided by the application are easy to access and understand”

II-9: “I think I could improve my health using the vINCI app”

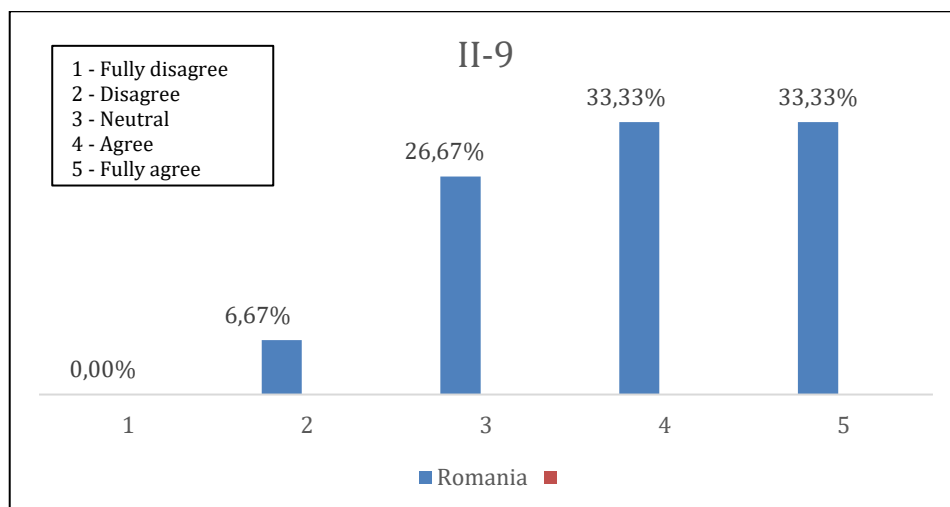


Figure 2.43 II-9: “I think I could improve my health using the vINCI app”

II-10: “The information provided by the vINCI application is complete and useful”

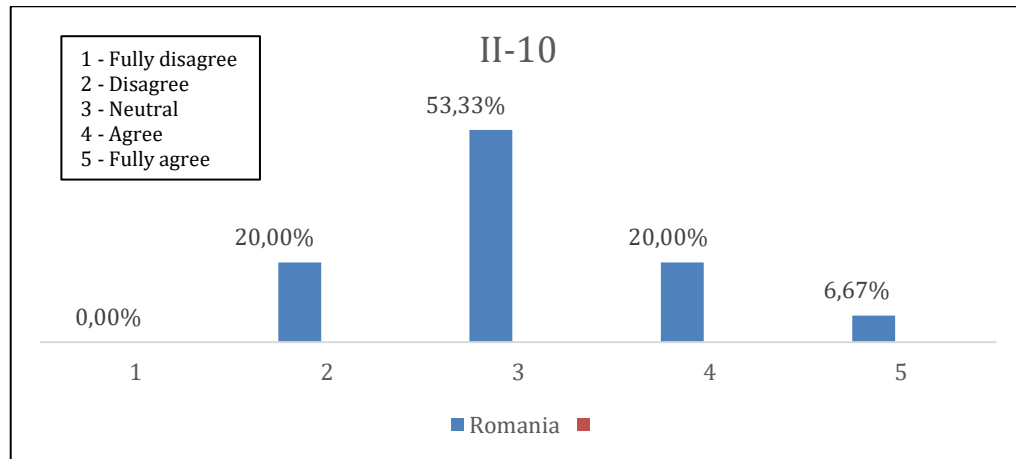


Figure 2.44 II-10: “The information provided by the vINCI application is complete and useful”

II-11: “The daily monitoring performed through the vINCI application does not interfere with my personal data”

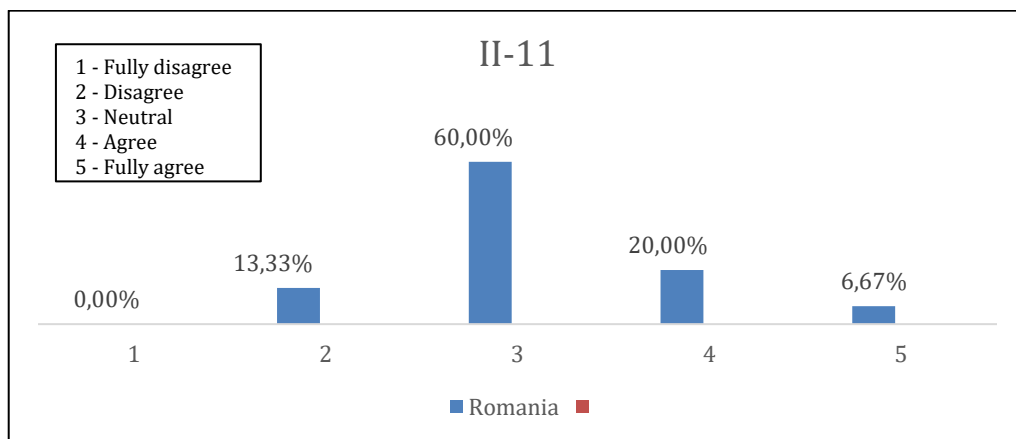


Figure 2.45 II-11: “The daily monitoring performed through the vINCI application does not interfere with my personal data”

II-12: “The vINCI application has improved the quality of medical services received”

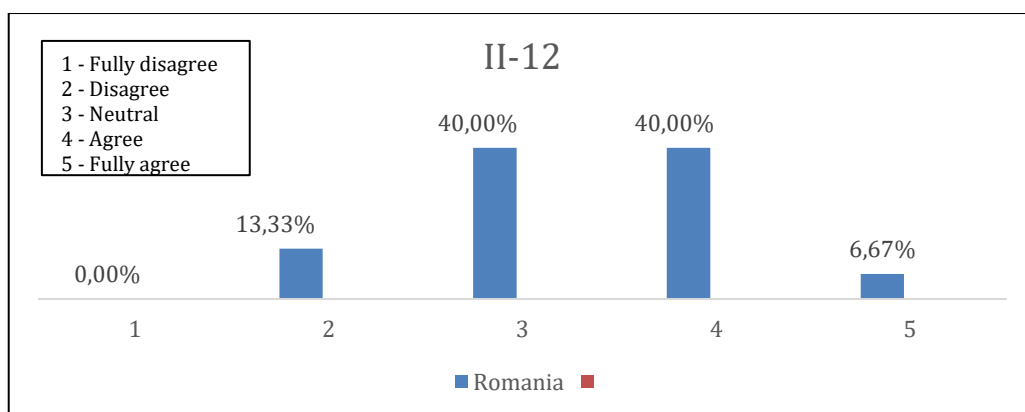


Figure 2.46 II-12: “The vINCI application has improved the quality of medical services received”

II-13: “The interaction with the vINCI application is clear and easy to understand”

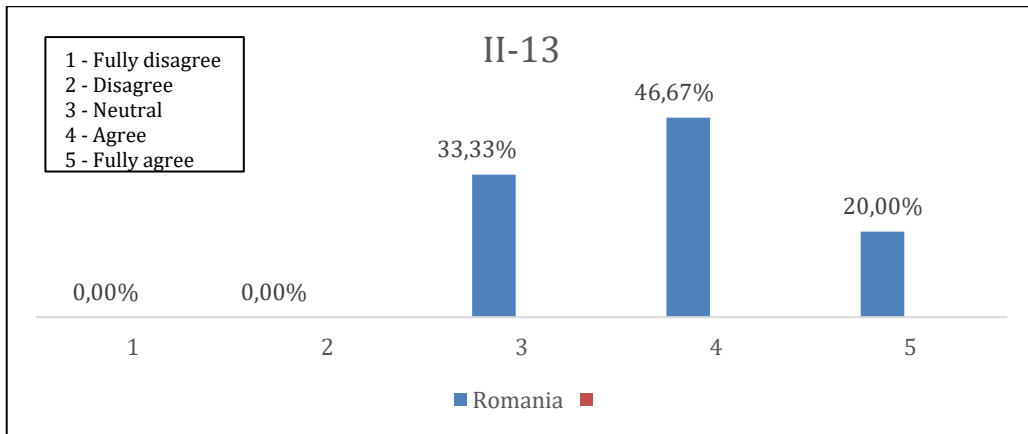


Figure 2.47 II-13: “The interaction with the vINCI application is clear and easy to understand”

II-14: “The organization of the information on the screen of the devices running the vINCI application is clear and intuitive”

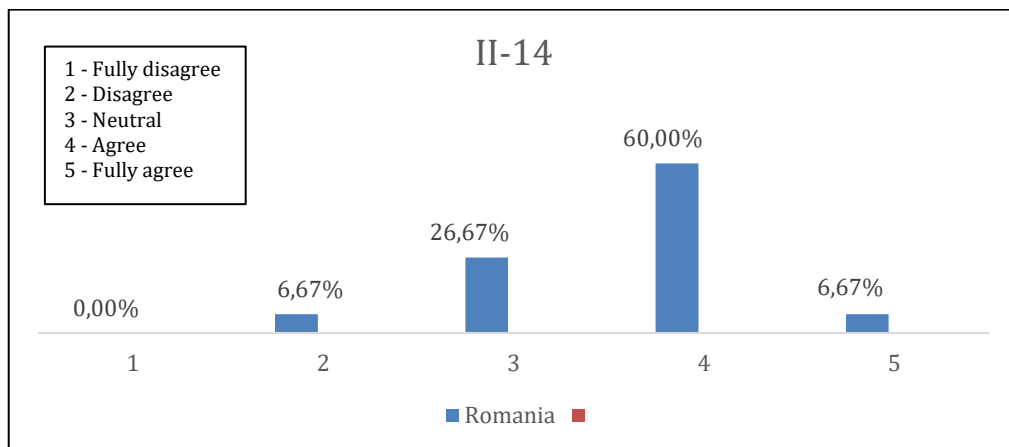


Figure 2.48 II-13: “The interaction with the vINCI application is clear and easy to understand”

II-15: “The vINCI application is very useful for me in my daily life”

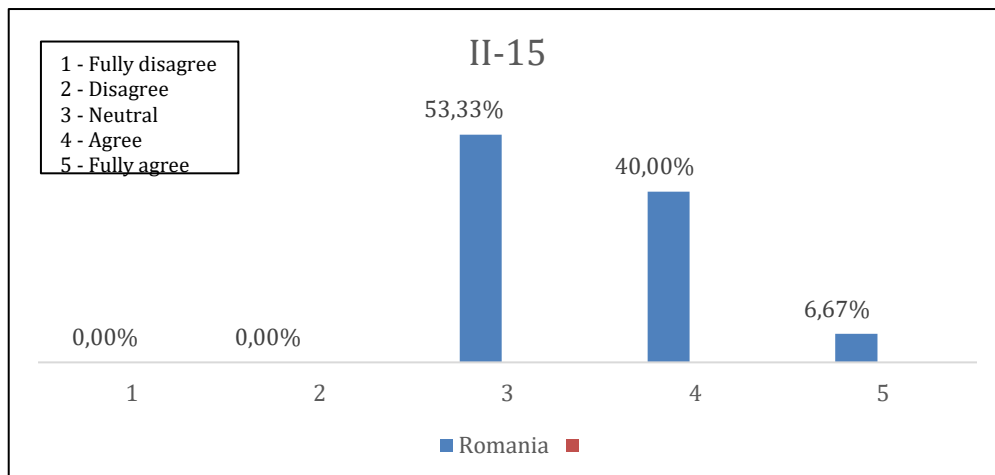


Figure 2.49 II-15: “The vINCI application is very useful for me in my daily life”

II-16: "Using the vINCI application is very exciting"

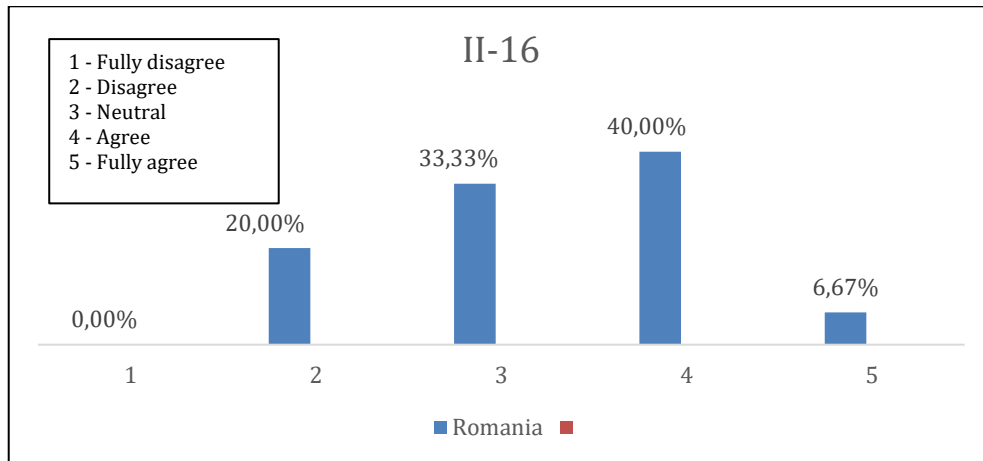


Figure 2.50 II-16: "Using the vINCI application is very exciting"

II-17: "I like to interact with the vINCI application interface"

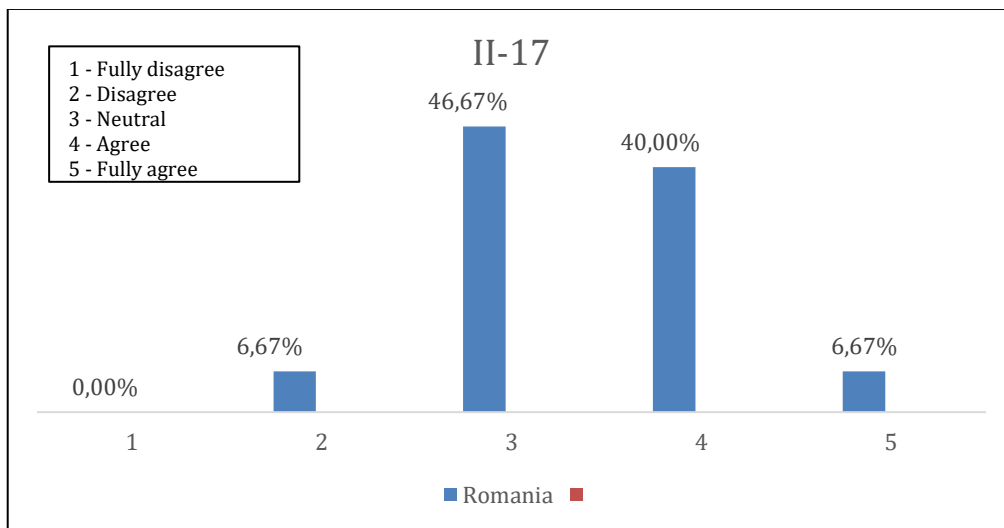


Figure 2.51 II-17: "I like to interact with the vINCI application interface"

II-18: "I use the vINCI application with confidence"

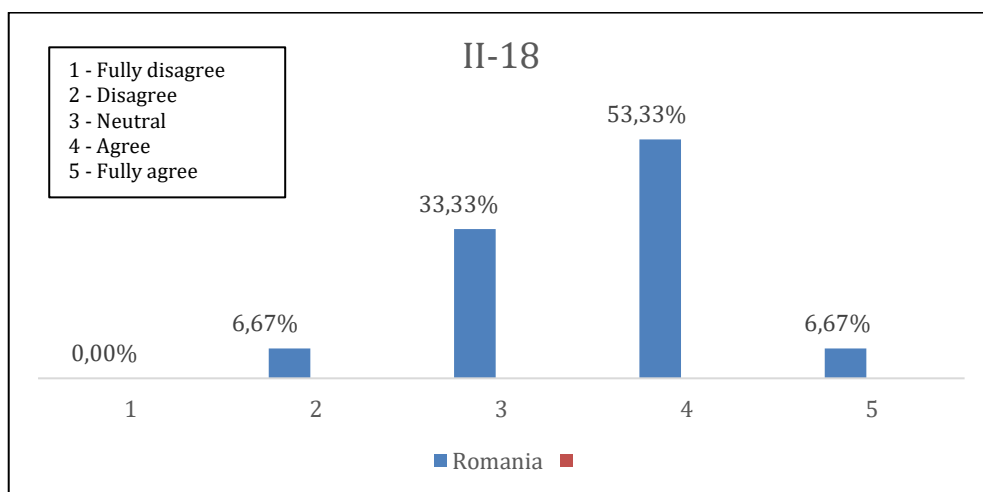


Figure 2.52 II-18: "I use the vINCI application with confidence"

II-19: “Overall, I am satisfied with how to use the vINCI application”

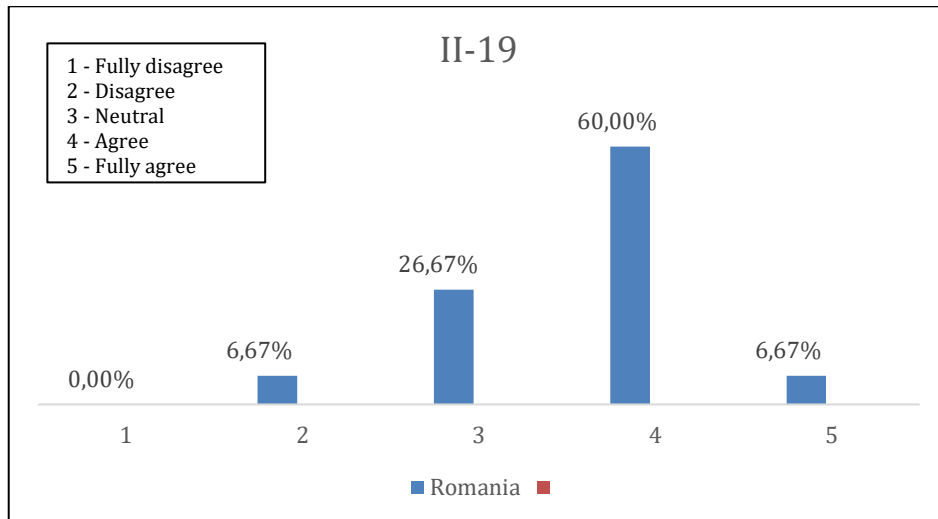


Figure 2.53 II-19: “Overall, I am satisfied with how to use the vINCI application”

2.6 Poland NIT Pilot

For Poland, 3 older adults were contacted and invited to test of the vINCI app.

Polish users

Thus, the sample consisted of 2 men (66,67%) and 1 woman (33,33%) with a mean age of 82 years (range of 71–90). The majority had secondary education (66.67%) and the rest had higher education (33.33%). All of the participants (100%) were married. More information on socio-demographic characteristics of participants is shown in Table 2.65.

Table 2.65 Participant characteristics

| N=30 | |
|------------------------------|-----------|
| Sex, <i>n</i> (%) | |
| Male | 2 (66,67) |
| Female | 1 (33,33) |
| Age | |
| Mean | 82 |
| Range | 71–90 |
| Marital status, <i>n</i> (%) | |
| Single | 0 (0) |
| Married | 3 (100) |
| Divorced | 0 (0) |
| Living as married | 0 (0) |
| Widowed | 0 (0) |
| Education, <i>n</i> (%) | |
| Primary school | 0 (0) |
| Secondary school | 2 (66.67) |
| Tertiary / Higher education | 1 (33.33) |

The participants responded to vINCI App User - Feedback Questionnaire, that contains the following questions:

- Q1 - The instructions on how to use the vINCI app were clear.
- Q2 - The completion of the WHO-QoL and IPAQ questionnaires in the vINCI app was easy.
- Q3 - Font type, colour, and size, as well as the general interface, facilitated interaction with the app and the completion of the questionnaires.
- Q4 - The feedback I received from the vINCI app regarding my quality of life was useful.

- Q5 - Considering the use of the vINCI app, how would you evaluate it?
- Q6 - Considering your experience with the vINCI app, please describe what was good and what you think should change.

The results are presented in the following figures.

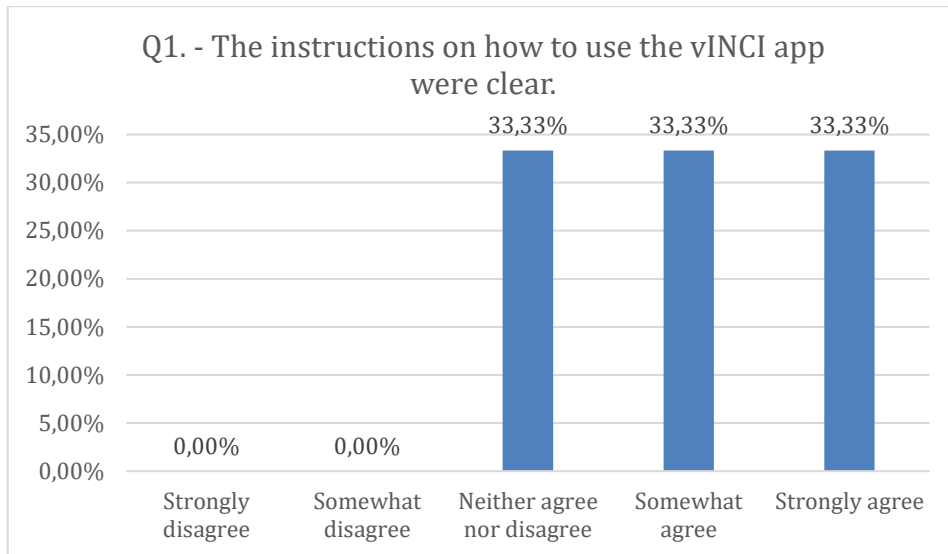


Figure 2.54 Q1. - The instructions on how to use the vINCI app were clear.

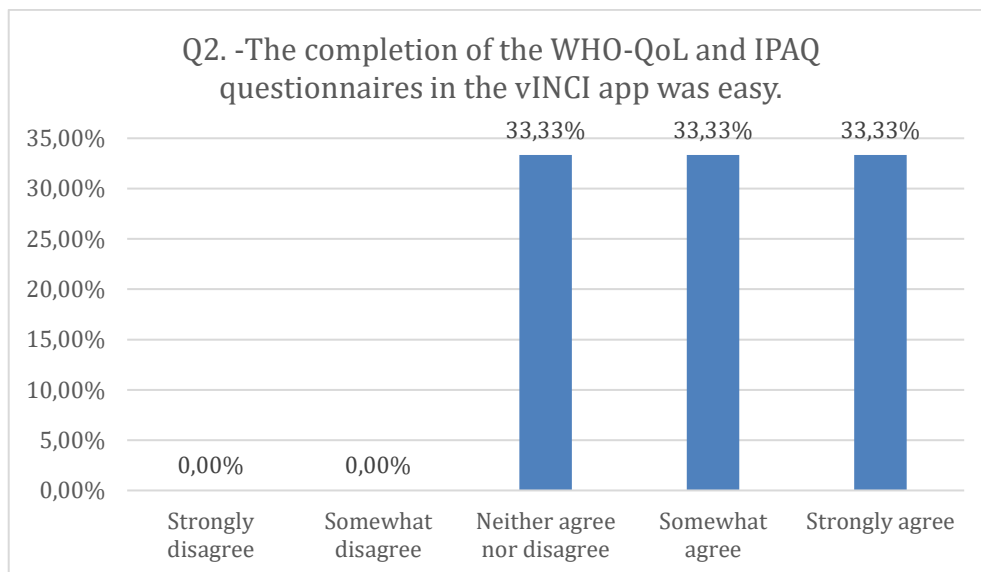


Figure 2.55 Q2 - The completion of the WHO-QoL and IPAQ questionnaires in the vINCI app was easy.

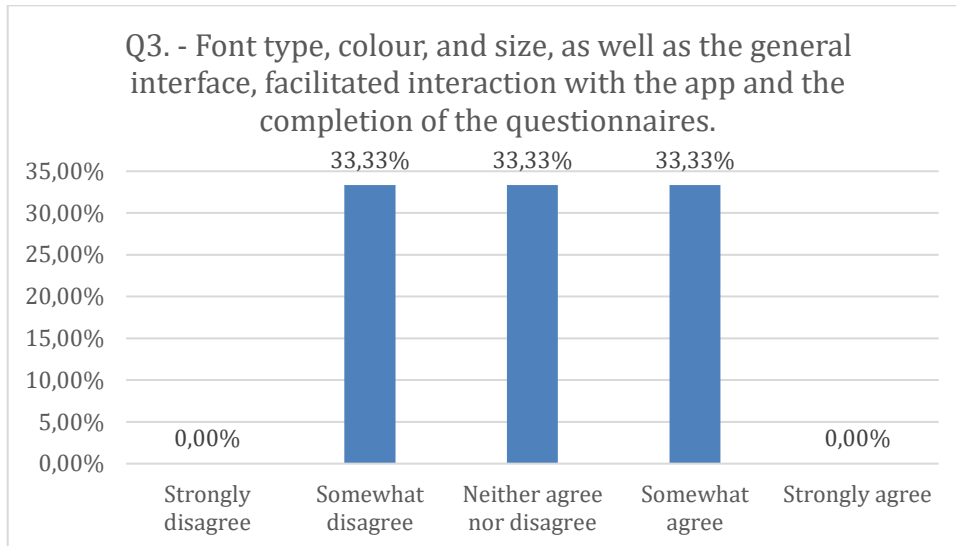


Figure 2.56 Q3. - Font type, colour, and size, as well as the general interface, facilitated interaction with the app and the completion of the questionnaires.

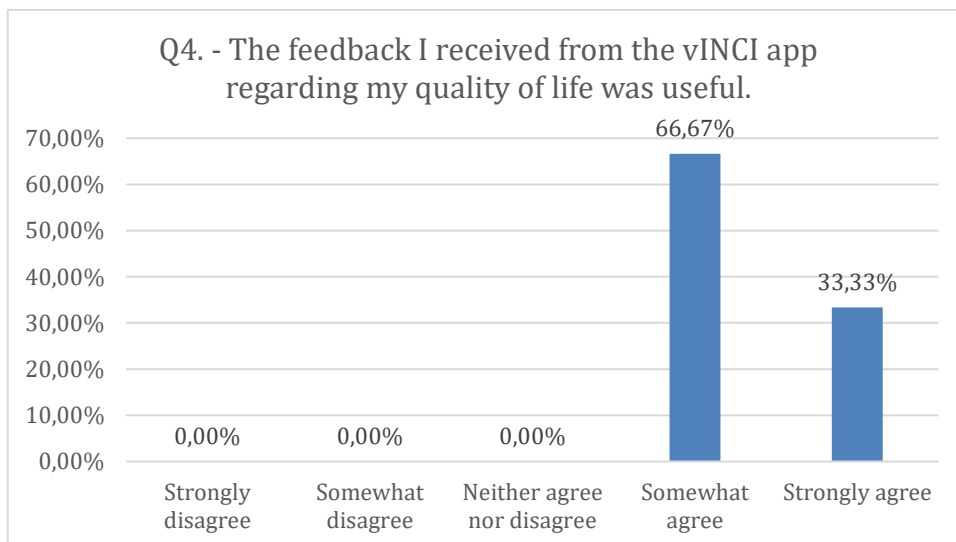


Figure 2.57 Q4. - The feedback I received from the vINCI app regarding my quality of life was useful.

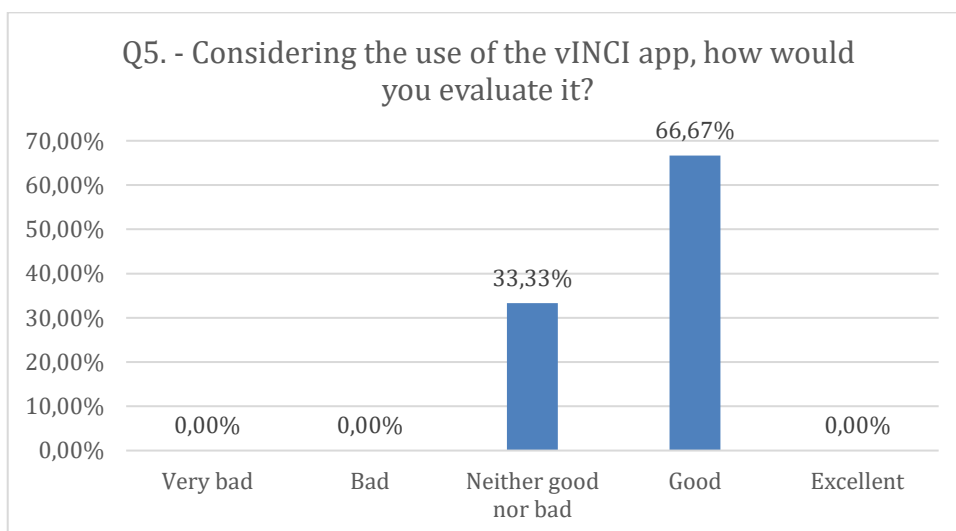


Figure 2.58 Q5. - Considering the use of the vINCI app, how would you evaluate it?

In addition, the users were asked for their own comments, observations and any suggestions regarding the extension of the application's functions. Their answers are as follows:

User 1:

This is very useful and helpful application. I know the importance of maintaining adequate physical and mental activity as I have a medical background (I was a dentist). However, I myself often do not pay attention to how long I spend without any physical activity. If the application monitors this and reminds me to exercise, it will be very useful for my health.

In general, using the application is not very difficult, however the fonts could be larger and I sometimes had problems moving to the next field in the questionnaire.

[Comment from authors – the user had problems with filling some fields of questionnaire because the keyboard field was obscuring the form field]

User 2:

I find the application interesting, but I need to use it longer to see how it could be extended in more detail.

At this point, I can tell that I am having a hard time typing answers into specific form fields. I prefer questions where I can select an answer from those given.

[Comment from authors – the user used vINCI app using smartphone, the answer might have been different if she had used a tablet with a larger screen]

Some questions in the questionnaire were not entirely clear to me.

[Comment from authors – this is probably due to an inaccurate translation from the English version of the questionnaires; the translation needs to be reviewed by persons with medical and/or sociological background]

User 3:

Nice application, I think it can be useful. In general, I have no trouble using the app. But I think it is because I am using a tablet, with a large screen. On the other hand, I don't carry a tablet with me all the time (in fact, I rarely carry it with me). Therefore, the reminder functionality does not meet the requirements in this case.

In contrast, I always have my phone with me. However, it has a much smaller screen. Therefore, I suspect that using the app on a smartphone would not be as convenient as on a tablet. In my opinion, the ideal case would be to receive notifications on the phone that the questionnaire available on the tablet needs to be completed - in this way we would combine the advantages of both devices.

I like the color scheme.

2.7 Ireland NCI Pilot

For Ireland, the test user was located in Dublin - adult male 53 years old with general good health condition but in need of additional physical activity.

The person was monitored over one week in December 2021, and the general response to the different areas of interaction within the vINCI application was positive.

The person did not fill the usability form and he had a positive perception of vINCI as a project.

For the future, in Ireland, NCI intends to use the vINCI software in more methodical study employing a more representative older adult population.

2.8 Comparative analysis between Romania NIGG Pilot and Cyprus Pilot

2.8.1 Comparative Analysis QoL – Before and After Use vINCI Technology

An QOL ≥ 60 cut-off point moderately sensitive for recognizing patients with good / Good QOL and a QOL < 60 cut-off optimum negative predictive value for screening patients whose QoL was poor / Impaired QoL. A total score below 60 points signals impaired QOL (all domains).

Figure 2.59 shows the perceived level of quality of life of the 2 target groups, the NIGG Romania pilot and the Cyprus pilot. The level of QoL perception is slightly higher for the Romanian pilot, and significantly higher for the social component.

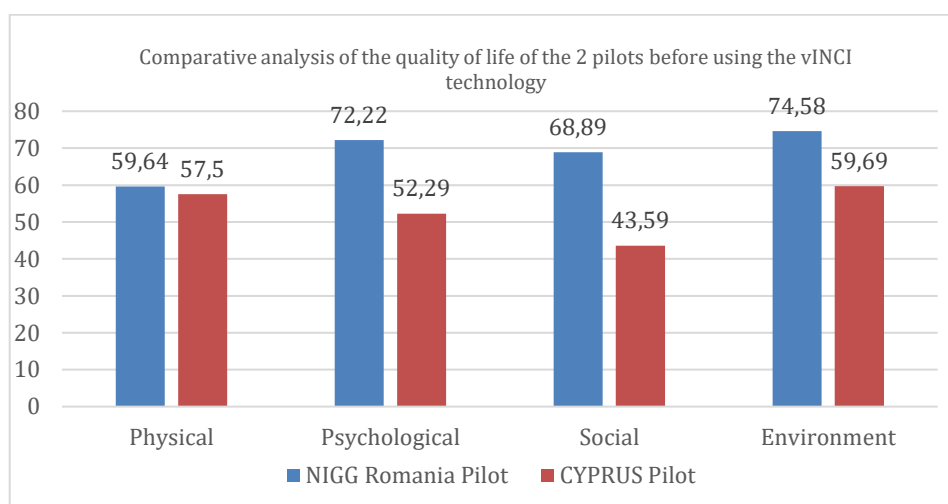


Figure 2.59 Comparative analysis of the quality of life of the 2 pilots before using the vINCI technology

After using the vINCI technology, an improvement can be seen on all QoL domains for both groups (Figure 2.60).

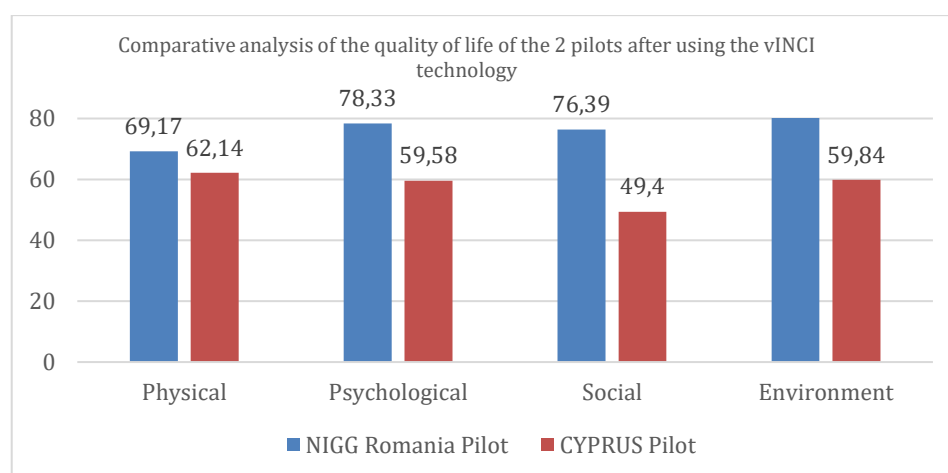


Figure 2.60 Comparative analysis of the quality of life of the 2 pilots after using the vINCI technology

2.8.2 Comparative analysis of IPAQ level of the 2 pilots before and after using the vINCI technology

Figure 2.61 shows the IPAQ level of the 2 pilots before using the vINCI technology of the 2 target groups, the NIGG Romania pilot and the Cyprus pilot. The IPAQ level is significantly higher for the Romanian pilot.

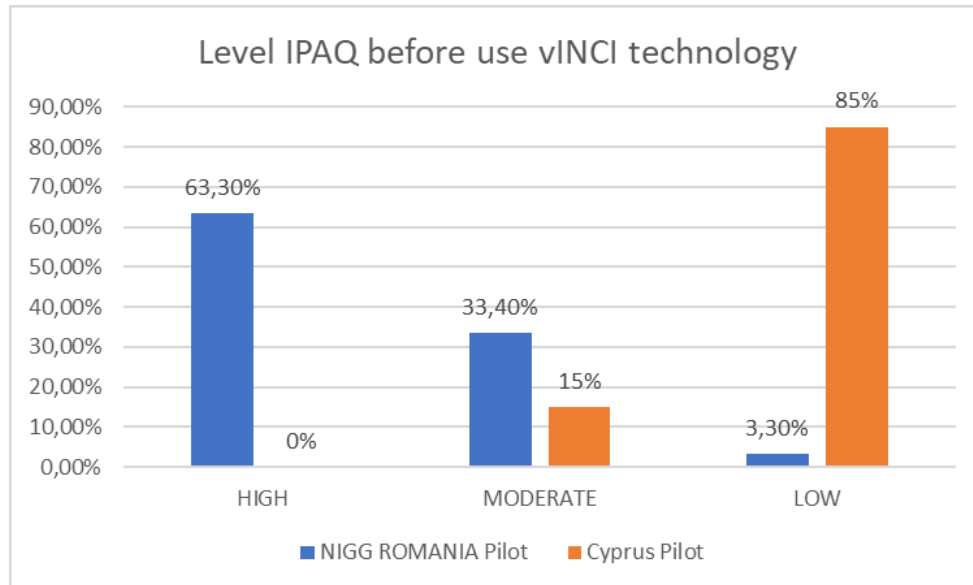


Figure 2.61 Level IPAQ before use vINCI technology

After using vINCI technology, an improvement in the physical condition of the study participants in both groups can be observed (Figure 2.62).

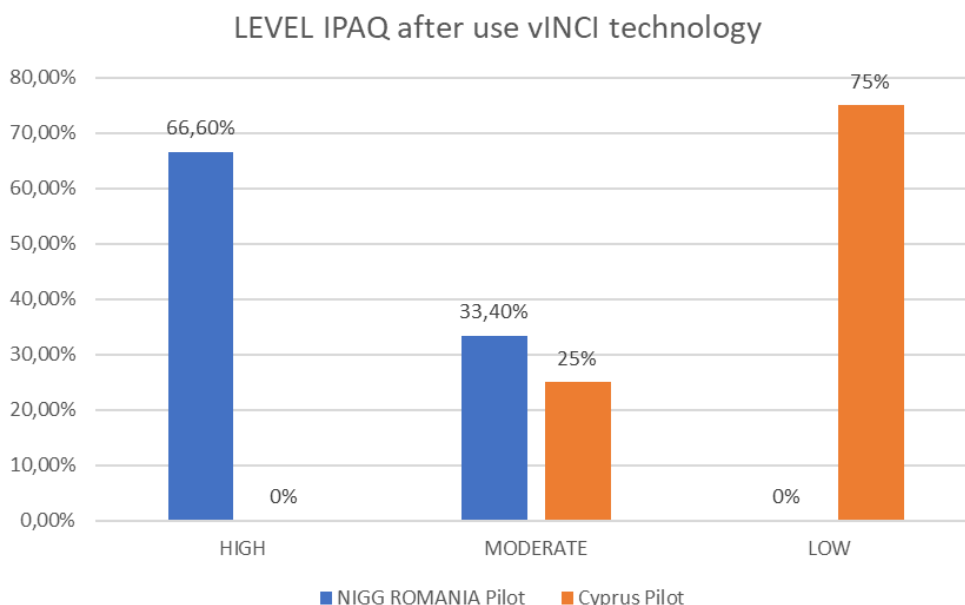


Figure 2.62 Level IPAQ after use vINCI technology

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