

ENGAGEMENT OF TEST PERSONS AND CONSIDERATION OF LEGAL ASPECTS

Deliverable D.T3.4.2

Version 1
04 2021





Table of Content

1. Introduction	2
2. Methodology	2
3. Meeting minutes	2
4. Conclusion	5
ANNEX 1: Written Consent between STU and Social Care Home Warsaw	6

1. Introduction

This document, the engagement of test persons and consideration of legal aspects, presents the most important information regarding the selection of residents from the Social Care Home Warsaw and their involvement in “Output O.T3.3 - Pilot testing of AP-NURSE - persons suffering from Alzheimer’s disease in Social Care Home in Warsaw”. It is also one of the deliverables in thematic work package WP T3, D.T3.4.2.

2. Methodology

The deliverable deals with the engagement of minimum 10 residents of Social Care Home (SCH) Warsaw upon the consultation with the STU team, initial meeting, explanation of principles and benefits of pilot action, contact with care givers and Written Consent with the representative of the SCH Warsaw. The initial meeting between the STU team and the representatives of the SCH Warsaw took place on 29th April, as part of the briefing and training of test persons, home care givers and nurses using the online MS Teams platform. The meeting served to identify the clients of the SCH Warsaw for the pilot testing, select the version of AP-NURSE devices to be deployed in SCH Warsaw and to discuss the details of Written Consent between STU and SCH Warsaw. This deliverable includes the meeting minutes and the scan of the signed Written Consent in ANNEX 1.

3. Meeting minutes

Attendants:

Štefan Čerba (STU, PP4), Jakub Lüley (STU,PP4), Branislav Vrbán (STU,PP4), Magdalena Wieczorek (City of Warsaw - PP9) Jerzy Pawlowsky (Social Care Home Warsaw).

Selection of the patients for the pilot action:

- Monitoring of clients’ rooms
 - 8 rooms in the red zone
 - 4 single rooms
 - Monitoring of the patient in the bed
 - Monitoring of environmental parameters
 - Monitoring of the door to the garden
 - 4 double rooms
 - Monitoring of the main patient in the bed
 - Monitoring of the other patient in the room
 - Monitoring of environmental parameters
 - Monitoring of the door to the garden
 - 8 rooms in the green zone
 - 3 single rooms
 - Monitoring of the patient in the bed



- Monitoring of environmental parameters
 - Monitoring of the door to the garden
- 5 double rooms
 - Monitoring of the main patient in the bed
 - Monitoring of the other patient in the room
 - Monitoring of environmental parameters
 - Monitoring of the door to the garden
- 7 rooms in the orange zone
 - 3 single rooms
 - Monitoring of the patient in the bed
 - Monitoring of environmental parameters
 - Monitoring of the door to the garden
 - 4 double rooms
 - Monitoring of the main patient in the bed
 - Monitoring of the other patient in the room
 - Monitoring of environmental parameters
 - Monitoring of the door to the garden
- Monitoring of corridors
 - Monitoring of passage from/to red, green and orange corridors to the patients common areas, main corridor, side corridor and caregivers areas
 - Monitoring of activity patterns and passage
 - 6 monitoring positions
 - Focus on monitoring the potential activity over night
 - All mobile clients and all caregivers involved (approx. 150 people)
- Monitoring of the exits from/to the controlled areas
 - Monitoring of patients approaching the exits from the main and side corridor
 - Monitoring of activity patterns and passage
 - 4 monitoring positions
 - Focus on monitoring the potential activity over night
 - All mobile clients and all caregivers involved (approx. 150 people)

Monitoring of kitchens

- Monitoring of the small kitchen where meal for mobile patients is served
 - Monitoring of approaching the kitchen
 - Monitoring of gas, humidity and temperature patterns
 - Prevention of fire

- 3 monitoring positions
- All mobile clients and all caregivers involved (approx. 150 people)
-

Selection of the versions of the AP-NURSE

- AP-NURSE Home platform
 - Using with the Information system
 - No AP-NURSE wearables used
 - Monitoring from the nurses' desks using standard internet browser
 - Deployment of the following versions:
 - AP1-H
 - AP4-H
- AP-NURSE Care M5stack platform
 - Using with the Information system
 - Monitoring from the nurses' desks using standard internet browser
 - Deployment of the following versions
 - AP1-M
 - AP2-M
 - With ToF sensors
 - With Hall effect sensors
 - AP4-M
- AP-NURSE Care Wasmote platform
 - Using with the Information system
 - Monitoring from the nurses' desks using standard internet browser
 - Deployment of the following versions
 - AP1-W
 - AP4-W
 - AP6-W

Content of the Written Consent

- Purpose
 - Comprehensive explanation of the purpose of the Pilot Testing
- Procedures
 - Preparation of testing
 - Installation of devices



- Operation of devices and collection of data
- Analysis of data
- Collection of feedback
- Risks
 - COVID-19
 - Violation of privacy
 - Reduced care
- Benefits
 - Using a modern modular monitoring tool for free
 - Easing the day and night duties of caregivers
 - Gathering of experience with an IoT to easy caregiving
 - Providing fast alerts on possible danger
 - Easy traffic light logic used to monitor the conditions of clients
 - Availability of devices after the pilot testing
 - AI (artificial intelligence) based evaluation of sleep patterns of the clients
- Confidentiality
 - Anonymous assignment of patients to the tested devices
 - No voice and video recording applied
 - Sending of encrypted data
 - No data provision to third parties without additional written consent of the subjected party
- Consent
 - Who should sign

Time Schedule of the Pilot Action

- According to the procedures in the Written Consent

4. Conclusion

The Briefing with the representatives of Social Care Home Warsaw has met its objectives and the work on Output O. T3.3 - Pilot testing of AP-Nurse - person suffering from Alzheimer's disease in Social Care Home in Warsaw as well as in the related deliverables is in a very good way. The representatives of the SCH Warsaw were informed about all aspects of the pilot testing and helped to select the clients of the centre as well as the versions of AP-NURSE for the Pilot. The logistics and the details on testing procedure were discussed in details and the Written Consent including all necessary information and legal aspects was created and signed by the representatives.



ANNEX 1: Written Consent between STU and Social Care Home Warsaw



Informed Consent

TITLE OF STUDY

Testing of the AP-NURSE digital tool in Social Care Home in Warsaw

PROJECT SUPERVISOR

Prof. Ing. František Janíček, PhD.

Slovak University of Technology in Bratislava, Faculty of Electrical Engineering and Information Technology, Institute of Power and Applied Electrical Engineering
Director

Ilkovičova 3, 812 19 Bratislava, Slovakia

+421 2 60291 298

frantisek.janicek@stuba.sk

PURPOSE

The purpose of this study is to perform the testing of the AP-NURSE modular platform in the pilot action of the Interreg CE niCE-Life CE1581 project, especially as part of Output O.T3.3 "*Pilot testing of AP-nurse - persons suffering from Alzheimer's disease in Social Care Home in Warsaw*". This pilot action tests AP-NURSE for persons suffering from Parkinson's disease, Alzheimer's disease and frail elderly by utilizing ambient sensors preventing events endangering the health of clients, like falling from bed or stairs, fire, gas leakage or leaving the area of care center. Its aim is to simplify work of home caregivers or nurses by monitoring basic interactions of the patient with environment during night or job duties and provide fast alert about possible dangers when abnormal patterns would be observed. The pilot action is performed in Social Care Home in Warsaw (SCH) with the technical support of the staff of the Slovak University of Technology in Bratislava (STU).

PROCEDURES

The pilot testing of AP-NURSE in Social Care Home Warsaw includes the following procedures:

1. Preparation of the testing

- The preparation of the pilot testing started in January 2021 and includes the development of prototypes, their production, software implementation, 3D print of the casing, laboratory testing of devices and management of the installation and data collection activities. Some of the preparatory actions were performed under the work package WP2 of the project. The last step of this procedure collection and categorization of devices for implementation to the IS and their transport to Social Care Home in Warsaw by 10th May 2021

2. Installation of devices

- The installation of devices is in line with the project deliverable D.T3.4.1 – Design of the pilot action in Warsaw. It includes information about the

Informed Consent

type of clients treated in the center, the deployment of devices in dedicated rooms and common areas and the physical installation including their connection through the local WiFi network to the information system (IS). This phase of the pilot action is scheduled between 10th and 17th May 2021

3. Operation of devices and collection of data

- The operation of devices starts after their connection to the information system. The IS provides notifications, which could be evaluated as alerts to abnormal or critical conditions of pre-defined scenarios. More information on the IS and the types of AP-NURSE devices can be found in D. T2.2.5 of the project. The Status of connected devices as well as the notifications from the IS are available for the caregivers at SCH Warsaw and the STU staff. This procedure starts directly after the installation of AP-NURSE devices and will be performed while the devices are operational and do not required significant maintenance.

4. Analysis of data

- Notifications and operation data from the connected devices are stored in the information system and are available for subsequent analyses. The collected data are anonym, therefore they cannot directly identify the test persons and are in line with GDPR and the data protection policies of interested parties. Data related to sleep patterns and frequency of notifications will be made available only to partners of the Integer CE NiCE-Life project and the staff of SCH Warsaw for the purpose of the deliverable D.T1.2.3 – “Analysis of the statistical data and interoperability of data”. Sharing of data beyond the scope of the Interreg CE niCE-Life project cannot be done without the written consent of SCH Warsaw and STU.

5. Collection of feedback

- Feedback from caregivers and the staff of SCH Warsaw will be collected after the data analysis has been finished. It will be through dedicated meetings and electronic survey prepared by the STU staff.

RISKS

During the pilot testing several risks may occur, some can be predicted, but some cannot. Based on the analysis of planned actions in the pilot testing, the following risks were identified.

1. Risk of COVID-19 infection

- Severity: High
- Probability: Low
- Corrective measures taken by the members of the STU staff performing the pilot action:
 - i. vaccination by the first dose of a EU certified vaccine (Astra Zeneca)
 - ii. entering the building only with negative antigen or PCR COVID-19 test not older than 7 days



Informed Consent

- iii. use of FFP2 respirators and protective gloves
 - iv. minimization of the contact with the clients
 - v. avoiding contact with unknown people outside of the center, household and workplace
2. Violation of client's privacy
- Severity: Low
 - Probability: Moderate
 - Corrective measures taken by the members of the STU staff performing the pilot action:
 - i. minimization of contact with clients
 - ii. installation devices in the absence of clients in the rooms
 - iii. placement of devices in places, which do not attract the attention of patients
3. Reduced care of patients
- Severity: Moderate
 - Probability: Low
 - Corrective measures taken by the members of the STU staff performing the pilot action:
 - i. minimization of contact with clients
 - ii. installation of devices in the absence of clients in the rooms and in line with daily routines of caregiving
 - iii. selection of those clients for testing, who may not significantly suffer if this risk occurs

BENEFITS

AP-NURSE is a modular platform developed for home and medical use, tailored to the needs of caregivers and patients. The AP-NURSE devices as well as the pilot testing were designed in a way that the benefits significantly outweigh the associated risks. The main benefits of the AP-NURSE pilot testing are:

1. Using a modern modular monitoring tool for free
2. Easing the day and night duties of caregivers
3. Gathering of experience with an IoT to easy caregiving
4. Providing fast alerts on possible danger
5. Easy traffic light logic used to monitor the conditions of clients
6. Availability of devices after the pilot testing
7. AI (artificial intelligence) based evaluation of sleep patterns of the clients

CONFIDENTIALITY

In order to preserve the confidentiality of clients and caregivers during pilot testing, the following measures will be taken:



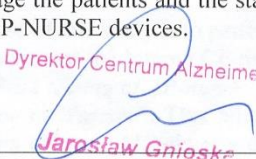
Informed Consent

1. Anonymous assignment of patients to the tested devices
2. No voice and video recording applied
3. Sending of encrypted data
4. No data provision to third parties without additional written consent of the subjected party

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that participation of clients and employees of the Social Care Home in Warsaw, for who I am responsible, is voluntary and anonym and the collected data will be used only as stated. I understand that I will be given a copy of this consent form. I am aware of my right to withdraw this consent at any time, which however shall not affect the lawfulness of processing based on consent before withdrawal. I agree to engage the patients and the staff of the Social Care Home in Warsaw in the pilot testing of AP-NURSE devices.

Dyrektor Centrum Alzheimer'a


Jarosław Gnioska

Date 12. 05. 2021

Jarosław Gnioska

Director of the Social Care Home in Warsaw



Date 13.05.2021

Prof. Ing. František Janíček, PhD.

Project Supervisor

