

# Instructions for data collection

Version 4.0.

Release: December 9th, 2016



## 1. Document Information

### 1.1. Purpose of the document

Dear colleagues,

In this document you can read the new protocol, you can also find all the documents you need for the implementation of our study in the coming months, as well as an explanation of how we wish to receive all the data you collected. The purpose of this document is to carry out the study in the same way in the three locations. This is required for the analysis of the data and the formulation of the conclusions afterwards. If things are not clear, or if you have any questions you can always reach Ellen or myself via e-mail (ellen.decuyper@odisee.be, mieke.beckwe@odisee.be).

Good luck!

Kind regards,

Mieke

### 1.2. Responsible organisation

Odisee

### 1.3. Authors and Contributors

Ellen De Cuyper and Mieke Beckwé

### 1.4. Version History

Versie 4.0. (Adjustments conform our decisions during the meeting in London on November 29th and 30th.)

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### 3. Glossary

AAL	Active Assistive Living
IntegrAAL	Project acronym for Integration of AAL (Active Assistive Living) Components for Innovative Care Pathways
Formal caregiver	A caregiver who is trained and paid for his performances to help the patient, in this case the older adults, for example a nurse or a therapist but also a domestic helper.
Informal caregiver	A person who voluntarily helps the participant in some of his daily activities, for example a daughter or a son, a person living next door.
IntegrAAL Platform	Cloud-based data management platform to support care providers in managing care data in a person-centered manner. It enables assessment, care planning, care recording using mobile devices, and outcome management as well as reporting. It also enables care providers to make use of IoT devices as well as wearable devices in the context of care provision.
IoT device	Internet of Things device, normally a sensor device connected to the internet enabling the monitoring of location, movement, or temperature amongst others.

## 4. Timeline

	2016												2017					
	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	
<b>Dorset</b>																		
Recruitment period																		
Testing period																		
<b>Brussels</b>																		
Recruitment period																		
Testing period																		
data analysis and writing a report																		
<b>Miranda do Corvo</b>																		
Recruitment period																		
Testing period																		

## 5. New Protocol

### 5.1. Informed Consent

It is important to inform subjects about the precise content of the study in which they participate. Subsequently, all participants can decide whether or not they want to consent to their participation. Therefore it is important that all participants read the participant information and sign the informed consent document. You have to develop these documents yourselves. (If you doubt about the content of these documents you may always e-mail them to Ellen or me.)

## 5.2. Participants

In Belgium and Portugal there are about 80 older adults people (40 in Belgium and 40 in Portugal) as well as their network of informal and formal caregivers participating in the study. In the UK about 50 older adults people and their network will participate. It is impossible to determine the number of informal and formal caregivers because it is very different for every older adults. Do try to implement only older adults people with at least one informal caregiver or one formal caregiver in this study.

All older adults people participating in this study must be over 64 years old, live independently at home, and make use of home assistance (e.g. home nursing, cleaning services,...).

We briefly summarize the inclusion and exclusion criteria:

### **Inclusion criteria older adults:**

- > 64 years old
- Living at home
- At least one informal or formal caregiver wants to participate

### **Exclusion criteria older adults:**

- Unable or unwilling to consent
- Highly-dependent care needs due to short term medical intervention
- Severe cognitive impairment (MMSE < 11)

## 5.3. Experimental versus control condition

Participants will be allocated **at random** to one of two groups:

- In the **experimental condition** the older adults will test the IntegrAAL platform and associated IoT devices. Older adults have to complete a questionnaire before the beginning of the study, after 6 weeks, after 3



months, after 6 months and at the end of the study. The formal and informal caregiver will use only the IntergrAAL platform and share their experiences by completing a questionnaire before the beginning of the study, after 6 weeks, after 3 months, after 6 months and at the end of the study.

- In the **control condition** older adults can use the devices and will complete a questionnaire before the beginning of the study, after 6 weeks, after 3 months, after 6 months and at the end of the study. The informal caregiver and the formal caregiver only fill in a questionnaire at the beginning of the study.

In Belgium, we will try to have about as much as possible older adults people with their network in the experimental condition and 1 in 4 older adults with their network will be assigned to the control condition. In Portugal and the UK you must also try to have this ratio of 3 parts of experimental condition and one part control condition.



**Desired number of participants in both conditions**

	<b>experimental</b>	<b>control</b>	<b>Total</b>
<b>Dorset</b>	<ul style="list-style-type: none"> <li>• 40 older adults</li> <li>• at least 40 informal caregivers</li> <li>• at least 40 formal caregivers</li> </ul>	<ul style="list-style-type: none"> <li>• 13 older adults</li> <li>• at least 13 informal caregivers</li> <li>• at least 13 formal caregivers</li> </ul>	<ul style="list-style-type: none"> <li>• 53 older adults</li> <li>• at least 53 informal caregivers</li> <li>• at least 53 formal caregivers</li> </ul>
<b>Brussels</b>	<ul style="list-style-type: none"> <li>• 30 older adults</li> <li>• at least 30 informal caregivers</li> <li>• at least 30 formal caregivers</li> </ul>	<ul style="list-style-type: none"> <li>• 10 older adults</li> <li>• at least 10 informal caregivers</li> <li>• at least 10 formal caregivers</li> </ul>	<ul style="list-style-type: none"> <li>• 40 older adults</li> <li>• at least 40 informal caregivers</li> <li>• at least 40 formal caregivers</li> </ul>
<b>Miranda do Corvo</b>	<ul style="list-style-type: none"> <li>• 30 older adults</li> <li>• at least 30 informal caregivers</li> <li>• at least 30 formal caregivers</li> </ul>	<ul style="list-style-type: none"> <li>• 10 older adults</li> <li>• at least 10 informal caregivers</li> <li>• at least 10 formal caregivers</li> </ul>	<ul style="list-style-type: none"> <li>• 40 older adults</li> <li>• at least 40 informal caregivers</li> <li>• at least 40 formal caregivers</li> </ul>



Older adults with their network should be **randomly** assigned to one of the two conditions. So make a list of all participants with their participant number and assign every 4th participant to the control condition. If you let start each potential participant before you have an overview of all the participants who will eventually participate, then let every 4th participant start in the control condition. In the UK you may start counting with respondent number (resp. nr.) 1, in Belgium with respondent number 401, and in Portugal you may begin counting at 801.

### Allocation of study arms

	Experimental condition	Control condition
<b>Dorset</b>	Resp. nrs.: 1, 2, 3, 5, 6, 7, 9, 10, 11, 13, 14, 15, 17, 18, 19, 21, 22, 23, 25, 26, 27, 29, 30, 31, 33, 34, 35, 37, 38, 39, 41, 42, 43, 45, 46, 47, 49, 50, 51, 53, 54,...	Resp. nrs.: 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52,...
<b>Brussels</b>	Resp. nrs.: 401, 402, 403, 405, 406, 407, 409, 410, 411, 413, 414, 415, 417, 418, 419, 421, 422, 423, 425, 426, 427, 429, 430, 431, 433, 434, 435, 437, 438, 439,...	Resp. nrs.: 404, 408, 412, 416, 420, 424, 428, 432, 436, 440,...
<b>Miranda do Corvo</b>	Resp. nrs.: 801, 802, 803, 805, 806, 807, 809, 810, 811, 813, 814, 815, 817, 818, 819, 821, 822, 823, 825, 826, 827, 829, 830, 831, 833, 834, 835, 837, 838, 839,...	Resp. nrs.: 804, 808, 812, 816, 820, 824, 828, 832, 836, 840,...

## **5.4. The intervention (independent variable)**

The older adults and their network in the experimental condition will use the new technology that Nourish Care provided us with as long as possible. Informal and formal caregivers in the experimental condition will use the integrAAL platform. The older adults will also be able to use connected devices. Not all older adults people in the experimental condition will use all the possibilities of the technology, it is intended that the older adults themselves decide what options they find useful to increase their self-reliance.

Older adults people can use their own smartphone and if needed some tablets will be provided by Nourish Care. Normally a user guide is not necessary.

## **5.5. Measurements (dependent variable)**

Before the start of the study, after 6 weeks, after 3 months, after 6 months and at the end of the study, all the participants in the experimental condition have to complete the questionnaires. A first time at the start of the study before the participants get started with the technology (t0). A second time after 6 weeks using the technology (t1). A third time after 3 months of using the technology (t2) and a fourth time after 3 months of using the technology (t3). If t3 is not the end of the study, the questionnaires may be filled out again at the end of the study (t4).

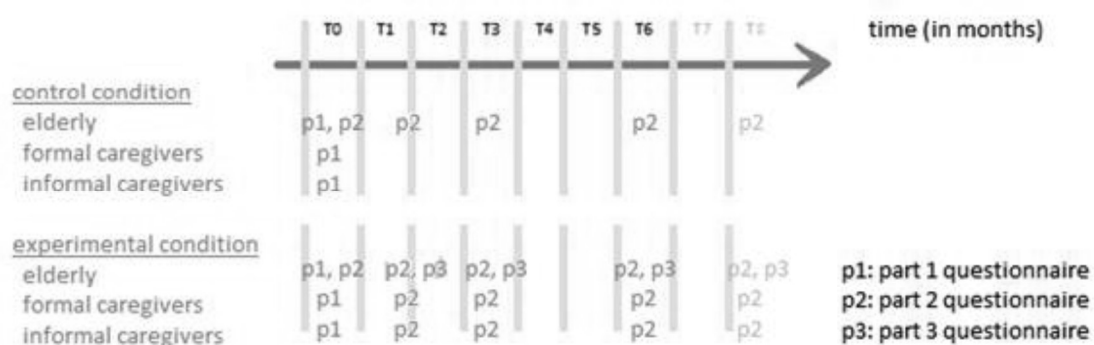
Part 1 of the questionnaire (personal data) must be completed once before the start of the study by the participating older adults (t0). Also, Part 2 of the questionnaire, "the quality of life index" should be filled out at t0. At t1, t2, t3 (and possibly also at t4) the 10 older adults in the control condition only fill in the second part of the questionnaires. The 30 older adults people in the experimental condition complete Part 2 and Part 3 of the questionnaires. The 3rd part of the questionnaire is more specific about experiences with the technology. See Appendix 1 for the questionnaire for the older adults. If the older adults want to report any additional issues during their participation in the study, they can do so in the communication diary (see Appendix 4). This communication diary will be added to the integrAAL platform. If you think this is

appropriate, you can also leave a paper version of the communication diary at the participants house. After the study, you can add the information from this paper version to the system. Do not forget to fill out the exit interview (see Appendix 5) at the end of the study (t4).

The network (informal and formal caregivers) of the older adults is classified in the same condition as the older adults themselves. Before the start of the study (t0), informal and formal caregivers have to fill out part 1 of the questionnaire. Part 1 questions personal data and the relationship with the older adults. The network of the older adults in the experimental condition will then use the new technology and will be asked to fill out Part 2 of the questionnaire every 3 months (t1, t2, t3 and t4 if necessary). See Appendix 2 for the questionnaire for informal caregivers and Appendix 3 for the questionnaire for formal caregivers. Do not forget to fill out the exit interview (see Appendix 6) at the end of the study (t4).

You can decide yourself how you communicate to your participants that it is time to fill in the questionnaires, but we recommend a personal approach (visit the older adults, or call them).

## 5.6. Design



## 6. Data collection

Each site is responsible for acquiring data through online questionnaires available via the AAL platform. This way all data is stored centrally, ready for analysis. The Portuguese versions of the questionnaire can be added when

translated. If you still choose to use a paper version of the questionnaire (e.g. because the older adults find it difficult to use a the computer), you have to add the data afterwards via the AAL platform.

We want to receive the data from the questionnaires in an excel sheet via e-mail on April 17th, 2017 the latest. We also wish to receive a case study with a fully detailed description of a situation that is typical of the region before the end of April 2017.

Note for team Portugal: Antonio, when you're ready, can you send us an example of how an Excel file with the data will look like? Thanks!

## 7. Drop-out

We can best assume a quite large drop-out. I spoke to someone who has a lot of experience with this type of study, and she advised us to implement some 50 subjects in the experimental condition if we wish to save 30. So keep in mind in Portugal and the UK to implement enough participants so you can collect enough data. In order to persuade older people to participate and to encourage them not to quit the study, a personal approach works probably best. Ensure that older adults who wish to participate are always contacted by the same contact person and call them rather than write (or e-mail) them.

If older adults, informal or formal caregivers then still decide to stop with the study, it is very important to question the reason for this drop-out. This provides us with a lot of information. To ensure that this is done the same way in the 3 locations we provide you with a checklist with questions you can ask participants at the end of the study (see Appendix 5 'exit interview'). It is important to ask these questions anyway at the end of the study. Even if participants do not drop out earlier.

## 8. Appendices

For the appendices, see attachments of the e-mail. I send the appendices preferably in separate files, this way the layout is retained.

1. Questionnaire older adults
2. Questionnaire informal caregivers
3. Questionnaire formal caregivers
4. Communication diary
5. Exit interview older adults
6. Exit interview caregivers

Note for team Portugal:

Dear Antonio, João and Luis, All these appendices must be translated into Portuguese. After this, the attachments (in the four languages) should be added to the system. Thanks!

