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- **Draft (D)**: describes planned contents and main structure of the different sections. Document is between 0% - 50% completed.
- **Intermediate (I)**: document is approximately between 50% - 100% completed. It is the previous step before it could be released.
- **Released (R)**: document is 100% completed, reviewed and authorized for release by the partner responsible of the deliverable or the WP leader.

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Executive summary

This document presents the trials strategic plan, developed to a level of detail and specificity that is appropriate at this stage of the project's work plan and its progress against this. It includes a number of elements.

One important part provides a description of the national framework conditions in the countries where trials are planned (Spain, UK, Ireland), covering the legal/regulatory contexts and research ethics processes. These are central to the planning and design of the field trials. Any trials that are to be conducted must be appropriate and feasible within the parameters that are laid down in these framework conditions. The report also examines and discusses some other practical considerations that need to be taken into account in the trials strategy. These include issues arising from the planned schedule of release of the various elements of the BREATHE functionality by the technology work packages (WPs), and issues linked to the capabilities and interests of the three sites for the user trials. The report then provides a presentation of some of the main methodological options that may be considered in the trial design and implementation processes under WP4. This is intended to provide a useful analysis of the range of issues that will need to be considered in WP4 and in the interactions between WP4 and the two technology development WPs (2 and 3). This document also includes an initial presentation and discussion of possible methods and instruments for user feedback and outcome evaluation, mapped to some of the main methodological options. This is intended to provide a starting point for deeper consideration and refinement in WP4, when more clarity has been achieved in relation to the open issues mentioned above.

1 About this document

1.1 Structure of this document

This document presents the trials strategic plan, developed to a level of detail and specificity that is appropriate at this stage of the project's work plan and deliverable progress. It is structured as follows:

• Chapter 2 - Description of the national framework conditions in the countries for the trials (Spain, UK, Ireland), covering the legal/regulatory contexts and research ethics processes.

• Chapter 3 - Practical considerations that need to be taken into account in the trials strategy, including issues arising from the planned schedule of release of the various elements of the BREATHE functionality by the technology WPs, and issues linked to the capabilities and interests of the three sites for the user trials.

• Chapter 4 - Provides a presentation of some of the main methodological options that may be considered in the trial design and implementation processes under WP4, and initial presentation and discussion of possible methods and instruments for user feedback and outcome evaluation.

2 Framework conditions in the trial countries

This Chapter provides a description of the national framework conditions in the countries where user trials are planned (Spain, UK, Ireland), covering the legal/regulatory contexts and research ethics processes. These are central to the planning and design of the field trials. Any trials that are to be conducted must be appropriate and feasible within the parameters that are laid down in these framework conditions.

Each partner site has its own research ethics procedural contexts as well as legal and regulatory requirements that will apply for the conduct of research for the BREATHE project, including data protection requirements, and insurance and liability. Procedures for third part involvement in the project are also outlined in this Chapter.

2.1 Ethical committee requirements at partner sites

The ethical principle governing all research is that respondents should not be harmed as a result of participating in the research, and they should give their voluntary, informed consent to participate. Informed consent means that potential research participants should be given as much information as possible to make a decision about whether they wish to participate in the research study. At all times, the confidentiality of participant information should be respected and protected. At all stages of this research, these ethical principles shall be upheld and the rights of participants under The European Charter of Fundamental Human Rights shall be upheld and the Declaration of Helsinki[1].

The BREATHE project has established its own Ethics Board (EB)[2]. The main role of the EB is to guarantee the accomplishment of European and National laws regarding ethics in research. The mission of the EB is to ensure ethical issues are taken into account when dealing with end users' activities and participate in providing advice as well as solutions before problems appear (see Section 3.4 of The Quality Handbook for more details). Separate to the BREATHE EB, each of the partner sites are governed by different structures and requirements for approval from institutional ethics committees as outlined below.

2.1.1 Ireland (TCD and TER)

Ethical approval is required for TCD from the Faculty of Health Sciences Research Ethics Committee (REC) at TCD[3]. Applicants must complete a detailed Ethics Application Form (MS Word, 157 kB)[4] which describes the study aims, objectives and methodologies, alongside any supplementary materials (e.g. participant information

[1] EU Charter of fundamental rights: http://ec.europa.eu/justice/fundamental-rights/charter/index_en.htm (Accessed on April, 2014).
[2] http://breathe-project.eu/en/governance/#Board (Accessed on April, 2014.)
[3] Faculty Research Ethics Committee: http://www.healthsciences.tcd.ie/research-ethics-committee (Accessed on April, 2014).
[4] Download the Ethics application form: http://www.healthsciences.tcd.ie/assets/doc/Ethics-Form-Revised-August%2012%20(3).docx (Accessed on April, 2014).

sheets, questionnaires) for review at an Ethics Committee meeting (usually held monthly). The outcome of the meeting is usually known within a month and the committee may approve the application with/without amendments or reject the application. If they require amendments, these must addressed and re-submitted to the committee before a letter of official approval will be issued. For the BREATHE study, the process has been split into two separate applications as these will require different methodological approaches and will pose different ethical challenges:

- Phase 1: Application to conduct the WP1 interviews and focus groups for user-requirements:
    - Date submitted: September, 2013.
    - Outcome: 07.10.13. Amendments were required, these were addressed and a letter of approval from the REC was received 22.10.13 for WP1.
- Phase 2: Application to conduct field trials during WP4:
    - Expected submission: Friday 6th June 2014.
    - Expected outcome: Tuesday 24th June 2014.

2.1.2 UK (CYB and KU)

CYB does not require ethical approval from an external board. Approval for participation was obtained from the Cybermoor Board for conducting the interviews and focus groups for the user-requirement stage of this research. The BREATHE EB will provide guidance on ethical issue during this project. On the other hand, KU will require ethical approval to conduct field trials in 2014. The process will be similar to that outlined above for TCD in that an application will need to be submitted (MS Word, 114 kB) to the university Research Ethics Committee[5] for review at a committee meeting. Again, the committee may approve the application with or without amendments or reject the application outright.

2.1.3 Spain (ISI)

ISI does not require ethical approval from an external board so will therefore not be required to submit an application for data collection for the user-requirements stage or to conduct the field trials. At all stages of the study, the BREATHE Ethics Board will provide guidance and support to ISI on any ethical aspects of the project.

2.2 Data protection and data privacy

Overall the Project Consortium will follow EU Directive 95/46/EC on both personal and local data protection laws and will ensure that personal data will be treated in line

[5] Application form for Ethical review (RE4) for research involving human participants: http://www.kingston.ac.uk/research/research-policies-and-guides/documents/RE4_form.doc (Accessed on April, 2014).

with that legal directive. In terms of protection of personal data this research Project will enforce the EU Directive 2002/58/EC on Privacy and Electronic Communications (amending Directive 97/66/EC).

Within each specific country special attention will be paid to the national laws and regulations derived from this EU Directives, in case they are more restrictive. An outline of these National Laws presented in this below. Where possible, any specific recommendations with regard to the use of cameras (predominantly this is in reference to CCTV use) will be presented.

2.2.1 Ireland (TCD and TER)

In Ireland the collection, storage and utilization of personal data are subject to the provisions outlined in the Irish Data Protection Act 1988 and the Data Protection (Amendment) Act 2003[6,7]. The Acts set out the general principle that individuals should be in a position to control how data relating to them is used. All research conducted must follow the constraints as outlined in this document. In particular, all participants need to provide consent to participate, to be informed as to who will access their data and how data will be stored securely in line with Data Protection guidelines. The Data Protection Commissioner is responsible for upholding the rights of individuals as set out in the Acts, and enforcing the obligations upon data controllers. There are eight rules which must be followed by Data Controllers (individuals/legal person who controls and is responsible for the keeping and use of personal information). We must:

- Rule 1: Obtain and process the information fairly.
- Rule 2: Keep it only for one or more specified and lawful purposes.
- Rule 3: Process it only in ways compatible with the purposes for which it was given to you initially.
- Rule 4: Keep it safe and secure.
- Rule 5: Keep it accurate and up-to-date.
- Rule 6: Ensure that it is adequate, relevant and not excessive.
- Rule 7: Retain it no longer than is necessary for the specified purpose or purposes.
- Rule 8: Give a copy of his/her personal data to any individual, on request.

[6] Data Protection Act 1988: http://www.irishstatutebook.ie/1988/en/act/pub/0025/index.html (Accessed on April, 2014).
[7] Data Protection Act 2003: http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html (Accessed on April, 2014).

CCTV and images

Recognisable images captured by CCTV systems are personal data and are therefore subject to the provisions of the Data Protection Acts. The processing of personal data kept by an individual and concerned solely with the management of his/her personal, family or household affairs or kept by an individual for recreational purposes is exempt from the provisions of the Acts. This exemption would generally apply to the use of CCTVs in a domestic environment. However, the exemption may not apply if the occupant works from home.

2.2.2 UK (CYB and KU)

In the UK, the Data Protection Act 1998 (DPA) is the Act which defines the law on the processing of data on identifiable living people[8]. All research conducted must follow the constraints as outlined in this document. Under this Act, every data controller (e.g. organisation, sole trader) who is processing personal information is required to register with the Information Commissioner's Office (ICO)[9]. Cybermoor is registered with the Data Protection Officer.

In this case, the eight principles/rules to the Data Protection Act are:

- Rule 1: Personal data shall be processed fairly and lawfully.
- Rule 2: Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
- Rule 3: Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
- Rule 4: Personal data shall be accurate and, where necessary, kept up to date.
- Rule 5: Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
- Rule 6: Personal data shall be processed in accordance with the rights of data subjects under this Act.
- Rule 7: Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- Rule 8: Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

[8] Data Protection Act 1998: https://www.gov.uk/data-protection (Accessed on April, 2014).
[9] Data Protection and Freedom of Information advice: http://ico.org.uk (Accessed on April, 2014).

CCTV and images

The use of images of people is covered by the Data Protection Act, and organisations who use CCTV must comply with the Data Protection Act 1998. The Data Protection Act does not apply to individuals' private or household purposes. For example, if a camera is installed in a home to protect it from burglary, the Act will not apply.

2.2.3 Spain (ISI)

In Spain, the collection, storage and utilisation of personal data are subject to the provisions outlined in the Organic Law 15/1999 December 13th on the Protection of Personal Data (LOPD) and amendments pertaining to Law 2/2011, March 4th[10]. Under the provisions of these Laws, when an organisation collects personal data, it must inform the individual explicitly beforehand of the following:

- The existence of a file collecting his or her data, the objectives of storing the data and the recipients of this information.
- The mandatory or the optional character of the information collected.
- The consequences of providing or not providing the data.
- The rights to access, rectify, delete or oppose the data stored.
- The identity of the individual responsible for the treatment and the storage of the data or his or her representative.
- If the personal information has been collected indirectly, there is the obligation to inform the person within 3 months from the initial data storage.

CCTV and images

Under the provisions of these laws, images constitute personal data when they refer to identified or identifiable persons. Therefore, personal data protection principles should be applied to the use of cameras under the following circumstances[11]:

- There is recording, capturing, transmission, preservation or storage of the images, including their reproduction or broadcasting in real time or the processing of the personal data derived from these images.
- These activities refer to the data of identified or identifiable persons.

The LOPD is not applicable to image processing in the personal and domestic spheres, understanding this to be image processing performed by an individual in the context of an exclusively private or family-based activity.

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[10] Spanish Data Protection Agency: http://www.agpd.es/portalwebAGPD/canaldocumentacion/publicaciones/common/pdfs/AEPD_en.pdf (Accessed on April, 2014).

[11] Spanish Data Protection Agency. Guide on Video Surveillance: https://www.agpd.es/portalwebAGPD/canaldocumentacion/publicaciones/common/pdfs/guia_videovigilancia_en.pdf (Accessed on April, 2014).

2.3 Insurance and liability

The BREATHE platform prototype will be validated with real end-users in the partner countries during the field trials. During the field trials, the research sites will be responsible for prior arrangements for insurance and indemnity. TCD is covered by the College Professional Indemnity Scheme[12]. Cybermoor and ISI have public liability insurance. All TER equipment is subject to stringent licensing and quality controls.

Once the BREATHE system is fully developed it will need to be licensed prior to bringing it to market and as such will be subject to a number of EU directives controlling such products such as:

- European Directive (1999/5/EEC) about radio control equipment.
- European Directive (2002/95/EEC) about using substances in electronic devices.
- European Directive (2002/96/EEC) about on waste electrical and electronic equipment.
- European Directive (85/374/EEC) about liability for defective products.

2.4 Third party involvement

Involvement of third parties across all partner sites will follow the procedure as outlined in the Quality Handbook, section 4.7. Since the content of the Quality Handbook is restricted for partners within the BREATHE Consortium, a summary is provided below with the most important topics:

- Identification of relevant third party involvement is specified and outlined to BREATHE Consortium by the nominating BREATHE partner.
- The nominating BREATHE partner is to complete the designated 'Third Party Project Inclusion Form', which will outline and justify the need, purpose, role and duration of external third party involvement with BREATHE. All necessary relevant support information (i.e. CV of the person/entity) should also be included with this form.
- The Project Board will approve external or third party inclusion based on submission of all relevant documents and justification of third party relevance and benefit to the project. The Project Board will appoint a key person from the nominating partner, to guide approved third parties into their defined activity. If there is no consensus the Project Board will report feedback to the nominating partner to either request further information to better inform the decision making process or outline reasons why they have on this occasion not been approved.

[12] Royal College of Nursing: https://www.rcn.org.uk/support/legal/indemnityscheme (Accessed on April, 2014).

- Prior to involvement with the BREATHE project all external entities must sign a BREATHE Non-Disclosure Agreement (NDA) based on the terms and conditions of the BREATHE Consortium Agreement (CA).
- Liability of third party involvement will fall under the terms for the nominating partner under the CA.
- The external third party will then be able to participate in project activities for the agreed duration.
- All Intellectual Property created by external third parties will fall under the BREATHE Consortium Agreement and remain the property of the BREATHE Consortium.
- Results and outputs from the BREATHE project (outside of those publicly published) will not be made available to third parties unless agreed to by the Project Board at the nomination approval stage.

3 Practical considerations for the trials strategy

This chapter presents and discusses some important practical considerations that influence the trials strategy. These include issues arising from the nature of the various elements of the BREATHE functionality and the planned schedule of release by the technology WPs, linked to the capabilities and interests of the three sites for the user trials.

3.1 The elements of BREATHE functionality and their release schedule

3.1.1 The core elements of the BREATHE system functionality

The BREATHE concept is based on an integration of a number of key elements of functionality:

- The AAL home system. The AAL home system is composed by the indoor video-based monitoring system, the array of multi-function sensors and one interaction device which (1) allows the AP to turn the indoor video-based monitoring system on and off and (2) sends RAW data gathered from the AP´s home to the server side system (Google App Engine, back-end) of the informal caregiver tool.
- The informal caregiver tool. The informal caregiver tool is a server side system which offers, to the informal carer, a bunch of useful services. The informal caregiver tool is composed by a front-end and a back-end. The front-end relies on standard web technologies (HTML, CSS, JavaScript, PHP and MySQL) while the back-end is based on the Google App Engine (GAE) cloud computing technology. Regarding the interaction devices, a laptop or desktop are expected in those use cases where the carer is at home and decides to interact with the platform in an efficient way (a keyboard and a mouse are required) and a mobile device (smartphone or tabletPC) with Android OS for those use cases when the carer is on the go.

These different elements of functionality each have value in their own right as well as in the envisaged eventual integrated and complete package for the entire BREATHE system. The user trials strategy needs to address each of the types of functionality outlined above through methods appropriate to the characteristics, level of development and maturity of each given release versions of the BREATHE system (including support tools). On review of the envisaged release schedule for the various elements of the BREATHE functionality (section 3.1.2) and of the trial sites capabilities and interests (section 3.2), an indicative mapping of types of trials to the different elements of functionality is provided in section 3.3.

3.1.2 The currently envisaged release schedule for the BREATHE functionality

The BREATHE system functionality is planned to be developed and released in three different phases:

- First release (1st): Pre-Trial (month 15).
- Second release (2nd): Full Trial (month 21 - 30).
- Final release (3rd): Product ready to market (month 30).

Moreover, according to Deliverable D1.2 (Technical specifications of BREATHE platform), there are six different actors who interact with some parts of the system under certain conditions to meet a specific goal:

Role	Short definition
Human actors	
Informal caregivers (ICs)	Typically family carers who may or may not live with the person, for whom they care who care for an assisted person.
Assisted person (APs)	Typically people with at least one long-term condition (LTC), who may or may not live with their main carer.
Formal carers (FCs)	Typically officially employed paid carers who care for one or more assisted persons.
Technological provider (TPs)	Typically a technological company, which develops, installs and maintains an ICT based solution.
Service provider (SPs)	Typically a company, which provides care services to alleviate the lack of time and education of informal carers.
Non-human actors	
AAL home system (AALHS)	Technological system installed at the assisted person´s home, which collects information in a continuous way about his/her daily life activities, moods and behaviour. It is composed by cameras and an alternative array of sensors, complementing and replacing the camera functionality.

Table 1 - Human and non-human actors involved in BREATHE

Relationships between actors and interactions with some parts of the BREATHE system are carried out through use cases. The following tables list the functionalities ('use cases') that, according to D1.2, are envisaged as being available at the time of each release:

INFORMAL CAREGIVER (IC)			
Identifier	**Name**	**Release**	**Equivalence from D1.2**
Sub-system: WEB (front-end)			
UC-W-1	Log in	1st	-
UC-W-2	Recover my lost password	1st	-
UC-W-3	Configure own account	1st	
UC-W-4	Access to adapted video signals in real-time	1st	UC-0
UC-W-5	Access to periodic reports and trends about the AP	2nd	UC-1 and UC-11
UC-W-6	Configure periodic reports: daily, weekly, monthly and yearly	2nd	UC-2
UC-W-7	Access to proposed training material	3rd	UC-4
UC-W-8	Search for available training material	3rd	UC-4
UC-W-9	Access to the complete list of advices and recommendations	2nd	UC-9
UC-W-10	Write a diary	2nd	UC-6
UC-W-11	Search for old diary posts	2nd	UC-6
UC-W-12	Ask for advice to FCs	3rd	UC-7
UC-W-13	Access to the complete list of questions/answers to/from	3rd	UC-7 and UC-12

	FCs		
UC-W-14	Visualize the current status of the AP and IC	1st	UC-11
UC-W-15	Configure predefined alerts of the AP	1st	UC-10
UC-W-16	Complete self-assessment questionnaires	1st	-
UC-W-17	Access to the complete list of filled questionnaires	1st	-
UC-W-18	Alert when the AAL home system is down	2nd	-
UC-W-19	Alert when the AAL home system is turned OFF/ON by the AP	2nd	-
UC-W-20	Set up the assisted person emergency response contact list	2nd	UC-14
UC-W-21	Request for help to the family network	3rd	UC-8
UC-W-22	Set up the IC family network contact list	3rd	UC-13
Sub-system: MOBILE			
UC-M-1	First access to the mobile app	1st	-
UC-M-2	Access to settings to change basic parameters	1st	-
UC-M-3	Access to adapted video signals in real-time	2nd	UC-0
UC-M-4	Visualize the current status of the AP and IC	2nd	UC-11
UC-M-5	Receive real-time alerts	2nd	UC-3
UC-M-6	Receive daily and personalized advice	1st	UC-5
UC-M-7	Continuous self-reporting	2nd	-
UC-M-8	Notifications about pending messages to be read	2nd	-
UC-M-9	Access to daily reports (timeline)	2nd	UC-1
UC-M-10	Alert when the AAL home system is down	3rd	-
UC-M-11	Alert when the AAL home system is turned OFF/ON by the AP	3rd	-
UC-M-12	Request for help to the family network	3rd	UC-8

Table 2 - Release schedule for ICs UCs

ASSISTED PERSON (AP)			
Identifier	**Name**	**Release**	**Equivalence from D1.2**
AAL home system			
UC-H-27	AP turns OFF the AAL home system	1st	UC-15
UC-H-28	The AAL home system sends an alert to the IC when its turned OFF	1st	UC-15
UC-H-29	AP turns ON the AAL home system	1st	UC-15
UC-H-30	The AAL home system sends an alert to the IC when its turned ON	1st	UC-15
UC-H-31	The AAL home system is automatically turned ON after a predefined interval of time	2nd	UC-15
UC-H-32	A message is shown in the interaction device to inform the AP that he/she is being watched in real-time	1st	UC-15
UC-H-33	The AP sends an alert to the IC in a deliberate way	1st	UC-16

Table 3 - Release schedule for APs UCs

SERVICE PROVIDER (SP)			
Identifier	**Name**	**Release**	**Equivalence from D1.2**
WEB (front-end)			
UC-W-23	Fill in a form to create a new account for ICs	3rd	-
UC-W-24	Send credentials to the ICs (username, password)	3rd	-

Table 4 - Release schedule for SPs UCs

AAL HOME SYSTEM (AALHS)			
Identifier	**Name**	**Release**	**Equivalence from D1.2**
Sub-system: video-based recognition system			
UC-H-1	Initial user configuration	1st	-
UC-H-2	Initial technical configuration	1st	-
UC-H-3	Recovery after system failure	3rd	-
UC-H-4	Authenticate adapted video request	1st	UC-0
UC-H-5	Adapt video signal to type of request	2nd	UC-0
UC-H-6	Transmit real-time adapted video signal through secure channel to web	2nd	UC-0
UC-H-7	Transmit real-time adapted video signal through secure channel to mobile	2nd	UC-0
UC-H-8	Collect and send data about daily life routine at home	3rd	UC-35
UC-H-9	Collect and send data about the level of intensity doing activities at home	2nd	UC-36
UC-H-10	Collect and send data about location and tracking at home	1st	UC-37
UC-H-11	Collect and send data about the level of social activities at home	3rd	UC-38
UC-H-12	Detect predefined risky situations and report alert	3rd	UC-39
UC-H-13	Send alert when the AAL home system is down	2nd	-
UC-H-14	The AAL home system is turned ON by the AP (video-based monitoring system)	2nd	UC-15
UC-H-15	The AAL home system is turned OFF by the AP (video-based monitoring system)	2nd	UC-15
UC-H-16	Transmit a regular ACK to indicate that all is working properly (video-based monitoring system)	1st	-
Sub-system: array of sensors			
UC-H-17	Initial user configuration	1st	-
UC-H-18	Initial technical configuration	1st	-
UC-H-19	Recovery after system failure	3rd	-
UC-H-20	Collect and send data about daily life routine at home	1st and 2nd	UC-35
UC-H-21	Collect and send data about the level of intensity doing activities at home	2nd	UC-36
UC-H-22	Collect and send data about location and tracking at home	1st and 2nd	UC-37
UC-H-23	Collect and send data about the level of social activities at home	2nd	UC-38
UC-H-24	The AAL home system is turned ON by the AP	2nd	UC-15
UC-H-25	The AAL home system is turned OFF by the AP	2nd	UC-15
UC-H-26	Detect environmental alerts and report alert to the IC	1st	-

Table 5 - Release schedule for AALHS UCs

In summary, the following phasing of 'release' of user-facing functionality is recommended:

- Month 15 (M15): This release will have some basic AAL functionalities both fixed and mobile involving the system collecting information about the AP's daily routine from the video-based monitoring system as well as the array of sensors. Moreover, this release will set up all interfaces between sub-systems and components in order to be able to exchange information between all of them.

- Month 21 (M21): This release will have the month 15 functionality plus some additional more complex AAL functionalities for informal and formal carers. This will include access to events, alerts and video in real-time from the informal caregiver tool to the assisted person home.
- Month 30 (M30): This release will have the aforementioned list of use cases which means all desired functionalities described in the document of work.

3.1.3 Overview of types of user trials

A variety of different types of user trials may in principle be considered for the different release phases of the BREATHE functionality. Those relevant include:

- Trials in laboratory or demonstration environments. These types of trials are useful and appropriate when the technologies and applications are still relatively immature and/or where the research is intended to be more exploratory in nature to feed back into the design process. It is possible that this type of approach will be most appropriate for providing feedback on user views and preferences (mock-up phase) in relation to the video monitoring component of the BREATHE AAL home system, including the video monitoring itself as well as different forms of presentation of the video to the informal carers (real video and various other formats). Further discussion of this type of trial and possible methods are provided in Chapter 4.
- Field trials of carer support tools for carers without home trials of the AAL home system. These types of trials are also useful and appropriate when the technologies and applications are a bit more mature but the research is still intended to feed back into the design process. It is possible that this type of approach will be most appropriate for providing feedback on user views and preferences in relation to the care support tools component of the BREATHE system, especially those parts of the care support toolkit that are not fed directly by the AAL home system. Essentially, this would comprise 'beta' trials of relevant features of the BREATHE informal caregiver platform, implemented on both a smartphone and desktop platform. Further discussion of this type of trial and possible methods is provided in Chapter 4.
- Field trials with the AAL home system installed in assisted person´s home (with the array of sensors or with the indoor video-based monitoring system). These types of trials are useful and appropriate when the technologies and applications are a relatively mature and suitable for installation in real homes and real everyday life usage situations. Such trials can in principle be used to provide feedback into the design process and/or to begin to assess impacts for carers or other stakeholders. However, there are much more stringent ethical and clinical governance considerations that apply for such trials, and they could only be implemented where the partner sites have the requisite capabilities. There are also many practical considerations around disruption in the home and in people's everyday lives, as well

as risk management and other emergency issues. Further discussion of this type of trial and possible methods is provided in Chapter 4.

- Field trials of the whole AAL home system in the assisted person´s home linked to and combined with the informal caregiver tool. These types of trials would involve getting user feedback and/or impact assessment for the entire set of BREATHE functionality (the AAL home system and the informal caregiver tool that are fed by the array of sensors and the indoor video-monitoring system).

3.2 The trial sites capabilities and interests

In addition to these issues around the phased development and release of the BREATHE system, there are also issues around the capabilities of the trial sites in terms of what types of trials they will be able to establish. In order to plan the approach for the trials, further clarification is required of the capabilities of the sites for conducting laboratory-type trials as well as for real-world' trials, including 'beta' trials of carer support tools with informal and formal carers and trials of home installations of the whole AAL home system.

3.2.1 Ireland (TCD and TER)

In Ireland there is the capacity and interest in principle to conduct trials in 'laboratory'-type environments and/or in real homes, at either the pre-trial or main trial stages or both. An optimal approach in terms of the use of these options can be decided at a stage when the release schedule for the BREATHE functionality is clearer and the project as a whole has clarified and agreed the overall trial strategy that best aligns with this. In terms of functionality to be trialled the Irish site partners are also open to discussing the mix that might be involved for the pre-trials and main trials. In principle it could be possible to trial a variety of mixes of functionality, including: AAL home system (with or without video-based monitoring system), informal caregiver platform (not dependent on or fed by the AAL home system), and/or a combination of the AAL home system and the informal caregiver platform (including those dependent on or fed by the AAL home system).

3.2.2 UK (CYB and KU)

In the UK it is planned to set up an initial trial system in a building which is a controlled environment where no one is living. This provides two benefits: (1) allows trouble-shooting of technology and training of installers and (2) acts as a "show home" to let people see how the technology works. The second stage will deploy systems in assisted person's (AP's) homes. It is envisaged that all cameras (video-based monitoring system) and array of sensors will not be required for each home, but a survey will be carried out with each home to identify what is appropriate. This will be followed by deployment of the systems in the homes and their operation.

3.2.3 Spain (ISI)

The pre-trials and trials will link directly with informal caregivers using the personal relationships that formal carers have already developed in their daily activities with families. We are going to focus on real households. We are very interested in testing the tools and devices, not only in urban but in rural areas, because this will be a very good opportunity to check the relevant elements for BREATHE, no matter how far the users are from big cities. We will train BREATHE´s users as an important activity inside WP4 and guide them, while we will collect the relevant feedback from them: informal and formal caregivers, and caretakers. Training, pre-trial and trials include AAL home system (indoor video-based monitoring system and array of multi-function sensors), as well as both versions of the informal caregiver tool: home and mobile.

4 Discussion of methodological options for the trials

This Chapter provides some further elaboration of some of the main methodological options that are outlined in Chapter 3 as possibilities for further consideration in the trial design and implementation processes under WP4. It also provides an initial presentation and discussion of possible methods and instruments for user feedback and outcome evaluation that could be considered. This is intended to provide a starting point for deeper consideration and refinement in WP4, which can be amended in D4.1 (Validation methodology and indicators) following clarification of the issues outlined in chapter 3 around the release schedule for BREATHE functionality and capabilities at the different sites.

4.1 General considerations and some previous approaches of relevance

The envisaged BREATHE project trials combine elements of design refinement as well as impact evaluation. This requires a flexible and iterative approach regarding trials. Conducting evaluation in this field is not a straightforward task, and there are many issues that need to be considered. BREATHE also has additional complexities that need to be catered for. These include the desire to have as much commonality as possible in the evaluation approach across the sites, while at the same time accommodating the specific characteristics of each, together with the need to fit the evaluation within the overall project timeframe and the timing of each of the various tasks within the pilot implementation processes. In this section we present and discuss some previous approaches to field trials in somewhat similar projects.

4.1.1 Approaches to design refinement

Cardinaux et al (2011) conducted a review of the literature on video-based technology for ambient assisted living and found that qualitative approaches such as focus groups and video-based drama (Marquis-Faulkes et al 2005; Turgeon Londei et al 2009) have been used at the stage of gathering requirements and perceptions of end users. Scenario-based dramas or theatre have been used to portray a situation (such as an end user interacting with prototype technology) in a very naturalistic and immediate manner. The SOPRANO project[13] developed supportive environments for older people based on ambient assisted living and used ICT in the homes of older people to support them in living independently in their own homes. The project used both theatre methods and multi-level prototyping in the phases of requirements gathering and prototyping. Specifically, SOPRANO used theatre methods in combination with a focused design discussion (FDD). This is a structured and moderated discussion and can be used in combination with theatre methods. The moderator of the discussion uses target-oriented questions to encourage participants to develop their own idea or give feedback to

[13] Service Oriented Programmable Smart environments for older Europeans (FP6-IST-2005-2.6.2): http://cordis.europa.eu/projects/rcn/80527_en.html (Accessed on April, 2014).

presented solutions. Participants are introduced to a scenario either via a theatre play or via a multi-level prototype. The moderator supports and guides the discussion of the user group. Multi-level prototypes are based on multi-media mock-ups of different functionalities of the system. Multi-level prototyping is a step-wise progressive process leading from general to more specific aspects of the interaction with the prototype technology. At least three cycles can be conducted:

- Round 1: Feedback about the design idea, e.g. overall experienced service usefulness and service acceptance.
- Round 2: Feedback about interaction with the device, i.e. the focus is on the overall experienced service usefulness, service acceptance and usability.
- Round 3: Feedback about changes based on point 2 above.

4.1.2 Approaches to AAL systems demonstration and evaluation

A key approach used in gathering user feedback on ambient assisted living projects is the implementation of the potential AAL system in a demonstration home or lab. These demonstration homes or labs can have a range of important functions including:

- Demonstrating to researchers, stakeholders and the interested public the results of ongoing AAL development and promising AAL solutions.
- Investigate how to reliably collect data of the typical daily routine in a real world environment by means of advanced sensing, reasoning and acting capabilities, in order to study personal health and wellness.
- Evaluate prototypes with regard to technical evaluation of functionality and reliability, or goal achievement regarding effectiveness and efficiency.
- Use evaluation results for iterative improvement of research and development of AAL solutions in field trials.
- Including end users in the development process.
- Offer services for research consortia and product development.

With this approach, not all use cases and technical devices are normally implemented into every user's home. In the full function trials, users are invited to demonstration houses where they can experience the whole integrated system and provide feedback on their perspectives. In the home trials, user homes are equipped with the most well-developed use cases in order to find out how users accepted the system at home in their natural environment.

4.2 Laboratory or demonstration environment trials

Some of the goals of the laboratory or demonstration environment trials might be:

- To show the BREATHE system as a whole and demonstrate the different functionalities to users.
- To show preliminary designs to get feedback from users.

- To get evaluative feedback about specific functionalities, or about the system as a whole.
- To find out how people accept the system after a limited amount of contact.

Some examples of themes that might be addressed in laboratory trials could include:

- How do participants feel being surrounded by the system, knowing that there are sensors/video cameras in the area? Do participants trust the system? Do they feel observed? Do they feel protected by the system?
- What types of presentation of video do the participants prefer?
- Which of the functionalities people assess as most valuable?
- How do participants like interacting with the system?
- How do participants evaluate the usability of the system?
- Overall ratings of the usefulness and likely benefits of the system.

The steps involved in laboratory trials might include:

- Free exploration of the BREATHE system.
- First impressions of the laboratory/demonstration home and BREATHE system.
- Insight into the feeling of being surrounded by technology.
- Guided exploration of the BREATHE system.
- Using the use cases as a basis to explore the possibilities and show added value of the system.
- In-depth analysis of specific parts of the BREATHE system.
- Data to be gathered can include factors like perceived usefulness, perceived ease of use, enjoyment, system quality, anxiety, perceived safety, aesthetics, privacy and loss of control.

Guided exploration supported by moderators is at the core of the laboratory work. A participant group size of 5-10 may be preferable. The moderators support the discussion with activating questions or by making sure that all participants have the chance to experience and comment on a protocol. The moderators also record their own assessment of how the users understood and liked the system. After experiencing a function and after discussing it, each user should fill in a very short questionnaire. The whole trial should not take longer than 1.5 hours for each session. After the guided exploration, users might have a final discussion and fill in an overall questionnaire, asking about overall acceptance of living with the system, about feelings regarding the sensors and forms of interaction and about which functions seemed the most valuable to them. If laboratory work is undertaken at a particular site, local technicians and/or consortium partners will install the technology and will be present during the actual tests to assist if necessary.

4.3 Carers Support Application (CSA) trial implementation

4.3.1 Overview of literature on CSA evaluation

Methodologically, the success or otherwise of interventions for carers has been largely determined using experimental or quasi-experimental models which rely on quantifiable measures of outcome, such as a reduction in burden, stress or general physiological morbidity, and an improved quality of life. However, most of these studies have failed to demonstrate the effectiveness of current interventions (Cooke et al, 2001). Consequently, there have been calls for clearer conceptual links between the support provided and the measures used to indicate its success (Zarit, Gaugler and Jarrott, 1999) with outcomes being meaningful to family carers (Thompson and Briggs, 2000; Beck, 2001; Magnusson et al, 2001) and reflective of what is reasonable and modifiable within a given caregiving context (Zarit and Leitsch, 2001).

Regarding family carer support with ICT, the majority of studies to date have been of US telephone-based models (Magnusson, Hanson and Borg, 2004). The interventions are usually managed by professional carers who provide counselling and support, mainly to dementia or stroke family caregivers, to reduce their stress and to promote optimal coping. Schulz (2001) argued that there was also a need to address several important questions including who is the primary beneficiary of the intervention (e.g. the caregiver or the person cared for), what is the target or goal (e.g caregiver skills or knowledge), how is the intervention to be delivered (e.g. individually or in groups, face-to-face or distant) and when is it most effectively delivered (e.g. at what stage of the caring career). Such questions need to be considered when developing new approaches to carer support, such as the use of information technology.

The ACTION study (Magnusson et al, 2005) was an EU-funded project that aimed to enhance the independence, autonomy and quality of life of frail older people and their family caregivers by providing information, education and support through information and communication technologies (ICTs). The project was implemented in England, Northern Ireland, the Republic of Ireland, Portugal and Sweden. Following the EU project, funding was secured from the Swedish Ministry of Social Affairs to develop and evaluate the concept in Sweden. Their initial services were several multi-media caring programmes that participating families could access using a television remote control. The TV set was connected to a personal computer that stored the information programmes. Families also had access to videophone facilities through the television, which enabled them to have direct verbal and visual contact with professional carers and other families involved in the project. Family carers worked in local groups across the partner countries to develop the scope, content and layout of the multi-media educational programmes (Tetley and Hanson, 2000), with a focus on practical caregiving skills, available social security benefits and services, and ways of coping. The ACTION services were field-tested in the homes of frail older people and their family carers (Magnusson et al, 2002). In the Swedish project, to enable the families involved in the project to access more readily professional advice and support, a call centre was established in each participating municipality. Additional multi-media programmes covering stroke, dementia, pressure sores and end-of-life care were also

developed and tested with several carers (Magnusson, 2002). The Swedish project in ACTION was evaluated using a multi-method pluralistic evaluation model, in order to capture the views of all key stakeholder groups (Bond, 2000). Magnusson et al (2005) focus on the PREP model of nursing interventions that aims to increase the knowledge and skills of family carers by raising their Preparedness (PR) for, Enrichment (E) from, and the Predictability (P) of their personal caring situation. A modified version of the PREP evaluation questionnaire was used with family carers. It comprised 40 statements that explored the PREP domains of preparedness for, predictability of, and rewards and satisfaction with caring. Family carers evaluated each item on a five-point Liker scale: not at all (1), a little (2), some (3), quite a bit (4) and a great deal (5). Finally, a global item asked about the utility of the intervention as a whole, using an 11-point Likert scale, from 'not at all useful' (0) to 'extremely useful' (10). Finally, the families were interviewed after the field tests about their experience and evaluation of the project. Similar interviews were conducted with the call centre staff on the benefits of the project for the participating families and its impact on their ways of working. Three focus group interviews were also carried out with staff from the participating care settings about their experiences of using ACTION with older people, family carers and other care staff.

More recently, Powell et al (2008) conducted a systematic review of the effectiveness of networked ICT interventions in supporting carers of people with dementia. Five bibliographic databases were searched and a total of 1456 abstracts were identified as potentially relevant. From these 15 papers were identified that described five interventions: ComputerLink, AlzOnline, Caring for Others and two studies from the REACH project. The interventions reviewed were complex and included various elements of networked support. All of the studies were undertaken in North America and most of them were relatively small. All the included studies with the exception of one were randomised controlled trials (Bass et al 1998; Brennan et al, 1995; Casper et al, 1995; McClendon et al, 1998; Payton et al, 1995; Mahoney et al, 2003; Mahoney et al, 2001; Czaja and Rubert, 2002; Eisdorfer et al, 2003; Bank et al, 2006; Finkel et al, 2007; Marziali and Donahue, 2006; Marziali et al, 2006). The non-RCT study utilised a pre- and post-test study design (Gluekauf et al, 2004; Gluekauf and Loomis, 2003). The interventions reviewed were complex and included various elements of networked support.

4.3.2 The BREATHE Carer Support Application (CSA)

The CSA will be deployed to a number of informal caregivers. The goal of the product will be to periodically sample the mood, cognitive state and lifestyle of the carer. The support application will use a mix of qualitative (through notes, diaries etc.) and quantitative (e.g. questionnaires) information gathered to score the lifestyle of the carer and provide support, feedback and information that may be helpful to them. It will also attempt to encourage positive behavioural change in the participants.

Concept implementation

The CSA will provide a digital, mobile resource with useful and supportive information which responds to the needs of the carer (also called as informal caregiver tool/platform). It also reviews the carer's wellbeing and helps organise their important information. The application should provide a digital assistant, which will help carers access the information they need. The form factor housing the application should be reasonably lightweight but sufficiently large to allow large area for grip. This allows the application to be convenient to use in a variety of situations. Periodically, the application will remind the caregiver that there are reviews to be completed. These will be quick and easy to fill in and a realistic expectation of time to completion will be given. Progress will be displayed. A carer will be able to hide or dismiss these reminders for a time enabling the tool to be sensitive to their rhythms and routines. Furthermore, the reminders should be subtle and gentle, rather than invasive alerts. The assessments will be based on validated scales and carefully selected for suitability to caregivers. The questions asked will encourage the carer to think about the rewards of caregiving, their own wellbeing and any difficulties they may have faced. This gives the carer an opportunity to reflect on what resources may be of benefit them.

Using the scores of the assessment, the application should make new content available to the caregiver. This recommended content will be relevant to their needs. The library of content it contains will provide intuitive and on-demand access to support information and resources. It should contain a range of content sources including articles, videos, guides and tips on a wide range of topics like looking after health and wellbeing and coping. It will also have directories for contacts, and helpful tips and quick guides. The content will be suited to a variety of needs. By making content available following assessment the content it provides can adapt over time to the current needs of the carer. By adding new content progressively in response to assessment completion, it will motivate and encourage the carer to regularly consult the tool and complete assessments. It is important that the recommendations not be overtly tied to one or two elements of assessment scores and diversity in the new content should be encouraged to avoid negative feedback being provided. The content should be related not only to areas of concern for the caregiver but also areas of improvement to continue to motivate that improvement.

While this is a personal application for the carer, we must be sensitive that this is a piece of technology introduced into the home where two people may or may not live together (the carer and the person being cared for). The CSA will mediate this and attempt to reduce any anxiety around technology introduction for the caregiver alone by also providing opportunity for shared experiences (e.g. via social networking). The application, being a within physical product such as a mobile phone or tablet will also need physical resources to be maintained and organized within its enclosure. The application should dedicate space for notes and jottings and include physical resources of importance that can be quickly accessed. These might include key contacts, tips or quick guides for wellbeing. It should be used to store and organise information and resources or things like diaries and useful information. It should also allow users to save content of relevance that they may review in the future. It is important that the

application is empathetic to the carer and their needs. This will be achieved in two ways: (1) in order to make it a more personal enjoyable and engaging experience, the application should embody an easily navigation system to guide the caregiver to relevant support content and resources. The language to be employed should be friendly, conversational and informal. System-style language should be avoided in place of this. It should appear to invite conversation and engage with the caregiver. It should also employ a set of stock phrases rather than single static sentences, this will provide the appearance of adapting to a caregivers current circumstance. For example, a greeting might be "*Good morning*", "*Nice to see you again*", "*Hello again*", etc. and (2) the supportive content should not only provide functional information on daily functioning for caregivers but should provide empathetic perspectives. The tool should seek to integrate multimedia presentations, which will share accounts/experience on a wide range of topics from other caregivers, and possibly healthcare professionals or formal caregivers. This hopes to emulate an empathetic support network on top of a social network.

4.3.3 CSA trial research questions and explorations

Several CSA research questions to be investigated within the BREATHE trial including but not limited to:

- Can validated assessments be completed in home by the participant themselves with efficacy and provide reliable data for use with the main AAL BREATHE solution?
- Can technology intervention using assessments to facilitate self-reflective thought encourage and motivate positive behavioural change for caregiver wellbeing?
- By recommending content in response to assessment information, how can that content be more made relevant to the caregiver needs?
- By progressively disclosing content over a period of time, and in response to the completion of assessments, how do we increase and sustain motivation to adhere to future assessment completion and engagement with the BREATHE solution and CSA?

4.3.4 CSA trial development & implementation stages and progression summary

Tool design, development and testing will primarily occur across in 3 phases across WP1, 2, 3 and 4 as outlined below, with stages completed and to be completed shown:

<u>Phase 1 (WP1): Scoping, design and trial implementation</u>

- Project definition and scoping document of the goals of the project (completed).
- Initial concept design and development (completed).
- Provisional trial implementation document (completed).

<u>Phase 2 (WP2 and WP3): Tool implementation</u>

- Concept design (to be completed).

- Review of concept design (to be completed).
- Iteration and final application Design with concept video to highlight CSA (to be completed).
- Functionality (to be completed).

Phase 3 (WP4): Required material construction

- Ethical approval and participant recruitment (to be completed).
- Content generation (protocols, guides, etc.) (to be completed).
- Individual interviews and focus groups with UCs to assess design and functionality (to be completed).
- Consolidate focus group info; for final application development (to be completed).
- Deployment and home testing of final application in trial setting (to be completed).
- Final review and design iteration: for market roll out at Month 30 (to be completed).
- Analysis and dissemination of findings from WP4 (to be completed).

	WP1 and WP2 2013/2014	WP3 2014	WP4 2014/2015
Project Definition			
User Scoping Analysis			
Internal Concept Design			
Focus groups and personal interviews			
In Home Visits			
Design & Development			
Content Prep.			
Deployment			
Analysis			

Table 6 - High level development and implementation timeline

4.3.5 WP4: CSA implementation strategy in detail

Evaluation of the Carer Support Application will occur over WP4 in two formats:

- Pre-trial: user interface design (mock-up validation) and trials with basic features (M15).
- Trial: home based long term deployment trials of CSA separately and linked to the BREATHE system (M21–30). Including both mobile and stationary scenarios as well as the array of sensors and the indoor video-based monitoring system in the assisted person´s home.

User interface design (mock-up validation) and functionality trials (pre-trial and trial)

To evaluate the user interface design and functionality of the CSA in the pre-trial (M15) and main trial phases (M21-30) a number of interviews (primarily home based) and focus groups will be conducted with appropriate stakeholders in order to explore the concept of the CSA and the support information to be delivered through the system. Informal and formal caregivers will be recruited for a short informal focus groups and interviews during the pre-trial phase. During each focus group the participants will be introduced to the vision of the informal caregiver platform and the AAL home system which gives a high level view of the application, functionality and role in the caregiving process. This will be used to inspire discussion and feedback around the design possibilities of the CSA. In some sites, demonstration homes or laboratories will be fitted out with the CSA technology. Participants will be invited to take part in walkthroughs and guided exploration of the demonstration homes or laboratories as described in section 4.2. Further methodological details are outlined in section 4.4.

Focus group and interview schedule (pre-trial and trial)

Detailed interviews and guided explorations will occur in lab/research settings with a minimum of 5-10 informal and formal carers at each trial phase to give richer more detailed insights from users.

- Informal caregivers: One or two focus groups with a minimum of 6-8 individuals will be recruited to evaluate the design and functionality of the CSA during both trial phases.
- Formal caregivers: One or two focus groups with a minimum of 6-8 individuals will be recruited to evaluate the first version of the CSA during the pre-trial and modified version at the full trial deployment phase. Participants will vary from professionals to recently employed qualified formal carers. Calls for participation will be circulated and endorsed by caregiver associations and related health services in each of the trial site regions.

Focus group and interview protocols:

Focus groups and interviews will be conducted to probe four primary areas:

- Technology: The CSA concept video will be played and feedback garnered on its suitability for use by carers.
- Challenging areas: The focus group and interviews will next probe the primary concerns and challenges facing the caregivers to which the CSA can support.
- Resources in support: What resources and support information should be made available to the carers to meet these demands?
- Assessments: What information about the caregivers should be assessed, why might this be useful, how regularly should this occur and what feedback might this enable?

Additional information from home based interviews

Home-based interviews will be ethnography driven and seek to expose the underlying requirements for the CSA. The experiences, pain-points, motivations and contexts of use will be probed during these sessions. Some participatory exercises may also be

included. Optionally, it is expected that a concept video would also be employed to introduce the CSA to participants. The in-home interviews will have two major sections: (1) the participant and their lived experience of caring for a person will be explored and (2) they will be introduced to the technology and asked to complete some short tasks using it. In particular, the use of the interface and the completion of assessments using technology will be explored. The outcomes from month 15 will be used to inform the design of the tool for deployment in the trial from months 21-30. The interviews and focus groups from months 21-30 will be used to guide the iterative design and development process of the CSA supplementing the BREATHE main trials. Interviews will probe:

- Situational and contextual factors for in-home deployment: Observation of the in home setting and probe of the daily activities as well as burdens faced by carers.
- Ease of use of technological devices: Technological devices will be presented as part of the CSA and the participants asked to complete a short assessment to assess design considerations.
- Suitability of a variety of interface navigations: A variety of interface navigations will be presented and feedback garnered.
- Explore what would motivate continued use: A series of questions will be used to explore user motivation factors to sustain use of the CSA in the home environment both in isolation and in combination with the BREATHE AAL solution.

Recruitment

- Recruitment for the pre-trial stage will commence in month 14 with focus groups and personal interviews/guided explorations to be conducted from month 15 to month 18. Analysis of trials will begin in mid in month 18 (6 weeks) with a mid-term report due after 3 weeks from the beginning of the analysis period and a final-term report at the end of the process. Trial site partners (TCD, TER, ISI and CYB) will be responsible for recruitment at each of the trial sites (Ireland, Spain and UK) respectively and for the release of the expected reports in due time and proper form.
- Recruitment for the main trial stage will commence in month 21 with focus groups and interviews/guided explorations to be conducted from month 21 (4 weeks recruitment) to month 23 (8 weeks). Analysis will begin in mid in month 26 with a report due at the end of month 23 (6 weeks). This will allow any further iteration to the product development to occur between months 24 – 30. Trial site partners (TCD, TER, ISI and CYB) will be responsible for recruitment at each of the trial sites (Ireland, Spain and UK) respectively and for the release of the expected reports in due time and proper form.

Pre-trial requirements

- Working prototype with basic features and the ability to complete assessment (at least one), sample content and a number interface designs to guide the process.

- Concept of the array of sensors and the indoor video-based monitoring system for gathering information in the assisted person´s home.
- In home interview guide for more information to participants.

Hardware form

The final section for CSA implementation will involve the hardware requirements for delivery of the system. Table 5 below outlines important requirements necessary for delivery of the CSA along with an understanding of using these devices in online and offline contexts. It is recommended for the BREATHE trials that participants recruited to the study have online access.

Initial technical requirements	
Platform	• Indoor: laptop or desktop PC. • Outdoor: Smart phone or tablet with either WiFi or 3G Connection.
Additional technology	• In home broadband connection (WiFi). • 3G mobile signal.
Recruitment	• May require the participant to already have wireless in their home *or* have good coverage of a 3G network in their area.
Cost	• Potential increased cost for hardware and technology platform especially if to be 3G enabled.
Content authoring	• Can deploy digital content at regular intervals throughout trial spreading burden on content authoring.
Application updates	• Application updates, fixes and corrections can be applied remotely through automatic over the air updates.
Data access	• Collected data can be regularly uploaded to BREATHE servers to monitor the progress and facilitate data analysis on logs and usage metrics prior to cessation of trials.

Table 7 - CSA estimated hardware requirements

4.4 Home trials of AAL systems (including CSA)

4.4.1 Overview of literature on methods used in home trials of AAL systems

In terms of AAL system home trials, evaluation of ambient assisted living is best served by multi-method and multi-perspective approaches, involving multi-stakeholder perspectives and data gathering. Cardinaux et al (2011) state that video-based ambient assisted living systems can be evaluated at multiple levels:

- Technical performance evaluation consists of measuring the accuracy to which the proposed system achieves the designed tasks.
- Outcome evaluation aims to determine the effect of the system on users, carers and society in general. While dependent on the technical performances, outcome evaluation is strongly linked to the way that informal and professional carers respond to the information provided by the system.
- Privacy protection validation aims to ensure that the system fulfils the required level of security.

- User acceptability evaluation aims to analyse how the system is perceived by potential users. Demiris et al (2000) developed a questionnaire to assess patients' impressions of the risks and benefits of home telecare.

Brownsell et al (2011) conducted a systematic review of lifestyle monitoring technologies, where such technologies are defined as sensors installed in the home to monitor behaviour in order to gain an understanding of normal activity so that any unusual changes over time can be recognised and responded to. The literature review aimed to summarise the current position with regard to lifestyle monitoring based on sensors in the home. Of the 74 full articles reviewed, only four (Barnes et al, 1998; Sixsmith, 2000; Alwan et al, 2006; Brownsell et al, 2008 and Kaye 2010) were concerned with trials involving more than 20 subjects, whilst a further 21 papers reported trials with fewer than 20 subjects. The majority of articles provided only an overview of the methods that were applied along with, where appropriate, brief details of the evaluations being undertaken. It is therefore difficult to obtain a complete understanding of what systems and methods have been deployed and in what context. Where evaluation with users has taken place, studies have not yet addressed the clinical and cost effectiveness of the intervention when compared to conventional care delivery.

Sixsmith (2000) conducted an evaluation of an early intelligent home monitoring system. The system used sensors to monitor the home environment and build up profiles of the daily activity of the resident. These profiles were then used to identify alerts or deviations from normal activity patterns. The system was designed to work in conjunction with existing, human-operated alarm systems to provide a more comprehensive service. The field trial lasted for three months. Twenty-two older people agreed to participate, along with 20 carers. A multi-methods research approach was used, involving both qualitative and quantitative techniques. Before implementation of the system, three focus groups were set up with 28 older people, carers and care professionals, in order to identify the key needs and expectations of users regarding the system. The focus groups began with a presentation about the system, followed by open-ended discussions covering the needs of users, potential benefits of the system, potential problems and system usability. The information from this preliminary research was used to design the evaluation instruments in the main phase of the study. A questionnaire survey of clients covered overall satisfaction with the system, perceived benefits and problems, and system performance. A questionnaire survey of carers elicited their perspective on the system. The format and content were similar to the clients' questionnaire. In addition, interviews with 14 of the 22 clients were carried out to gain a deeper insight into their attitudes, opinions and experiences of the system. Semi-structured agendas covered overall evaluation of the system, perceived benefits and problems, description of alert situations and the importance of the system to the client. Finally, alert follow-up interviews were carried out in order to detail the experiences of people when the system had generated an alert call.

Brownsell et al (2008) conducted a controlled study of older people living in sheltered housing. The goal of the study was to quantify the impact of telecare equipment on end users, specifically to understand the impact on health and well-being. This controlled trial compared people in a sheltered housing scheme provided with telecare and Internet

access, against people in other similar sheltered housing schemes in the area. Questionnaires conducted at baseline were completed at six and 12 months after installation.

In other telecare and telehealth projects, such as the INDEPENDENT project[14] as implemented in Ireland, common, standardised quality of life and related instruments were administered to informal carers. Baseline assessment was followed up at 6 months and included self-rated physical and mental health (using the SF-12), and carer burden (using the Zarit Burden Interview or ZBI). The SF-12 Health Survey is a generic measure of functional health from the respondent's point of view. The questionnaire measures health along a number of dimensions and gives two summary scores for physical and mental health. The two summary scores are the physical component summary (PCS) and the mental component summary (MCS). Carer burden was measured using the Zarit Burden Interview (short version). The Zarit Burden Interview was developed to measure subjective burden among family carers of adults with dementia. Items were generated based on clinical experience with family carers and previous research, resulting in a 22-item self-report inventory that examines burden associated with functional or behavioural impairments and the home care situation. Most researchers use the 22-item version of the ZBI. However, the length of the instrument may be a deterrent to its use in clinical and research environments. Bédard et al (2001) produced a short version consisting of 12 items, with results comparable to the full version.

4.4.2 The BREATHE AAL Solution

This section will outline the preliminary trial implementation methodology for the use of the full BREATHE system including integration of the CSA, which will be further developed in WP4. Overall the BREATHE AAL system and CSA will be implemented as part of the active research strategy employed to finalise a new go-to market remote monitoring and support system for caregivers and/or those in receipt of care. In line with the person receiving care and the caregivers' needs, the BREATHE AAL Solution will address throughout the trial implementation the following high level priority functions:

- Customisation: The system will need to consider the variety of abilities, functional differences, problems and pain points present within the candidate population.
- Privacy and ethics: Privacy and ethical concerns will be of paramount importance when dealing with an aging population and their carers. The availability of data to third parties, data security, the feedback and the manner in which it is presented, etc. should be fully considered.
- Motivation to adopt the technology: The feedback should motivate and encourage the user to continue with the use of the system. Clear benefit(s) to the carer should

[14] Independent Project (ICT-250521): http://www.independent-project.eu/home/ (Accessed on April, 2014).

be evident for doing so. It should not discourage adherence by burdening the user, requiring overly frequent collection of data, or by being inflexible, prescriptive or time-consuming.

- Location in home - a context aware system: The tool should be sensitive to the complex situational factors in the home and the personal dynamics between the carer and person receiving care.
- Understanding caregiver routines: The carers within the participant population will have a range of availabilities during the day and their daily routine and patterns of activity may vary widely. The system and support application (CSA) must be flexible enough to cater for this and must be mindful not to be too time demanding.

Study design, participants, sample size and selection criteria

Quantitative and qualitative methodologies using semi-structured interviews and focus groups will be employed in this project in an action research capacity. These methodologies will also be used in line with analysis of data collected by the system in order to understand in greater depth user interactions and outcomes from use of the BREATHE system and CSA. Action research is a process by which behavioural science knowledge is integrated with scientific knowledge and applied to solve real organisational problems' (Shani and Passmore, 1985). The strength of this process of inquiry lies in its capability to generate solutions to practical problems. This flexible research design affords the opportunity to select methods that garner understanding of the context of care needs of this client group, drawing upon a range of research methods in order to involve and build relationships with these participants. In this study it is proposed that an initial reflective process in the first release phase (pre-trial, M15) will enable user/carer support needs to be identified prior to the larger trial from months 21-30. To complete the action research cycle, participants of the carer group will be invited to evaluate the developed product in a larger trial from months 21 to 30, leading to a final release in month 30.

Selection inclusion and exclusion criteria for this project has been outlined in work document D1.1 (Needs and requirements of AAL and ICT solutions for informal long-term care of elderly people[15]) and sample size calculations for the larger trial will be determined in D4.1 (Validation methodology and indicators). Persons caring for individuals at home will be recruited from each of the trial sites with assistance from community based support groups and health services in each trial site region (Ireland, Spain and UK). Data will be collected and analysed via three different sources:

- BREATHE and CSA system data: Data from the individuals who are piloting the system and CSA in their home.
- Personal interviews: With individuals who are piloting the system and CSA in their homes (including those receiving care, informal caregivers and formal caregivers).

[15] White paper on needs and requirements of AAL and ICT solutions for informal long-term care of elderly people: http://breathe-project.eu/en/publications (Accessed on April, 2014)

- Focus groups: A randomised sample of users/carers involved in the home trials will be brought together to understand and discuss shared experiences. Focus groups may also occur with other stakeholders to discuss outcomes of the trial and get feedback before the final release version in month 30.

4.4.3 Recruitment methodology

Individuals receiving care and their carers based at home and in the community across each region (Ireland, Spain and UK) will be recruited for the interviews/focus groups using a range of recruitment strategies. The main recruitment method will be via community based support groups and services, inviting service users and their carers to participate. Selected carer related events (e.g. support meetings and special interest groups) will be attended by project researchers to invite participants to this project. Lists of these potential events will be compiled from each regional trial site contact. Study information sheets with contact details including the project's e-mail address will be distributed at these events. Interested participants will be screened for the selection criteria before being invited to participate.

Interviews and focus groups will be conducted to gain in-depth insight into the views of informal carers and their loved ones. Discussions will be centred on areas that include; attitudes, current practices, behaviours, support, technological aids, concerns, management, self-management and knowledge of the condition individuals are living with and without at home and in the community. The purpose of the focus groups is to build on the interviews to inform the thematic development of content for the BREATHE system as well as on best practice for user sensitive design and development of both software and hardware functionalities.

Interview participants

Eligible interview participants will provide informed consent to be contacted for individual home interview sessions, arranged at a time convenient to them. Each interview participant will provide full written consent using ethically approved consent forms prior to the commencement of the first interview. Semi-structured, face-to-face interviews with the participants will be conducted at a time convenient to each participant. Interviews are anticipated to last between 60 to 90 minutes. An open-ended question schedule constructed from topics prevalent in caregiver literature will be developed to guide the participant through the interview. Participants will also be allowed to freely speak at all times about their experience.

Focus groups

Focus group participants will be provided with written informed consent immediately before commencement. Individuals that consent to be part of the individual interviews will be also invited to participate at focus groups also.

Home trials

Participants in the home trials will provided with full written informed consent prior to the installation of the BREATHE AAL home system in their home. Technology partners will undertake to install the system within two weeks of consent being obtained. Participants will be given a number to contact for troubleshooting and support and response times to client enquiries regarding technology trouble-shooting will be within 24 hours. Home trials will be conducted in the pre-trial phase and in the full trials at different capacity levels in line with the release schedule and functionality.

4.4.4 Pre-trial (1st release)

During the pre-trial (1st release phase) the initial version of BREATHE will be deployed for a period of 1-3 months in up to 5 participants' homes per trial site. Data from these pilots will be used to understand design implications around the functional requirements for the first set of use cases outlined in D1.2 (Technical specifications of BREATHE platform). The information will also be used as part of an iterative design cycle in order to refine the BREATHE solution system for the 2nd release phase at month 21 and beyond.

4.4.5 Full trial (2nd and 3rd release)

During the full trial phase the second and third set of use cases for release (section 3.1.2, page 16) will be tested, in line with a review of improvements to the first set of use cases (those that were first implemented in the pre-trials). Between 5 and 10 homes per trial site will have the BREATHE system installed with a different set of features depending on the real needs of the carer and the cared for person.

4.4.6 Outcome measures and methods for informal carers

This perspective concerns informal carer outcomes. Informal carer level impact focuses especially on the outcome impacts of the BREATHE system/service for the informal carers. From literature as outlined in section 4.4.1 and from the outcomes in D1.1 it is recommended that the following assessment measures are included in the AAL solution and CSA.

Assessments to be implemented in the AAL system
Barthel Index/Katz Index –Activities of Daily Living
SF-12v2 – Self Rated Health-Related Quality of Life
Hamilton Rating Scale for Depression
Zung Self-Rating Anxiety Scale
PANAS (Positive and Negative Affect Schedule)

Table 8 - Provisional informal carer assessment measures to be included in BREATHE

Further refinement of the measures to be selected for informal carers and assisted people will be collated in D4.1 depending on the outputs of WP2 and WP3.

4.4.7 Project data analysis methodology

Themes and issues from the interviews and focus groups will collated and explored by both quantitative and qualitative methods. Optionally, some of the recordings from the interviews and focus groups will be transcribed by trial partners to English language. Data generated from the focus groups and interviews are to be thematically analysed (Burnard, 1991) and responses grouped into themes and key issues using textual content analysis. Approach techniques will include: (1) organising the data, (2) immersion in the data, (3) generating categories and themes, (4) coding the data, (5) offering interpretations through analytic memos, (6) searching for alternative understandings and (7) reporting.

In case of additional software will used to assist in this process, with initial open codes assigned to the data, followed by axial and selective coding to link concepts together, these will be then grouped to create categories, concepts and properties. All documents will be coded by substantive, line-by-line opening coding. Auto-coding will not be employed within these trials as it is not deemed not suitable for an effective grounded theory approach to analysis. A constant comparative methodology will be used throughout the process to find patterns in participant responses and unify concepts defined from the coding into core categories. Findings will be extracted and reported to the point of theoretical saturation.

Taped interviews and written transcripts will be reviewed by research teams (TCD and KU) within the Consortium to ensure consistency in coded findings. This is in line with Lincoln and Guba's (1985) guidelines for ensuring trustworthiness in qualitatively interviewing. Overall analysis of qualitative data will combine interviews relevant to each phase merged with findings from the relevant focus groups.

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