CARESSES
Culturally-Aware Robots and Environmental Sensor Systems for Elderly Support
EU Grant No 737858

Work Package 10: Ethics Requirements

Deliverable 10.1

Lead Beneficiary: UNIGE

Deliverable Leader: Linda Battistuzzi, UNIGE

Contributors: Linda Battistuzzi, UNIGE
Nak Young Chong, JAIST
Christina Koulouglioti, MU
Hiroko Kamide, Nagoya
Chris Papadopoulos, BEDS
Irena Papadopoulos, MU
Antonio Sgorbissa, UNIGE

Deliverable No.	D10.1
Due Date	06/30/2017
Issue Date	06/30/2017
First Update	01/20/2019
Status	☐Draft ☐Working ■Released ☐Delivered to EC ☐Approved by EC

Dissemination level			
	PU=Public		
	PP = Restricted to other programme participants (including the Commission Services)		
	RE = Restricted to a group specified by the consortium (including the Commission Services)		
X	**CO** = Confidential, only for members of the consortium (including the Commission Services)		
Document history			
V	Date	Author	Description

0.1	5/13/2017	Linda Battistuzzi	General structure of the deliverable ready
0.2	5/15/2017	Chris Papadopoulos	Section 3 added – Ethics Requirements
0.3	5/24/2017	Linda Battistuzzi	Section 4 added – Incidental Findings Policy
0.4	5/26/2017	Irena Papadopoulos, Christina Koulouglioti	Documents for Research Ethics Committee of MU added (Attachment 1-7)
0.5	6/01/2017	Chris Papadopoulos	the draft informed consent forms and information sheets from BEDS added (attachments 8-11)
0.7	6/03/2017	Nak Young Chong Hiroko Kamide	the regulations for the proper conduct of human subject research at JAIST translated from Japanese to English and added (attachment 12)
0.8	6/16/2017	Linda Battistuzzi	Section 5 added - Adopting the Ethical Guidelines of Alzheimer Europe
0.9	6/19/2017	Linda Battistuzzi	the "ethically tagged" Scenarios. (Templates Attachment 8-11 added
1.0	6.23/2017	Linda Battistuzzi	Full version ready
1.1	6.23/2017	Antonio Sgorbissa	First revision ready
1.2	12/21/2018	Linda Battistuzzi	First draft of update
1.3	01/22//2019	Linda Battistuzzi	Full version of update ready
1.4	07/01/2020	Linda Battistuzzi	First draft of final update
1.5	14/01/2020	Linda Battistuzzi	Second draft of final update
1.6	28/01/2020	Linda Battistuzzi	Full version of final update ready

Executive Summary

Deliverable D10.1 provides an update and an extension of the Ethics Requirements section included in Grant Annex B.

In addition, it sets forth a framework to handle incidental findings within CARESSES, and describes the approach developed to ensure compliance with the Ethical Guidelines of Alzheimer Europe concerning the Use of Assistive Technologies.

Since it first release, the Ethics Requirement Document has been updated to include the Ethics Section of the end-user experiment protocol (previously released within D6.1) along with a description of the ethics training developed for CARESSES researchers directly involved with the pre-trial and the end-user experiments, as well as findings on the outcome of that training.

Finally, it also includes a section devoted to "Lessons learned", which describes a mixed methods exploration study of ethically relevant events in the CARESSES trials and some of its early results.

Contents

1. Description of the deliverable[1]

Deliverable D10.1 is the only deliverable in Work Package 10 – Ethics Requirements. It should be noted, however, that the duration of this WP is the entire 37 months of CARESSES.

According to the CARESSES DoA:

> *"The 'ethics requirements' that the project must comply with are included as deliverables in this work package. D10.1 : H - Requirement No. 1 [6]*
>
> *2.1. Additional details on the procedures and criteria that will be used to identify/recruit research participants must be provided.*
>
> *2.2. Detailed information must be provided on the informed consent procedures that will be implemented for the participation of humans.*
>
> *2.3. Templates of the informed consent forms and information sheet must be submitted on request.*
>
> *2.4. The applicant must clarify whether children and/or adults unable to give informed*
>
> *consent will be involved and, if so, justification for their participation must be provided, as well a description of procedures to obtain their consent/assent.*
>
> *2.6. Details must be provided about the measures taken to prevent the*
>
> *risk of enhancing vulnerability/stigmatisation of vulnerable individuals/groups (i.e. frail older individuals, people with cognitive impairments, etc.).*
>
> *2.8. Details on incidental findings policy must be provided.*
>
> *2.9. Copies of ethics approvals for the research with humans must be submitted.*
>
> *2.10. Other. The applicant is asked to address the risks for the human subjects associated with the termination of the research program, with protocols being specified in advance for addressing any consequent needs on the part of the subject.*
>
> *4.1. Copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority must be submitted (which ever applies according to the Data Protection Directive (EC Directive 95/46, currently under revision, and the national law).*

[1] This Section has been updated.

4.4. Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.

4.5. Detailed information on the informed consent procedures that will be implemented in regard to the collection, storage and protection of personal data must be submitted on request.

4.6. Templates of the informed consent forms and information sheet must be submitted.

4.9. Other. An external independent Ethics Advisor must be nominated in the Ethical Committee to oversee the ethical concerns involved in this research.

6.1. The applicant must confirm that the ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the country in which the research is carried out."

In Section 3 of this Deliverable we therefore provided itemized responses to these requirements, consolidating the items where suitable.

Section 4 is entirely devoted to Incidental Findings (item 2.8 in the requirements above), given the complexity and novelty of the issue in a social intervention research setting.

Section 5 describes the approach we developed to ensure compliance of CARESSES with the Ethical Guidelines of Alzheimer Europe concerning the Use of Assistive Technologies.

Section 6 discusses and describes the measures put in place to ensure that the CARESSES end-user experiments were conducted in an ethically appropriate manner, as detailed in the study protocol.

Section 7 describes the ethics training developed to ensure that all CARESSES researchers directly involved in the pre-trial or in the end-user experiments had an understanding of the relevant ethical concerns.

Section 8 describes the mixed methods exploration study of ethically relevant events in the CARESSES trials that is currently being conducted.

Section 9 explains how the Ethics Requirements Document was used.

Section 10 briefly outlines compliance and achievements.

2. Methodology[2]

In order to clarify the Ethics Requirements of CARESSES and ensure that the work carried would be ethically appropriate, the first version of this document included an itemized description of

- procedures and criteria for recruitment;
- detailed information on informed consent procedures and compliance with General Data Protection Regulation [EU] 2016/679;
- the involvement of children or adults unable to provide consent;
- measures to prevent the risk of enhancing vulnerability/stigmatization of vulnerable individuals;
- details regarding ethics approval and the approval of the Data Protection Officer;
- how the risks for the human subjects associated with the termination of the research program would be addressed;
- procedures for data collection, storage, protection, retention and destruction and confirmation that they would comply with national and EU legislation (General Data Protection Regulation [EU] 2016/679);
- the appointment of an External Independent Ethics Advisor;
- compliance with the ethical standards and guidelines of Horizon2020.

Furthermore, it included a general framework for handling incidental findings, and described the approach we developed to ensure that the Ethical Guidelines of Alzheimer Europe for the Use of Assistive Technologies would be adopted by CARESSES.

The first update of this document added two sections devoted to:

- a discussion and description of the measures put in place to ensure that the CARESSES end-user experiments would be conducted in an ethically appropriate manner, as detailed in the study protocol and delivered under D6.1

- a description of the ethics training developed to ensure that all CARESSES researchers directly involved in the pre-trial and in the end-user experiments would have an understanding of the relevant ethical issues and concerns.

The final update of this document includes

- a more detailed description of the training offered to all researchers involved in the end-user experiments along with some results on researchers' perception of that training;

- a new section devoted to lessons learned, i.e. to the mixed methods exploration study being conducted on ethical issues that emerged during the CARESSES trials, along with some very preliminary findings from this study.

[2] This Section has been updated.

3. Ethics Requirements[3]

3.1. Procedures and criteria to identify/recruit research participants.

Fifteen clients from three cultural groups (white-English, Indian, Japanese) will be purposively recruited from UK-based (white-English and Indian groups only) and Japanese-based testing sites (45 clients in total). The samples from both facilities will be purposively constructed to be as diverse as possible.

With regard to the UK-based clients, potentially eligible participants will first be identified with Advinia's support. Advinia routinely electronically record the demographic information for each of the clients that are currently residing across their care home network including those in supported home care settings. Therefore, the participant eligibility criteria will be disseminated to each care home manager (n=16) via email. Managers will cross-check the criteria against their records. A list of clients who managers feel are reasonably likely to meet the criteria will then be disseminated to the study researchers who will compile the data into a database. To help construct a balanced sample as possible, managers will also provide the socio-demographic and other background characteristics that they have already previously recorded including age, gender, client diagnosis, educational level, and religion. Client names (and any other identifiable information provided) will be anonymised using pseudonyms. We will ensure that all processes and procedures fully comply with the General Data Protection Regulation (EU) 2016/679.

The client eligibility criteria will be as follows:

- Clients who reside in one of Advinia's care homes or as part of Advinia's network of supported home care
- Clients that identify themselves as primarily belonging to the Indian culture
- Clients that identify themselves as primarily belonging to the white-English culture
- Clients that are unlikely to express aggression towards themselves, the robot, and/or the researcher;
- Clients who possess the cognitive ability to provide informed consent and participate in the study
- Clients who are able to verbally communicate in English

If the database consists of more than potentially eligible 30 clients per cultural group then, for the purposes of screening, the study researchers will initially select a socio-demographically diverse set of 30 clients per cultural group as possible with gender being the primary strata (as explained in section 1.3.11 of the Proposal). For example, if there are 45 white-English clients identified in the database, 15 of whom are male and 30 female, then all of the males will remain included but only 15 of the 30 females will be retained for the next stage of elibility screening (described below). The 15 white-English females selected will be those which together represent a diverse spread of socio-demographic characteristics. We are also keen to recruit a balanced number of clients residing in care homes and supported care home settings. This will increase the range of activities and therefore potential usefulness of the robot, thus eliciting analytically richer data. We also expect that the robot may be particularly successful in reducing caregiver burden among older adults residing in supported care homes.

[3] This is the original draft of this Section and has not been updated.

The remaining clients will subsequently each be screened for their eligibility by Advinia staff who are familiar with the clients. These staff will assess eligibility but answering questions from the InterRai-LTCF tool, specifically all items from the 'Cognitive Performance Scale' [CPS] (which assesses clients' cognitive ability) and the 'Aggressive Behaviour Scale' [ABS] (which assesses clients' aggressive mood) scales. A cut-off point of ≥3 will be adopted for the ABS scale, whereas a cut-off point of ≤3 will be used for the CPS (Carpenter, 2006).

These scales, while brief, have been shown to be reliable and valid among the older adult care home population (Carpenter, 2006; Gray et al., 2009). This will enable the identification of clients without severe cognitive impairment and at low risk of aggressive behaviour. Each client that meets these criteria will be entered into our 'final pool of potential participants.'

These clients will then be purposefully approached and invited to participate. This will involve the study researcher being introduced to the eligible client by an appropriate staff member and at an appropriate time (as judged by Advinia's staff). During this meeting, the researcher will introduce themselves, and explain clearly and simply to the client the nature of the study, answer any questions, and provide the client with a participant information form. This form will fully describe the nature and purpose of the study, the eligibility criteria, what participation involves (including engagement in evaluation procedures), why they have been specifically invited, whether taking part is voluntary, how collected data will be handled and used, what the possible advantages/benefits and disadvantages/risks of taking part are, reimbursements, what happens when the study stops, what will happen if there are any unanticipated problems during the study period, who has funded and reviewed the study, and key contact information.

If the client wishes, the study researcher will read out the information form and answer any further questions the client may have. We will offer clients time to consider this information and follow-up 48 hours later (unless Advinia's staff have reason to believe this would be too soon, for example, if the client became unwell).

If clients consent and are selected for participation, a family informal carer of their choice will also be invited to participate through (as would have been explained on the participant information form and consent form). The eligibility criteria for informal carers will be as follows:

- Individuals who provide help and support to the client. These individuals may be any relative, partner, friend or neighbour who has a significant personal relationship with, and provides a broad range of assistance for, the client. These individuals may be secondary caregivers and live separately from, the person client care.
- Individuals who are not employed to provide their care to the client (i.e. formal carers)
- Individuals who are able to verbally communicate in English

Recruitment of the carers will involve the study researcher emailing him/her (or phoning them if the email address is not known. In this case the researcher will ask for an email address for full details to be sent to). The email will explain why they are being contacted and attach with it the participant information and consent form (the informal carer version). If the carer wishes, the researcher will speak with the carer via phone and/or in person to answer any questions they may have prior to deciding whether to participate.

3.2. Detailed information on the informed consent procedures that will be implemented for the participation of humans, in compliance with General Data Protection Regulation [EU] 2016/679

The legal basis for data processing in CARESSES, pursuant to the GDPR, is provided by informed consent. As detailed below, participation in the project will be entirely voluntary and written consent will be obtained prior to the beginning of the end-user experiments. The informed consent process will be sensitively designed and carried out, as appropriate to older persons and their informal caregivers. It will be supported by information sheets. Every care will be taken to ensure that the information sheets:

- are written in clear, simple language that prospective participants can easily and fully understand;
- describe the aims, methods and implications of the end-user experiments, what is involved in participating in the project, and any associated benefits or risks;
- clearly state that participation is voluntary, and that refusal to participate or withdrawal from the project at any time are rights and will have no implications in terms of care;
- explain in simple terms data collection, protection and use policies;
- explain how any incidental findings that should arise during the project will be handled.

Clients who have been identified as potentially eligible will be purposefully approached and invited to participate in the study. Each client will be introduced to the researcher by an Advinia staff member at an appropriate time. This meeting will take place in a quiet and private space away from interruption.

Written informed consent will be sought if clients are able to provide such consent. If not, verbal consent will be sought (the process for this is explained below). For the former, the information that is imparted to the client will be communicated in a clear and simple fashion as possible. This is important since the testing procedures will be complex and therefore it is crucial that the participants are fully informed and not confused over what to expect. As there are no significant disadvantages or risks involved in participation, we do not expect that this meeting will trigger any distress. However, despite this, the researcher will maintain a sensitive approach during this interaction being mindful of any stress that may occur. If this is perceived, the researcher will pause their interaction and ask the client whether they are comfortable to continue. If not, the meeting will cease at this stage. If no stress is perceived, the meeting will continue in a standard fashion whereby the researcher explains the nature of the study, answer any questions, and provides the client with a participant information form. The researcher will at this stage invite the client to choose whether they wish to read this document in their own time and contact the researcher later about it, or if they would prefer the researcher to read out the information then.

The information sheet will describe the nature and purpose of the study, the eligibility criteria, what participation involves (including engagement in evaluation procedures), why prospective participants have been specifically invited, that taking part is entirely voluntary, how collected data will be handled and used, the period for which the personal data will be stored, what the possible advantages/benefits and disadvantages/risks of taking part are, reimbursements, what happens when the study stops, what will happen if there are any unanticipated problems during the study period, who has funded and reviewed the study, and key contact information.

The client will be offered time to think about the information and encouraged to discuss their possible participation with family members, close friends, or trusted advisors. If they choose to participate without

informing their family, they will be invited to read and sign the informed consent form that summarises the key points raised in the participant information form. The client will be asked to provide his/her initials and sign the form. One copy of this form will be left with the client, while another will be held by the researcher

Those who do wish to have time to consider this information will be followed-up 48 hours later (unless Advinia's staff have reason to believe this would be too soon, for example, if the client became unwell).

In cases where written consent is not possible (e.g. because of illiteracy or a physical disability), the researcher will seek verbal consent. Here, the researcher, having already read out the participant information form and answered any additional questions the client may have had, will seek to obtain verbal consent through reading out (in a clear manner) the informed consent document in the presence of a literate witness (e.g. a care home staff member) who will countersign the consent document on behalf of the client if he/she verbally agrees to consent. This exchange will also be audio-recorded by the researcher. The witness (who cannot be not another researcher/member of the study team) must sign and date the consent form attesting that the requirements for informed consent have been satisfied; that consent is voluntary and freely given by the client, without any element of force, fraud, deceit, duress, coercion, or undue influence.

There will be four versions of the information and consent forms. Four versions will be constructed for the clients who have been purposefully allocated to the experimental arm (i.e. the culturally aware robot) or control arm 1 (i.e. the culturally non-aware robot). Another version will be constructed for the family caregivers that have been nominated by clients allocated to the experimental arm or control arm 1. A third version will be constructed for clients allocated to control arm 2 (i.e. no intervention/care as usual) while a fourth version will be constructed for the family caregivers nominated by clients allocated to control arm 2.

3.3. Templates of the informed consent forms and information sheet (to be submitted upon request).

Attached to this document we are including:

- the informed consent forms, information sheets and the letter of approval from the Research Ethics Committee of MU for the "CARESSES: Capturing snapshots of the everyday life of older adults living in a care home facility" study in WP1 (which were prepared, submitted for ethical approval and approved by the Research Ethics Committee prior to completion of this version of the Ethics Requirements Document) (attachments 1-7)
- draft consent forms and information sheets for the end-user experiments (BEDS) (attachments 8-11); these draft versions are incomplete; for instance, they do not mention the period for which the personal data will be retained nor how incidental findings will be managed; final versions will be available upon request once design of the protocol for the end-user evaluation experiments has been completed
- document detailing the Regulations for the Proper Conduct of Human Subject Research at JAIST (attachment 12).

3.4. Involvement of children and/or adults unable to give informed consent.

This study will not involve children and/or adults unable to give informed consent. As explained in 1.1 above, only adults who pass the minimum acceptable Cognitive Performance Scale threshold on the InterRai-LTCF tool will be eligible for participation.

3.5. Measures to prevent the risk of enhancing vulnerability/stigmatization of vulnerable individuals/groups (i.e. frail older individuals, people with cognitive impairments, etc.).

Sensitive quantitative and qualitative data pertaining to topics such as subjective well-being, quality of life, caregiver burden and independence will be collected among clients and/or informal carers. Qualitative data in particular may include very personal accounts and experiences related to being the provider and recipient of care.
We will minimize the likelihood of enhancing vulnerability, stigmatization and distress through a number of measures. These include:

- the use of previously validated and reliable, widely used structured instruments which have consistently been applied safely and without harm;
- our measures and data collection procedures will be subject to thorough scrutiny from the University of Bedfordshire's Research Ethics Committee. We will integrate all useful critical feedback associated with our measures and procedures so to further reduce the likelihood of harm to the study participants.
- the likelihood of distress arising from the study interviews and the disclosure of potentially sensitive information will be limited by involving researchers who have proven experience and expertise in such methods: study researchers will also be subject to supervision;
- the potential for harm will be minimized by the researchers being transparent about their role boundaries, and by ensuring that appropriate information and support are available. The researchers conducting interviews will be trained and supervised to be very sensitive and mindful of potential distress occurring. Researchers will employ a conservative and cautious approach during the observation of participants' potential manifestation of distress. This means that where researchers have any suspicion of distress or harm being manifested, the researcher will take planned measures accordingly to prevent further harm from occurring, such as inviting the participants to discuss any issues which concern them or making them feel anxious or vulnerable. Compassionate listening, assessment, problem identification, its verification and action taking such as the provision of information and re-assurance may help to alleviate their feelings of vulnerability.
- all study participants will be treated with dignity and respect, and all necessary measures will be taken to avoid the stigmatisation of certain groups (e.g. frail older adults) when undertaking and presenting the research. This will involve approaching all participants with discretion, ensuring their anonymity, and treating their experiences and contributions equally and with full respect. As part of the researchers' supervision and training, they will be made aware of the stigma associated with older adults and caregivers since increased knowledge of the issues will help protect against researchers thinking and acting in a stigmatizing manner.

- while we will ensure that the research data we collected is treated confidentially, sensitively, and anonymously, if we observe any events that cause us significant concern about the wellbeing of the client (or caregiver), and/or breach legality, we will report such events to the authorities we view to be appropriate in each instance;
- we will work very hard to ensure that no undue harm comes to the client or caregiver during the testing period. This includes working towards ensuring that the tests do not impact upon their usual care. As part of achieving this we will request that staff, as much as possible, do not change their usual practices during the testing; it will be made clear to staff that the robot is not being implemented to replace formally provided care. It also includes making it clear to clients that they should not necessarily change their usual daily activities, such as spending time with visitors. This is important because (a) these activities may protect or boost their wellbeing and (b) part of the premise of the intervention is for the robot to be exposed to a range of the daily activities that clients would normally engage upon;
- we are working to ensure that it is not reasonably likely that the clients and caregivers who are allocated to control arm 1 (the non-culturally aware robot) will experience any negative outcomes. Our working solution to this important issue is for the non-culturally aware robot to (a) be blinded to the culture to which the client belongs and (b) not take advantage, from the outset, of stereotypical information about the client's cultural background. As a consequence, it should take longer for the robot to ask and collect relevant information about each client, and for it to apply this knowledge in employing culturally appropriate behaviours and interactions. This essentially means that, while the robot will be trying to be assistive, it will take longer for it to understand what to do and when to do it. Therefore, the non-culturally aware robot is just as unlikely as the culturally aware robot to produce negative outcomes. Rather, the non-culturally aware robot will be more likely to be perceived as not as useful by clients and caregiver as compared to clients and caregivers using the culturally aware robot;
- all consortium partners involved in the implementation of activities involving participants from different socio-economic and demographic backgrounds will consider and treat all participants with discretion, dignity and respect.

3.6. Ethics approvals for the research with humans.

Ethics approval will be sought from the University of Bedfordshire Research Ethics Committee and the Research Ethics Committee of the Japan Advanced Institute of Science and Technology once design of the protocol for the end-user evaluation experiments has been completed.

Attached to this document we are including the Letter of Approval from the Research Ethics Committee of MU for the "CARESSES: Capturing snapshots of the everyday life of older adults living in a care home facility" study in WP1.

3.7. Addressing the risks for the human subjects associated with the termination of the research program, with protocols being specified in advance for addressing any consequent needs on the part of the subject.

It is anticipated that the participant will miss having the robot around as well as the attention given to her/him by the researchers. To help the participants remember their experiences and reminisce about them with their family and friends, as well as to thank them for their participation, the research team will produce (with the participants consent of being photographed) a journal chronicling their time and experience. The journal will contain photos embedded within a simple short story which can easily be adapted for each participant. We believe that this will be a memento which will reduce their feeling of loss. In addition, the research team will telephone the participant after one week and after 3 weeks of the end of their participation for a social chat. However, if there is any risk of the person being excessively upset, the research team will bring this to the attention of their formal carers. If appropriate, and in consultation with the formal carers, volunteers from a relevant local organization will be asked to pay a few visits to the participant.

3.8. Opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority must be submitted (which ever applies according to the Data Protection Directive (EC Directive 95/46, currently under revision, and the national law).

We confirm that copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority will be sought and submitted (which ever applies according to the Data Protection Directive (EC Directive 95/46, currently under revision, and the national law), once the end-user evaluation study protocol is finalized.

3.9. Procedures for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation (General Data Protection Regulation [EU] 2016/679)

Data collection, usage, storage, protection and security will comply with national laws and General Data Protection Regulation [EU] 2016/679, and particularly with the following data subject rights identified in the GDPR:

- the right of access
- the right to be informed
- the right to erasure

Furthermore, we will comply with the provisions in the GDPR that establish the following data protection principles:

- data processing must be lawful, fair and transparent
- data collection must be for specified, explicit and legitimate purposes
- data collection must be accurate and, where necessary, up to date
- data collection must be adequate, relevant and limited to what necessary

- data must be stored so as to permit identification of data subjects only as long as necessary to the purposes of the collection
- data processing must be performed so as to ensure appropriate security of personal data
- accountability and governance

As explained in subsection 2 above, the legal basis for data processing in CARESSES, pursuant to the GDPR, is provided by informed consent.

No information that would enable one to identify the study participants will be included in our data collection files. All data will be pseudonymized across all of our dissemination activities and outputs in order to prevent any data being attributed back to a particular study participant without the use of additional information, which shall be stored separately.

Only where participants explicitly (verbally and in writing) state that they wish to remain identifiable (e.g. to maintain ownership of the content and implications of their responses), their data will be connected to their person. If they wish, participants can even support the dissemination of research results themselves participating, for instance, in the development of a project video reporting personal stories.

The data collected from the study participants will comply with the principle of data minimization, in that it will be "adequate, relevant and limited to the minimum necessary in relation to the purposes for which they are processed". The collection of personal information from study participants will be limited to what is directly relevant and necessary to accomplish the specific goals of the end-user experiments. We expect that the data collected from study participants shall be retained only for the time required to reach the goals of the project, although a definitive determination in this direction will be made once the design of the end-user experiment protocol has been finalized.

Data will be securely stored online on a password protected and encrypted Google Drive cloud that will be created for the purposes of this study. To ensure safety, security and reduce risk no collected data will be stored locally on computers during the testing and evaluation work packages. Any hard copy data collection notes will be digitally scanned and also uploaded into the study's cloud account, after which the hard copies will be shredded. Included within the cloud file directory will be four higher-level folders titled, 'current document versions', 'backups of current document versions', 'older document versions', and 'backups of older document versions'. These folders will enable us to conduct document version controls and the backup of all files. These procedures will ensure clarity, safety and security of all study documents. We do not anticipate any difficulties in data sharing as Google Drive is a highly reliable and secure source of file keeping and sharing.

In the event of a breach in data protection management that is likely to result in a risk to the rights and freedoms of the research participants, the Research Ethics Committee at BEDS will be notified.

Dr Chris Papadopoulos (BEDS) will take responsibility in directing the overall data management process, including the sharing and archiving of produced datasets. The study researchers will be responsible for conducting daily data management checks, ensuring that the quality control activities described above are maintained, and that data collection, analysis, processing and inputting are undertaken as described

within produced protocols. The key persons associated with the testing and evaluation work packages will support the researchers in data collection, analysis, and will adhere to the responsibilities and activities set out across developed protocols.

3.10. Appointment of the External Independent Ethics Advisor.

Dr Stephen Holland has been appointed as the study's external independent Ethics Advisor and as such will oversee the ethical concerns involved in this study. Dr Holland is a Reader in the Departments of Philosophy and Health Sciences at the University of York. He has expertise in applied philosophy, especially bioethics, public health ethics, and death studies. Dr Holland is the author Public Health Ethics (2nd edn 2014, Polity), and the second edition of Bioethics: A Philosophical Introduction is in press (1st edn 2003, Polity); he edited the anthology, Arguing About Bioethics for Routledge in 2014. He is a member of the Coma and Disorders of Consciousness Research Centre, and is the founder and Chair of Public Health England's Research Ethics and Governance Review Group.

3.11. Compliance with the ethical standards and guidelines of Horizon2020.

We confirm that the ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the country in which the research is carried out, in all EU Member States involved in the project.

3.12. References

1. Carpenter, G. I. (2006). Accuracy, validity and reliability in assessment and in evaluation of services for older people: the role of the interRAI MDS assessment system. Age & Ageing 35, 327-329.
2. Gray, L. C., Berg, K., Fries, B. E., Henrard J. C., Hirdes, J. P., Steel, K. and Morris, J. N. (2009) Sharing clinical information across care settings: the birth of an integrates assessment system. BMC Health Services Research 9, 1-10

4. Incidental Findings Policy[4]

4.1. Incidental findings, social intervention studies and older research participants.

Developing an incidental findings (IFs) policy for CARESSES involved two major difficulties. First, to the best of our knowledge, the issue of IFs in social intervention studies has remained virtually unexplored to date. Second, research with older participants involves additional layers of complexity, some of which are especially relevant to researchers' duties towards participants and the benefits and harms to research participants that may derive from disclosing IFs.

We therefore chose to develop and set forth a series of high-level guidelines, with the expectation that they would be reconsidered and revised, giving specific attention to respecting the autonomy, confidentiality and best interests of the older participants involved in CARESSES, once the design of the end-user experiments has been finalized. (This is described in Section 6, under paragraph 6.13)

4.2. What are Incidental Findings?

IFs are generally defined as observations concerning an individual research participant that have potential health or reproductive importance and are discovered in the course of conducting research but are beyond or unrelated to the aims of the study (1). According to some scholars, IFs may also be encountered when establishing whether a candidate for research qualifies for inclusion in the study, or when collecting baseline information. (1)

IFs have become increasingly prominent in research with human participants. Most of the attention has focused on IFs generated by next generation sequencing in genetics and genomics and by other advanced medical technologies that produce, collect and analyze vast amounts of information about research participants (2,3,4,5). However, IFs can occur in other types of research (4), including, as the American Psychological Association points out: "cognitive research (e.g., unexpectedly low memory scores in a control participant), and mental health research (e.g., unexpected psychotic symptoms endorsed on a rating form by a research participant)"(6).

4.3. Returning IFs: Researchers' Ethical Duties

IFs can have serious implications for research participants' health and psychological well-being, but also for researchers and their institutions. Thus, the possibility of an IF raises issues related to researchers' responsibility to identify and return unsought for abnormal findings to research participants. (7). Indeed, such a responsibility has been recognized by major international organizations, including the International Human Genome Organisation (HUGO) (8,9,10), and the Council for International Organizations of Medical Sciences (CIOMS) (11).

[4] This Section has had very minor updates.

As articulated, among others, by Wolf and colleagues (4), the growing consensus that researchers have a duty to return certain types of IFs (12) is generally based on the ethical concepts of reciprocity, concern for participants' welfare, and respect for participants' autonomy (4,13).

Reciprocity refers to researchers' obligation to help or benefit research participants in return for their contribution and for bearing the associated risks and burdens (14). This duty falls under researchers' broader duty of beneficence to research participants, which involves maximizing benefits and minimizing harms (4). Reciprocity can also be understood as "what people deserve as a function of what they have contributed to an enterprise or society" (15), and thus be grounded in justice.

Secondly, support for a duty to return IFs can stem from a concern for research participants' welfare: because volunteers who participate in research implicitly entrust their health and well-being to researchers, those researchers have a duty to manage IFs within the context of their ancillary-care obligations (16). The scope and breadth of this entrustment depends on "the vulnerability of the subjects, the extent of uncompensated risks or burdens, the depth of the researcher-subject relationship, and the subjects' dependence on the researchers" (16).

A third justification for a duty to handle IFs and possibly feed them back to research participants is based on respecting their autonomy (17), which translates into a respect for participants' self-determination and their entitlement to (and need for) information that is relevant to their health and well-being. As emphasized by Shalowitz and Miller, treating research participants as "conduits for generating scientific data without giving due consideration to their interest in receiving information about themselves derived from their participation in research" would be disrespectful (18).

4.4. Returning IFs: Harms and Benefits to Research Participants

According to qualitative and quantitative investigations of researchers' and clinicians' views, the main rationale for returning individual research results, including IFs, is to offer information that will be clinically useful (19-22). At the same time, the possibility that returning IFs may harm research participants rather than provide benefits must be taken into serious consideration. Indeed, being informed of an IF can cause worry and alarm, and research participants may not be prepared to receive the information that is offered, or undergo unnecessary confirmatory testing, all of which can place them at risk of both physical and psychological harm. (23). Equally, disclosure of IFs, when a participant has not elected to receive them, may interfere with a participant's right "not to know" (24, 25).

4.5. Handling IFs

We provide here a series of high-level guidelines for handling IFs.

4.5.1. Likelihood of identifying IFs

A determination should be made of the likelihood of identifying IFs in CARESSES, based on:

- the type of data collection approach used within the study
- the number of study participants

- the amount and type of data collected from each
- the type of interaction with Pepper
- the duration of participants' involvement with the project

4.5.2. Threshold for disclosure

Disclosure of IFs should be considered when they are of health importance to research participants. What is of "health importance" should be established by giving consideration to research participants' objective welfare, as determined by the participant's formal caregivers, GP or an expert consultant, as required. If appropriate, the possibility that the research participant herself may contribute to defining which IFs are beneficial and should be disclosed may also be taken into consideration: adopting such an approach would "recognize a spectrum of utility to the participant, and reject a view of utility grounded solely in what a clinician would find useful" (1).

4.5.3. Framework for handling IFs

Current ethical guidance recommends that a pathway for handling IFs should be developed at the outset of the research program, reviewed by an ethics committee, and communicated to research participants as part of the informed consent process [1, 26]. The pathway below, which we have adapted from (3), highlights the IFs-related decisions required.

Framework for handling IFs		Requirements
1.	Anticipation of IFs	Incidental findings should be anticipated.
		IFs should be discussed in the research protocol, anticipating the situations in which IFs may arise and possibly the types of IFs that are most likely, and stipulating their management.
2.	Information provision and informed consent	As part of the informed consent process, research participants should be informed about the possibility that IFs may be detected and about the pathway for handling such findings. In determining what is of "health importance", consideration should be given to research participants' objective welfare and possibly to their subjective interests, as explored during the informed consent process.
		Research participants should be given the opportunity to opt out of receiving information about IFs.
3.	Addressing IFs	IFs that arise should be identified and responsibly addressed, and a first determination about their health importance – as defined above - should be made
5.	Consultation on detected IF	Detected abnormalities and their relevance in terms of the research participant's health and psychological well-being should be confirmed before they are reported back. If necessary/appropriate researchers should make prior arrangements with expert consultants.
6.	Communication of the IF	Policies for the communication of the IF to the research participant should align with national regulations and customs. Final decisions about feeding back IFs should be made on a case-by-case basis, in the light of considerations of potential harms, benefits, and respect for research participants, and taking into account feasibility, logistics and cost.

Figure 1 Framework for Handling IFs - adapted from (3)

4.6. Conclusions

We outlined here a series of high-level guidelines for handling IFs. While these guidelines directly draw on the extensive literature on research IFs, most of this rich scholarship focuses on research in genomics or imaging. Indeed, as mentioned above, the question of IFs in social intervention research appears to be uncharted territory, and doing research that involves older persons presents its own set of specific ethical challenges. Ultimately, team leaders at BEDS and JAIST responsible for the end-user experiments had the final responsibility of deciding how any IFs should be handled. It is our view that such determinations should ultimately be made on a case-by-case basis and in accordance with team leaders' experience with this type of research, their understanding of the research setting, their ethical sensitivity and their professional judgement, as well as with the advice of the Internal and External Ethics Advisors and the requirements and recommendations of their local Ethics Committees.

4.7. References

1. Wolf SM, Lawrenz FP, Nelson CA, Kahn JP, Cho MK Clayton EW et al. Managing incidental findings in human subjects research: analysis and recommendations. J Law Med Ethics. 2008 Summer;36(2):219-48, 211.
2. De Clercq E, Kaye J, Wolf SM, Koenig BA, Elger BS. Returning Results in Biobank Research: Global Trends and Solutions. Genet Test Mol Biomarkers. 2017 Mar;21(3):128-131
3. Bunnik EM, van Bodegom L, Pinxten W, de Beaufort ID, Vernooij MW. Ethical framework for the detection, management and communication of incidental findings in imaging studies, building on an interview study of researchers' practices and perspectives. BMC Med Ethics. 2017 Feb 6;18(1):10.
4. Wolf SM, Paradise J, Caga-anan C. The Law of Incidental Findings in Human Subjects Research
5. Establishing Researchers' Duties. J Law Med Ethics. 2008; 36(2): 361–214.
6. Callier SL, Abudu R, Mehlman MJ, Singer ME, Neuhauser D, Caga-Anan C, Wiesner GL. Ethical, Legal, and Social Implications of Personalized Genomic Medicine Research: Current Literature and Suggestions for the Future. Bioethics. 2016 Nov;30(9):698-705.
7. American Psychological Association Committee on Human Research. Incidental findings in research with human participants: Ethical challenges for psychologists. http://www.apa.org/science/about/psa/2011/04/human-research.aspx
8. Booth TC, Jackson A, Wardlaw JM, Taylor SA, Waldman AD. Incidental findings found in "healthy" volunteers during imaging performed for research: current legal and ethical implications. Br J Radiol. 2010 Jun;83(990):456-65.
9. HUGO Ethical, Legal, and Social Issues Committee. Statement on the Principled Conduct of Genetics Research, 1995. http://www.hugo-international.org/img/statment%20on%20the%20principled%20conduct%20of%20genetics%20research.pdf. Accessed 4 April 2011.
10. Knoppers BM, Joly Y, Simard J, Durocher F. The emergence of an ethical duty to disclose genetic research results: international perspectives. Eur J Hum Genet 2006;14:1170–1178.
11. Zawati MH, Van Ness B, Knoppers BM. Incidental findings in genomic research: a review of international norms. GenEdit 2011;9(1):1–8.

12. Council for International Organizers of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002. www.cioms.ch/publications/layout_guide2002.pdf.
13. Ewuoso C. A Systematic Review of the Management of Incidental Findings in Genomic Research BEOnline. 2016; 3(1): 1–21.
14. Beskow LM, Burke W. Offering individual genetic research results: context matters. Sci Transl Med. 2010 Jun 30;2(38):38cm20.
15. Illes J, et al. Incidental findings in brain imaging research. Science. 2006;311:783–84.
16. National Bioethics Advisory Commission (NBAC). Ethical Policy Issues in International Research: Clinical Trials in Developing Countries (Bethesda, MD, 2001), 59.
17. Richardson HS, Belsky L. The ancillary-care responsibilities of medical researchers. An ethical framework for thinking about the clinical care that researchers owe their subjects. Hastings Cent Rep. 2004;34:25–33
18. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Federal Register 44 (1979)23192–97
19. Shalowitz DI and Miller FG. Communicating the Results of Clinical Research to Participants: Attitudes, Practices, and Future Directions. PLoS Med. 2008 May; 5(5): e91.
20. Meacham MC, Starks H, Burke W, Edwards K. Researcher perspectives on disclosure of incidental findings in genetic research. J Empir Res Hum Res Ethics. 2010 Sep;5(3):31-41
21. Lemke AA, Bick D, Dimmock D, Simpson P, Veith R. Perspectives of clinical genetics professionals toward genome sequencing and incidental findings: a survey study. Clin Genet. 2013 Sep;84(3):230-6.
22. Klitzman R, Appelbaum PS, Fyer A, Martinez J, Buquez B, Wynn J, Waldman CR, Phelan J, Parens E, Chung WK. Researchers' views on return of incidental genomic research results: qualitative and quantitative findings. Genet Med. 2013 Nov;15(11):888-95.
23. Ramoni RB, McGuire AL, Robinson JO, Morley DS, Plon SE, Joffe S. Experiences and attitudes of genome investigators regarding return of individual genetic test results. Genet Med. 2013 Nov;15(11):882-7.
24. Parker LS. The future of incidental findings: should they be viewed as benefits? J Law Med Ethics. 2008 Summer;36(2):341-51, 213.
25. Christenhusz GM, Devriendt K, Dierickx K. To tell or not to tell? A systematic review of ethical reflections on incidental findings arising in genetics contexts. Eur J Hum Genet. 2013 Mar;21(3):248-55
26. Jelsig AM, Qvist N, Brusgaard K, Ousager LB. Research participants in NGS studies want to know about incidental findings. Eur J Hum Genet. 2015 Oct;23(10):1423-6

5. Adopting the Ethical Guidelines of Alzheimer Europe concerning the Use of Assistive Technologies[5].

Elderly persons are often identified as a potentially vulnerable population deserving special ethical protection. To this end, while CARESSES aims to recruit clients without severe cognitive impairment and at low risk of aggressive behavior, the project will adopt the Ethical Guidelines of Alzheimer Europe (EGAE), as applicable to elderly individuals without dementia.

5.1. Background

Research focusing on the development of socially-assistive robots (SARs) to promote health and well-being, and improve quality of life for elderly individuals and for their caregivers, has been flourishing in recent years. This growth has prompted a great deal of ethical reflection on the future of SARs in care for older persons, much of which has centered on six main areas of ethical concern: "(i) the potential reduction in the amount of human contact; (ii) an increase in the feelings of objectification and loss of control; (iii) a loss of privacy; (iv) a loss of personal liberty; (v) deception and infantilization; (vi) the circumstances in which elderly people should be allowed to control robots" (1).

Ethical thinking on such issues has been key: it has shed light on ethical sensitivities about introducing SARs in healthcare, analyzed the associated societal concerns, and furthered our understanding of the interplay between technology, robotics and healthcare. However, this way of "doing" ethics is often of limited use when it comes to ensuring that it is included in the design process of future care robots. The underlying reason is that, as Stahl and Coeckelbergh recently noted, "the context in which academic reflection and research in ethics takes place is largely divorced from the context of innovation and practice." (2).

Different frameworks have been proposed to handle the ethical dimension of technology from within the design and development process, including Value Sensitive Design (VSD). VSD is a "theoretically grounded approach to the design of technology that accounts for human values in a principled and comprehensive manner throughout the design process" (3). VSD is a methodology with a highly complex structure, but at its core it includes three basic, different types of investigation:

- conceptual investigations, which typically examine the moral questions associated with the development, application and use of the artifact at hand;
- empirical investigations, which explore the human context in which the artifact will be situated, relying on the qualitative or quantitative tools that are typical of social sciences research, and
- technical investigations, which attempt to understand how existing technologies support or hinder certain values, or inform the proactive design of technologies that support the values identified earlier in the VSD process itself. (3).

[5] This is the original draft of this Section and has not been updated.

The decision to adopt the Ethical Guidelines of Alzheimer Europe Concerning the use of Assistive Technologies (EGAE) (4) in CARESSES has given us the opportunity to reflect on how we could translate those Guidelines into a hands-on approach that would ensure compliance while at the same time

- help embed ethics into our project;
- allow us to engage with ethical problems as they emerge during the design process rather than confine ethics to an after-the- fact assessment;
- open up a conversation about ethics that would promote the ethical sensitivity of all those involved.

Loosely inspired by VSD, we have thus developed a process geared towards placing ethics in the foreground from the beginning of our project, enabling us to identify and proactively engage with ethically relevant questions as they arise. This process involved

- analyzing the EGAE to extract the main ethical concepts;
- using those ethical concepts to develop a version of the Scenarios that includes "ethical tags" highlighting the ethical implications of Pepper's tasks.

5.2. The EGAE

The EGAE contain general guidelines for ethical decision making targeted at a wide, varied audience including "informal and professional carers, policy makers, service providers, voluntary workers, emergency and security forces (such as members of the police force and fire brigade), researchers, AT designers and last but not least, people with dementia for whose benefit AT is intended and who should be kept involved in decisions relating to its use". The authors point out that "it is impractical and perhaps even undesirable to try to make absolute recommendations based on the application of particular ethical principles." and they acknowledge that "Ethical decision making is a complex task, situations are rarely in effect identical and even those which seem to be so, involve different people who may have different perspectives and have different culturally-determined assumptions."

The authors of the EGAE thus suggest that their guidelines should not be adopted "as is" but will require a degree of critical appraisal and adaptation.

Within CARESSES, the adaptation has already involved:

- thinking of the EGAE in terms of how they could apply to
    - a socially assistive robot (SAR) such as the culturally aware Pepper
    - the development and experimental use of a SAR in a research setting, as well as its use in care environments
    - older adults who, like our research participants, may have early or mild dementia, but are nonetheless cognitively competent;

- including in the analysis the EGAE's reflections and guidance regarding types of assistive technology such as movement sensor and detectors, which are not the primary focus of CARESSES but may become features, capabilities of or add-ons to the culturally-aware Pepper robot in the future.

Along with the guidelines themselves, we decided to include in our analysis Alzheimer Europe's background document "Ethical issues linked to the use of specific forms of AT" (5), which provides a rich backdrop for contextualizing the guidance provided by the EGAE; for brevity's sake, we will hereafter refer to both documents as the EGAE.

5.3. Extracting guidance from the EGAE

As mentioned above, we designed a straightforward, two-step process to extract ethical guidance from the EGAE and use it to identify ethically relevant aspects of the research being conducted and inform further developments of the project. At the current stage of CARESSES, the research output that is available and that we can focus on consists of the 32 Scenarios developed in WP1, which provide situations/activities and indicate the human and robotic capabilities needed to respond to older persons in the specific situation in a culturally appropriate, sensitive and acceptable way.

5.3.1. Identifying the ethical themes in the EGAE

Our approach is comparable to the process that is typical of VSD in that it starts from a conceptual premise. Unlike in VSD, however, the ethical concepts, values and principles that inform our effort are derived from the EGAE rather than from a novel examination of the moral questions associated with the development and experimental use of the culturally aware SAR in CARESSES.

To extract those concepts, values and principles from the EGAE we utilized an approach that draws on qualitative thematic analysis (6). In some instances, QTA presupposes an existing theoretical framework, and is thus used for theoretical coding, i.e. to identify the presence or absence of particular themes or issues within documents. Here, we operated inductively, focusing on themes that we observed within the EGAE. We began by reading through the EGAE and identifying the subsections of the document that are not relevant to our project. We then analyzed the text by breaking it down into meaningful segments (paragraphs, sentences or phrases), and labeled these units of meaning as instances of ethically relevant concepts, in a process termed "coding" the units. Polkinghorne usefully reminds us that this process is not unlike "indexing a book in which items mentioned in the book are gathered together as instances of concepts listed in the index." (7). While qualitative analysis usually proceeds by breaking down the text into first-level conceptual units and then examining them to establish whether they can be organized under higher-level, more general concepts, we directly aimed for identifying broad ethical themes, which we then used as tags to highlight ethically significant facets in the robot tasks, when analyzing the Scenarios in the second stage of our approach.

Our qualitative analysis was supported by the web application Dedoose, Figure 2 (www.dedoose.com).

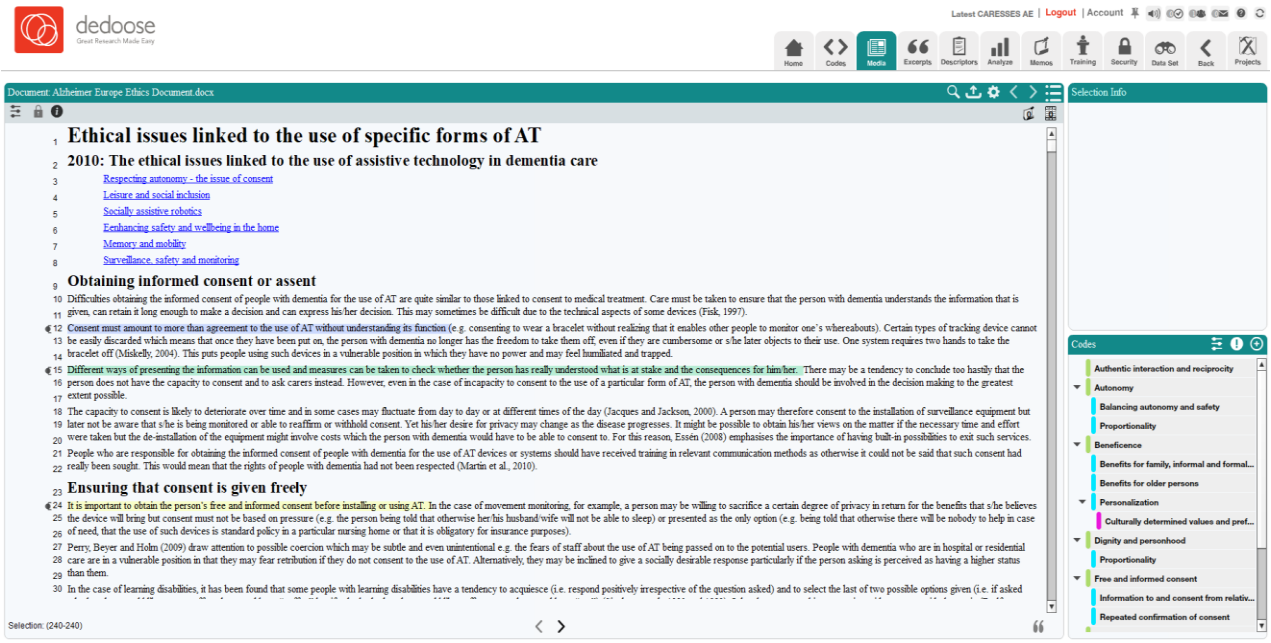


Figure 2 Qualitative document analysis of the EGAE in Dedoose.

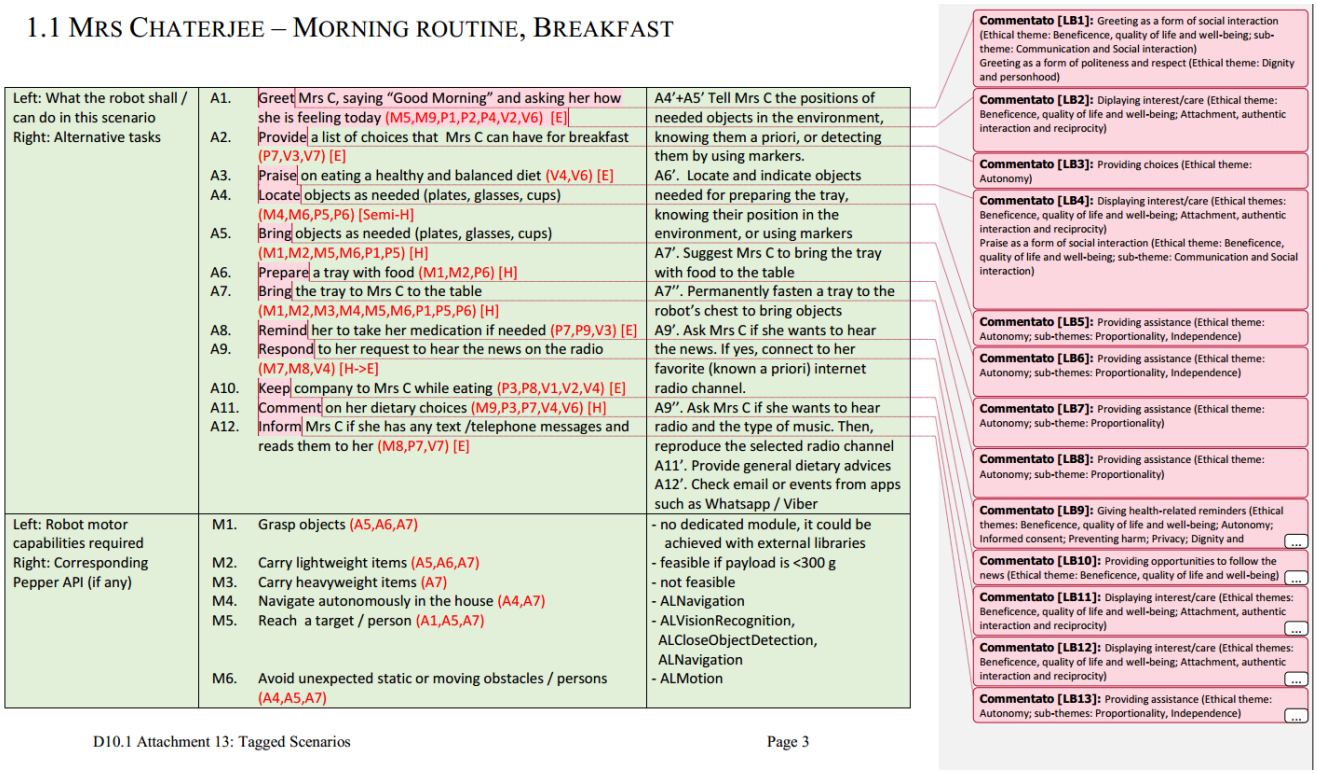
5.4. The themes

We identified nine broad ethical themes within the AEGE: Attachment, authentic interaction and reciprocity, Autonomy; Beneficence, quality of life and well-being; Culturally determined values and preferences; Dignity and personhood; Informed consent and shared decision-making; Preventing harm; Privacy, and Stigma, as shown in Figure 3:

Figure 3 Ethical themes identified in the EGAE.

Having identified the main ethical themes in the EGAE, we proceeded to use those themes as tags to highlight the ethically relevant elements in the 32 Scenario Tables (10 Scenario Tables for Mrs Chaterjee, 10 for Mrs Smith, eight for Mrs Yamada and four for Mrs Khan) that have been developed in CARESSES in Work Package 1 - Transcultural Robotic Nursing (Deliverable D1.1 Detailed Scenarios). Such scenario Tables describe the activities to be performed by robots when interacting with clients during daily-routine, and are aimed at providing guidance for all the subsequent RTD activities, including the implementation of motor, perceptual, cognitive and verbal robotic capabilities.

Rather than tag the Scenario Table themselves, which are rich in narrative elements and background information that are not strictly related to the robot, we analyzed the robot tasks that are contained in the Scenarios. This analysis will be reviewed and applied to alternative tasks in the Scenario tables once we have a clear idea of the actual capabilities of Pepper and the list of tasks to be implemented has been defined. Figure 4 shows a tagged Scenario Table for purely illustrative purposes: the whole set of tagged Scenario Tables is available as Attachment 13.



1.1 MRS CHATERJEE – MORNING ROUTINE, BREAKFAST

Left: What the robot shall / can do in this scenario Right: Alternative tasks	A1. A2. A3. A4. A5. A6. A7. A8. A9. A10. A11. A12.	Greet Mrs C, saying "Good Morning" and asking her how she is feeling today (M5,M9,P1,P2,P4,V2,V6) [E] Provide a list of choices that Mrs C can have for breakfast (P7,V3,V7) [E] Praise on eating a healthy and balanced diet (V4,V6) [E] Locate objects as needed (plates, glasses, cups) (M4,M6,P5,P6) [Semi-H] Bring objects as needed (plates, glasses, cups) (M1,M2,M5,M6,P1,P5) [H] Prepare a tray with food (M1,M2,P6) [H] Bring the tray to Mrs C to the table (M1,M2,M3,M4,M5,M6,P1,P5,P6) [H] Remind her to take her medication if needed (P7,P9,V3) [E] Respond to her request to hear the news on the radio (M7,M8,V4) [H->E] Keep company to Mrs C while eating (P3,P8,V1,V2,V4) [E] Comment on her dietary choices (M9,P3,P7,V4,V6) [H] Inform Mrs C if she has any text /telephone messages and reads them to her (M8,P7,V7) [E]	A4'+A5' Tell Mrs C the positions of needed objects in the environment, knowing them a priori, or detecting them by using markers. A6'. Locate and indicate objects needed for preparing the tray, knowing their position in the environment, or using markers A7'. Suggest Mrs C to bring the tray with food to the table A7''. Permanently fasten a tray to the robot's chest to bring objects A9'. Ask Mrs C if she wants to hear the news. If yes, connect to her favorite (known a priori) internet radio channel. A9''. Ask Mrs C if she wants to hear radio and the type of music. Then, reproduce the selected radio channel A11'. Provide general dietary advices A12'. Check email or events from apps such as Whatsapp / Viber
Left: Robot motor capabilities required Right: Corresponding Pepper API (if any)	M1. M2. M3. M4. M5. M6.	Grasp objects (A5,A6,A7) Carry lightweight items (A5,A6,A7) Carry heavyweight items (A7) Navigate autonomously in the house (A4,A7) Reach a target / person (A1,A5,A7) Avoid unexpected static or moving obstacles / persons (A4,A5,A7)	- no dedicated module, it could be achieved with external libraries - feasible if payload is <300 g - not feasible - ALNavigation - ALVisionRecognition, ALCloseObjectDetection, ALNavigation - ALMotion

D10.1 Attachment 13: Tagged Scenarios Page 3

Commentato [LB1]: Greeting as a form of social interaction (Ethical theme: Beneficence, quality of life and well-being; sub-theme: Communication and Social interaction)
Greeting as a form of politeness and respect (Ethical theme: Dignity and personhood)

Commentato [LB2]: Diplaying interest/care (Ethical theme: Beneficence, quality of life and well-being; Attachment, authentic interaction and reciprocity)

Commentato [LB3]: Providing choices (Ethical theme: Autonomy)

Commentato [LB4]: Displaying interest/care (Ethical themes: Beneficence, quality of life and well-being; Attachment, authentic interaction and reciprocity)
Praise as a form of social interaction (Ethical theme: Beneficence, quality of life and well-being; sub-theme: Communication and Social interaction)

Commentato [LB5]: Providing assistance (Ethical theme: Autonomy; sub-themes: Proportionality, Independence)

Commentato [LB6]: Providing assistance (Ethical theme: Autonomy; sub-themes: Proportionality, Independence)

Commentato [LB7]: Providing assistance (Ethical theme: Autonomy; sub-theme: Proportionality)

Commentato [LB8]: Providing assistance (Ethical theme: Autonomy; sub-theme: Proportionality)

Commentato [LB9]: Giving health-related reminders (Ethical themes: Beneficence, quality of life and well-being; Autonomy; Informed consent; Preventing harm; Privacy; Dignity and ...

Commentato [LB10]: Providing opportunities to follow the news (Ethical theme: Beneficence, quality of life and well-being) ...

Commentato [LB11]: Displaying interest/care (Ethical themes: Beneficence, quality of life and well-being; Attachment, authentic interaction and reciprocity) ...

Commentato [LB12]: Displaying interest/care (Ethical themes: Beneficence, quality of life and well-being; Attachment, authentic interaction and reciprocity) ...

Commentato [LB13]: Providing assistance (Ethical theme: Autonomy; sub-themes: Proportionality, Independence) ...

Figure 4 A "tagged scenario", built starting from CARESSES scenario tables (Deliverable D1.1) .

Below we provide a brief overview of each theme and of the main sub-themes, including relevant sample extracts from the EGAE and from the Scenarios, and showing where and why those ethical themes and sub-themes are relevant. The aim here is not to conduct in-depth analyses but rather to provide straightforward reference and examples.

In several instances extracts from the Scenarios can be viewed as referring to more than one ethical theme. However, for sake of simplicity, we will discuss themes separately.

The full list of extracts is available on request.

5.4.1. Attachment, authentic interaction and reciprocity

SARs are often built to resemble humans and to have human-like qualities or behaviors. Because of this, a person may become attached to the robot and even consider it "real" or "alive". The robot, however, may have to be shared with others - in a care home for instance – or break down, or not live up to the person's expectations. Feelings of jealousy, disillusionment or disappointment may thus arise. Ethical concerns may also emerge due to the fact that robots may emulate empathy, or display caring behaviors; this is especially of concern with older people whose ability to interact with fellow humans may be failing.

Sample extracts - EGAE

- *"Some people may feel that there is something uncanny about a computer which seems to show concern or exhibit caring behaviour, whereas others might appreciate this or simply have no problems with it."*
- *"Ethical questions may nevertheless arise such as whether it is right to give SARs of this kind to people whose ability to interact with humans is declining, who might at some point be unable to understand that something is not "alive" and who may be feeling isolated."*

Within the Scenarios, the robot tasks that are relevant to this ethical theme are those in which Pepper praises, congratulates, shows interest, comments or simply keeps company with Mrs Chaterjee, Mrs Smith, Mrs Khan and Mrs Yamada, since all of these actions can be viewed as replicating human behaviors that characterize companionship and caring. See for instance:

Sample extracts – Scenarios

- "*Show interest in Mrs Khan's praying customs asking her about her religion, for instance how long she normally prays for, how many times a day, etc."*
- *"Keep company with Mrs Smith while she is eating."*
- *"Praise (Mrs Chaterjee) for eating a healthy and balanced diet."*

Although interaction with SARs may involve the risks described above, it can also, as the EGAE themselves acknowledge, "*make a person feel cared for, wanted, of interest to someone/thing else and drawn into interaction*". By sending and receiving expressions of interest and care, the SAR can relieve feelings of isolation (8) and, to some extent, meet the older person's need for companionship (9).

5.4.2. Autonomy

Autonomy is often defined as a person's ability to make her own decisions about her life, based on her principles, values, beliefs, priorities and goals. It is traditionally considered to be linked to self-determination, exercising choice, and informed consent (10), and provides one of the central principles of practice with older people (11). Thus, the experience of autonomy is fundamentally linked with dignity, self-worth, and positive experiences of care, so that notions of autonomy and independence underpin much guidance for improving the care of older people.

Sample extracts – EGAE

- *"SARs could be used to carry out certain tasks on behalf of the user or to provide a sufficient level of support to enable the person to complete the task himself/herself. This should promote the autonomy of the user."*
- *"AT can be used as a memory aid to enable people to carry out tasks which would otherwise be difficult or impossible to accomplish on their own due to difficulties remembering what to do, which items are needed for the task, or in which order to carry out each stage of the task."*

A great number of the tasks that Pepper carries out in the Scenarios (e.g. bring objects, remind, suggest, store or retrieve information) precisely reflect one or both of the goals that the EGAE identify: to promote user autonomy by carrying out certain tasks on the user's behalf or by behaving as a memory aid. For instance:

Sample extracts – Scenarios

- *"Ask Mrs Khan if she wants to make a shopping list and prepare it on the tablet"*
- *"Ask Mrs Smith when she will see her son again and store the information"*

Autonomy has the following sub-themes: independence, proportionality, balancing autonomy and safety

a) Independence

According to the EGAE,

- *"People with dementia express satisfaction about not having to rely on other people, so in some cases an advantage to AT could be that it enables people to express their independence."*

SARs like Pepper, who generally do not give physical aid to older persons, may be viewed as supporting and maintaining the independence of those older persons because the suggestions, cues, reminders and encouragement they provide help users to take care of tasks on their own, care for themselves and manage their life.

The same extracts listed above to illustrate how autonomy plays out in the Scenarios can be conceptualized as instances in which users' independence is fostered:

- *"Ask Mrs Khan if she wants to make a shopping list and prepare it on the tablet"*
- *"Ask Mrs Smith when she will see her son again and store the information"*

b) Proportionality

Closely linked to the promotion of autonomy and independence, is the risk of over-reliance on Pepper. The EGAE reminds us that:

- *"It is important to respect the principle of proportionality, which means that the level of intervention should be restricted to what is really needed for a particular person in a particular situation. Providing more assistance than is actually needed may result in the premature loss of capacities which may foster a new form of dependency, namely on AT rather than people."*

This suggests that, should SARs be incorporated in care settings, regular revision of how they interact with users in terms of the type and amount of support they offer will be required in order to ensure appropriate matching with users' capacities.

c) Balancing autonomy and safety

Many of the ethical dilemmas that arise in elderly care revolve around how risk should be managed to ensure safety while respecting older persons' autonomy. According to the EGAE:

- *"When faced with decisions about the use of AT which necessitate balancing the management of risk with the promotion of the person's autonomy, the following should be considered:*
    - *the real rather than hypothetical risks involved;*
    - *the necessity to focus on risks to the individual and not primarily on risks to the establishment (care home or hospital);*
    - *considering potential benefits at the same time as potential risks;*
    - *people have different perceptions of risk and of what level of risk is acceptable to them;*
    - *it is unrealistic and even undesirable to try to eliminate every possible risk in the life of the person with dementia. Moreover, this would be likely to have a negative impact on their quality of life."*

Analyzing Pepper's tasks in the Scenarios reveals significant instances in which it could be used to mitigate risks or ensure user safety. For example:

- "*Remind Mrs Smith to take her medication if needed"*
- *"Remind Mrs Chatterjee to check that there are no flames"*

While such reminders may provide valuable, independence-enhancing solutions to typical problems, we cannot rule out that they could be perceived by users as controlling or interfering with their autonomous decision-making. One way of balancing respect for users' autonomy with using the SAR to mitigate risks and ensure user safety is to ask for the older person's consent to such a use in a personalized, shared

decision-making approach. For instance, it might be possible to offer the user and caregivers the option to consider a range of reminders that can be activated, and choose different quantitative and qualitative features for each type of reminder (e.g frequency and intensity).

5.4.3. Beneficence, quality of life and well-being

In every-day language, the term beneficence refers to acts of mercy, kindness, and charity. In ethical theory, the term encompasses actions intended to benefit or promote the good of other persons. As the Stanford Encyclopedia of Philosophy explains, "The language of a principle or rule of beneficence refers to a normative statement of a moral obligation to act for the others' benefit, helping them to further their important and legitimate interests, often by preventing or removing possible harms." (12) When considering the use of AT or SARs in elderly care, beneficence should always be the guiding ethical principle.

Beauchamp and Childress point out that the "best interests" standard frequently used when making decisions about beneficence is inescapably a quality of life criterion (10). They also suggest that quality of life considerations should be based on whether a particular intervention is beneficial to the person concerned.

Quality of life (QOL) is a multi-layered concept that usually includes subjective evaluations of both positive and negative aspects of life. While health is one of the main domains of overall quality of life, notions of culture, values, and spirituality are also key (13).

The term well-being is generally considered to include a range of positive emotions, such as fulfillment and happiness, and the absence of negative emotions, such as fear or worry (14-16). It is often associated with having good health and access to such basic resources as shelter and an income. One of the main predictors of well-being is having meaningful relationships. (17).

Sample extracts – EGAE

- *"The interests and wellbeing of the person with dementia must always come first in decisions relating to the use of AT for or by people with dementia."*
- *"There are also numerous stand-alone devices which may contribute towards self-esteem, autonomy, safety and wellbeing (as mentioned earlier depending on the devices, the people involved and the situation) such as picture telephones, digital pens, calendar clocks and medicine dispensers."*
- *"Doing what is best/most beneficial for the person with dementia (...) It should be considered whether and if so how the use of AT:*
    - *would be beneficial to the person with dementia;*
    - *would respond to the needs and wishes of the person with dementia, and where appropriate, his/her carers;"*

It would be reasonable to say that all of Pepper's tasks in the Scenarios have been developed to further, promote and respect the older person's benefit.

Beneficence has the following sub-theme: Communication and Social Interaction

One sub-theme of Beneficence, Communication and Social Interaction, provides an especially eloquent example of how AT can be used to promote the quality of life and well-being of older users. This role of AT in facilitating communication and maintaining relationships is repeatedly emphasized by the EGAE; just to mention a few instances:

- *"The use of various devices has also been shown to promote social interaction amongst residents in residential care."*
- *"Some forms of AT, such as video-telephoning, can be equally important in breaking the isolation of carers as that of people with dementia. It may also serve as a means of mutual support amongst carers or to help maintain communication between couples when one goes into residential care (Sävenstedt et al., 2003). Video-telephoning may also enable relatives and friends who are unable to visit as regularly as they would like to keep in touch with a person with dementia in residential care, reassure themselves that s/he is alright and perhaps reduce feelings of guilt about not visiting (Sävenstedt et al., 2003)."*
- *"Multimedia software can be used in a variety of ways to stimulate physical and cognitive capacities, and to increase social interaction or contact with the outside world. Computer-based activities, for example, may be either solitary or involve interaction with others. Some may be based on cognitive stimulation; others may provide a pleasant experience or be combined with physical exercise. Whilst elderly people of today are not generally as knowledgeable about computers as the younger generation, using computer technology may help bridge the gap between generations and provide a common interest or activity which can be shared with younger people, thereby promoting inter-generational social interaction and in some cases helping maintain family ties."*

Many of Pepper's tasks in the Scenarios provide such type of opportunities, for example:

- *"Ask Mrs Khan if she wants to place a videocall to her daughter"*
- *"Check email or events from applications such as Whatsapp"*
- *"Ask Mrs Smith if she wants to listen to or watch the news"*

5.4.4. Culturally determined values and preferences

As illustrated by Hofstede's cultural dimensions model and by Papadopoulos and others' work on transcultural nursing and cultural competence (two of the main theoretical groundings that underpin CARESSES), different cultures prioritize or place greater emphasis on different values (18,19). Significant differences across cultures exist, for instance, in terms of individualism and independence or interdependence and collectivism. Great variation also exists if we look at privacy, as different cultures

have different boundaries for their private sphere. The EGAE recognize the importance of understanding culturally determined priorities and preferences:

Sample extracts - EGAE

- *"It should be considered whether and if so how the use of AT respects or corresponds with the cultural traditions of the person (…)"*
- *"Should, for example, male carers have access to video recordings of female residents in nursing homes or residential care (or female carers of male residents)? This may be particularly relevant for people from certain cultural or religious backgrounds. In cases where special attire is required in public places (e.g. the burkha or the Sikh turban), the boundaries between the private and the public sphere may need to be clarified, especially in residential care settings (bearing in mind how each person interprets religious or cultural obligations)."*

The entire development of the Scenarios is underpinned by concepts of cultural competence. It would thus be misleading to single out specific tasks as being more culture-oriented than others. However, cultural knowledge, awareness and sensitivity also determine quantitative and qualitative features of Pepper's behaviors in all of the Scenarios, as exemplified in Figure 5.

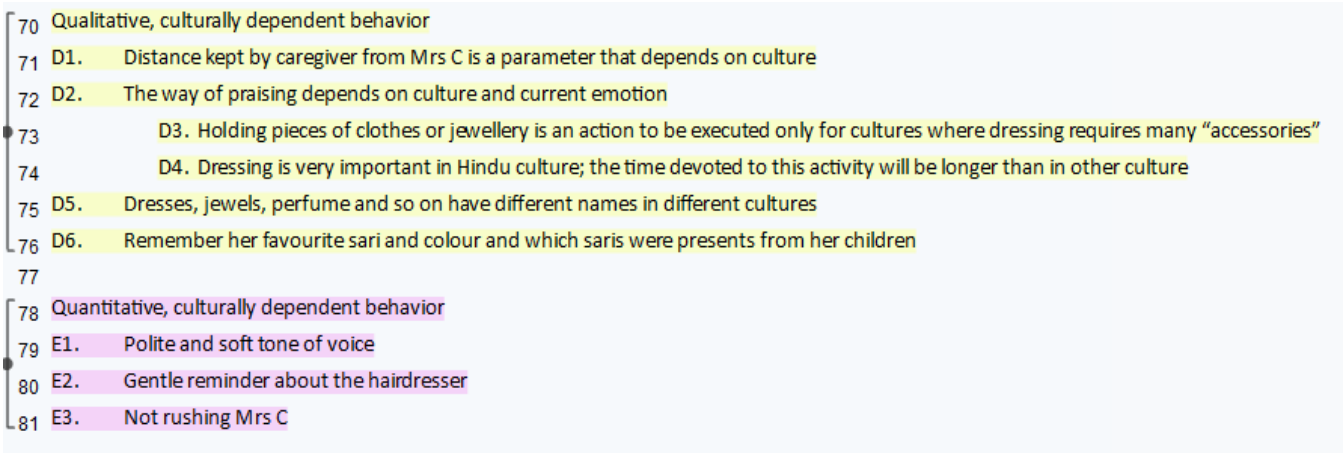


Figure 5 Qualitative and quantitative behaviors in Scenario 1.1, Mrs. Chaterjee, Morning Routine: Breakfast.

5.4.5. Dignity and personhood

Numerous theoretical accounts of dignity have been developed over the centuries and are found in contemporary literature. Many such accounts agree that dignity refers to the inherent value or worth of all human beings, regardless of their condition, and is related to notions of self-respect, integrity, autonomy and inclusion.

When they are insulted, infantilized, ridiculed, humiliated, or ignored, older persons are deprived of their dignity (20,21). Conversely, respect for their dignity contributes to their well-being, to the maintenance of their relationships with other people, and to positive relationships with caregivers.

As the AEGE point out, treating people without dignity may result in their being seen as objects and losing their personhood (5). Personhood is a complex and widely debated concept that is frequently taken to encompass capacities or attributes such as human nature, agency, and the possession of rights and duties.

The EGAE's attention to issues of dignity and personhood is exemplified below.

Sample extracts – EGAE

- *"As people may feel more or less at ease interacting with SARs, the interaction promoted and required by the SAR may suit some people more than others. It could even be problematic if people realise that they are dependent on the SAR but feel ridiculous using it."*
- *"Some concerns about dignity may be valid and care must be taken to ensure that people are not being pressurised to take part in activities which they personally find demeaning or of no interest."*

In the Scenarios, all the robot tasks associated with actions such as reminding, suggesting or even encouraging, are meant to promote autonomy and independence, as discussed above. However, they could be ceonceivably perceived as disrespectful or interfering with the older user's dignity:

Sample extracts – Scenarios

- *"Remind Mrs Yamada to switch on/off the lights."*
- *"Remind Mrs Yamada to be careful while pouring hot water and to switch off the heat."*

Indeed, they may serve as unwanted reminders of diminished competencies, lack of independence from others (including Pepper) or inability to take care of oneself. Like in the case of autonomy and user safety, personalized, shared decision-making may help avoid such undesirable consequences of interactions with Pepper: including the user in choosing which type of suggestions or reminders to activate may be a way to ensure that her dignity is always preserved.

At the same time, robot actions that express politeness, praise and respect like those in the Scenarios, can contribute to enhancing the older person's feelings of dignity and self-worth.

Sample extracts – Scenarios

- *"Greet Mrs S, saying "Good Morning" and asking her how she is feeling today."*
- *"Praise Mrs S for her look and beautiful blouse."*

5.4.6. Privacy

Privacy refers to the ability of individuals or groups to choose which information about themselves they want to share with others. Sharkey and Sharkey have expressed concerns about the potential loss of privacy when SARs are used in the care of older persons (1): "Older adults might not like to find that an

operator could remote control a robot to peer round their apartment before they are dressed, or when they are taking a bath. They might prefer the robot to have to do the equivalent of knocking on the door and waiting to be invited in."

While they repeatedly acknowledge the importance of respecting older persons' privacy, the EGAE also mention a different view of the relationship between SARs and privacy, pointing out how relying on robot assistance may actually increase it rather than interfere with it.

Sample extracts - EGAE

- *"Although SARs are not human, programmed reactions towards the behaviour and movement of the user may affect users' sense of privacy in that people may feel that they are not alone (which can also be positive) or that they are being watched. If the user can control privacy levels, such problems can easily be overcome. SARs may also increase the level of privacy by side-stepping the need for human assistance for tasks which are potentially embarrassing or private (e.g. going to the toilet or getting washed)."*

In the Scenarios, privacy mainly comes to the fore when the user is getting dressed, is using Pepper for video-calls with family or friends, has visitors, or is engaged in activities such as meditation or prayer. The Scenarios clearly state that Pepper will provide privacy to users in all such situations:

Sample extracts - Scenarios

- *"Provide privacy to Mrs Yamada while she is talking to her family"*
- *"Provide privacy to Mrs Yamada while she is visiting with her friend"*
- *"If in the room, provide privacy, observing Mrs Khan quietly during prayer"*

Considerations about privacy, however, are also relevant when Pepper provides assistance by checking emails or messages:

- *"Check email or events from applications such as Whatsapp"*
- *"Inform Mrs S if she has any text /telephone messages and read them to her"*

As the user may conceivably prefer not to share the content of such messages with carers or other people in the room, performance of this type of tasks should be explicitly required or authorized by users.

Privacy has the following sub-theme: Ensuring privacy of staff, visitors and family members.

Respecting the privacy of older persons should go hand-in-hand with respecting the privacy of informal and formal carers, family and friends.

Sample extracts – EGAE

- "*Video-phoning, like monitoring for safety purposes, may be perceived as an invasion of a person's privacy. Whilst someone is sitting in front of the screen talking to someone, anyone who walks past may be captured on screen against their will or without their knowledge. In families with children and teenagers, it is unlikely that every one of them would have been asked to consent to the installation of such equipment. There may also be visitors who are unaware that their image is being recorded. Some people are very susceptible about their image and would be disturbed if they realised that they had been filmed in their pyjamas, without make-up, wearing curlers or having just woken up etc."*

Careful positioning of the SAR in the room and appropriate scheduling of video-calls might help ensure the privacy of all those who are present.

NB: In the end-user evaluation, any video data acquired by Pepper will be processed to extract anonymous information and will not be stored, thus respecting the privacy of research participants and of any other person in the room at the time.

5.4.7. Informed consent

As mentioned in sub-section 5.3.2 above, respecting the principle of autonomy requires that individuals should be able to make free and informed decisions, particularly about their own care. Therefore, SARs cannot be involved in care practices without the informed consent of users.

The issue of what constitutes truly informed consent is a long-standing question: how to ensure that professionals have provided and users understood the information necessary? (22,23) When contemplating the introduction of SARs in the care of older persons, this is further complicated by the realities of advanced technology being offered to individuals whose cognitive capacities may be declining, and by the fact that the outcome of interactions between robots and humans is somewhat unpredictable.

Furthermore, consent must be voluntary and freely given, without any form of pressure or coercion. This is not always straightforward, as people in care homes are vulnerable and may fear retribution if they do not consent, or feel they need to agree with caregivers.

The EGAE devote much attention to the issues of informed consent; for example

<u>Sample extracts</u>

- *"Consent must amount to more than agreement to the use of AT without understanding its function"*
- *"As a general guideline, the issue of consent should be approached from the perspective of shared decision making, involving people with dementia, carers and health and social care/service providers, in a collaborative effort to define mutually acceptable goals of care or support."*
- *"The consent of the person with dementia by/for whom the AT will be used should be sought irrespective of the complexity of the technology or stage of the disease."*

In the Scenarios, the issue of informed consent is especially prominent in situations where Pepper may remind users to take their medication, or store information for future use:

- *"Remind Mrs Chaterjee her to take her medication if needed"*
- *"Ask Mrs Yamada for information about medicine and doctor's advice and store it"*

As mentioned above in sub-sections 5.3.2 and 5.3.5 discussing autonomy and dignity, informed consent and shared-decision making can enable individuals to make decisions about their care that protect their health and well-being while at the same time reflecting their priorities and values

5.4.8. Preventing harm

When thinking about SARs in care settings, the ethical principle of preventing harm may be viewed in a top-down fashion, that is as associated with harm caused by the SAR, but possibly also in a bottom-up view, as linked to the SAR's role in helping to make sure that no harm comes to the user (24).

In terms of the former, SARs have the advantage that they tend to come into minimal contact with persons, as physical assistance is not what they are designed for Thus their safety mostly has to do with how carefully they are able to move within the environment and avoid obstacles, e.g. without knocking over chairs or bumping into walkers.

This type of situation, as well as the risk of users relying on a malfunctioning or unreliable SAR, is envisaged by the EGAE:

Sample extracts – EGAE

- "*It is essential that SARs are stable and not likely to provoke accidents (e.g. through their colour, size, shape, movement or sound). In all cases users need to feel safe when using the robot and positive about it."*
- *"In some cases, elderly people may rely heavily on the AT device or system to the extent that they trust it more than they trust their own judgement. If the device then malfunctions and gives out faulty information (e.g. regarding taking medication), they would be less likely to detect the error and this makes them vulnerable (Ho et al., 2005). Apart from the need to take this into account during the design of various forms of AT, regular review and maintenance of AT is needed. Providers of AT also have an obligation to ensure that it is safe and reliable, particularly when used by people who may not have the capacity to check this themselves."*

In the Scenarios, instead, Pepper's protective, safety-enhancing role with older persons comes into relief:

Sample extracts – Scenarios

- *"Remind Mrs Yamada to switch off the heat after tea"*
- *"Remind Mrs Yamada to check that there are no flames"*

As discussed earlier, the SAR's potential to mitigate risks through this type of reminders could be perceived by older users as interfering with their autonomy and dignity. Thus, safety-oriented robot behaviors such as these might be discussed with users and caregivers, with a view to reaching personalized solutions that reflect a shared decision-making approach.

5.4.9. Stigma

Stigma is a social process whereby an individual experiences exclusion or rejection owing to negative social judgement associated with a feature related to a health problem or a health condition. Stigma is relevant to older adults because signs of physical aging are viewed negatively in contemporary youth-oriented cultures (25), in which prejudice against older individuals as a group is common (26). To prevent stigma or self-stigma in older individuals using SARs, the EGAE recommend that:

- *"Measures should be taken to ensure that AT is used discreetly so as to avoid inadvertently "labelling" the person using it as this may contribute towards stigmatization or lead to self-stigmatization including feelings of shame, humiliation, social withdrawal and low self-esteem;"*

We cannot rule out the possibility that relying on a robot for assistance, entertainment, and, to some extent, companionship, may result in negative judgements about users or by users about themselves. However, interactions with Pepper may also elicit positive responses, and be viewed as a valuable means of engaging in novel activities, providing older people with opportunities for social interaction, and helping to improve their quality of life.

5.5. The "Ethically Tagged Scenarios".

We have briefly outlined the meaning of the broad ethical themes identified in the EGAE and shown how they apply to the robot tasks in the Scenarios.

Overall, we added 478 ethical tags across the 32 Scenarios, with almost 15 tags per Scenario. Figure 6 shows the occurrence of the different ethical themes/tags across the groups of Scenarios.

We found that virtually all of the tasks in the Scenarios have ethical relevance, and, as such, can impact on users in terms of their autonomy, independence, social interaction, well-being, privacy, or dignity. The ethical richness and depth of the Scenarios has thus come to the fore.

The goal of the ethically tagged Scenarios is to provide project partners with a simple tool that, drawing on the guidance of the EGAE, clearly displays the ethical relevance and implications of Pepper's actions and behaviors. Because the Scenario document will be continuously revised and updated in the course of the project, as robotic implementation of the tasks is developed and refined, project partners will often have the opportunity to peruse the ethical content of the document by simply clicking on the comments. The brief outlines on the ethical themes provided above will be available for quick reference, and will be the starting point for conversations involving all partners aimed at developing practical technological solutions that will protect and promote the autonomy, dignity, privacy and quality of life of older users.

Media \ Codes	Attachment, authentic interaction	Autonomy	Balancing autonomy and	Independence	Proportionality	Beneficence, quality of life and well-	Benefits for family, informal	Benefits for older persons	Communication and	Personalization	Culturally determined values and	Dignity and personhood	Proportionality	Informed consent and shared	Information	Information to and consent	Repeated confirmation of	Preventing harm	Privacy	Ensuring privacy of staff,	Stigma	Totals
Ethics_Mrs Yamada.docx	1	67	9	66	67	44		6	38		12	44		6			1	9	12	4		386
Ethics_Mrs Smith.docx	6	66	2	66	66	35		4	20	1	8	41		3				3	16	2		339
Ethics_Mrs Khan.docx	5	41	1	41	41	13			7	1	4	22							8			184
Ethics_Mrs Chaterjee_rev.docx	2	93	9	83	76	61		4	51		14	17	1	6			2	9	13	4		445
Alzheimer Europe Ethics	7	20	8	1	3	14	1	5	6	7	2	17	1	25	5	1	2	6	16	5	4	156
Totals	21	287	29	257	253	167	1	19	122	9	40	141	2	40	5	1	5	27	65	15	4	

Figure 6 Occurrence of ethical themes in the groups of Scenarios.

Thus, our approach will contribute to develop a technology that will support the ethical themes identified in the EGAE, in accordance with the goals of VSD (3).

5.6. Conclusions

The Scenarios are the converging point of all the competencies in CARESSES, the document that provides both the grounding for Pepper's cultural competence, and the description of how such competence is expected to influence its actions and behaviors.

By analyzing the EGAE to identify the ethical themes that underpin its guidance, and applying those themes to the Scenarios, we have embedded awareness of the ethical dimension into the core of the project, and developed an approach that, when refined, may be usefully applied in other research projects involving SARs.

The process has involved discussions between partners with backgrounds in transcultural nursing, public health, robotics, and the Internal Ethics Advisor. Over the coming months we expect that conversation to continue, with partners contributing additional views as the technological core of CARESSES takes shape and the culturally competent Pepper's actual capabilities become clear.

5.7. References

1. Sharkey A, Sharkey N. Granny and the robots: ethical issues in robot care for the elderly. Ethics and Information Technology. 2012;14(1):27–40.

2. Carsten Stahl B, Coeckelbergh M. Ethics of healthcare robotics: Towards responsible research and innovation. Robotics and Autonomous Systems 86 (2016) 152–161
3. Friedman B, Kahn PH, Borning A, Huldtgren A. Value Sensitive Design and Information Systems. In: Early engagement and new technologies: opening up the laboratory. Springer, 2013; pp 55-95
4. Alzheimer Europe. Our guidelines and position on the ethical use of AT for/by people with dementia. Available for download at http://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2010-The-ethical-issues-linked-to-the-use-of-assistive-technology-in-dementia-care/Our-guidelines-and-position-on-the-ethical-use-of-AT-for-by-people-with-dementia#fragment1
5. Alzheimer Europe. The Ethical issues linked to the use of assistive technology in dementia care. Available for download at http://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2010-The-ethical-issues-linked-to-the-use-of-assistive-technology-in-dementia-care/Ethical-issues-linked-to-the-use-of-specific-forms-of-AT#fragment1
6. Clarke, V. and Braun, V. Teaching thematic analysis: Over-coming challenges and developing strategies for effective learning. The Psychologist,26 (2). pp. 120-123.
7. Polkinghorne DE. Qualitative Research and Media Psychology. In: The Oxford Handbook of Media Psychology. Oxford University Press. 2013, pp 137-156.
8. Dahl TS, Kamel Boulos MN. Robots in Health and Social Care: A Complementary Technology to Home Care and Telehealthcare? Robotics 2013, 3, 1-21
9. Egolf, D.B. Using Robots as Companions for the Elderly: Research and Controversy. In Proceedings of the 23rd Annual International Conference on Technology and Persons with Disabilities, Los Angeles, CA, USA, 10–15 March 2008.
10. Beauchamp TL, Childress J. Principles of biomedical ethics. New York: Oxford University Press, 1st ed, 1979; 7th ed, 2012
11. McCormack, B. (2001) Autonomy and the relationship between nurses and older people, Ageing and Society, 21: 417–46.
12. Stanford Encyclopedia of Philosophy. The Principle of Beneficence in Applied Ethics. Available for download at https://plato.stanford.edu/entries/principle-beneficence/
13. The WHOQOL Group. The World Health Organization Quality of Life Assessment (WHOQOL). Development and psychometric properties. Soc Sci Med 1998;46:1569-1585.
14. Andrews FM, Withey SB. Social indicators of well-being. NewYork: Plenum Press; 1976:63–106.
15. Diener E. Subjective well being: the science of happiness and a proposal for a national index. American Psychologist 2000;55(1):34–43.
16. Ryff CD, Keyes CLM. The structure of psychological well-being revisited. Journal of Personality and Social Psychology 1995;69(4):719–727.
17. Myers DG. Close relationships and quality of life. In: D Kahneman, E Diener, N Schwarz. (eds.) Well-Being: The foundations of hedonic psychology. New York: Russell Sage Foundation Publications; 2003:374–391.
18. Hofstede G. Culture's Consequences: comparing values, behaviors, institutions, and organizations across nations (2nd ed.). Thousand Oaks, CA: SAGE Publications: 2001.
19. Papadopoulos I (Ed). Transcultural Health and Social Care: Development of Culturally Competent Practitioners. Churchill Livingstone Elsevier. Edinburgh, 2006

20. I Holmerová et al. Dignity and Palliative Care in Dementia J Nutr Health Aging 11 (6), 489-494. Nov-Dec 2007
21. Jacobson N. Dignity and Health: a review. Soc Sci Med. 2007 Jan;64(2):292-302.
22. Beauchamp TL, Faden RR. Informed consent: II. Meaning and elements of informed consent. Encyclopaedia of Bioethics. Edited by: Reich WT. 1995, New York: Simon & Schuster Macmillan, 3: 1240-1245.
23. McCormick TR- Informed Consent, its basis, problems, uncertainties. 1998, University of Washington School of Medicine.
24. Feil-Seifer D, Skinner K, Matarić MJ. Benchmarks for evaluating socially assistive robotics. Interaction Studies: Psychological Benchmarks of Human-Robot Inteaction, 8(3), 423-429 Oct, 2007.
25. Schoemann, A. M., & Branscombe, N. R. (2011). Looking young for your age: Perceptions of anti-aging actions. European Journal of Social Psychology , 41 , 86–95.
26. Cuddy AJ, Norton M I, Fiske ST. This old stereotype: The pervasiveness and persistence of the elderly stereotype. Journal of Social Issues , 2005. 61 , 267–285.

6. Ethical considerations in the CARESSES study protocol[6]

Taking into consideration that the CARESSES study will involve older adults, who are a potentially vulnerable population, ethical protection for the participants has been carefully scrutinized. This includes the use of the Ethical Guidelines of Alzheimer Europe concerning the use of Assistive Technologies that has shaped our assessment and management of the key ethical issues inherent to this study.

More specifically, in identifying the most relevant concepts from the Guidelines of Alzheimer Europe that could be applied to the CARESSES study, an approach that draws on qualitative thematic analysis was utilized . Based on this analysis, nine broad ethical themes were identified that outline the key ethical issues that may occur during the experimental studies with older adults utilizing Socially Assistive Robots. These themes are as follows: Attachment, authentic interaction and reciprocity; Autonomy; Beneficence, quality of life and well-being; Culturally-determined values and preferences; Dignity and personhood; Informed consent and shared decision-making; Preventing harm; Privacy, and Stigma. To address each of these issues, a number of thoroughly considered measures where developed, which are in turn are described below under the umbrella of the identified themes.

6.1. Attachment, authentic interaction and reciprocity.

The CARESSES robots are developed in a way to replicate human-like qualities or behaviours. Additionally, these robot's behaviours will be exhibited following a culturally-competent approach (in the experimental group), which means that the robot may emulate empathy, display caring behaviours, which can potentially raise some ethical issues and especially of concern with older people whose ability to interact with fellow humans may be failing. The robots will also provide a number of various entertainment and assistive functionalities that may make participants get used to them and become overly attached to them.

Therefore, after the study period ends, it is reasonable to expect that participants may feel disappointed, saddened and even distressed from no longer having access to the robot (and/or the attention given to them by the researchers). To help prevent and/or alleviate such feelings, after a participant's involvement with the study ends, an attachment reduction procedure will be commenced.

This procedure, which will be offered to all participants, will include providing a personalized, picture journal that chronicling their time and experience with the robot. The journal will contain photos embedded within a simple short story adapted for each participant. Participants will also be offered a DVD which contains video-recordings of their time with the robot during the testing period (if participants consent to be recorded during the experimental trials at the recruitment stage). Both of these should help the participants to remember their experiences and provide opportunity to reminisce about them, including with their family and friends. These measures will also be considered as non-monetary incentives for their participation in the study and a way to thank them for their participation in the study.

In addition, the research team will telephone the participant after one week and after 3 weeks of the end of their participation for a catch-up, social chat. If during this conversation the researcher feels that the person remains upset and/or distressed, he/she will bring this to the attention of their formal carers. If

[6] This is the original draft of this Section and has not been updated.

appropriate, and in consultation with the formal carers, volunteers from a relevant local organization will be asked to pay a few visits to the participant.

6.1.1. Substitution for social contact

Another ethical issue that may arise due to anticipated possibility of the robot to recreate authentic interaction and reciprocity is the concern that the robot might be perceived by the participants and their carers as a substitute for forms of social contact that the participant may have otherwise engaged in, including regular social interactions and planned activities. However, in the context of the current study, the use of robots is considered as a net gain in social contacts; the robot will not be intended to substitute social contacts and will instead encourage increased social engagement and more meaningful social experiences. This may be in the form of recommendations made during conversation or assisting the resident to communicate with others, including formal and informal carers, through text messaging and/or Skype audio/video calling.

Residents will also be explained, during training and within their guidebook, that they should not feel obliged to remain with the robot if they prefer to go elsewhere or engage in any other social activities. This includes cases where visitors enter the testing environment; while we will encourage visitors not to interfere with the testing, if the resident prefers he/she should feel free to interact with their visitors in any time he/she wants. The resident can also choose to put the robot into sleep mode if he/she wishes during these cases (or any other time).

6.2 Autonomy

One of the main purposes of the CARESSES intervention is to offer assistance for particular tasks on behalf of the participant. However, it is ethically important to ensure that the intervention does not reduce participants' feelings of autonomy as this could have an adverse impact upon their physical and mental well-being. To address this, the CARESSES robot will only offer assistance for tasks if the participants requests such assistance. This helps to ensure that the robot does not intervene and provide support for a task that the participant would rather have conducted him/herself. Another key approach to maintaining autonomy is to make it clear to participants that they should feel free to accept or reject the robot's assistance as they wish, and should not ever feel obliged to use the robot, follow any suggestions it provides, or offers of assistance, if they would rather not. This includes leaving the robot and engaging in other activities as they wish. This will be made clear on the participant information form, during training, and within the guidebook that they will receive during the testing period.

Additionally, the robot may be used as a memory aid to enable older adults to carry out tasks which would otherwise be difficult or impossible to accomplish on their own due to difficulties remembering what to do, which items are needed for the task, or in which order to carry out each stage of the task. This functionality is also expected to enhance participants' autonomy and dignity and prior to setting any reminders the robot will always confirm with the participant if he/she is happy to be reminded of any event / tasks; the participants will also be able to disable this function any time they want.

Autonomy can also be described through the following sub-themes of independence, proportionality, balancing autonomy and safety, which are outlined in detail below.

6.2.1 Independence

Although older adults may not have some capabilities to complete various every-day tasks by themselves, they still wish not to have to rely on other people and to remain independent. Considering that the robot cannot give physical aid to participants, it will provide other types of assistance which are expected to support and maintain the independence of older adults through the suggestions, cues, reminders and encouragement they provide to take care of tasks on their own, care for themselves and manage their life.

6.2.2 Proportionality

The principle of proportionality outlines the importance of developing interventions with SARs restricted to what is really needed for a selected sample. Providing more assistance than is actually needed may result in the premature loss of capacities in older adults which may foster a new form of dependency, namely on the robot. Additionally, formal carers may also over-rely upon the robot for caring duties, which can potentially cause harm. If formal carers do not carry out their regular caring duties because they perceive the robot to be conducting these for them, then the resident may be put at risk.

In order to eliminate these risks, all care home staff will be given a presentation prior to the commencement of testing as outlined in section 4.2.1. A key part of this presentation is the request that staff must continue providing their care as usual and not rely on the robot to perform any of their usual activities. This includes drop-ins and visits; it is important that a carer does not feel they need to drop-in and check a resident if they are aware that the robot is with the resident. This presentation will also be used to highlight the study commitment to working around carers' duties and schedules, so that the study procedures do not interfere with their regular activities. This includes scheduling testing times that, as much as reasonably possible, do not clash with planned activities that require the resident's presence. This presentation will also be e-mailed to all staff members, and copies of leaflets that explain these and other points will be made available in staff office areas.

To prevent the participants from relying on the robot for caring activities, it will be clearly highlighted during the training session and within the guidebook that participants should not rely upon the robot for any caring duty that staff would ordinarily have been expected to perform. In addition, to protect participants' autonomy, they will be encouraged (in training and within the guidebook) to take actions or conduct activities that they perceive to be achievable and wish to perform themselves, without feeling obliged to request the robot's assistance. For example, if a resident would prefer to leave their room and walk to find a carer, they should feel free to do so as opposed to feeling obliged to request that the robot contacts a carer on their behalf.

6.2.3 Balancing autonomy and safety

Many of the ethical dilemmas that arise in elderly care revolve around how risk should be managed to ensure safety while respecting older persons' autonomy. Although the robot is expected to provide participants with a number of independence-enhancing solutions, such as reminders and suggestions, we cannot predict at this stage how participants may perceive these solutions, and whether these will not interfere with their autonomous decision-making. One way of dealing with this issue and to balance

respect for older adults' autonomy with using the robot to mitigate risks while ensuring their safety is to ask for the older person's consent to such a use in a personalized, shared decision-making approach. For instance, the robot will offer participants the option to set up a range of reminders that can be activated, and choose different quantitative and qualitative features for each type of reminder (e.g., frequency and intensity). The robot may also provide suggestions regarding various aspects of participants' everyday life, however, if the latter expresses a negative reaction to it, the robot will not repeat a suggestion again. Additionally, during the training session and within the guidebook, participants will be instructed how to deactivate suggestions or any other functions robot has that are perceived as interfering or unnecessary.

Although the robot's software will be pre-tested multiple times prior to experiments, both the robot's designers and manufacturers cannot guarantee that no system failures will occur during the experiments. In particular, these failures could potentially endanger participants' safety when it comes to health-related reminders and suggestions. For this reason, to eliminate this risk, we will request that residents and carers do not set (or rely) medication or treatment reminders. This will also be stated in the guidebook. Further, considering that the robot will provide various suggestions regarding healthy behaviors, it will be highlighted to participants during the training session that they are free to follow or unfollow these suggestions.

It can also be expected that participants may perceive the robot as an extension of the researcher or technician, believing that the research team remotely controls each of the robot's actions, which can potentially make them follow the robot's suggestions even if they do not wish to do so. Given this, it will be highlighted to the participants during the training sessions that the robot should be perceived as an autonomous agent that is not remotely controlled by the research team and any suggestions it provides should be followed only out of participants' will.

A key approach to ensure the safety of the participants during the testing periods is to conduct live video and audio surveillance. This will involve a technician and/or researcher monitoring the video, audio and robot software during each experiment just outside the participant's bedroom where the experiment is taking place. The robot's on-board camera will be utilized for the video monitoring, whereas for audio monitoring an external microphone will be installed in a position safely away from the participant.

If during monitoring, the researcher or technician becomes concerned, he/she can request to intervene prior to any call for help/assistance, or in cases of significant concern or emergencies, will immediately intervene without requesting. The researcher or technician will monitor not only the technical and software issues but also watch for any calls for assistance by the participant. Further, if a technical problem occurs during testing, it may be useful for a technician to be able to retrospectively review and assess exactly what occurred in order to help prevent the same issue occurring again in future experiments.

Participants will be also repeatedly reassured that the researcher and technician will always be nearby to provide any help and assistance whenever called for, and that a technician may request to intervene if they feel necessary prior to any call for help by the participant. Participants will be informed during training that they can switch off the robot (or put it into sleep mode) for any reason including if they feel unsafe or concerned.

6.3 Beneficence, quality of life and well-being

It is hypothesized that both robots will provide assistance in a way that can be considered as beneficial for older adults, and help them to further their important and legitimate interest, which is expected to improve participants' quality of life and subjective well-being.

The utilization of the CARESSES control robot in control group 1 may potentially be considered as less beneficial in comparison to the CARESSES robot as the latter is expected to provide assistance in a more culturally competent way. However, it remains reasonably unlikely that the participants allocated to control group 1 will experience any negative outcomes. This is because it will be able to provide the same suite of functionalities that will be provided by the CARESSES robot, only in a different manner that we hypothesize to be less culturally appropriate (although this purely theoretical and we do not know if the will be perceived less well and as less culturally competent than the CARESSES robot). Thus, we expect participants to positively evaluate both robots, particularly in week 2 when personalization shall occur, only that we expect the CARESSES robot to be particularly well received. We also expect participants in both the experimental and control group 1 to produce at least as good as health-related outcomes as the participants in control group 2 (care as usual).

6.4 Culturally determined values and preferences

As illustrated by Hofstede's cultural dimensions model (2011) and by Papadopoulos and others' work on transcultural nursing and cultural competence (2006), different cultures prioritize or place greater emphasis on different values. The Ethical Guidelines of Alzheimer Europe also recognize the importance of understanding culturally determined priorities and preferences by suggesting that the use of the robot should respect and correspond with the cultural traditions of the person.

The CARESSESS robot is entirely programmed to provide assistance based on concepts of cultural competence, therefore all of the expected scenarios of interaction between the participant and robot are underpinned by these models. It would be misleading to single out specific tasks as being more culture-oriented than others. However, cultural knowledge, awareness and sensitivity also determine quantitative and qualitative features of the robot's behaviours in all testing scenarios. Although the CARESSES control robot will be less likely to demonstrate cultural competence than the CARESSES robot (given it will be using a smaller, more generic cultural knowledge database), in week 2 we expect this robot to increase its ability to interact in a culturally competent manner.

6.5 Dignity and personhood

Dignity refers to the inherent value or worth of all human beings, regardless of their condition, and is related to notions of self-respect, integrity, autonomy and inclusion. Personhood is a complex and widely debated concept that is frequently taken to encompass capacities or attributes such as human nature, agency, and the possession of rights and duties.

In the scenarios of interaction with participants, all the robot tasks associated with actions such as reminding, chit-chatting, suggesting or even encouraging, are meant to promote autonomy and independence, as discussed above. However, it is possible that the intervention may serve as unwanted

reminders of diminished competencies and independence. Like in the case of autonomy and user safety, personalized, shared decision-making will be used to avoid such undesirable consequences of interactions with the robot. This includes the robot's interactions primarily as a response to a request made by the older adult. Through maximising the likelihood that the interactions are initially triggered and requested by the older adult, as opposed to the robot, concerns about diminished dignity and undesirable reminders about lack of competence and independence are minimised. In addition, the robot will express politeness, praise and respect during its interactions which we anticipate will contribute to enhancing the older person's feelings of dignity and self-worth.

6.6 Privacy

One of the key study's commitments is to maintain participants' privacy where possible. Although a number of measures will be followed that are outlined in section 3, it is reasonably likely that other care home residents, staff and visitors will become aware of who is participating in the study testing procedures. To address this, it will be made explicitly clear in the information forms (and during all recruitment interactions) that this is the case, and that if they express informed consent to participate then they accept that the privacy of their participation within the testing procedures may not be fully protected from care home staff, residents and visitors.

As it has been described in section 8.1.2.3, the testing sessions will be monitored through the robot's on-board camera (located within the robot's eyes) and an additional separate microphone, which can be potentially perceived as invasion of privacy. Surveillance is a safety requirement (as has been expressed by our external ethics advisors) and therefore cannot be removed if participants do not wish to be monitored. This will be made clear in the participant information document, consent form and verbally during all recruitment and technical set-up interactions. The benefits and importance of surveillance will also be highlighted during these interactions, as will if and when the monitoring footage will be used by the research team (e.g. to retrospectively review a technical issue that may have emerged, and to produce a DVD for them to keep as a memory of their time with the robot should they wish this), that the footage will not be shared outside of the team, securely and confidentially stored, and will be permanently discarded after the end of the study. Of course, if the participant changes their mind during the two weeks they can drop-out of the study, if they wish.

It is also possible that the robot's programmed reactions towards the behavior and movement of the participant may affect their sense of privacy in that they may feel that they are not alone (which can also be positive) or that they are being watched.

Concerns over privacy may also increase when the participant is getting dressed, is using the robot for video-calls with family or friends, has visitors, or is engaged in personal activities such as meditation or prayer. To manage this, the participant will be informed during their training session (and stated within the guidebook) that the participant can simply ask the robot to provide them with some privacy (which will result in the robot turning around, facing away from the participant and covering its eyes), or to go into 'sleep mode' which may be particularly useful if they have a visitor, or to become silent during prayer. It will also be made clear to participants that the robot will not follow them to bathrooms.

The use of Skype video-calls may be perceived by the participants as an invasion of their privacy. However, to eliminate this issue, they will be clearly informed that video calls will not be recorded and

therefore no information will be stored. Residents will also have the option of being able to send photographs or videos to friends and family through Telegram, Line or emails. These documents are not stored or collected by the research team but rather privately saved on each resident's personal accounts and held by each of these application's servers, as would normally be the case.

6.7 Informed consent

The key principle in obtaining consent is that it is given voluntary and freely, without any form of pressure or coercing. However, due to the nature of the study, it can be expected that some of the residents may feel under pressure to participate in the study. To address this issue, it will be highlighted to residents that they do not have to participate in the study if they do not want to and, if they provide their consent, they can withdraw at any point during the study without giving a reason. In addition, information sheets will describe in detail what will happen during the study in order to mitigate any risks associated with frustration due to unpredictable events that might occur during the experimental trials with the robot. For these purposes, the following two versions of the participant information sheets and informed consent forms will be used (see Appendices B, C and D):

1. Version 1 will be provided to older adult participants.
2. Version 2 will be provided to the informal carers nominated by the participants in the experimental and control group 1.
3. Version 3 will be provided to the informal carers nominated by the participants in the control group 2.

The process of seeking informed consent will comply with guidelines of Alzheimer Europe and EU legislation (General Data Protection Regulation [EU] 2016/679; GDPR).

Taking into consideration the specifics of conducting research using a sample composed of care home residents, the following approaches will be employed during the recruitment and consent process to ensure it is clearly and fully understood by prospective participants:

- **Establishing trust and rapport.** Prior to commencing the recruitment and consent procedures, the researcher will be trained to establish a contact with the potential participants by initiating and maintaining neutral conversations not related to the study. This step will also enable the researcher to confirm that the potential participants meet the eligibility criteria.
- **Clear and concise structure of the information sheets and informed consents.** The information sheets and informed consents will be constructed in a way to present information clearly and concisely. They will be written in clear, simple language that prospective participants can easily and fully understand.
- **Allocating a sufficient amount of time for the procedure of seeking consent.** The researcher will spend as much time as it will be required explaining the details of participation in the study.
- **Revisiting consent.** Not just during the recruiting procedure but also during the further stages of the study, specifically during the baseline data collection and testing stages, the researcher will readdress consent every time they engage with participants by using repeated conversations with the participants to secure they are happy to participate in the study and data collection.
- **Provide residents with the information sheets and cards.** To ensure that older adults can recall the details of study and their consent to participate in it, they will be provided with a copy of

information sheet describing the study in full detail. Additionally, throughout the study, the participants will be provided with a card detailing the date, time and length of the next visit with a photograph of the researcher and their name.

- **Provide residents with a manual on how to use the robot.** During the experimental trials, the participants will be provided with a guide-book that describes all of the functions that robot can perform in a very easy way to eliminate any frustration that may occur due to forgetting how to use the robot while enhancing participants' autonomy.

To ensure that participant information sheets and informed consents provide sufficient level of detail that is easily perceived and understood by older adults, as well as all of the documents and approaches previously described are useful, a pre-trial pilot will be run to evaluate the success of all this documentation and to refine it if required.

6.8 Preventing harm

It is unlikely that any direct physical harm can come about from the robot mainly due to the robot's particular design. For example, the robot has no sharp edges, there are soft parts of the cover, and the centre of mass is at the base to keep the robot from falling over. If pushed back, the robot has a built in self-correcting mechanism that detects this and automatically restores its balance. The motors are also just powerful enough to move the joints but not so strong as to hurt someone through an accidental blow. The robot is also equipped with bumpers. At the mechanical and hardware level, it uses software control to check the behaviour of each joint and detect whether an external force is applied on the arm. Additionally, the functioning of the software will be monitored by the research team throughout the experiments.

While the robot's functionalities are considered to be of low risk of causing distress to participants, if distress is suspected or observed, the researcher will take measures to address and manage this as part of the distress protocol (described in section 8.6) in order to alleviate distress and prevent any further harm(s) from emerging.

In terms of the data collection methods used in the study, the following measures will be taken to minimize the likelihood of harm:

- Most of the scales that will be used in the study are validated, reliable, and proven to be acceptable within the older adult population and care home settings. It is therefore unlikely that their application would be unsafe or result in harm.
- Measures and data collection procedures will be subject to thorough scrutiny from the University of Bedfordshire's Research Ethics Committee. All useful critical feedback received from this exercise will be considered and used.
- The study researchers will all have appropriate qualifications to interact with older adults predominantly in psychology. They will also have training, supervision and expertise in employing all data collection procedures and tools in a sensitive, appropriate manner. This includes the researchers being transparent about their role boundaries.
- The study researchers will also be provided with ethical decision-making guidelines that will enable them to be coherent and consistent in addressing various issues that may occur during the experimental trials.

- Researchers will employ a conservative and cautious approach during the observation of participants' potential manifestation of distress. This means that where researchers have any suspicion of distress or harm being manifested, the researcher will take planned measures accordingly to prevent further harm from occurring, such as inviting the participants to discuss any issues which concern them or making them feel anxious or vulnerable. Compassionate listening, assessment, problem identification, its verification and action taking such as the provision of information and re-assurance may help to alleviate their feelings of vulnerability.

6.9 Stigma

Stigma and self-stigma are linked with a variety of deleterious consequences for the stigmatised older adults. Stigma can be defined as a social process whereby an old adult experiences exclusion or rejection owing to negative social judgement associated with a feature related to a health problem or a health condition. Stigmatisation with regard to socially assistive robots may be caused by inadvertent "labelling" of the person using the robot as this may contribute towards stigmatization or lead to self-stigmatization including feelings of shame, humiliation, social withdrawal and low self-esteem. In the CARESSES study, we cannot rule out the possibility that relying on a robot for assistance, entertainment, and, to some extent, companionship, may result in negative judgements about users or by users about themselves. However, interactions with the robot may also elicit positive responses, and be viewed as a valuable means of engaging in novel activities, providing older people with opportunities for social interaction, and helping to improve their quality of life.

At all times, all individuals that we come into contact with during the study procedures will be treated with dignity and respect, and all necessary measures will be taken to avoid the stigmatization (including self-stigma) of certain groups (e.g., frail older adults) when undertaking and presenting the research. This will involve approaching all participants with discretion, ensuring their anonymity, and treating their experiences and contributions equally and with full respect. As part of the researchers' supervision and training, the research team will be made aware of the stigma associated with older adults and carers. This is important as increasing knowledge and understanding of how and why older adults might be stigmatized (and why they might self-stigmatize) will help protect against researchers thinking and acting in a stigmatizing manner.

6.10 Data protection

Data collection, usage, storage, protection and security will comply with national laws and GDPR [EU] 2016/679, and particularly with the following data subject rights identified in the GDPR: i) the right of access; ii) the right to be informed; and iii) the right to erasure.

Different kinds of data will be collected, processed, stored and released at different stages of the CARESSES trials and project.

- During the screening process: only information that the staff can use to safely identify residents will be communicated between the care home staff and the research team. All screening data will be discarded after the screening stages are complete.

- During recruitment, we will not record study names on the informed consent documents; all details regarding who has been recruited to the study will be stored securely by the research team and not shared elsewhere.

- During the testing procedures, the robot will process visual, auditory and sensory data to function as planned. All of these data will be automatically discarded at run-time. The only exception to this is the collection of speech recognition data that the robot logs with each participant, which will be securely stored for the duration of the study and then for at least five years, to be used for future studies. All identifiers will be permanently removed from any data that is to be shared with other researchers or publicly released, so that it will be no longer possible to link the data to the data subject using reasonable means.

- Testing procedures will be remotely monitored for safety reasons. Prospective participants who do not wish to be monitored will not be able to participate. The video data obtained during the remote monitoring procedures will be securely stored for the duration of the study and then for at least five years, to be used for future studies. All identifiers will be permanently removed from any data that is to be shared with other researchers or publicly released, so that it will be no longer possible to link the data to the data subject using reasonable means.

  While every effort will be made not to collect data from non-participants, such as audio or video data related to visitors or staff members who enter a bedroom during testing, this may not always be possible. Such data, however, will not be analyzed for study purposes. All identifiers related to non-participants will be permanently removed from any data that is to be shared with other researchers or publicly released, so that it will be no longer possible to link the data to such individuals using reasonable means.

- After the testing procedures, a range of quantitative and qualitative data will be collected. These data are necessary for the evaluation of our research questions and study objectives. All collected data will be securely stored on a password encrypted cloud service and no hard copies will be retained. None of these data will be shared with any individuals outside of the research team during the study. All identifiers will be permanently removed from any data that is to be shared with other researchers or publicly released, so that it will be no longer possible to link the data to the data subject using reasonable means.

- During our dissemination activities, including journal articles, conferences and presentations, no identifiable information about trial participants shall be reported. The exception to this will be the personal information of participants who may agree (and provide specific consent) to being interviewed about the project or to having excerpts of videos of their interactions with the robots being made public. Should those videos include images of non-participants, specific consent will be sought from them prior to public release.

6.11 Subject withdrawal

6.11.1 Reasons for withdrawal

As stated earlier, participants may withdraw from the study at any point and for any reason. A researcher will record the reason(s) for withdrawal if the participants are happy to provide the reason(s).

Further, there may be cause for the researcher to make a decision to withdraw a participant from the study and follow-up procedures. This includes if the participant:

- Has been feeling unwell for some period of time and their physical health has been drastically worsening.
- No longer has the cognitive or mental ability to participate in the study and their cognitive abilities have been dramatically declining.
- Experiences a serious or intolerable adverse event.
- Has started to express aggression and / or violence towards themselves, the robot and / or the researcher.
- Becomes too distressed and frustrated with the experimental study or for any other unrelated reasons.
- Is in the violation of the protocol.
- Has to be referred to the hospital or changes the care home.

6.12 Adverse events

If adverse events occur during any point of the study, this information will be reported to the care home staff and addressed in accordance with the Advinia Safeguarding of Vulnerable Adults (SOVA) and "Whistle-Blowing" policies (see Appendix J). If the researcher witnesses bad practice or a serious incident, they will make a note and report it to carers and relatives of the participant. The following information will be outlined:

- Times and dates of specific incidents or when evidence of bad practice was detected.
- Names of the carers or other care home staff who were on duty.
- A brief description of an incident outlining what happened.
- Names of other staff / witnesses who were nearby.
- The nature of any injuries, thefts or losses.
- The actions that are taken by the researcher and response received when the incident was reported.

If the researcher is concerned the issue has not been addressed, it will be raised with the carers' manager. If the researcher continues to have concerns, then a senior member of Advinia will be contacted to report this incident.

In case of adverse events, there are no guarantees of a completely confidential management of the incident, but at all times the views and wishes of the participant at risk will be respected. The requirement for confidentiality will be balanced with the consideration that in order to protect older adult who has experience an adverse event, the information may be shared with the members of staff that will help to resolve the situation.

6.13 Incidental findings

Incidental findings (IF) are generally defined as observations concerning an individual research participant that have potential health or reproductive importance and are discovered in the course of conducting research but are beyond or unrelated to the aims of the study. According to qualitative and quantitative investigations of researchers' and clinicians' views, the main rationale for returning individual research results, including IFs, is to offer information that will be clinically useful. At the same time, the possibility that returning IFs may harm research participants rather than provide benefits must be taken into serious consideration.

CARESSES is a medium risk project in terms of IFs, as interacting with the robot will be a novel, unusual activity for the older participants, which could potentially uncover issues that would not emerge otherwise. The study researchers will need to balance their obligation to protect the research participant's confidentiality with their limited obligation to protect the participant's health-related interests.

The possibility of IFs will be sensitively raised during the informed consent process and researchers will ask participants for permission to discuss anything of potential health importance that they should observe during the experiments (e.g., a pronounced tremor, a peculiar gait, a significant change in behavior) with the participants' carers or other care home staff, as appropriate.

Incidental findings will not however be raised during the informed consent process when recruiting informal carers. This is because the likelihood of any IFs being observed in these participants is very low.

6.14 Management of distress

Psychological distress is a general term used to describe unpleasant feelings or emotions that may severely impact older adults' level of functioning and well-being. In other words, it is psychological discomfort that interferes with their activities of daily living. It has various manifestations, which may be exhibited in the following symptoms:

Behavioral symptoms

- Avoiding objects or situations for no reason.
- An urge to perform certain rituals in a bid to relieve negative feelings / emotions.
- Lack of assertiveness / absent-minded (i.e. avoiding eye contact).
- Difficulties in making decisions.
- Being startled easily.
- Tearfulness or crying for no reason.
- Agitation, including pacing, wringing hands, pulling hair or other fidgeting.
- Wandering.
- Difficulty managing basic activities of daily living.
- Not engaging in activities (related or unrelated to the robot) that they normally enjoyed.

Emotional symptoms

- Verbal reports of or giving the appearance of feeling sad, worried, angry or lonely.
- Irritability or angry outbursts.
- Suspiciousness and/or fearfulness (particularly when facing certain objects or events).
- Reports little or no contact with friends or family.
- Excessively "high" mood.
- Rapid changes of mood.
- Worries about physical symptoms (such as fearing there is an undiagnosed medical problem).
- Dread (such as fearing that something bad is going to happen).

Physical symptoms

- Negligence of personal hygiene or / and unkempt appearance.
- Rapid changes in weight.
- Complaints on physical pain.
- Feeling detached from physical self or surroundings.
- Having trouble sleeping.
- Sweating and / or excessive trembling.
- Dizziness, feeling lightheaded or faint.

Cognitive symptoms

- Repeatedly asking the same questions.
- Not remembering to do routine things.
- Disoriented presentation, such as not knowing what day or time it is.
- Believing that the present is actually the past.
- Not remembering familiar people or objects.
- Sees, hears or smells things that others do not.

Our approach to preventing and managing distress includes several strategies that were previously identified in the literature as effective in addressing and managing distress (e.g., Griffin, Resick, Waldrop & Mechanic, 2003; Hawton, Houston, Malberg & Simkin, 2003):

1. The researchers, who will be collecting quantitative and qualitative and will be supporting the experimental sessions, will be trained to be able to observe and manage psychological distress.
2. The researcher and technician will consistently monitor participant's emotional reactions.
3. The participants will be informed during the recruitment procedure and training session what to anticipate during their interactions with the robot, including that they should expect the robot will try to talk to them about different topics of conversation, some of which may be upsetting to them. The participants will be suggested that if they feel uneasy they can always talk to the researchers or the care homes members of staff.
4. If it is observed that participants are struggling, frustrated or becoming tired during the testing sessions, then a researcher will remind the participant that they can put the robot on sleep mode, ignore the robot and/or carry on with their day as they usually would.
5. After each testing sessions and instance of data collection, the participants will be debriefed and asked about how they feel.

It should be anticipated that participants may experience anxiety, depression, embarrassment, or acute stress reactions due to utilization of the robot, to the fact that they are participating in the experiment, or

for any other reason unrelated to the experiment. Although it is not anticipated that both robots can directly cause any distress as they are not programmed to initiate any overly-personal or sensitive topics, the possibility of it triggering distress cannot be ruled out (e.g., when the robot asks about the participant's family members and that appears to be a sensitive topic). It can also be presumed that older adults may experience technology anxiety and frustration due to not remembering or understanding how to use the robot. Taking into account that distress in participants is considered as a risk, the research team will be prepared to identify and minimize potential risks and ensure that the benefits of the study outweigh these risks. Therefore, if at some point during the study the research team become concerned about emotional distress emerging among a participant, either through observation or by being informed by the participant or others, they will follow a distress protocol to help eliminate this risk (see Table 7). This protocol has been constructed based on the distress protocols adopted by Drauker and Martsolf (2008), Haigh and Witham (2015), and the Guidelines on Caring for Someone with Dementia developed by Alzheimer Society Europe (2018).

Table 1: Distress Management Protocol

	Stage	Method(s) of management
1.	**Detection of distress**	❖ Participants or a member of staff or an informal carer(s) indicate that the participant is experiencing emotional distress. ❖ The researcher identifies that the participant exhibits behaviours suggestive that they are in distress.
2.	**Distress source identification**	❖ The session / data collection will be stopped as soon as distress is expressed or detected. ❖ The researcher will provide immediate support and assess mental status of the participant: • They will be asked to share what thoughts they are having. • They will be asked how they are feeling. • It will be queried with them whether they feel they are able to carry on the session. • They will be asked whether they feel safe being with the robot. ❖ If and when appropriate, the researcher will query what is making them upset. ❖ Throughout this stage the researcher will adopt a respectful, accepting, compassionate and understanding approach.
3.	**Mitigation of the distress source**	❖ If the participant signals that the reason they are experiencing distress is because of the robot, then the following measures will be taken: • The session will be paused, the source of the distress will be established and then an assessment will be made with the team as to whether this can be resolved prior to continuing and ahead of the next testing period.

		• If this is not possible or takes too long, then this will be explained to the participant and they will be asked if they would prefer to withdraw from the study. • If the participant does not wish to withdraw, the researcher will guide the participant towards minimising the likelihood of triggering whatever resulted in the participant experiencing distress. • If the participant is happy to continue, the session will be un-paused and continued. • If the participant is not happy to continue (but does not want to withdraw from the study), the session will be rescheduled. • The researcher will debrief with the participant to talk through and offer support after the session has ended.
4.	**Management of reoccurring distress**	❖ If the participant is distressed for a reason unrelated to the study, the following measures will be taken: • If the participant is happy to discuss the reason why they are distressed, then the researcher will pause the session and devote some time to talk through it. However, depending on the nature of issue, the participant will be advised to talk through this issue with the care home staff or, if they provide their consent, the research team will discuss this issue with the care home staff. ❖ If the session continues and the participant continues to experience distress, the researcher will intervene by pausing the session and recommend that the testing period ends immediately. ❖ If, after the session ends, the participant continues to experience distress, or if the participant continues to experience distress during the following testing session, the researcher will cease testing and withdraw the participant from the study (with their consent). ❖ If the participant withdraws from the study due to distress, a researcher will offer debrief and talk, so to provide the participant with psychological support.
5.	**Action if participant is withdrawn from the study due to distress**	❖ If the researcher feels it appropriate, the participant may be encouraged to ask the care home staff to contact their GP. If the participant would rather the researcher speak to the nursing staff on their behalf, the researcher will act accordingly. ❖ The researcher will recommend to the care home staff that they talk through and offer support to the participant about the issue and keep check of their well-being perhaps more than usual.
6.	**Follow up**	❖ If the participant withdraws from the study, the researcher will make a phone call to the participant one week after their study participation ended to check in on them and, if

appropriate, offer guidance on how to access psychological support.

6.15 Addressing cognitive decline in older adults

It can be anticipated that during the study the participants may, simply due to the ageing process, experience a decline in their cognitive functioning, the symptoms of which can be exhibited in a similar way to distress. According to Alzheimer Europe and Alzheimer's Association USA, the most common signs of dementia that may be observed are as follows:

Cognitive signs

- Memory loss.
- Difficulties in communication or in finding words.
- Inability to complete complex tasks (e.g., to calculate).
- Difficulty with planning and organizing.
- Disorientation.
- Poor or decreased reasoning and judgement.
- Inability to perform everyday tasks.
- Hallucinations and delusions.

Emotional signs

- Lack of enthusiasm, apathy and withdrawal.
- Drastic personality changes, such as suspiciousness, fearfulness and paranoia.
- Mood swings and senile syndrome.

It should be noted, however, that these signs may be related to other health problems, and therefore, if they continue to be observed during the sessions, the researcher will report their observations to the care home staff (if it has not been previously noticed by them already). Taking into consideration that cognitive decline may be episodic (e.g., happen only one time) or permanent (e.g., permanent memory loss), the following measures will be taken by the researcher:

- If any signs of dementia are observed during the session, depending on their perceived severity, the researcher will either pause the session (e.g., to enable the participant to feel better and observe whether after some rest they may be able to continue with the experiment) or will terminate it at that point and reschedule it for another day.
- If the researcher observes any changes during the session, they will ask the participant about how they are feeling and try to make them feel at ease and reassure that any difficulties they are experiencing are not their fault.
- Although memory loss, decreased reasoning and judgement are common symptoms that may occur among frail older adults, the researcher will not terminate the session because of these

symptoms, and provide opportunity for the participant to interact with the robot with additional assistance (e.g., reminding them of the functions, offer them help).

If the signs of cognitive decline persistently continue to occur and it becomes clear that the participants condition is deteriorating, the researcher will report this to the care home staff to provide care to the participant and the withdrawal procedure will be followed.

7. Ethics training[7]

Researchers within CARESSES have different backgrounds and had different roles within the end-user experiments. However, it was essential that all researchers involved with research participants, to greater or lesser extent, receive appropriate ethics training, in order to behave in an ethically appropriate manner as they conducted the experiments, be able to identify any ethical issue that should arise and understand when they needed to seek support from their Team Leader and the Internal Ethics Board (see below).

7.1 Training completed before the pre-trial feasibility pilot

7.1.1 Mandatory training on care standards for all researchers involved in the pilot

Prior to the pre-trial feasibility pilot, all researchers involved (from BEDS, ADVIN, UNIGE and ORU), both those expected to carry out technical work and those directly working with the research participant, completed a section of the mandatory training that care-workers in the UK are required to take in order to obtain the Care Certificate.

The Care Certificate is an agreed set of standards established by the Care Quality Commission, the independent regulator of health and adult social care in England whose mission is to make sure that health and social care services in England provide clients with safe, effective, compassionate and high-quality care. The Care Certificate sets out the knowledge, skills and behaviors expected of specific job roles in the health and social care sectors. It is made up of the 15 minimum standards that should be covered by individuals who are "new to care". These standards derive from a human rights approach to care regulation. They reflect a commitment to promote equality, diversity and human rights, and are grounded in the human rights principles of fairness, respect, equality, dignity, autonomy, right to life and rights of staff.

CARESSES researchers received instruction on the topics outlined below along with the associated learning outcomes.

a. Safeguarding adults at risk (level 2)

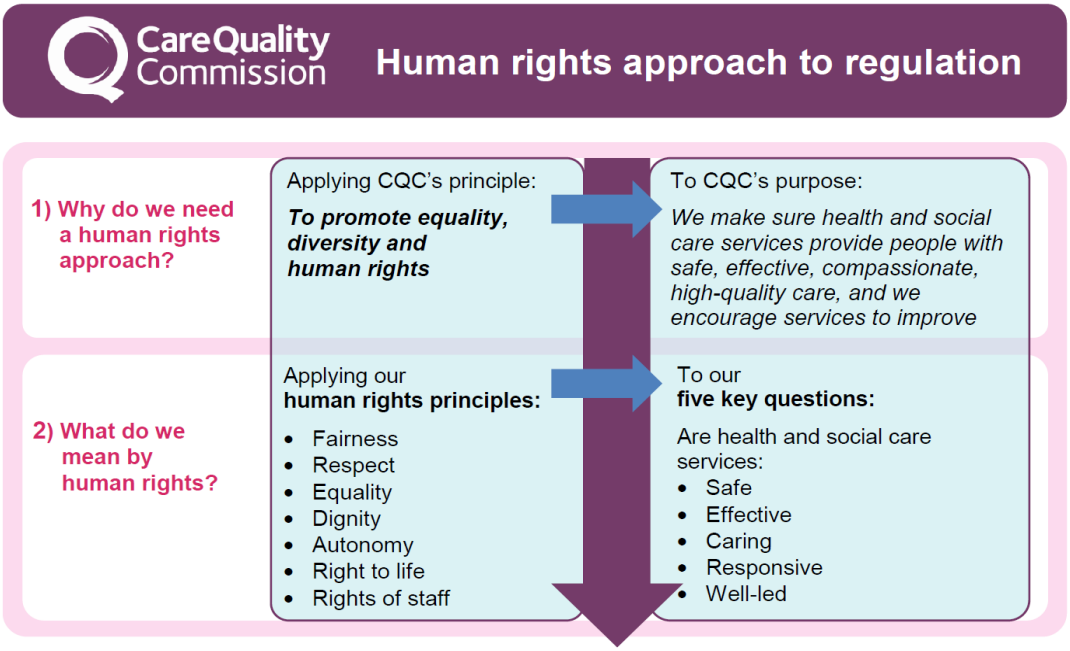
- Understand the concept of vulnerability
- Develop a better understanding of who is an adult at risk, who the potential abusers are and the actions that care workers must take where abuse is disclosed
- Increase knowledge of identifying and reporting actual or potential abuse and initiating formal investigation procedures
- Recognize the differing types of abuse and their related signs
- Be able to spot the range of people who may be potential abusers in given contexts

[7] This Section has been updated to include details of the ethics training provided to all researchers involved in the end-user experiments and findings related to their views of that training.

- Be familiar with pertinent legislation and regulatory frameworks in order to protect adults at risk
- Know the importance of reporting and whistle-blowing on actual or potential abuse.

b. Recognizing and appreciating the differences among people in care homes

- Know the responsibilities of employees and employers
- Know what beliefs, values, and attitudes are
- Understand what is meant by Equality, Diversity, Inclusion and Discrimination.



- Know the legislation in place covering Equality and Diversity
- Know each of the Protected characteristics.
- Understand the different forms of discrimination, and how they can occur.

Figure 1. Care Quality Commission Human Rights approach to regulation (https://www.cqc.org.uk/sites/default/files/20150416_our_human_rights_approach.pdf)

c. Respecting dignity and maintaining privacy while promoting choice and independence

- Understand what Privacy and Dignity mean in a healthcare setting
- Be aware of the importance of person-centered dignity
- Recognize the importance of maintaining dignity for someone living with dementia
- Understand the importance of a resident's personal space
- Know how to gain trust and confidence by maintaining confidentiality
- Know a care worker's responsibilities regarding safeguarding, and when it is appropriate to break confidence
- Understand the factors that shape personal choices

- Know how to help residents maintain independence and make informed choices
- Know how to risk assess a person's choices
- Understand the importance of residents being active participants in their care
- Know the key principles of self-care

d. Complying with protocol regarding Health and Safety

- Understand what Health and Safety means.
- Know a care worker's responsibilities and those of employers.
- Understand the relevant Health and Safety legislations.
- Be aware of tasks that will require special training.
- Be aware of common accidents and sudden illnesses.
- Know what to do in an emergency.
- Understand how to create a Risk Assessment.
- Understand methods of working safely with hazardous materials
- Know methods and procedures to prevent fires.
- Recognize the symptoms, causes and treatment for work-related stress.

Training was delivered through the https://yourhippo.com/e-learning-courses/ platform; it lasted approximately 2.5 hours and included quizzes both during each module and at the end.

7.1.2 Ethics training for researchers at BEDS and ADVIN

BEDS and ADVIN researchers directly working with the research participant in the pilot, who were then also directly involved with research participants in the trials, were given additional ethics training.

This training was offered during a dedicated 4-hour meeting that was organized by the Internal Ethics Advisor and the researchers at BEDS. The meeting was held in London on November 8th, 2018.

Because these researchers contributed to drafting the CARESSES study protocol and participated to the development of the measures aimed at ensuring ethical protection for the participants and the researchers (described under the "Ethics" section of the study protocol, i.e. Section 6 above), this training was of a more advanced level.

It aimed to help researchers

- develop their ethical sensitivity, i.e. their ability to identify an ethical issue and understand the consequences of decisions made to solve or manage that issue
- improve their practical skills in ethical reasoning and deliberation
- apply a framework for ethical decision-making.

These goals were achieved by relying on two components: the Brown University Framework for Making Ethical Decisions and the discussion of cases.

a) The Brown University Framework for Making Ethical Decisions

Prior to the meeting in London the researchers were asked to familiarize themselves with a document entitled "Making Choices: a Framework for Making Ethical Decisions", published by Brown University in 2011[8]. The document is designed as an introduction to making ethical decisions. It acknowledges the complexity of ethical decision-making and recognizes that decisions about "right" and "wrong" may be related to individual context. It first provides a summary of major sources for ethical thinking, and then presents the framework for decision-making shown in Table 1 below.

b) Case-based training

The teaching approach chosen to improve researchers' ability to identify ethical issues, enhance their ethical reasoning skills and give them opportunities to apply the Framework for making ethical decisions, was case-based discussion, or more specifically, Case-Based Learning (CBL).

CBL is an approach to learning and instruction that uses factual or fictional scenarios exemplifying the issues at hand and is regarded as a highly valuable and effective method across multiple disciplines (Kim et al. 2006). CBL has been described to have positive effects on learners' decision-making, critical thinking, and deductive and inductive reasoning skills (Menzel 2009). CBL has thus been extensively applied in ethics education, as it has proven to have clear benefits for individuals facing high-risk problem scenarios (Kolodner 1997). Indeed, CBL promotes knowledge transfer in ethics because it provides learners with opportunities to work through real ethical issues which may be relevant to their work. Cases are especially beneficial for the ethics domain because they mirror the complexities and ambiguities inherent in actual ethical dilemmas, simulating a realistic context in which to learn relevant ethical decision-making skills (Menzel, 2009). Open-ended, ill-defined cases have been found to be particularly helpful for providing trainees with practice navigating and interpreting equivocal situations while still providing enough context to discuss typically abstract ethical principles (Plinio et al., 2010).

We thus developed three ethically problematic cases for discussion that reflect situations that could emerge during the CARESSES trials. In accordance with recommendations in the literature, the effort was made to ensure that the cases developed for discussion would be relevant, realistic and descriptive (Falkenberg and Woiceshyn 2008). Cases were also kept brief and simple, avoiding irrelevant material, which has been found to hinder knowledge acquisition (Johnson et al., 2012). Additionally, we attempted to infuse the cases with emotion (Thiel et al., 2013), omitted certain key information to emphasize the importance of gathering all the relevant facts, and avoided pointing to clear-cut, obvious solutions (Falkenberg & Woiceshyn, 2007).

[8] "Making Choices: a Framework for Making Ethical Decisions" (available at https://www.brown.edu/academics/science-and-technology-studies/framework-making-ethical-decisions) is the product of dialogue and debate in the seminar Making Choices: Ethical Decisions at the Frontier of Global Science held at Brown University in the spring semester 2011. It relies on the Ethical Framework developed at the Markkula Center for Applied Ethics at Santa Clara University (http://www.scu.edu/ethics/practicing/decision/) and the Ethical Framework developed by the Center for Ethical Deliberation at the University of Northern Colorado (http://mcb.unco.edu/ced/frameworks/stages-virtue.cfm).

Step 1- Recognizing an Ethical Issue	One of the most important things to do at the beginning of ethical deliberation is to locate, to the extent possible, the specifically ethical aspects of the issue at hand. Sometimes what appears to be an ethical dispute is really a dispute about facts or concepts. For example, some Utilitarians might argue that the death penalty is ethical because it deters crime and thus produces the greatest amount of good with the least harm. Other Utilitarians, however, might argue that the death penalty does not deter crime, and thus produces more harm than good. The argument here is over which facts argue for the morality of a particular action, not simply over the morality of particular principles. All Utilitarians would abide by the principle of producing the most good with the least harm.
Step 2 – Considering the parties involved	Another important aspect to reflect upon are the various individuals and groups who may be affected by your decision. Consider who might be harmed or who might benefit.
Step 3 – Gather all the relevant information	Before taking action, it is a good idea to make sure that you have gathered all of the pertinent information, and that all potential sources of information have been consulted.
Step 4 – Formulate Actions and Consider Alternatives	Evaluate your decision-making options by asking the following questions: - Which action will produce the most good and do the least harm? (The Utilitarian Approach) - Which action respects the rights of all who have a stake in the decision? (The Rights Approach) - Which action treats people equally or proportionately? (The Justice Approach) - Which action serves the community as a whole, not just some members? (The Common Good Approach) - Which action leads me to act as the sort of person I should be? (The Virtue Approach)
Step 5 – Make a Decision and Consider It	After examining all of the potential actions, which best addresses the situation? How do I feel about my choice?
Step 6 – Act	Many ethical situations are uncomfortable because we can never have all of the information. Even so, we must often take action.
Step 7 – Reflect on the Outcome	What were the results of my decision? What were the intended and unintended consequences? Would I change anything now that I have seen the consequences?

Table 1. Brown University Framework for Making Ethical Decisions

The cases (see Table 2 below) incorporate ethical themes such as:

- informed consent
- data protection/confidentiality
- role boundaries
- protection of research participant from harm
- duties of researchers towards research participants
- health-related/incidental findings

Discussion of the cases revealed that the researchers at BEDS and ADVIN have a well-developed ethical sensitivity. Working through the cases by following the steps in the Brown Framework for Ethical Decision-Making outlined above, they were able to identify all of the main ethical issues in the cases presented, to imagine different ways of handling them and the consequences of the associated decisions, including straightforward solutions as well as more nuanced approaches, and to reflect on potential outcomes. They also showed an ability to transfer the knowledge generated through these cases to other potential ethically problematic situations that could emerge during the experiments.

Case 1	Mrs. Yamada has agreed to participate in your project. During the consent process, you explain to Mrs. Yamada that the data obtained during the remote monitoring procedures will not be recorded unless she wishes to retain it and in this case the data will be securely stored for the duration of the study and then for at least five years to be used for future studies. Mrs. Yamada agrees to having the data retained. You then ask her whether she would like to have a DVD containing some video-recordings to remember the experience. Mrs. Yamada is excited about having a DVD about her experience with the robot. She looks forward to sharing it with her family. Just a week after the beginning of the experiments, Mrs. Yamada passes away. Her death is totally unexpected and comes as a real shock. A few months later, her nephew Takeshi contacts the research team. Mrs. Yamada had told him about the DVD and he would really like to have it. Takeshi was very close to his aunt and having something special to remember her by would mean a lot to him.
Case 2	Since the project has started, you have become rather friendly with Mark, a 78-year old former civil servant, one of the few men who qualified for the study and accepted to participate. You enjoy Mark's jokes and humorous anecdotes. As for Mark, he thinks the robot is great fun and really helpful, and spending a little time with you between sessions, chatting and exchanging stories, has given him something to look forward to. At the beginning of the second week of the experiments, the principal investigator asks you to move to another care home where the project is being conducted, as certain issues have emerged that need to be taken care of. You go and say goodbye to Mark, but when you tell him another researcher will be replacing you, Mark becomes very upset and says he no longer wants to participate in the project.

Case 3	Jane and her daughter Sara have agreed to participate in the project and are excited about having the opportunity to interact with the robot. During the third week of the experiments, you notice that there has been a sudden decline in Jane's cognitive and mental abilities. She is having trouble understanding what the robot is doing in her room and seems annoyed by its presence. Sara, however, doesn't seem to notice that anything is wrong. You decide to share your concerns with the care-home staff and since they confirm your observations, you conclude that Jane no longer qualifies for the study. This means that Sara will also no longer be participating. You start thinking about how best to go about withdrawing them both from the study.

Table 2. Ethics cases developed for training

7.2 Ethics training for all researchers directly involved in the end-user trials[9]

Prior to the trials, all the researchers who were expected to be directly involved with research participants who had yet to receive ethics training (overall ten researchers from UNIGE, ORU, SBRE, BEDS, MU and, JAIST) were required to participate in a modified version of the ethics training, suitable to being delivered remotely; this included

- studying the Ethics section of the study protocol (i.e. Section 6 above) carefully;
- answering a 22-item online questionnaire to demonstrate knowledge and understanding of the Ethics section of the study protocol, including topics such as:

    - attachment, authentic interaction and reciprocity
    - autonomy
    - proportionality
    - dignity and personhood
    - privacy, anonymity and confidentiality
    - informed consent
    - preventing harm
    - data storage
    - subject withdrawal
    - incidental findings
    - management of distress

[9] This work is described in greater detail in a manuscript entitled "Socially Assistive Robots, Older Adults and Research Ethics: The Case for Case-Based Ethics Training" by Linda Battistuzzi, Chris Papadopoulos, Tetiana Hill, Nina Castro, Barbara Bruno and Antonio Sgorbissa, which has been submitted for publication and is currently undergoing second review.

- participating in video-conferences with the Internal Ethics Board (see paragraph 7.3 below) to discuss the questionnaire, the answers provided and the ethics section of the study protocol more in general. During these video-conferences researchers were also asked to participate in a guided analysis of one of the cases described above. The following ethics training video-conferences were held, each lasting approximately 90 minutes:

  February 20, 2019 (UNIGE + Internal Ethics Advisor)

  February 25, 2019 (ORU + Internal Ethics Board)

  March 1, 2019 (MU + Internal Ethics Advisor)

  March 8, 2019 (ORU, SBRE, BEDS + Internal Ethics Board)

  March 26, 2019 (JAIST, BEDS + Internal Ethics Board)

The discussion included a guided case analysis that was structured around questions relevant to the scenarios described. Trainees were encouraged to analyze the cases and apply relevant knowledge to "solve" the ethical problems, simulating the ethical decision-making process. Specifically, they were asked variations on the following questions, which are based on the Markkula Center Framework for Ethical Decision-Making [10]:

- What is/are the ethical issue/s illustrated in this case?
- What are the facts? Is any important information not available in the case description?
- Who are the stakeholders?
- Which is the course of action that best fits with the recommendations and requirements set out in the "Ethical Considerations" section of the CARESSES study protocol?
- How can that course of action be implemented in practice?
- Could the ethical issue/s presented in the case be prevented? If so, how?

7.2.1 Trainee knowledge of the "Ethical Considerations" document and perceptions about the ethics training

Seven out of ten trainees obtained a perfect 22/22 score on the online quiz on the "Ethical Considerations" document, one made one mistake, one made two and one made three. These results suggest that they had understood the material and had acquired the basic knowledge required.

[10] Velasquez M, Moberg D, Meyer MJ, et al (2015) Markkula Center Framework for Ethical Decision-Making. https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/a-framework-for-ethical-decision-making/. Accessed 24 May 2019

One week after completing the training module, the trainees were asked to respond to an anonymous feedback survey which used a 5-point Likert scale (Figure 2), and 9/10 agreed. The instrument had been previously piloted with a convenience sample of robotics fellows to test for content and clarity.

Responses to the survey items showed that satisfaction was high (M = 4.69; SD = 0.457). Trainees reported that the training had been helpful (3/9) or very helpful (6/9) to achieve learning objectives, and 9/9 expressing agreement or strong agreement with the suggestion that similar training be offered in other projects involving SARs and vulnerable individuals

In their answers to the open-ended questions contained in the survey, 8/9 trainees stated that the ethics cases had been the most useful part of the ethics training. One trainee commented that the cases had given them the chance to "really think about situations that I would not have considered otherwise"; according to another, the case discussions "greatly facilitated moving from abstract concepts to practical situations". When asked about their views on how the training module could be improved, 6/9 trainees stated that increasing the number of cases would be helpful; 3/9 suggested spending more time on discussing individual cases, one of whom also suggested that short vignettes could be usefully included in the "Ethical Considerations" document to illustrate the ethical issues discussed therein.

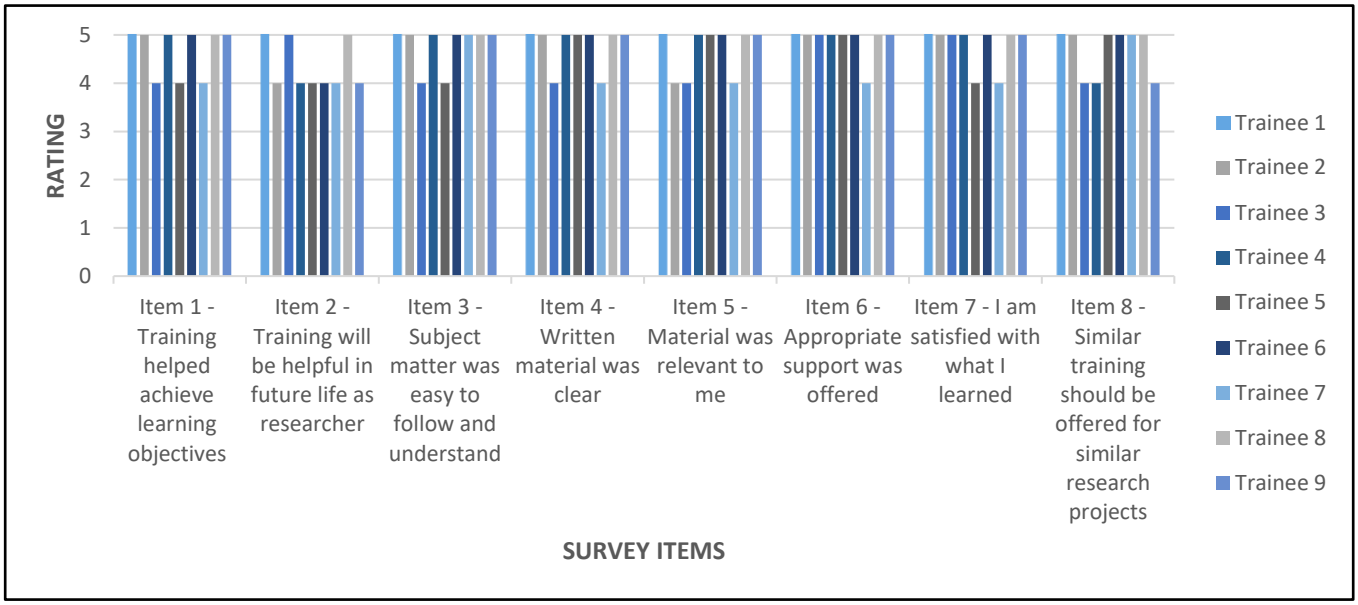


Figure 2. Trainee feedback on the CARESSES ethics training (rating: 1= strongly disagree, 5= strongly agree).

Eight weeks after completing the training, the trainees were asked to participate in another survey. The specific goal of this instrument was to assess the perceived impact of the ethics training. The instrument used a 5-point Likert scale and was piloted as done for the feedback survey.

The first section was designed as a retrospective pre-post survey (Lam & Bengo, 2003). This type of tool is useful to explore the knowledge or attitude that participants in a training program had toward a subject before that program, experience, treatment or intervention, and after. If participants are asked to report how much they know about a specific topic once they have acquired at least some basic knowledge of the topic itself, they are better able to reflect on how much their knowledge or attitude have changed. In addition, there is evidence that when using the traditional pretest-posttest, respondents tend to overestimate their level of knowledge on a particular subject (Pratt, McGuigan, & Katzev, 2000).

Eight out of ten trainees agreed to complete this survey. In the first section of the instrument (Figure 3), they reported positive or very positive perceptions in terms of how successful the training had been in achieving each of its learning objectives (improving levels of awareness, basic understanding and ability to identify ethical issues). A paired t-test of differences between pre and post-training measures was conducted and rendered the following: Pair 1: t (7) = -9.029, p= <.001; Pair 2: t (7) = -6.148, p= <.001; Pair 3 t (7) = -14.346, p= <.001, showing very significant results.

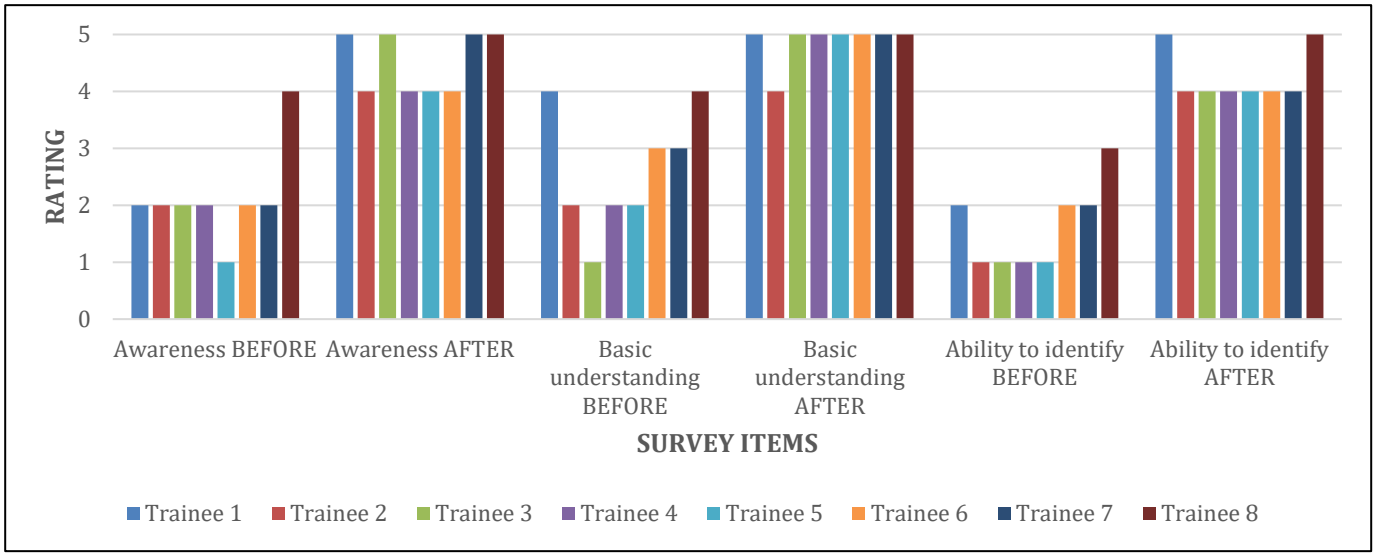


Figure 3. Perceived improvements afforded by the CARESSES ethics training (rating: 1= very little, 5= very much)

In the second section of the instrument (Figure 4), questions focusing on how useful familiarizing with the Ethical Considerations document and discussing the ethical cases had been in helping trainees achieve those goals revealed that both were perceived as helpful or very helpful (M = 4.73, SD = 0.446).

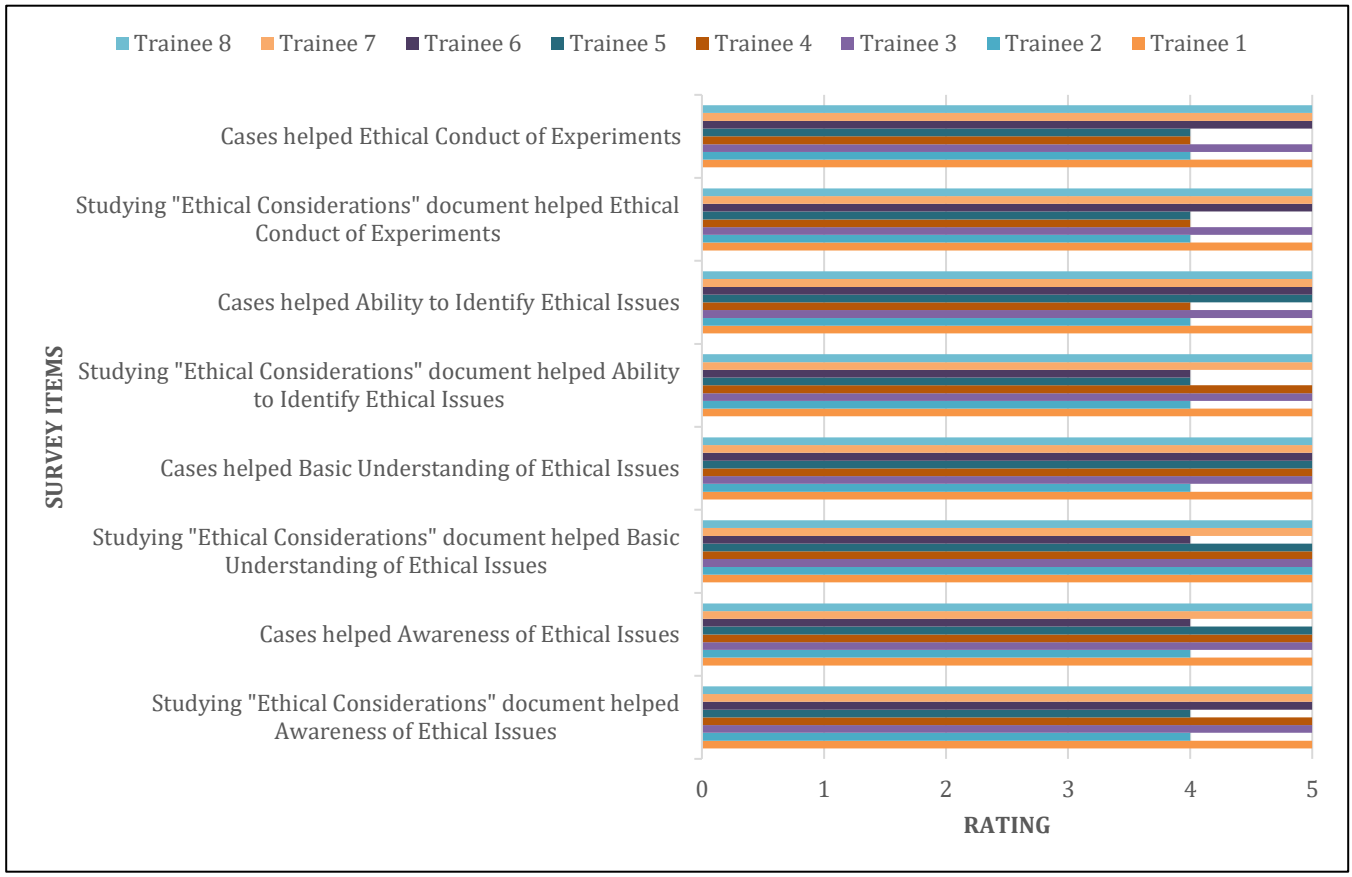


Figure 4. Perceived improvements afforded by the CARESSES ethics training tools (rating: 1= strongly disagree, 5= strongly agree)

Developed as a project-tailored educational intervention and delivered remotely, this part of the CARESSES ethics training was successful in increasing trainees' knowledge of the principles and concepts that provide the ethical grounding for the study protocol. Furthermore, our findings on the trainees' perception of how effective the training was, are encouraging.

Now that the experimental phase of the project is completed, we are conducting a further study that explores the range of the researchers' attitudes and views of the research ethics training, and their experience and views of the ethical concerns that emerged during the CARESSES end-user experiments (see Section 9 below).

7.3 Ethics Support in UK and in JPN

In order to provide ethics support to the researchers directly involved in the end-user experiments both in the UK and in JPN, an Internal Ethics Board was established with the following members:

Hiroko Kamide (NAGOYA, JPN Ethics Supervisor)

Chris Papadopoulos (BEDS, UK Ethics Supervisor)

Linda Battistuzzi (UNIGE, CARESSES Internal Ethics Advisor)

The Internal Ethics Board had two main roles:

a) to assess whether researchers have developed an appropriate understanding of the main ethical considerations associated with the end-user experiments and of the measures developed in CARESSES to manage them , as discussed in the study protocol and evaluated by means of the ethics questionnaire;

b) to provide ethics support to researchers should any ethical issues arise during the end-user experiments.

7.4 Resolution of ethical issues in the end-user experiments

a) Researchers who were unsure how to behave in a particular situation and thought they may be faced with an ethical issue were required to seek the support of their Team Leader, and of the Internal Ethics Board if appropriate, before taking any action. In some situations, it was expected that it would be appropriate or necessary to involve care home staff.

b) The researcher and the Team Leader, as well as the Internal Ethics Board if appropriate, were required then discuss the situation at the earliest time possible.

c) The Team Leader and the Internal Ethics Board (if involved) would identify and suggest an appropriate course of action.

d) Problems deemed especially complex or difficult would be referred to the local Research Ethics Committee.

e) Final responsibility for ethical decisions would rest with team leaders at BEDS, ADVINIA and JAIST.

7.5 References

1. Falkenberg, L., & Woiceshyn, J. (2007). Enhancing business ethics: Using cases to teach moral reasoning. Journal of Business Ethics,79, 213–217.
2. Falkenberg, L., & Woiceshyn, J. (2008). Enhancing business ethics: Using cases to teach moral reasoning. Journal of Business Ethics, *79*(3), 213–217.
3. Johnson, J. F., Thiel, E. C., Bagdasarov, Z.,Connelly, S., Harkrider, L., Devenport, L. D., & Mumford, M. D. (2012). Case-based ethics education: How cause complexity and outcome valence affect ethicality. Journal of Empirical Research on Human Research Ethics; JERHRE, 7(3), 63–77.
4. Kim, S., Phillips WR, Pinsky L, Brock D, Phillips K, Keary J. (2006). A conceptual framework for developing teaching cases: A review and synthesis of the literature across disciplines. Med Educ 40:867–876.
5. Kolodner, J. L. (1997). Educational implications of analogy: A view from case-based reasoning. The American Psychologist, 52(1), 57–66.
6. Lam, T.C. M. & Bengo, P. (2003). A comparison of three retrospective self-reporting methods of measuring change in instructional practice. American Journal of Evaluation, 24, 65-80.
7. Menzel, D. C. (2009). Teaching and learning ethical reasoning with cases. Public Integrity, 11(3), 239–250.
8. Plinio, A. J., Young, J.M. and Lavery, L.M. (2010), The State of Ethics in Our Society: A Clear Call for Action, International Journal of Disclosure and Governance, 7, pp.172–197.
9. Pratt, C. C., McGuigan, W. M., Katzev, A. R. (2000). Measuring program outcomes: Using retrospective pretest methodology. American Journal of Evaluation. 21(3).
10. Thiel, C. E., Connelly, S., Harkrider, L., Devenport, L. D., Bagdasarov, Z., Johnson, J. F., & Mumford, M. D. (2013). Case-based knowledge and ethics education: Improving learning and transfer through emotionally rich cases. Science and Engineering Ethics, 19(1), 265–286.

8. Lessons learned[11]

The future of SARs in the care of older persons has been the focus of a great deal of regulatory and ethical reflection, much of which has centered on concerns relating to a loss of human contact, diminished autonomy and privacy, loss of dignity (Fosch-Villaronga & Albo-Canals, 2019; Sharkey, 2015; Sharkey & Sharkey, 2012; van Wynsberghe, 2013, 2016), and to negative impacts on professional caregiving and standards of care (Vallor, 2011). Ethical concerns that arise within research settings, when SARs are trialed with older persons, do not seem to have garnered as much attention despite, predictably, much of this research being conducted in care home facilities with vulnerable individuals and interaction with novel technologies possibly raising specific concerns (McGuire, 2009; Ramos, L & van den Hoven, 2015; Sedenberg, Chuang, & Mulligan, 2016). Acquiring ethical lessons from the CARESSES trials therefore seems an especially worthwhile endeavour.

8.1 Ethically relevant events in the CARESSES trials: A mixed methods exploration

To acquire insights about any ethically relevant or problematic events that may have occurred during the trials, understand whether the ethical guidelines outlined by Alzheimer Europe and included in the CARESSES trial protocol adequately covered such events or whether any weaknesses or limitations emerged, and further explore researchers' views regarding the ethics training they completed, we decided to conduct an exploratory mixed-methods study. We hope that our findings will allow for a deeper understanding of ethical issues associated with testing socially assistive robots in care homes with older adults and help ethical guidance for future studies involving socially assistive robots in similar contexts.

As the CARESSES trials were completed at the end of October 2019 and due to the time required for ethics review, study recruitment commenced in January 2020. Definitive study findings will therefore be available only after the end of the CARESSES project, but we expect that they will be disseminated via publication and presentation at conferences. Below we provide an overview of the study, as well as some preliminary results.

8.2 Objectives

The study will attempt:

1. To establish whether any ethically salient or problematic events occurred involving trial participants, CARESSES researchers, care-home staff, visitors and other individuals who were involved with or came into contact with the CARESSES trials, and if so, what ethical considerations were linked to such events.
2. To understand what kind of remedial action was taken for such events, if any was appropriate and necessary.
3. To gather researchers' views regarding what caused such events.

[11] This Section was added with the final update to this Deliverable.

4. To gather researchers' views regarding whether and how such events could be prevented, if appropriate and necessary.
5. To gather researchers' views regarding whether and how the ethical guidelines included in the CARESSES trial protocol adequately covered any such events
6. To gather researchers' views regarding how useful the CARESSES ethics training was, both in light of such events and more in general.

8.3 Experimental design

The study is structured into two sub-studies, Study 1 and Study 2.

Study 1 will achieve objectives 1-4 above by employing an *ad-hoc* form focusing on ethically salient events *involving study participants*. The form mainly utilizes a deductive approach to the identification of the associated ethical considerations as it lists the ethical themes previously highlighted through qualitative thematic analysis of the Ethical Guidelines of Alzheimer Europe (e.g. informed consent, autonomy, stigma, privacy) as described in (Battistuzzi, Sgorbissa, Papadopoulos, Papadopoulos, & Koulouglioti, 2019).

Study 2 will achieve objectives 1-6 above by using a qualitative, inductive approach (focus-group discussion, FGD) to elicit researchers' views, perceptions and experiences regarding any ethically salient events *involving care-home staff, visitors, etc*. The events described by participants in the form in Study 1 above will also be brought to direct discussion for further exploration, as will participants' views of how useful the ethical guidelines included in the CARESSES trial protocol and the project-specific ethics training provided were in enabling them to identify and handle such events appropriately and effectively. An inductive approach is appropriate as it will allow us to investigate issues that have not yet been researched extensively (Denzin & Lincoln, 2000).

8.4 Experimental protocol

Study 1) CARESSES researchers directly involved in the trials who agree to participate in the study were sent the *ad-hoc* form. They were asked to complete it and return it within 7 days.

Study 2) Once the questionnaires were returned, an FGD, via videoconference, involving all consenting CARESSES researchers directly involved in the trials, was organized and will be held shortly after the release of this Deliverable. The FGD will utilize a predetermined semi-structured interview approach and will be facilitated by the Internal Ethics Advisor. In order to generate the maximum amount of discussion and opinions within the given time period (roughly 90 minutes), the facilitator will ask broad questions to elicit responses and encourage discussion among the participants.
The FGD will include three types of questions:

- Probe questions: these will present the discussion topic to the participants and help make them feel comfortable sharing their opinion with the group
- Follow-up questions: these will go further in depth into the discussion topic and the participants' opinions

- Exit questions: these will ensure that nothing important has been missed
-

To avoid that poorly worded, biased or awkward questions derail the FGD and spoil the quality of the data, the following guidelines will be followed:

- The number of questions will be limited (max 15). This will prevent the participants from getting confused or worn out by a long discussion.
- The questions will be kept simple and short.
- Special efforts will be made to ensure that questions are worded clearly as to avoid confusion or digression into their semantics.
- Questions about sensitive issues or topics will be asked carefully to prevent any discomfort.
- Questions will be open-ended to avoid simple "Yes" or "No" answers. Using words like "Why" and "How" will help elicit better responses from participants.

8.4.1 Recruitment

The only participant inclusion criterion was to be a CARESSES researcher who had been directly involved in the practical implementation of the CARESSES trials in the UK and in Japan.

CARESSES researchers directly involved in the trials were contacted via individual email to inquire about their interest in participating in this study. In the email invitation, prospective participants were informed that participation was voluntary, that refusal to participate would involve no penalty or loss of benefits to which they were otherwise entitled, and that they could discontinue participation at any time.

Those who expressed interest were sent the information sheet and consent form and asked to return scanned, signed copies within three days. Once signed copies of information sheets and consent forms had been received, the form was circulated to all participants.

8.4.2 Data collection and management

Personal data collected was the following: name, years as a researcher, scientific background, role within CARESSES, prior experience with human subject research, prior training in research ethics/human subjects protection (excluding CARESSES training); audio-recording of the entire FGD.

Responses to the form are stored in a secure, GDPR-compliant Google Drive folder and will be retained for five years after the end of the study, along with audio-recorded files and transcripts of the FGD. The latter will also be stored in an ad-hoc folder in the database of the Dedoose web-based application (www.dedoose.com). Both folders will be only accessible to researchers involved in the study. Results of the study will only be published in aggregate/anonymous form and the identities of any individuals mentioned in the questionnaire, during the FGD or contributing to the FGD will be pseudonymized. All data will be securely erased from all the data repositories five years after the end of the study.

8.4.3 Ethical considerations

The study received ethics approval from the Research Ethics Committee of the Dept of Informatics, Bioengineering, Robotics and Systems Engineering of the University of Genoa on December 11, 2019.

The main ethical considerations within this study have to do with the sensitivity of the topics covered by the questionnaire and discussed during the FGD. To encourage participation in the study while ensuring that participants

- would be comfortable and at ease sharing their views of ethically complex situations and discussing sensitive topics

- did not feel pressured to contribute to the study

all CARESSES researchers directly involved in the trials were invited to act both as researchers and as participants in this study (Corti K, Reddy G, Choi E, 2015), in an exercise that we hope will also encourage reflexivity and critical thinking (Denzin & Lincoln, 2000). In addition, prospective participants were asked to join both Study 1 and Study 2 but, considering possible language barriers that may interfere with the FGD, the option was also offered to only participate in Study 1.

Informed consent

Prospective participants were informed about:

- the purposes of the research
- the expected duration of their participation
- the procedures to be followed
- any foreseeable risks or discomforts
- any expected benefits to them or to others
- the kind of data that will be collected and how long it will be stored
- how confidentiality of data will be managed
- insurance coverage
- whom to contact with questions about the research or research participants' rights

Furthermore, during the informed consent process it was made clear that participation is voluntary, that refusal to participate would involve no penalty or loss of benefits to which the participant would otherwise be entitled, and that the participant could discontinue participation at any time.

It was also be mentioned that study findings could potentially be used to develop commercially available ethics training packages in the future.

Data management and confidentiality

The study commits to the maintenance of participants' confidentiality throughout all procedures. Within-study confidentiality, however, will not be ensured, as all participants will know each other, would have worked together to some extent during the CARESSES trials and will jointly participate in the focus

group discussion. In addition, individuals who opted to join as "participant-researcher" will be involved in data analysis, interpretation and dissemination.

Data collection, usage, storage, protection and security will comply with national laws and the EU's General Data Protection Regulation (GDPR) including the commitment to participants' right of access, right to be informed, and right to data erasure. Data collection will further comply with the principle of data minimization i.e. the collection of personal information from study participants will be limited to what is directly relevant and necessary to accomplish the specific goals of the study. No data related to a third party will be stored.

8.4.4 Data analysis

Given its duration and requirements we do not expect significant drop-out from the study, which will, in any event, be reported. No mitigation measure is planned.

In Study 1, participant responses to the form will be coded in relation to the aims (Events, Actions, Causal Attribution and Preventive Strategy) and a descriptive analysis will be performed.

In Study 2, transcripts of the FGD will be analyzed using an inductive theoretical framework (Heath & Cowley, 2004) and data will be managed using the Dedoose web-based application. Two researchers will independently code all the transcripts, following a multi-step process involving open coding, axial coding and selective coding. First the researchers will label meaningful aspects of text, starting with a line-by-line analysis (open coding). Second, open codes will be categorized, with similar codes grouped, refined and combined into larger themes (axial coding). Through multiple, iterative discussion, researchers will then reflect on potential relationships between the codes and will continue to develop an in-depth understanding of themes. Coding disagreements will be resolved through discussion and further review of the transcripts until full consensus is reached. Third, the transcripts will be reviewed again to ensure the identified themes and concepts reflect the data and that important ideas of views have not been missed or over-represented. Selective coding will involve the integration and refinement of these concepts (Corbin & Strauss, 2008).

8.5 Preliminary results (Study 1)

Of the seven CARESSES researchers who met the criteria to participate, four agreed initially, and three consented to participate in the study as "participant-researchers". Two of these are psychologists and one is a robotics researcher, and all were involved in the CARESSES experiments that were conducted in the UK.

Participant features are summarized in Table 1 below.

	Participant-researcher 1 (PR1)	**Participant-researcher 2 (PR2)**	**Participant-researcher 3 (PR3)**
Age	30	30	30
Scientific background	Clinical Psychology	Health psychology	Robotics engineering
Role in CARESSES	Psychologist researcher	Psychologist researcher	Robotics researcher
Years in research	7	>1	3
Prior experience with human subject research	Research involving infants, children and parents, as well as young adults	No	No
Prior training in research ethics/human subject protection (excluding CARESSES training)	Training provided by several academic institutions involving human subject research; completion of university degrees covering modules on research ethics and subject protection.	Training in safeguarding procedures provided by an adult care provider.	No

Table 1. Participant characteristics

The reasons why four CARESSES researchers declined were not investigated. However, a likely explanation is that the research contracts of three of these four researchers expired while the study was awaiting ethics review or soon after.

Overall, participants reported 17 separate ethical events involving study participants, which are illustrated in Table 2 below.

Event # and (Participant ID)	Event in brief	Remedial action taken	Likely cause	Preventative measures taken/that could be taken	Reporting researcher
Event # 1 (R1)	Participant began to cry when robot started playing a song.	Interrupted song, asked resident how they were and if they wanted to interrupt session. Participant asked to resume session and seemed to be alright.	Not investigated. Song may have triggered sad thoughts.	None; such events cannot be prevented and feeling emotional does not necessarily represent distress.	PR1
Event # 2 **(R1)**	At the end of the session, participant was asked how they felt during the session and they mentioned feeling "lonely" as "it was weird having a robot looking at me". Participant suggested that the research team instead of the robot could be brought to their room for company.	Researcher suggested to participant that they might wait and see if they felt differently at following session. Participant agreed. Before following session, participant's wellbeing and intention to continue to participate were assessed. Participant was reminded of robot's communicative functions (chit-chat, sending messages and contacting informal carers). This suggestion was made based on the fact that resident tended to solely make "task execution" requests instead of using functionalities promoting social interaction.	Resident´s feelings of loneliness may be attributed to continued presence of researchers during training sessions which was followed by gradual distancing to promote independence and maintain healthy relationship boundaries. Attachment to researchers may have been enhanced by the fact that, prior to participation in CARESSES trials, participant's level of social interaction was close to none.	Paying attention to preventing attachment to specific researcher/s by rotating.	PR1
Event # 3 **(R1)**	Care home staff informed researchers that after their last session with robot participant repeatedly stated that they	Researcher met participant and assessed their wellbeing for any signs of distress or significant sadness. *(No information available to date about how event*	Prior to enrollment in CARESSES trials, participant's social interaction was close to none. Change in routine and increase in social	Assessing participants' mental health at enrollment may allow anticipating similar situations.	PR1

	missed Pepper and asked to see it.	*was managed further, to be explored during Focus Group Discussion)*	interaction may have caused missing robot.		
Event # 4 **(R2)**	Residents' limited ability to speak, read and use the tablet became apparent during early sessions. Resident showed limited capacity to interact independently and became tired very quickly. Researchers became concerned about participant´s capacity and eligibility.	Decision was made to continue with sessions as long as participant's wellbeing was not compromised. To ensure participant's wellbeing, researchers paid special attention to signs of tiredness and, if present, reminded participant that session could be terminated at any time. Researchers also established that participant would need continuous support throughout sessions as they were unable to interact independently.	Participant's ability to verbally communicate and read were not assessed during screening.	Questions regarding prospective participants' ability to communicate verbally and read were included in screening form and considered thereafter as criteria for prioritizing recruitment of most capable residents.	PR1
Event # 5 **(R2)**	Participant interacted independently for 40min, then asked Pepper to go to rest as they were feeling tired and short of breath. After some time, Pepper understood participant's coughing as a call and started interacting. Participant insisted that Pepper should go to rest, but Pepper did not. Participant then fell asleep and Pepper woke them up. Participant started to display signs of distress.	Researchers switched Pepper off remotely. Since participant was asleep and had clearly wanted. Pepper to be in rest mode, system was not re-started, because that would wake participant up.	Issues with speech recognition.	Instruction to remotely switch off Pepper when it understood background noise as a call for interaction and waking up the resident against their express wish was included in interruption protocol.	PR1
Event # 6 **(R3)**	Participant R3 expressed their belief that robots are the reincarnation of human beings. Researcher was concerned that any fault, bug or wrong/bad behavior of the robot could be	Participant did not become upset. No remedial action was taken.	Participants' understanding of robot's behaviors may be linked to their cultural and religious background.	Should robot's behavior somehow clash with participants' personal beliefs, researchers could highlight that what the robot says and does is	PR3

	associated with the reincarnated human being and upset participant.			programmed and caused by "technical reasons" while at the same time respecting participant's beliefs.	
Event # 7 **(R3)**	During the last session of the post-evaluation data collection, participant's cognitive condition declined and researcher became concerned about the accuracy of their responses owing to their memory difficulties.	As there was just one questionnaire to complete, researchers decided not to withdraw participant and use the data collected up to that point.	Fast cognitive decline of the resident.	Data collection should be performed promptly as cognitive decline may occur.	PR1
Event #8 **(R4)**	Participant received training on how to interact with Pepper and was happy to interact independently. However, participant ignored/did not understand most of the interaction´s basic rules and researcher needed to interrupt the session several times to provide assistance. Researchers became increasingly concerned with participant's cognitive capacity (eligibility criteria) and accuracy of the screening procedure.	Screening tools were not able to provide comprehensive picture of prospective participants' ability to understand verbal instructions and to execute them when interacting with Pepper. Participant was not withdrawn based on the following: memory seemed preserved; understanding of the study and capacity to consent seemed satisfactory; participant displayed enthusiasm and satisfaction for taking part, so there were no concerns regarding wellbeing. Researchers also concluded participant needed significant support which should be provided upon request or if participant showed signs of distress.	Screening tools cannot specifically inform about prospective participants' ability to understand and follow the rules of interaction with Pepper.	N/A	PR1
Event # 9 **(R4)**	Participant asked robot questions such as "What did you do in the weekend?", "What did you have for lunch?", suggesting they had personified the robot to a certain extent. Researcher				PR3

	was not sure how they should react to this, whether they should encourage personification or				
Event # 10 **(R7)**	. During the session, participant asked repeatedly to speak about their deceased partner, but Pepper continually changed subject. Participant insisted they wanted to talk about deceased partner. Pepper did not understand, referred to partner as if they were alive, then changed the subject again. Researchers became concerned about the negative emotions this interaction could trigger	Researchers added new keywords for Pepper to be able to discuss this topic during future sessions. The team also improved the system, making it easier for Pepper to understand when a participant mentioned a deceased person and to make appropriate observations and comments. Researchers then made sure participant was not distressed by the event and told them to try again in the next session as Pepper was being improved and should by then be able to talk about their loved one.	Issues with software and speech recognition system.	Improving the software by adding new keywords.	PR1
Event # 11 **(R8)**	During screening, prospective participant´s cognitive capacity concerned researchers as they seemed to be borderline in terms of their eligibility criteria.	Prospective participant was visited on different days by more than one researcher in order to assess their memory and for a second opinion. Because prospective participant passed screening, seemed to remember most information about the study and able to provide informed consent, they were enrolled.	Resident that scored satisfactorily in the screening instruments was showing signs of memory loss, sundowning and confusion.	N/A	PR1
Event # 12 **(R11)**	After the end of the testing sessions, care home staff told researchers that participant was feeling depressed and anxious as they were missing Pepper, feeling lonely and lacking	Research team contacted participant to assess their level of distress and emotional circumstance. *(No information available to date about how event was managed further, to*	PR1) Participant stated they had no social interaction and high expectations for their sessions. During the sessions, participant said they felt disappointed with human relations and how they preferred a reliable relationship with	PR1) Assessing participants' mental health at enrollment may help anticipate similar situations. PR3) Respecting participant dignity may involve	PR1, PR3

	companionship, and not adjusting to routine without Pepper.	*be explored during Focus Group Discussion)*	a machine which is always present. This may explain why participant became excessively attached to the robot. PR3) Participant personified robot	sensitively reminding them that interactions with Pepper are not authentic as Pepper cannot reciprocate	
Event #13 **(R11)**	Participant R11 saw Pepper interacting with the child of a member of care-home staff. During this interaction Pepper was not running the CARESSES system but was operated remotely by researcher purely for entertainment purposes. Participant tried to communicate with Pepper, which could not answer as they expected. Researcher was concerned that witnessing Pepper being operated remotely could cause disappointment and disillusionment.	Interaction between the child and Pepper was quickly terminated.		Care was taken that the robots only be seen by participants during experimental sessions.	PR3
Event # 14 **(R21)**	During a session, participant displayed difficulties and insecurities when interacting with the robot and needed support. Gradually, they started looking tired. At the end, they commented they had a nice session, but it had been "tiring for the brain", so they only wanted to have one other session that week.	Researcher expressed understanding regarding participant's tiredness and how demanding a session could have felt and tried to reassure participant that they did well and that it is normal to feel insecure. Researcher showed empathy, accepted and complied with participant's request, and reminded participant that researchers would continue to be available to offer any support needed, including presence during the entire session if participant preferred. Participant said they	Participant was somewhat dependent in interactions with Pepper as speech recognition was often unable to function owing to their low tone of voice. They also had trouble understanding and remembering how to interact with Pepper. These difficulties likely made the experience challenging, causing the participant to become anxious and tired.	N/A	PR1

		would request the researcher´s presence if needed.			
Event # 15 **(R21)**	At the end of a session, participant asked what the robot does after sessions are over. Researcher replied that after each session Pepper is turned off and stored in a locked closet until the following session. Researcher was concerned that this contradicts sentences Pepper said about itself, describing its own life and activities beyond sessions with participants.	None	During verbal interactions, Pepper occasionally made statements about going outside and doing activities, suggesting it had a life of its own beyond the trials.	Researcher wondered whether participant should be offered a consistent narrative about Pepper or whether this would amount to deliberate deception.	PR3
Event # 16 **(R25)**	Participant seemed to enjoy the sessions but had significant challenges understanding and responding to researcher guidance. Participant appeared to be lucid but could not grasp the concept of certain things such as Pepper's capacity to answer questions, acknowledge instructions while talking or the use of key words such as 'over and out'. This led to a lot of problems with human-robot interaction. Concern was raised to the research lead over the resident's lack of understanding of guidance and cues for Pepper. Participant had problems with hearing, so it was unclear what the reason was – even after adjusting the	None	Difficulty understanding why, despite apparent lucidity and energy, participant was unable to grasp instructions or would quickly forget things and would talk over the researcher complicating guidance.	None	PR2

	volume and speaking louder. It was determined that in light of a previous resident with similar behaviour, participant should not be withdrawn. Participant seemed to enjoy the sessions and it was determined that without more clear evidence of cognitive decline, it would be difficult to differentiate from problems such as bad hearing.				
Event # 17 **(R27)**	Participant told Pepper that most of their family members had passed away and Pepper changed the subject. Participant repeated their statement, but Pepper seemed unable to answer. After some time, Pepper asked participant about their family members, assuming they were alive. Participant appeared to be emotional and, at the end, when questioned about this, they explained they thought Pepper was not learning and understanding, and that hearing Pepper repeating the same painful facts was hard.	Researcher explained to participant that Pepper could be having some issues owing to speech recognition system and reassured them that it was not their fault. Researcher also explained this difficulty would be reported and that perhaps the system could be improved so that Pepper would be able to understand participant's explanation at the first try. Participant seemed satisfied with this solution.	Issues with speech recognition system and with specific keywords.	The software could have been improved in some way to enhance Pepper´s ability to perceive such a sensitive topic and to respond accordingly.	PR1

Table 2. Preliminary results from Study 1 (Ethical Event Forms)

Although the findings above only reflect the researchers' reports and have yet to be analyzed, it appears thus far that the main ethically relevant concerns that emerged during the CARESSES trials were the following:

- Pre-enrollment screening was not always able to accurately determine whether prospective candidates had the cognitive abilities required to participate

- Rapid decline in participants' cognitive abilities could cause concern regarding their continued participation in the trials
- The novelty and interest generated by the robot and the experiments could lead to feelings of loneliness and sadness in participants once sessions ended
- Attachment to researchers could also lead to feelings of loneliness and sadness in participants once sessions ended
- Technical issues with the robot's speech recognition system could potentially cause distress to participants, particularly when the participant was talking about sensitive topics.

There were also concerns regarding participants' beliefs regarding the authenticity of their relationship with the robot and researchers' duty of truth-telling.

These findings will be discussed and further explored during the upcoming Focus Group Discussion, which will also shed light on ethical issues involving visitors, care-home staff and other non-participants.

8.6 References

1. Alzheimer Europe. Our guidelines and position on the ethical use of AT for/by people with dementia. Available at: https://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2010-The-ethical-issues-linked-to-the-use-of-assistive-technology-in-dementia-care/Our-guidelines-and-position-on-the-ethical-use-of-AT-for-by-people-with-dementia. Last visited on: October 4, 2019.

2. Bruno B, Recchiuto CT, Papadopoulos I, Saffiotti A, Koulouglioti C, Menicatti R, Mastrogiovanni F, Zaccaria R, Sgorbissa A. Knowledge Representation for Culturally Competent Personal Robots: Requirements, Design Principles, Implementation, and Assessment. January 2019. International Journal of Social Robotics.

3. Battistuzzi L, Papadopoulos C, Papadopoulos I, Koulouglioti C, Sgorbissa A. Embedding ethics in the design of culturally competent robots. 2018 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS).

4. Battistuzzi L, Papadopoulos C, Hill T, Castro N, Bruno B, Sgorbissa A. Socially Assistive Robots, Older Adults and Research Ethics: The Case for Case-Based Ethics Training. *Submitted*

5. Corbin J & Strauss A. (Eds.) (2008). Basics of qualitative research: Techniques and procedures for developing grounded theory. Thousand Oaks, CA: Sage Publications.

6. Corti K, Reddy G, Choi E, Gillespie A. The researcher as experimental subject: using self-experimentation to access experiences, understand social phenomena, and stimulate reflexivity. Integr Psychol Behav Sci. 2015 Jun;49(2):288-308.

7. Denzin, N. K., & Lincoln, Y. (2000). Handbook of qualitative research. Thousand Oaks: Sage Publications

8. Fosch-Villaronga, E. & Albo-Canals, J. (2019). "I'll take care of you" said the robot. Reflecting upon the legal and ethical aspects of the use and development of social robots for therapy. Paladyn, J. Behav. Robot. 2019; 10:77–93

9. Heath H & Cowley S. (2004). Developing a grounded theory approach: A comparison of Glaser and Strauss. International Journal of Nursing Studies, 41, 141–150.

10. Sharkey A, Sharkey N (2012) Granny and the robots: Ethical issues in robot care for the elderly. Ethics Inf Technol 14:27–40. https://doi.org/10.1007/s10676-010-9234-6

11. Sharkey AJ (2015) Robots and human dignity: A consideration of the effects of robot care on the dignity of older people. Ethics Inf Technol 14:27–40. https://doi.org/10.1007/s10676-014-9338-5

12. Vallor S (2011) Carebots and Caregivers: Sustaining the Ethical Ideal of Care in the Twenty-First Century. Philos Technol 24:251–268. https://doi.org/10.1007/s13347-011-0015-x

13. van Wynsberghe A (2013) Designing Robots for Care: Care Centered Value-Sensitive Design. Sci Eng Ethics 19:407–433. https://doi.org/10.1007/s11948-011-9343-6

14. van Wynsberghe A (2016) Healthcare robots: Ethics, design and implementation., 1st ed. Routledge.

9. How to[12]

The Ethics Requirement document was used to provide ethical guidance throughout the project. In order to be relevant and meaningful, the document required revision and updating as progress was made.

Section 3 provides the basis for much of the information included in the final protocol of the end-user evaluation experiments.

Section 4 sets out a framework for handling incidental findings within CARESSES.

Section 5 describes the analysis and tool we developed to ensure compliance of CARESSES with the Ethical Guidelines of Alzheimer Europe concerning the Use of Assistive Technologies.

Section 6 discusses and describes the measures that were put in place to ensure that the CARESSES end-user experiments would be conducted in an ethically appropriate manner, as detailed in the study protocol and delivered under D6.1

Section 7 describes the ethics training that was developed and delivered to ensure that all CARESSES researchers who were directly involved with research participants had an understanding of the relevant ethical issues.

Section 8 describes the mixed-methods exploration that is being conducted to acquire insights about any ethically relevant or problematic events that may have occurred during the trials, understand whether the ethical guidelines outlined by Alzheimer Europe and included in the CARESSES trial protocol adequately covered such events or whether any weaknesses or limitations emerged, and further explore researchers' views regarding the ethics training they completed.

[12] This Section has been updated.

10. Conclusions[13]

10.1 Compliance with the DoA and corrective actions

The work reported in this document and its attachments fully complies with the plans in the DoA..

10.2 Achievements

Deliverable D10.1 shows how CARESSES has complied with Ethical Requirements. Furthermore, it provides evidence of the effort made to ensure that

- ethics was embedded into the process of technological innovation;
- we were able to engage with ethical questions as they emerged during the design process;
- the CARESSES experimental protocol fully took into consideration the ethical issues potentially associated with the end-user experiments and appropriate measures were developed to manage them
- CARESSES researchers directly involved in the pre-trial and in experiments with end users received appropriate ethics training
- a mechanism for ethics support for both the EU and the JPN arm of the study was in place
- ethically relevant issues that emerged during the trials were handled appropriately
- an ongoing conversation about ethics was established within the consortium.
- we acquire a deeper understanding of ethical issues associated with testing socially assistive robots in care homes with older adults and help ethical guidance for future studies involving socially assistive robots in similar contexts.

[13] This Section has been updated.