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Title:

Socially Assistive Robots, Older Adults and Research Ethics: The Case for Case-Based Ethics Training

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The authors declare that they have no conflict of interest.

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Informed consent was obtained from all individual participants included in the study.

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Abstract:

Most studies on Socially Assistive Robots (SARs) in elder care are conducted in care homes and recruit participants with some degree of cognitive impairment. The ethical dimension in these studies thus requires careful attention, suggesting that the researchers involved should be offered specific research ethics training. To meet this need in CARESSES - an international multidisciplinary project that aims to design and evaluate the first culturally competent SAR for the care of older adults - a Research Ethics Training Module for the project researchers was developed. The training module is largely based on Case-Based Learning (CBL), a widely recognized approach to learning and instruction that is regarded as highly effective across multiple disciplines. In this paper, we argue that research ethics training should be offered to robotics investigators involved in research on SARs in elder care, and we provide an overview of the ethical issues involved in conducting research with SARs and older adults in care homes. Finally, we show how CBL can be used for research ethics training in this context.

Keywords:

Robot Ethics; Socially Assistive Robot; Pepper; Elder Care; Research Ethics; Case-Based Learning; Ethics Training.

Socially Assistive Robots, Older Adults and Research Ethics: The Case for Case-Based Ethics Training

Linda Battistuzzi, Chris Papadopoulos, Tetiana Hill, Nina Castro, Barbara Bruno, Antonio Sgorbissa

I. INTRODUCTION

Ageing populations and shrinking caregiver numbers are one of the main societal challenges worldwide today [1]. The convergence between this challenge and recent advances in robotic technology has determined an increased interest in the possibility of using Socially Assistive Robots (SARs), to support the delivery of safe and efficient care to older persons [2]. Indeed, a recent scoping review designed to establish the clinical usefulness of SARs in elderly care found that, to date, 33 studies have been conducted focusing on the use of SARs with older persons, involving a total of 1574 participants and 11 different types of robots. Most of those studies enrolled participants with declining cognitive and mental abilities living in care homes [3].

Human subjects research involving vulnerable individuals such as persons living in long-term care facilities requires careful attention to its ethical dimension, as it is likely that investigators will encounter a broad array of ethical challenges [4, 5]. These challenges will often be associated with issues of informed consent, confidentiality and participant rights [5]

Research ethics training can help researchers conduct experiments with human subjects in an ethically appropriate manner, as well as improve their ethical sensitivity[1] and their practical skills in ethical reasoning and deliberation. We have therefore developed a Research Ethics Training Module (RETM) for the researchers participating in CARESSES (Culture-Aware Robots and Environmental Sensor Systems for Elderly Support), an international[2] multidisciplinary project that aims to design the first culturally competent SAR for the care of older persons [6]. CARESSES' innovative approach is expected to translate into socially assistive care robots that are sensitive to the culture-specific needs and preferences of older clients, while offering them a safe, reliable and intuitive system, specifically designed to support active and healthy ageing and reduce caregiver burden.[7]

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CARESSES includes an experimental phase in which the SAR, a Pepper robot [8] running an innovative custom-built software developed by the project, is trialed in care homes with residents belonging to different cultures. Informal caregivers are also recruited to establish whether the SAR can relieve caregiver burden. The CARESSES study protocol has been designed by health psychologists with the contribution of the roboticists who developed the CARESSES software, and of an internal ethics advisor. Both the psychologists and the roboticists conduct the trials and come into direct contact with the research participants during the experiments.

The RETM developed for the CARESSES researchers is largely based on case-based learning (CBL), an approach to learning and instruction that relies on scenarios to illustrate teaching points and issues [9]. CBL is acknowledged to have positive effects on learners' decision-making and deductive and inductive reasoning skills [6,7]. Because it has clear benefits for individuals grappling with complex situations, CBL is widely used in ethics education [11]. The core of the CARESSES RETM are thus three ethical cases that were developed for this project and exemplify situations that could realistically emerge during the project experiments.

This paper's purpose is three-fold: first, to emphasize the importance of providing research ethics instruction to robotics researchers involved in human subjects research, and specifically in research on SARs in elder care; second, to present the main ethical issues involved in conducting research in care homes and research with older adults and SARs; third, to show how case-based learning can be used for research ethics training in this context.

The article is organized as follows: Section II clarifies the need for research ethics training for investigators involved in research with human subjects; Section III provides an overview of the main ethical issues in research with older participants; Section IV specifically addresses ethical concerns that emerge when conducting research with SARs in long-term care facilities; Section V provides background knowledge on case-based learning and case design; Section VI outlines the ethics training approach designed for the CARESSES project along with the ethics cases developed; furthermore, it summarizes the feedback CARESSES researchers provided on the RETM and its perceived impact. We close with conclusions in Section VII.

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[1] Ethical sensitivity refers to the ability to identify an ethical issue and understand the consequences of decisions made to solve or manage that issue.

[2] The project involves researchers from Italy, the UK, France, Sweden and Japan, caressesrobot.org

II. THE NEED FOR RESEARCH ETHICS TRAINING

Research Ethics is often defined as the ethics of planning, conduct and reporting of research [12]. It aims at protecting human research participants, ensuring that research is carried out in ways that are beneficial to individuals, groups, communities or society as a whole, and at examining specific research activities and projects for their ethical soundness.

According to the Declaration of Helsinki, the recognized cornerstone of research ethics, investigators who conduct research with human subjects are responsible for the protection of participants' rights, safety, and welfare [13]. In many countries these protections are ensured through independent review of research projects by Research Ethics Committees (REC) or Independent Research Boards (IRB), consisting of both professionals and lay people. In addition, in some countries, and depending on the type of research funding organization, the protection of human research participants is enhanced by investigator training in the principles and regulations pertaining to the ethical conduct of human subjects research [9, 10].

There are at least three good reasons why training in human subject protections and ethical research conduct is often a requirement for investigators involved in human subject research. First, it enables researchers to understand the fundamental principles of research ethics, so they can then design, plan and conduct research in ways that position the protection of participants' rights, safety and welfare at its core. Second, RECs and IRBs will be more confident in approving a research application if they have evidence that the researchers involved have completed some form of research ethics training and possess at least a basic understanding of those fundamental principles [11,12]. The third reason is more complex. Education in research ethics aims to provide researchers with the knowledge and tools that will help them engage with the ethical issues and tensions they may encounter during research activities [16]. As iterated by Sedenberg and colleagues, those ethical tensions often stem from the need to balance the risks and benefits intrinsic to research activities with regard to individual participants, while at the same time considering their societal impacts [17]. Indeed, many of the principles and values that research ethics strives to safeguard specifically address the fact that tradeoffs may sometimes be necessary to increase generalizable knowledge and eventually benefit society as a whole. Thus, within research activities some risk to participants (in terms of, for instance, discovery of unexpected health-related findings, minor discomfort during experiments, etc.) may be acceptable in order to enable scientific discovery. Providing researchers with an understanding of the fundamentals of research ethics and an ethical framework to determine acceptable risk/benefits tradeoffs can enable them to balance ethical tensions in ways that protect participants, preserve ethical principles and values, and allow research activities [17].

III. ETHICAL ISSUES IN RESEARCH WITH OLDER PERSONS LIVING IN CARE HOMES

Conducting research in care homes can involve a number of specific challenges regarding research ethics and the protection of human participants [18]. We provide here a brief overview of some of the main challenges discussed in the literature.

The first source of ethical concern, as emphasized by Ramos *et al.*, is associated with the values and goals of a research project itself, when the benefits it is expected to generate for policy-makers, organizations, professional care-givers, families or other stake-holders (such as increased safety through the implementation of technology-based solutions) are not consistent with the preferences or needs of research participants. When this occurs, outcomes that may be viewed positively by the research can produce unintended or negative consequences for those participants and/or the population they represent [19].

Selection criteria and the procedures followed to recruit older participants or retain them in studies may also be of concern; for instance, the selection process may involve a risk of psychological harm to those who are found not to qualify or to no longer qualify for participation (e.g. owing to deteriorated cognitive abilities).

As Mody and colleagues point out [20], questions of reciprocity must be taken into account and the benefit to burden ratio maximized (e.g. is the research project expected to enhance the quality of care for the research participants?). Furthermore, a balance must be struck between accommodating the needs of the facility and preserving the integrity of the study protocol.

Some of the major ethical issues related with research involving older participants, particularly when it comes to care home residents, revolve around informed consent [4]. Protecting participants and respecting their right to self-determination and to exercise personal choice requires that researchers seek their informed consent to participate in a research study. Thus, candidate research subjects must be given the opportunity to learn what is expected of their participation and what will happen to them and to the data that is collected during the study. Prior to deciding whether they want to participate, they should also be given a clear description of risks and benefits related to the study and learn about their right to withdraw at any time and without penalty. The decline in cognitive abilities that often occurs with aging, however, is known to negatively impact on understanding and retention of informed consent information. At the same time, if at all possible, older persons and not surrogate decision-makers should give consent; this may require using targeted strategies or formats, such as easy-to-read text, the use of graphic illustrations and revisiting consent, which can help remind participants of key aspects of the research enterprise [21].

Protecting the welfare of older research participants also requires that special attention be paid to maintaining role boundaries: although trust and empathy should characterize the research relationship, emotional bonds should be avoided to preserve participants and researchers from psychological harm [22]. This will also prevent a personal relationship from

influencing research outcomes. Furthermore, clearly differentiating between research and care roles whenever possible allows investigators and care staff to demarcate and make clear the extent of their responsibilities towards the care home residents who are recruited to studies [23].

Elder abuse is a known problem in long-term care facilities [24], and handling suspected cases of abuse can be ethically fraught [25]. Researchers need to make themselves aware of any institutional rules and local or national laws requiring mandatory reporting. In cases where mandatory reporting is not required, researchers may be concerned about potential ethical violations when reporting such incidents and should establish procedures for actively handling suspected cases of abuse [26].

Finally, questions may emerge involving ageism, that is negative attitudes based on age, including negative feelings, age-based stereotypes and discrimination. As ageism is more likely to impact research design and conduct when researchers are unfamiliar with older populations, providing training and opportunities for discussion is often a helpful approach to prepare researchers to work with older adults and reduce ageist attitudes [27].

IV. ETHICAL ISSUES IN RESEARCH ON SARs IN ELDER CARE

The future of SARs in the care of older persons has been the focus of a great deal of regulatory and ethical reflection [28–30], much of which has centered on concerns relating to a loss of human contact, diminished autonomy and privacy, loss of dignity [31, 32], and to negative impacts on professional caregiving and standards of care [33]. 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 [13, 25, 26]. We discuss some of these issues below, with a focus on potential risks to participants associated with interactions with SARs during experimental trials.

A. Safety

Older individuals may experience difficulties with mobility, vision and coordination, which may be hazardous depending on the SAR's stability, color, size, shape, movement or sound [35]. Therefore, all the SAR's safety vulnerabilities should be identified and procedures to address them developed. Video and audio surveillance of interactions between research participants and the SAR, with the participants' consent, can be useful to monitor participants throughout experiments, so researchers can step in if necessary to protect participants' safety and well-being, and participants can easily call for help.

B. Attachment

SARs are generally characterized by some degree of human-like appearance, qualities or behaviors. These features may have impacts with ethical ramifications [36]. For instance, research participants who become psychologically attached to the SAR may experience disappointment if they have to share it with others [35]. Developing psychological and emotional bonds with the SAR can also have harmful effects on participants at the end of the project when they have to part with it. Accordingly, protocols must be specified in advance to address any consequent needs on the part of participants.

C. Privacy

SARs' programmed reactions towards the behavior and movement of research participants may affect participants' sense of privacy in that they may feel that they are not alone (which can also be positive) or that they are being watched. If participants can control privacy levels, such problems can easily be overcome [37]. Monitoring research participants for safety purposes or recording their interactions with the SAR for research purposes can both be perceived as invasions of privacy and require specific consent from participants. Researchers should also have guidelines on how to respect participant privacy even if participants do not specifically request it.

D. Data management and protection

The processing of any personal data collected during the research project (including any footage from safety monitoring) requires freely given, specific informed consent from research participants.

Data processing must employ appropriate technical and organizational measures to comply with national laws and regulations. In the US, for instance, this may be the Health Insurance Portability and Accountability Act (HIPAA), a set of standards created to secure protected health information [38]. In the EU, it will mean complying with the General Data Protection Regulation 2016/679 (GDPR), and particularly with the data subject rights identified in the GDPR such as the right to be informed, the right of access and the right to erasure. Data collected from the study participants, including data from video- and audio-monitoring, must also comply with the principle of data minimization, meaning that the collection of personal information should be limited to what is directly relevant and necessary to protect participants and accomplish the specific goals of the study [39, 40].

E. Participant autonomy and proportionality

In experiments with research subjects, SARs can be used to carry out certain tasks on participants' behalf or to provide support that enables them to complete the task on their own. Whether this will promote older users' autonomy and independence will depend on whether the SAR's interventions are restricted to what is required and useful for a selected population or individual. Providing more assistance than is actually required may result in the premature loss of capacities in older adults, generating dependency on the SAR [25, 27].

F. Dignity

Individuals may feel more or less at ease interacting with SARs, and interactions with the SAR may suit some research participants more than others. It could even be problematic if people find interactions with the SAR useful or enjoy them

but feel ridiculous using it [37]. The SAR may also remind them of the human contact that is not available to them. Some may be confused by the SAR, or have difficulty understanding how it works, what to do to make it work or what triggers its actions, which could lead to self-blame and lowered self-efficacy. It must be clear to participants that they can withdraw from the study at any time if they so wish.

G. Psychological harm

Older research participants may experience anxiety, depression, embarrassment, or acute stress reactions due to utilization of the SAR, to the fact that they are participating in the experiment, or due to other unrelated reasons. It can also be presumed that older adults may experience technology anxiety and frustration [41] due to not remembering or understanding how to use the robot. Researchers must therefore be prepared to identify and minimize these risks and ensure that the benefits of the study outweigh them. If at some point during the study the research team becomes concerned about psychological distress emerging in a participant, either through observation or by being informed by the participant or others, the researchers must take steps to help minimize this risk by, for instance, following a distress protocol [42]. In some situations, the appropriate course of action will be to withdraw the participant from the study.

H. Managing unexpected health-related findings

Interacting with the SAR is a novel, unusual activity that may uncover health-related issues in research participants that would not emerge otherwise. Protocols for managing such issues need to be developed ensuring that researchers can balance their obligation to protect confidential health-related information about participants, with their ancillary obligation to protect participants' welfare [34]. One way to do this is for researchers to sensitively raise the possibility of unexpected health-related findings during the informed consent process and 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 [34].

I. Stigma and self-stigma

Stigma can be defined as a social process whereby an older adult experiences exclusion or rejection owing to negative social judgement associated with a feature related to a health problem or a health condition. In studies with SARs and older adults, researchers cannot rule out the possibility that relying on a robot for assistance, entertainment, and, to some extent, companionship, may result in negative judgements about research participants by other care home residents, for instance, or by research participants about themselves, or by their family members [43]. Approaching all participants with discretion, ensuring confidentiality, and treating their experiences and contributions equally and with full respect can help avoid stigmatization and self-stigma, as can

increasing knowledge and understanding of how and why older adults might be stigmatized (and why they might self-stigmatize).

V. CASE-BASED LEARNING IN ETHICS TRAINING

Situations involving the ethical issues described above are often complex, dynamic and multi-faceted. They may present competing goals and values, so that resolutions may be far from clear and not univocal [44]. A helpful way to make sense of similar situations is case-based reasoning, in which reflection on experiences is used to help solve new problems [45]. Individuals can acquire experiential knowledge to apply to similar future problems relatively quickly through CBL, a widely used instructional method that enables them to adapt and respond to new situations [46]. CBL involves analyzing problems presented in study cases, drawing analogies, building inferences and forming decisions in ambiguous contexts that mirror real-world scenarios [47, 48]. Compared with traditional lecture-based approaches, CBL is considered to be a more effective instructional method in improving critical thinking and decision-making skills [10, 47]. Additionally, CBL is often reported to be more enjoyable than traditional lectures, which may improve learner engagement [45, 47].

CBL is well-suited for ethics training because cases can be designed to replicate the layered, ambiguous nature of actual ethical dilemmas [49, 50], providing trainees with practice navigating equivocal situations [45] but also with opportunities to discuss abstract ethical principles [51]. In addition, CBL may be especially beneficial with researchers who have little or no experience handling ethically problematic situations, because cases allow for the development and practice of skills without having to actually experience ethical situations [52].

Even in their simplest form, "good" cases should be characterized by having a specific setting, a logical sequence of events, and defined characters [46]. Several authors have discussed other features of case content in view of improving learning and the acquisition of decision-making skills [10, 53]. In their attempt to identify best strategies for case construction, Kim *et al.* [47] reviewed 100 studies on case-based teaching and learning. Based on their evaluation of the literature, they concluded that effective cases should be relevant, realistic, engaging, challenging, and instructional. Along with these core elements, Kim and colleagues suggested a number of strategies for successfully integrating these five elements into cases, among which: developing a case in a realistic and relevant setting, enriching it by providing sufficient information about the characters and ethical problems and dilemmas at hand, and increasing difficulty by adding or concealing certain information [47].

Cases should also prompt trainees to reach a decision, encouraging them to work through the controversial situation as if it were a first-hand experience [54]. Finally, cases must provide enough information about key aspects to elicit critical

thinking, but should not be so long that they become tedious or boring [54].

VI. RESEARCH ETHICS TRAINING IN THE CARESSES PROJECT

A. Training design

The purpose of the CARESSES Research Ethics Training Module was threefold:

- to provide the robotics researchers involved in the trials with a basic understanding of the main ethical concepts and principles that underpin the CARESSES study protocol [34] ;
- to improve their awareness of ethical issues that may arise during the experiments with a SAR and older adults in a long-term care setting;
- to improve their ability to identify those ethical issues and understand the consequences of decisions made to solve or manage them.

Although these goals go in the direction of improving researchers' ethical decision-making skills, it was explained to trainees they would not be asked to make any ethical decision independently during the experiments. Instead, to ensure protection of research participants, they would be required to discuss any issue with their Team Leader and the CARESSES Internal Ethics Board, comprised of the internal ethics advisor and the two health psychology leads of the project.

Based on the literature summarized in Section V above, CBL was chosen as the most suitable approach to achieve these goals. The RETM (Figure 1), which was entirely computer-based and delivered remotely, was developed by the CARESSES internal ethics advisor and jointly administered by the ethics advisor and the other members of the project's Internal Ethics Board. The RETM included multiple steps and employed a variety of delivery activities, which has been suggested to improve participant engagement with the content and ultimately facilitate knowledge and skill acquisition [55]. In addition, it structured opportunities for active trainee participation [56].

The training materials consisted of:

a) the "Ethical Considerations" section of the CARESSES Study Protocol: this document relies on previous work [34] to provide an ethical framework for the study and covers the topics described in Sections III and IV above; it also explains how those ethical issues and concerns, such as questions of dignity, autonomy, safety, privacy and data management and protection, may arise within the CARESSES experiments, and describes appropriate ways of handling them;

b) three study cases built around relevant ethical issues (see Tables 1-3) including informed consent, confidentiality, role boundaries and protection of research participants from harm; the cases describe ethically challenging situations that could emerge during the CARESSES trials.

In accordance with the recommendations in the literature, the effort was made to ensure that the cases would be realistic and descriptive [47]. Cases were also kept brief, avoiding
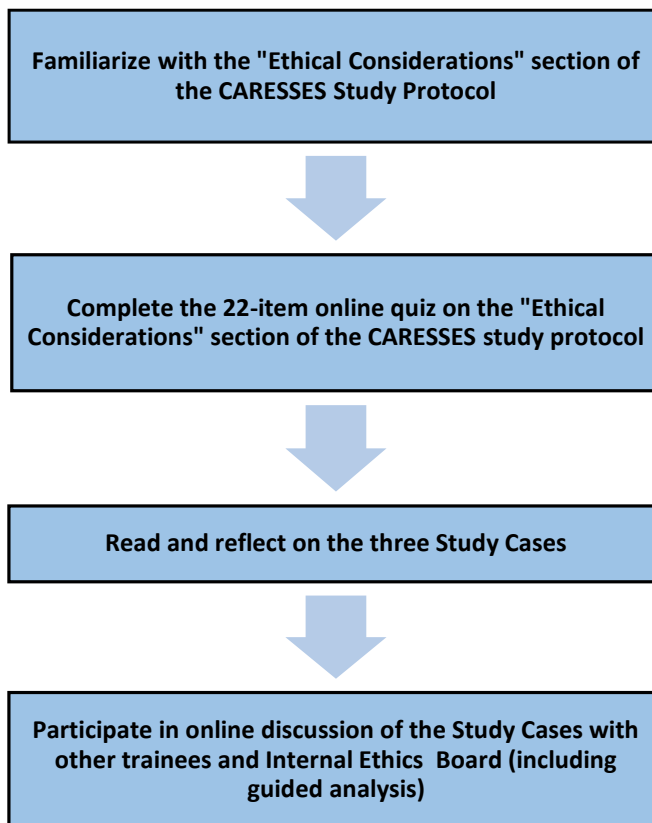

Figure 1. CARESSES RETM at a glance.

irrelevant material [44]. Additionally, we attempted to infuse them with emotion [45], omitted certain key information to emphasize the importance of gathering all the relevant facts, avoided pointing to clear-cut, obvious solutions , and included elements of ambiguity [47]. Overall, designing the instructional content so that it was specifically customized for the research project was expected to result in greater benefits to trainees, compared with standard off-the-shelf training programs [57].

B. Training delivery

Ten trainees (two robotics researchers in Italy, two in France, two in Sweden and four in Japan) participated in the training. All were male and 8 out of 10 were early stage career researchers. None had previously received any formal training in research ethics. In the first part of the training process, the trainees were asked to familiarize themselves with the "Ethical Considerations" document. Although none of the trainees were native speakers of English, they were all proficient readers. Having read the document and having had the opportunity to ask questions about it, they completed a 22-item online multiple-choice quiz. The purpose of the quiz was to enable participants to demonstrate that they had studied and understood the document, and not to formally assess their level of knowledge and understanding. Trainees were then asked to read and reflect upon the ethics cases independently before

Case 1 – Mr. Chaterjee
You are a robotics researcher involved in a project on SARs in elder care. The project includes trials with a robot, older persons living in care homes and their informal caregivers. In order to qualify for the study, the older persons must have sufficient cognitive abilities to learn how to interact with the robot. Since the project has started, you have become rather friendly with one of the trial participants, Mr. Chaterjee. You enjoy Mr. Chatterjee's jokes and humorous anecdotes. As for Mr. Chaterjee, he thinks the robot is great fun and very 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 require your attention. You go and say goodbye to Mr. Chaterjee, but when you tell him another researcher will be replacing you, he becomes very upset and says he no longer wants to participate in the project.

A) Recommended case features [47, 58] and how they apply	B) Main ethical considerations
Relevant: the case narrative is placed within the CARESSES project trials. *Realistic*: the issue presented could realistically emerge in the study experiments. *Engaging*: the case content allows multiple levels of analysis and interpretations and provides opportunities for trainees to determine its course and outcome. *Concise:* the case is long enough to detail key aspects, but not so long that it becomes tedious or boring. *Challenging*: the case involves more than one ethical issue; some key information is omitted in order to emphasize the importance of gathering all the relevant facts. *Instructional*: the case builds upon knowledge provided within the Ethical Considerations section of the Study Protocol.	*Informed consent:* participants' expectations regarding what will happen during the experiments must be managed to prevent disappointment; revisiting consent to remind participants of key aspects of the research enterprise can be helpful in this direction. *Participant rights:* participants have the right to withdraw from the study at any moment without providing any explanation if they so wish. *Protecting participants from psychological harm*: role boundaries should be maintained to preserve participants from psychological harm. *Role boundaries*: although trust and empathy should characterize the research relationship, the development of friendship or emotional bonds with participants risks harming them.

Table 1. The case of Mr. Chaterjee (sub-tables A and B were not shared with trainees.)

Case 2– Mrs. Smith

Mrs. Smith and her daughter Sara have agreed to participate in the project.

During the third week of the experiments, you notice that there has been a marked decline in Mrs. Smith's cognitive and mental abilities. She is having trouble understanding what do to with the robot and why it is in her room. Mrs. Smith's daughter, however, doesn't seem to notice that anything is wrong with her mother. You start worrying that interacting with the robot may be causing distress to Mrs. Smith and you decide to share your concerns about Mrs. Smith's apparent condition with the care home staff. Since they confirm your observations, you conclude that Mrs. Smith no longer qualifies for the study. This means that her daughter Sara will also no longer be participating.

You start thinking about how best to go about withdrawing them both from the study.

A) Recommended case features [47, 58] and how they apply	B) Main ethical considerations
Relevant: the case narrative is placed within the CARESSES project trials. *Realistic*: the issue presented could realistically emerge in the study experiments. *Engaging*: the case content allows multiple levels of analysis and interpretations and provides opportunities for trainees to determine its course and outcome. *Concise:* the case is long enough to detail key aspects, but not so long that it becomes tedious or boring. *Challenging*: the case involves more than one ethical issue; some key information is omitted in order to emphasize the importance of gathering all the relevant facts. *Instructional*: the case builds upon knowledge provided within the Ethical Considerations section of the Study Protocol.	*Informed consent:* recruitment criteria and withdrawal from the study must be discussed with participants during the informed consent process. *Unexpected health-related findings and confidentiality*: the possibility that health-related issues might emerge during the experiments must be discussed during the informed consent process and consent be sought to report any such issues to formal carers. *Protecting participants from psychological harm*: whenever interactions with the robot cause distress to a participant, and this cannot be remedied, then that participant must be withdrawn from the study. *Role boundaries*: any conversation about a participant's health, with the participant and/or with her informal carers, is the responsibility of the professionals who have her in their care.

Table 2. The case of Mrs. Smith (sub-tables A and B were not shared with trainees.)

Case 3 – Mrs. Yamada

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.

A) Recommended case features [47, 58] and how they apply	B) Main ethical considerations
Relevant: the case narrative is placed within the CARESSES project trials. *Realistic*: the issue presented could realistically emerge in the study experiments. *Engaging*: the case content allows multiple levels of analysis and interpretations and provides opportunities for trainees to determine its course and outcome. *Concise:* the case is long enough to detail key aspects, but not so long that it becomes tedious or boring. *Challenging*: some key information is omitted in order to emphasize the importance of gathering all the relevant facts. *Instructional*: the case builds upon knowledge provided within the Ethical Considerations section of the Study Protocol.	*Informed consent:* Processing of any personal data collected during the research project requires informed consent from research participants. Consent must be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the subject's agreement to the processing of their personal data. If personal data is to be shared with third parties, this should be clearly and specifically discussed during the consent process.

Table 3. The case of Mrs. Yamada (sub-tables A and B were not shared with trainees.)

discussing them with each other and the Internal Ethics Board during a series of dedicated videoconferences. 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 [59]:

- 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?

C. Knowledge, feedback and perceived impact

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. Furthermore, during the RETM videoconferences all trainees were able to identify the main ethical considerations in the ethics cases discussed and to describe ways of handling those cases that complied with the guidance provided in the "Ethical considerations" document.

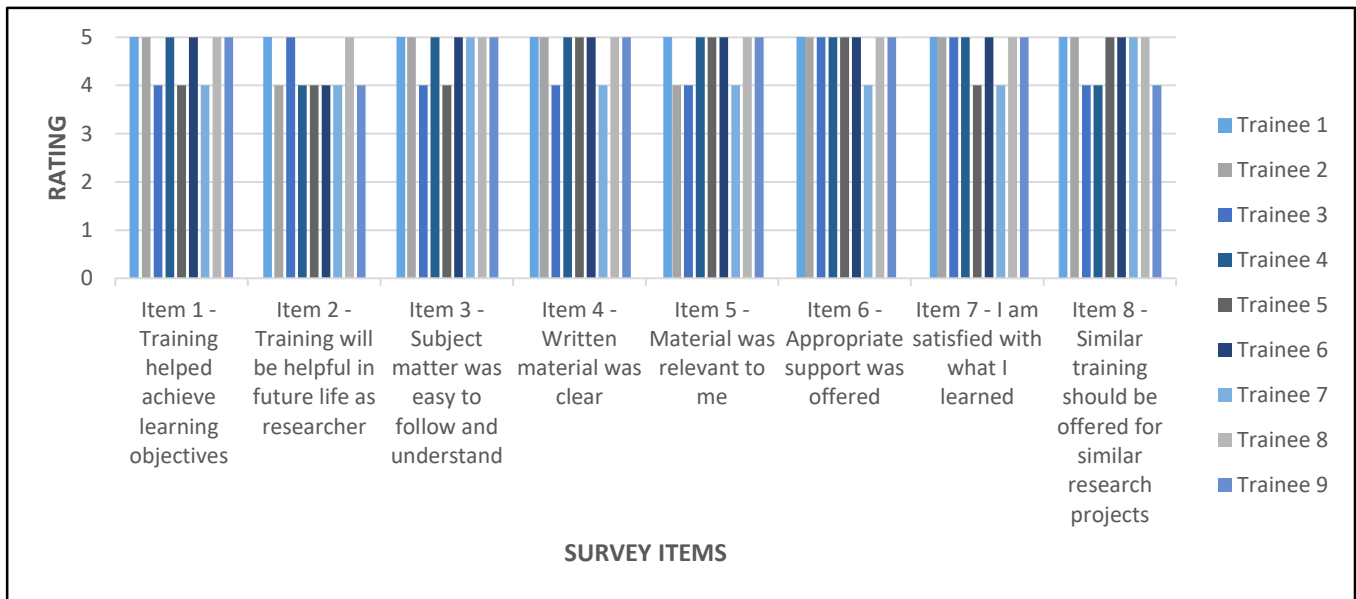One week after completing the training module, the

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

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 RETM. One trainee commented that the cases had given him 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.

Eight weeks after completing the training, the trainees were invited to 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. 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 [60]. 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 [61].

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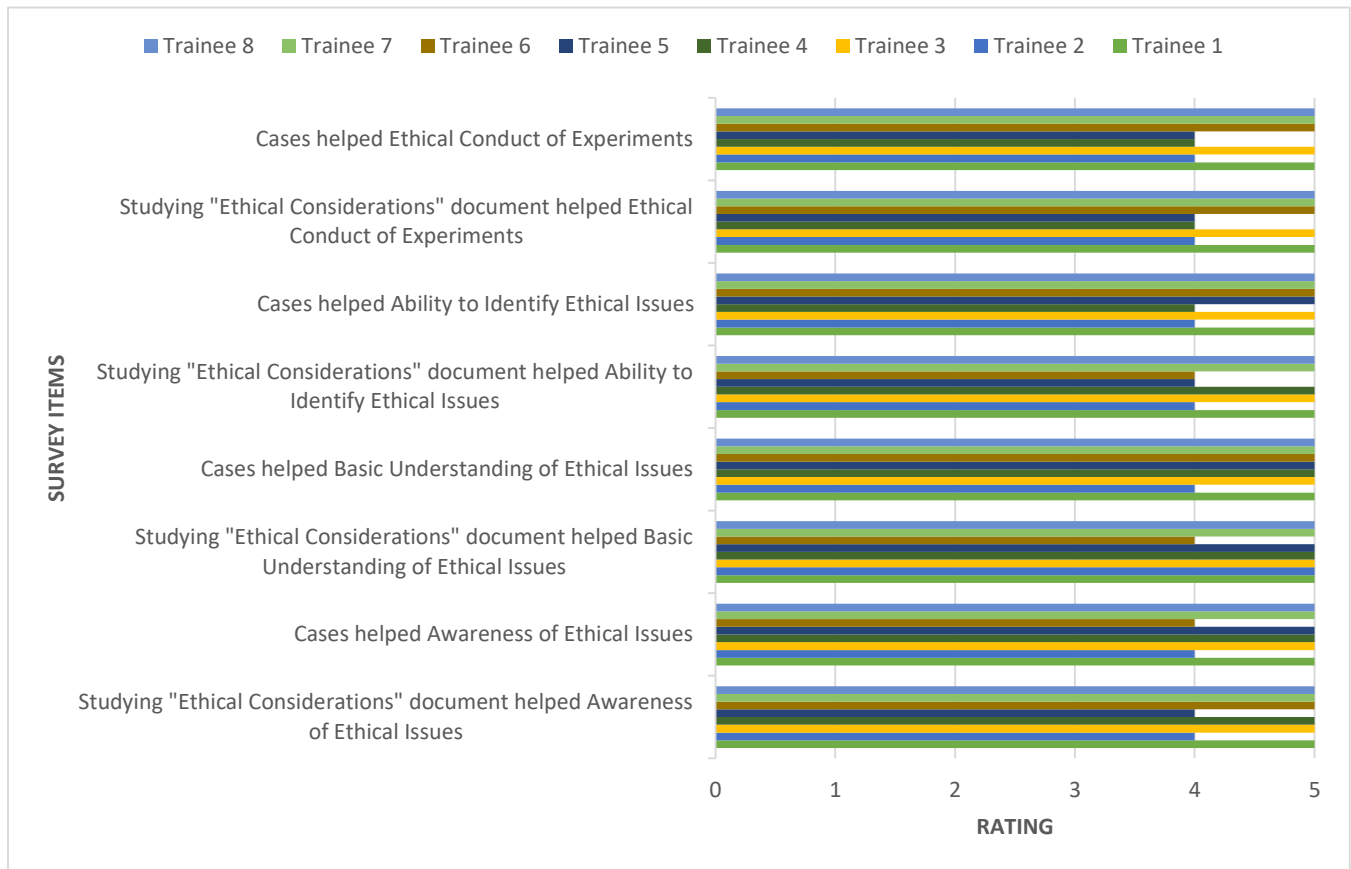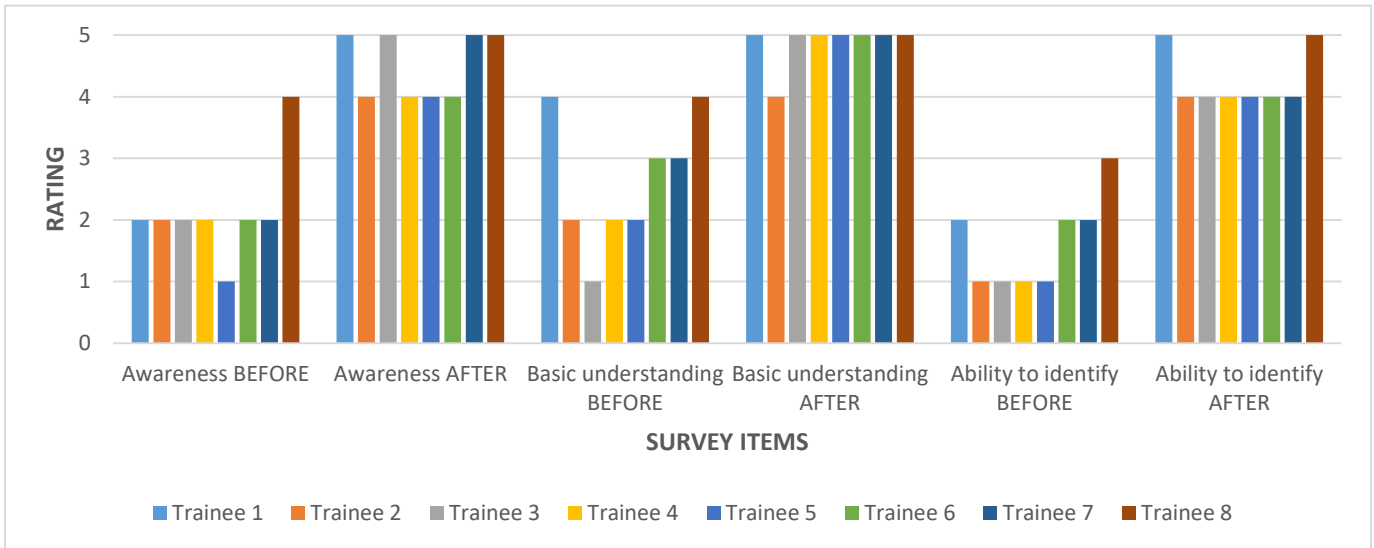

Figure 4. Perceived improvements afforded by the CARESSES RETM tools (rating: 1= strongly disagree, 5= strongly agree)

In addition, there is evidence that when using the traditional pretest-posttest, students asked to rate their knowledge or performance at the beginning of a course tend to overestimate their abilities as they are not able to fully appreciate the complexity of the content taught. Once they have acquired at least some basic knowledge of the topic, students are better able to reflect on how much their knowledge or skills have changed, resulting in less favorable ratings of initial performance levels. In other words, exposure to course content changes student's ability to benchmark their own performance. This well-known effect has been defined the "response shift bias"[62]. Finally, although recall bias and memory lapses are inherent limitations of the retrospective pre-post design, in this study we attempted to minimize their effects by administering the survey after a relatively short period of time (8 weeks).

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. 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).

VII. CONCLUSIONS

A large number of studies reporting on research ethics training efforts in the sciences have been conducted in the past twenty years [55]. This interest likely mirrors the growing consensus that research ethics training may result in sizable, concrete benefits to participants and be a key mechanism for ensuring their protection [63]. Yet, wide variation is known to exist across programs in terms of effectiveness [55]. Developed as a project-tailored educational intervention and delivered remotely, the CARESSES RETM was successful in increasing trainees' knowledge of the principles and concepts that provide the ethical grounding for the study protocol. It also enabled them to correctly identify the ethical issues illustrated in the case studies they were asked to analyze and to propose appropriate ways of handling them. Furthermore, in light of the statistical analyses conducted, our findings on the trainees' perception of how effective the training was, are encouraging. We are nonetheless aware that the small sample and the potential social desirability bias are limitations of the study. Once the experimental phase of the project is completed, we plan to conduct semi-structured qualitative interviews with the researchers to explore their experience and views on the ethical concerns that emerged during the study, if any, and the range of their attitudes and views of the research ethics training they completed.

Overall, we believe this paper shows that research ethics training is an important component in projects involving experiments with SARs and human participants, especially in the case of vulnerable research subjects such as older individuals residing in care homes. We are aware that the use of specific cases may seem to reduce the scope of applicability of our research ethics training approach and provide too specific a frame for the ethical questions that may emerge. However, the literature on case-based training suggests that relevant, customized cases like those described here are more effective than off-the-shelf solutions in providing instructional benefits to trainees [47, 57]. In addition, other studies have pointed out how the main information in a case (characters, plot, specific setting or context, conflict at hand) must all be apparent so that trainees can examine and identify potential causes and preventative strategies corresponding to the problem scenario [52, 54, 58]. Certainly, developing such project-specific cases requires close collaboration between ethics experts and roboticists, as indeed advocated by proponents of Responsible Research and Innovation [64]. Thus, with suitable modifications and appropriate contextualization, the training approach we designed could be usefully adapted for other human-robot interaction projects involving human subjects, to help ensure that the values and principles of research ethics are upheld, and the protection of human subjects is placed at the fore.

Conflict of Interest: The authors declare that they have no conflict of interest.

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