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Study protocol: a cross-sectional survey on expectations and attitude of patients and healthcare professionals towards the use of social humanoid robots in nursing during hospitalization

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Manuscripts

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3 **Study protocol: a cross-sectional survey on expectations and attitude of patients and**
4 **healthcare professionals towards the use of social humanoid robots in nursing during**
5 **hospitalization**
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Study protocol: a cross-sectional survey on expectations and attitude of patients and healthcare professionals towards the use of social humanoid robots in nursing during hospitalization

8
9

Abstract

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Introduction: The aging of the population, the rise of chronic diseases and the emergence of new viruses are some of the factors that contribute to an increasing share of GDP in health spending. COVID-19 has shown us that nursing staff especially represents the critical part of hospitalization. Technological developments in robotics and artificial intelligence can significantly reduce costs and lead to improvements in many hospital processes. The aim of this study is to determine professionals' and patients' attitudes and expectations towards social robotic system (SRS) integrated into care workflow during hospitalization and compare results with the results of similar studies to evaluate potential cross-cultural differences. Moreover, the authors aim to identify critical barriers and ethical restrictions that have to be considered when the robots will be introduced into real-life setting.

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Methods/Design: The study is designed as a cross-sectional survey which will include three previously validated questionnaires, Technology-Specific Expectation Scale (TSES), Ethical Acceptability Scale (EAS) and The Negative Attitudes towards Robots Scale (NARS). The employees of the regional clinical center will be asked to participate via an electronic survey and respond to TSES and EAS questionnaires. Patients will respond to TSES and NARS questionnaires. The survey will be conducted in paper-pencil format, by the hospital staff, and with inpatients of the UKC Maribor. In both cases the data collection will be limited to 30 days.

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Ethics and dissemination: Ethical approval for the study was obtained by the Medical Ethics Commission of the UKC Maribor. Results will be published in a relevant scientific journal and be communicated to participants and relevant institutions through dissemination activities of the Horizon 2020 funded project HosmartAI.

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8 **Ethical Approval Date:** 06th May 2021
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10 **Estimated Start of the Study:** September 2021
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15 **Keywords:** robots in nursing, social robotic systems, nursing, social and ethical barriers,
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17 patient expectations, artificial intelligence, health application
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21 **Article summary**
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23 **Strengths and limitations of this study**
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- 25
- 26 • A substantial and diverse study population of patients and healthcare professionals including
27 physicians, nurses, technologists and other staff.
 - 28 • The cohort will include subjects from the region rather than country.
 - 29 • Data will be collected based on subjective questionnaires, which may lead to information bias.
 - 30 • The applied questionnaires have undergone widespread use in several languages, allowing a
31 comparison between different populations, cultures, and contexts of use of SRS.
 - 32 • Broad assessment of expectations and barriers to use of social robotic systems during
33 hospitalization.
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43 **Introduction**
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45 Healthcare systems throughout the world are striving to rise to the challenges that result from
46 an ageing population, the growth in chronic disease prevalence, appearance of new viruses,
47 burgeoning technical possibilities, and a rise of public expectations [1]. With the increasing
48 economic burden of modern health, the Organization for Economic Co-operation and
49 Development (OECD) estimates that up to 20% of health spending in Europe is spent on
50 services that either do not deliver benefits or are even harmful, create additional costs and
51 could be avoided by substituting (cheaper) alternatives with identical or greater benefits [2].
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Technological developments in the fields of robotics and AI can provide significant cost savings and could lead to improvements in many hospital processes. In fact, the robotic systems are being increasingly utilized to improve accuracy [3], to improve diagnosis and enable remote treatment [4], in supporting mental health and daily tasks [5,6] and in complementing human workforce in auxiliary services [7]. Nursing and care, in particular, could gain much from the artificial systems' capacity to assist people with their daily living activities. Namely, nursing and care staff are a critical part of healthcare and make up the largest section of the health profession. According to the World Health Statistics Report, there are approximately 29 million nurses and midwives in the world [8,9], while current estimates suggest that additional 5.9 nurses are needed worldwide [10]

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Socially intelligent mobile robots have long been posited as a promising response to a chronic nursing shortage in the EU and U.S. Health systems [11]. As physically and socially interactive technologies, robots present new opportunities for embodied interaction and active as well as passive sensing in these contexts. They have also been shown to psychologically impact individuals, affect group and organizational dynamics, and modify our concepts and experiences of work, care, and social relationships [12]. Although the systems exhibit robust, autonomous capabilities and initial concerns regarding physical safety around people have been at least partially addressed, the uptake of the technology is arguably slow. In addition to ethical considerations [13] related to decreased social contact, there are additional barriers related to acceptance, such as patients' stigmatization and fear of the dehumanization of society. The first is related to non-acceptance from end users [14] and the second to non-acceptance from healthcare professionals, nurses in particular [15,16]. In general, both relate to oversimplifying the complexity of nursing and care context. "The implementation of a

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robotic system in nursing care must be seen as a complex intervention due to the number of involved stakeholders and their behaviors, the variability and number of outcomes and various interacting components.” [13:2]. The underestimation of the impact of user-perception fundamentally creates negative attitude. For instance, elderly may not recognize the added value if they are quite independent. Robots may be perceived as a local threat to their independence due to unfamiliarity and technical inexperience [17,18]. Although healthcare professionals are clearly facing high workloads and tend to recognize the potential value of care robots as an aid in “measuring/monitoring”, “mobility/activity” and “safety of care” [19], they are in fact challenged in understanding and prioritizing of the robotics units into fundamental aspects of care [20]. However, ‘reduction in workload’, and especially ‘other nursing services’ categorized as nonvalue-added nursing activities tend to be recognized as valued features.

To sum up, the SRS, if designed correctly, can have a significant impact especially on ‘other nursing services’. However, a more anticipatory and contemporary position towards technology in nursing must be established with both healthcare professionals and patients. Most existing studies focus on long-term (elderly) care or partial substitution of nursing activities rather than SRS as complementary service delivering ‘other nursing services’. The most frequently reported barriers fit in socioeconomic and ethical domains and are focused on the implementation outcomes domain. The quality of reporting and quality of evidence were low in most studies [20]. Building on this baseline the proposed study implements three questionnaires focusing on: i) general acceptance of robots in a setting of nursing (NARS [23]), ii) ethical and professional reservations (EAS [22]) and iii) functional (technological) expectations (TSES [21]). The tools chosen are widely used questionnaires for evaluating the

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acceptability of social robots [31]. The goal is to define design baselines and model implementation process and implementation strategies aligned with expectations of targeted end-users, recognizing sociocultural bias as a benefit rather than limitation. Since psychometrically evaluated tools will be used, cross-cultural differences will be evaluated against relevant studies in similar settings.

Objectives and hypotheses

The main objective is to assess applicability, ethical and technical considerations regarding integration of SRS into nursing and care workflow at the regional clinical center. With this study we will evaluate the prevalence of generally recognized barriers on the integration potential in the targeted institution and how the behavior of units must be designed to fit targeted population. Overall, the study will address the following research questions:

R1: What is the general attitude of healthcare professionals towards robotic units in hospital care?

R2: What is the general attitude of patients towards robotic units in hospital care?

R3: What are the main ethical reservations that may impact the acceptance of robotic units in hospital care in healthcare professionals?

R4: What are the main ethical reservations that may impact the acceptance of robotic units in hospital care in patients?

R5: What are the differences and which indicators affect the differences in the relationship between employees and patients to robotic units?

R6: What are the differences in attitudes towards SRS between targeted environment and setting and studies in other countries and contexts?

Hypotheses

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8 *H1: Patients' attitudes towards the robot are related to their age.*
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10 *H2: Patients with higher reported level of education have statistically significantly more*
11 *positive attitude towards the robot.*
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13 *H3: The higher the education of the employee, the more he / she is in favor of the robot.*
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15 *H4: There is a statistically significant difference in relation to the robot between the groups*
16 *of healthcare employees according to their profession and patients they care for in daily*
17 *routine.*
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20 *H5: There is a statistically significant difference in relation to the robot between the groups*
21 *of patients depending on their momentary status of dependence (i.e. disease/condition).*
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24 *H6: There is a statistically significant difference in relation to the robot between the groups*
25 *of patients depending on their duration of hospitalization.*
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35 **Methods**

36 ***Design and setting***
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38 The study is a cross-sectional survey investigating the feasibility and technical and non-
39 technical considerations of integration of social robotic systems as perceived by healthcare
40 professionals and patients in hospitals in the region.
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43 The cross-sectional study will include at least 1,000 healthcare professionals and at least 500
44 inpatients answering to two questionnaires. The healthcare professionals of the hospitals in
45 the region (Slovenia) will be asked to participate via an electronic survey and respond to
46 TSES [21] and EAS [22] questionnaires. Based on age, gender, department (medical or
47 support staff) and education, the initial attitude of healthcare employees before meeting the
48 robot – nurse will be assessed.
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Inpatients at University Clinical Center and Hospital (UKC Maribor) will be asked to respond to TSES [21] and NARS23[2021] questionnaires. The survey will be conducted with inpatients of the UKC Maribor, in paper format, and with support of the hospital staff. Based on age, gender, occupation, education and disease/condition we will determine the initial attitude of healthcare employees before meeting the robot - nurse.

The cross-sectional study is planned to begin in September 2021 and the data collection will last over a period of thirty (30) days for both populations.

Table 1 summarizes the study design:

Table 1: Outline of the study design

<i>Employees in the medical institution: UKC Maribor and other hospitals</i>	
Design:	Electronic survey among healthcare professional
Cohorts:	According to the questionnaire, employees will be divided according to age, gender, level of education and department (division into professional and medical).
Number of surveyed employees	> 1000
Inclusion period	30 days, after the survey becomes available
Exclusion criteria	none
Inclusion criteria	Employees in a medical institution between 18 and 65 years of age
Questionnaire	EAS and TSES, demographic data
Other requirements	willingness to participate
<i>Inpatients of UKC Maribor</i>	
Design	Physical survey executed with inpatients and with the support of hospital's staff
Cohorts:	According to the questionnaire, patients will be divided according to age, gender, level of education and department of hospitalization
Number of surveyed inpatients	> 500

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Inclusion period	30 days, after beginning
Exclusion criteria	Patients hospitalized at the pediatric clinic, department of psychiatry and the clinic for gynecology and perinatology
Inclusion criteria	Hospitalized patients in UKC Maribor at the time of the survey
Questionnaire	NARS and TSES, demographic data
Other requirements	willingness to participate

Participants

We estimate > 1000 healthcare professionals between 18 and 65 years of age to be invited and participate in the study. The inclusion criteria for the healthcare professionals is to be employed in a medical institution. There are no exclusion criteria for the healthcare professionals. Primary targeted will be employees of UKC Maribor. Additionally, we will ask healthcare professionals from other hospitals in Slovenia to participate.

We estimate >500 patients 18 years of age and above to be invited and participate in the study. The inclusion criteria for the patients is to be hospitalized during the execution of the study and willing to participate. No sensitive information or information through which individuals could be identified will be collected thus, letter of consent is not required. Participants will be informed that participation is completely voluntary, and they can terminate their involvement at any time without any consequences. They will also receive (orally and in writing) the relevant information explaining the intent of the survey and on how survey will be implemented, and results analyzed, and dissemination carried out. The exclusion criteria reflect the primary domains of possible integration, thus patients hospitalized at the pediatric clinic, department of psychiatry and the clinic for gynecology and perinatology will not be included. Since psychometrically validated tools will be used the

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8 results will be compared with studies in similar settings in order to estimate cross-cultural
9 differences.
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12 ***Ethical, legal and regulatory aspects***
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14 The study group will be fully committed to respecting the highest ethical, fundamental rights
15 and legal standards as recognized at European Union and international level, including the EU
16 Charter of Fundamental Rights (2000 / c 364/01) , the General Data Protection Regulation
17 (GDPR) (Regulation (EU) 2016/679), the European Code of Conduct for Research Integrity
18 and the OECD Council Recommendations on Health Data Management. In addition, the
19 project will be implemented in accordance with the Declaration of Helsinki and Taipei and
20 the Convention for the Protection of Human Rights and Human Dignity in Biology and
21 Medicine.
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33 As a rule, all research activities are carried out on the basis of the following principles of
34 bioethics to ensure the protection and dignity of patients:
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- 36 • **Autonomy:** An individual's right to free choice has to be respected
- 37 • **Non-maleficence:** No harm must come to the patient.
- 38 • **Beneficence:** Procedures must be done with the intent of doing good.
- 39 • **Justice:** Risks and benefits must be correctly balanced
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46 Researchers and any other person participating in the research will pay close attention to the
47 standard of ethics and integrity of the research, taking into account the following moral
48 constraints:
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- 50 • **Reliability** in ensuring the quality of research, which is reflected in the design,
51 methodology, analysis and use of resources.
- 52 • **Honesty** in developing, reviewing, reporting and communicating research in a
53 transparent, fair, comprehensive and impartial manner.
- 54 • **Respect** for collaborators, research participants, society, ecosystems, cultural heritage
55 and the environment.
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- 8 • **Responsibility** for research from idea to publication, for its management and
9 organization, for training, supervision, mentoring and for wider influences.
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11 ***Data storage and privacy***
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13 The study will not collect any personal information. The results of the study will be published,
14 and data made available in digital form upon reasonable request. However, as a general rule,
15 respect for fundamental rights to privacy and personal data, as set out in this document, is of
16 paramount importance to all partners and to the project.
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19 In view of this presumption and taking into account the different modes of flow of personal
20 data (including those categories of personal data that fall under sensitive data as set out in
21 Article 9 of the GDPR), the following compliance rules and management policies will apply.
22 Anonymous survey regarding patient attitudes towards the robot in a hospital environment for
23 the needs of the international project Horizon 2020 will be carried out for the preliminary
24 needs of the project. For the most part, questionnaires with the Likert scale will be used, and
25 among personal data we will only collect information on gender, age and level of education of
26 patients, and for employees, an additional information on their occupation. The time span of
27 the survey will be used and not the exact date of the completed survey for the individual. Data
28 will be processed using descriptive statistics and appropriate inferential statistical tests. The
29 data will be anonymized at the collection point.
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48 ***Management and reporting of adverse reactions***
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50 We do not expect any adverse effects in the study. The only adverse event could be
51 unwillingness of patients and staff to participate.
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54 **Patient and Public Involvement**
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56 Since the study is a survey, the patients' direct involvement in the study design was not
57 applicable. The results of the study will be disseminated to the participants and public via
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publication of open access research papers and dissemination channels of both participating institutions and the dissemination channels of H2020 Project HosmartAI, this study is part of. These include local and social media, website posts and blog posts.

Outcomes

This study will examine the research questions and hypotheses to determine the attitude in respect to age, gender, education and department of hospitalization in patients and also the attitude towards the robot in respect of age, gender, education and job (healthcare or other) in employees. Table 2 summarizes the expected outcomes.

Table 2: Expected differences in perception and expectations regarding SRS among the patients and employees

Employee categories	Expected cohorts	Measuring tool
Age	Younger employees are more open to the idea of implementing a robot into medical care.	TSES and EAS Questionnaires (electronic)
Sex	No expected difference in the groups.	
Education	We expect that employees with higher levels of education will be more open to the idea of implementing a robot into medical care.	
Department	Outcome uncertain.	
Inpatient categories	Expected cohorts	Measuring tool
Age	Younger patients are more open to the idea of implementing a robot into medical care.	TSES and NARS Questionnaires (physical form)
Sex	No expected difference in the two groups.	
Education	We expect that patients with higher levels of education will be more open to the idea of implementing a robot into medical care.	

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Education	We expect that patients with higher levels of education will be more open to the idea of implementing a robot into medical care.	
Department	We expect level of autonomy/independence during hospitalization and the duration of hospitalization to play a role in level of acceptance	

Data analysis and statistics

Sample size

Number of employees > 1000.

Number of inpatients > 500.

The sample sizes were selected based on previous studies, where they vary from 50 to 300 [24-27]. Based on the selected tools we estimate that a population of 500 healthcare professionals and 250 patients will be enough to achieve statistical significance (p-value) equal or below 0.05.

Expecting a response rate of approximately 50% in both groups, at least 500 patients and at least 1000 healthcare professionals must be invited to participate. The primary hospital (UKC Maribor) is a 1316-bed facility. Approximately 60,000 patients are treated annually. More than 390,000 outpatients are treated at 270 different outpatient clinics. The hospital employs approximately 3360 medical and non-medical staff members (approx. 600 medical doctors and 1500 healthcare workers). To further ensure relevant population samples other hospitals from the region will be invited to participate.

Analysis

We will use the program R 3.4.2 and IBM SPSS Statistics 19 for statistical analysis. Results with a p-value below 0.05 will be considered statistically significant. In the first steps, the

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8 missing values will be replaced (according to the logic of multiple imputation or using the
9 “missForest” procedure). In addition, we will perform basic psychometric analyses, namely
10 factor analysis and analysis of reliability as internal consistency (Cronbach's alpha). With a
11 sufficient sample, the measurement invariance of the questionnaires used will also be
12 checked. In accordance with the results of these preliminary analyses, the values of the parent
13 dimensions (factor scores) will be calculated.
14

15 Following that, basic descriptive analyses will be performed (calculation of M and SD), and
16 the normality of the distribution of the included variables and other assumptions of statistical
17 tests, outlined below, will be checked. Specifically, basic correlation analyses (Pearson's r)
18 will be used to provide insight into the associations between variables. In cases where
19 hypotheses assume the comparison of two or more independent groups, t-tests for two
20 independent samples (e.g. to identify gender differences) and one-way analysis of variance
21 analysis (ANOVA for independent groups; e.g. to identify differences between occupational
22 groups) will also be used. In cases of correlation of the studied dependent variables, the
23 MANOVA test (multivariate analysis of variance) will be used instead of the ANOVA test for
24 independent groups.
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26 ***Non-response***
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28 A tendency for people to be more inclined to answer the questionnaire when they are familiar
29 with the current subject. This situation will inflate the prevalence estimate found in our
30 sample in case of substantial non-response. To evade the non-respondent among the patient
31 population, healthcare professionals will inform patients regarding their value in the study
32 even though they do not have experience with social robotic systems. Moreover, when
33 necessary the healthcare professionals will provide further assistance and explanation.
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8 **Discussion**
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10 Technological developments in robotics and artificial intelligence can significantly reduce
11 costs and lead to improvements in many hospital processes. Artificial intelligence and digital
12 solutions are going to contribute to more efficient and automated work management processes
13 and continuous training of healthcare professionals. Most recently, COVID-19 has shown us
14 the need for understanding and coordination in dealing with new outbreaks. It tested the
15 ability of the global health community to collaborate, share information, and rely on proven
16 approaches to epidemics and in working with industry.
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29 The aim of this study is to assess the feasibility of integration of the social robotic system into
30 nursing and care during hospitalization. Social robotic systems are expected to be effective in
31 integrated nursing care services, particularly in delivering ‘other nursing services’ and
32 measuring/monitoring’ [19]. The goal of such units is not to replace human contact but to
33 improve quality of care and decrease the workload of healthcare professionals by delivering
34 ‘other nursing services’ categorized as non-value-added nursing activities. However, major
35 barriers related to such integration are associated with implementation outcomes,
36 socioeconomic and ethical domains [14]. From both the patient and professional perspective
37 they are realized as non-acceptance from end users due to unfamiliarity, manifestation either
38 as technological fear threatening independence [28] or as a lack of confidence in professional
39 use and in the safety of technology itself [29].
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54 Thus, within this study both expectations and possible reservation will be collected from
55 patients and professionals. The results of this study will be used to model the design of the
56 social robotics systems that will be further evaluated in a clinical study implemented under
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8 the umbrella of project H2020 project HosmartAI, Pilot 5: Assistive care in hospital: robotic
9 nurse [30], delivered in UKC Maribor.
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15 **Declarations**

16 *Ethics approval and consent to participate*

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18 This study has been approved by the Medical Ethics Commission of the UKC Maribor
19 (UKCM-MB-KME-40/21). The study will not collect sensitive data. Data will be anonymized
20 upon collection. . Explicit patient consent is not required.
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26 *Consent for publication*

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28 Not applicable.
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31 *Availability of data and materials*

32
33 No sensitive data will be collected. Anonymized data collected during study will be
34 made available to other researchers upon reasonable request.
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38 *Competing interests*

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40 The authors declare that they have no competing interests.
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42

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44
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46 and innovation program, project HosmartAI (grant agreement No. 101016834). The funding
47 source approved the funding of project HosmartAI of which this study is a part of and ensured
48 the funds for the implementation. The funding source had no role in the design of this study
49 and will not have a role beyond progress monitoring and evaluation or influence the
50 execution, analyses, interpretation of the data of this study, or decision to submit results.
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58 *Authors' contributions*

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8 All authors contributed to securing the funding of the project. All authors
9
10 conceptualized the study. IM wrote the original draft and the draft version of primary and
11
12 secondary endpoints. All partners contributed to refine the study. All authors read and
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14 approved the final manuscript.
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17 ***Acknowledgments***
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19 Not applicable.
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SPIRIT Checklist:

Item 1: Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym.	Title is descriptive and identifies the study design, interventions and primary endpoint
Item 2a: Trial identifier and registry name. If not yet registered, name of intended registry.	N/A
Item 3: Date and version identifier.	The content is highlighted under sections Ethical Approval Date and Estimated Start of the Study
Item 4: Sources and types of financial, material, and other support.	The content is highlighted under section Declarations, subsection Funding. A document highlighting more details about the study including the official link to web page of the project at the funding agency is given on page 15.
Item 5a: Names, affiliations, and roles of protocol contributors.	The content is highlighted under section Declarations, subsection Authors' contributions on page 15 of the manuscript.
Item 5b: Name and contact information for the trial sponsor.	N/A
Item 5c: Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities.	The content is highlighted under section Declarations, subsection Funding
Item 5d: Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for Data Monitoring Committee).	N/A
Item 6a: Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention.	The content is highlighted under section Introduction, pages 4 - 6
Item 6b: Explanation for choice of comparators.	The content is highlighted under section Background, page 6
Item 7: Specific objectives or hypotheses.	The content is highlighted under section Objectives and hypotheses, page 6-7
Item 8: Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single	The content is highlighted under section Methods subsection Study design, page 7-10

group), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory).	
Item 9: Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained.	The content is highlighted under sections: Methods, pages 7-9;
Item 10: Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists).	The content is highlighted under section, Outcomes – Participants, page 9
Item 11a: Interventions for each group with sufficient detail to allow replication, including how and when they will be administered.	The content is highlighted in Table 1: Outline of the study design. Page 8
Item 11b: Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease).	N/A
Item 11c: Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return; laboratory tests).	The content is available under section Data analysis and statistics, sub-section Non-response, page 13
Item 11d: Relevant concomitant care and interventions that are permitted or prohibited during the trial.	N/A
Item 12: Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.	The content is highlighted under Outcomes, pages 11-12
Item 13: Time schedule of enrolment, interventions (including	The content is highlighted under Table 1: Outline of the study design. Page 8

any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure 1).	
Item 14: Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations.	The content is highlighted under Data analysis and statistics, pages 12-13
Item 15: Strategies for achieving adequate participant enrolment to reach target sample size.	The content is highlighted under Data analysis and statistics, subsections Sample size and Non-response, pages 12-13
[16-17] Methods: Assignment of interventions (for controlled trials)	N/A
Item 18a: Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol.	The content is highlighted under sections Methods and Data analysis and statistics, subsection Data Collection
Item 18b: Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols.	N/A
Item 19: Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.	The content is highlighted under Methods, subsection Data storage and privacy, pages 10,11
Item 20a: Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol.	The content is highlighted under Data analysis and statistics, pages 12-13

Item 20b: Methods for any additional analyses (e.g., subgroup and adjusted analyses).	N/A
Item 20c: Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation).	N/A
[21-23] Methods: Monitoring	N/A
Item 24: Plans for seeking research ethics committee/institutional review board (REC/IRB) approval.	The study has received ethical approval. This is highlighted under Declarations, subsection Ethics approval and consent to participate, page 15
Item 25: Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators).	The content is highlighted under section Ethics and dissemination, pages 2 and 3
Item 26a: Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32).	The study will not collect sensitive data. The content is highlighted under section Participants, page 9
Item 26b: Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable.	N/A
Item 27: How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial.	No personal information will be collected during the study. This is highlighted under section <i>Data storage and privacy</i> , page 10
Item 28: Financial and other competing interests for principal investigators for the overall trial and each study site.	The content is highlighted under section Declarations, page 15
Item 29: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators.	The content is highlighted under section Declarations, page 15.
Item 30: Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation.	N/A
Item 31: Dissemination policy	N/A

Item [32-33] Appendices	N/A
References	Citations are made in line with the journal policy

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BMJ Open

Study protocol: A Cross-Sectional Survey on the Expectations and Attitudes of Patients and Healthcare Professionals Towards the Use of Social Humanoid Robots in Nursing during Hospitalization

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Study Protocol: A Cross-Sectional Survey on the Expectations and Attitude of Patients and Healthcare Professionals Towards the Use of Social Humanoid Robots in Nursing during Hospitalization

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Abstract

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Introduction: An aging population, the rise of chronic diseases, and the emergence of new viruses are some of the factors that contribute to an increasing share of gross domestic product in health spending. COVID-19 has shown that nursing staff represents the critical part of hospitalization. Technological developments in robotics and artificial intelligence can significantly reduce costs and lead to improvements in many hospital processes. The proposed study aims to assess expectations, attitudes, and ethical considerations regarding the integration of socially assistive humanoid robots (SAHR) into hospitalized care workflow from patients' and healthcare professionals' perspectives and to compare them with the results of similar studies. Moreover, the authors aim to identify critical barriers and ethical restrictions that have to be considered when the robots will be introduced into real-life settings.

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Methods/Design: The study is designed as a cross-sectional survey which will include three previously validated questionnaires, the Technology-Specific Expectation Scale (TSES), the Ethical Acceptability Scale (EAS), and the Negative Attitudes towards Robots Scale (NARS). The employees of regional clinical centers will be asked to participate via an electronic survey and respond to TSES and EAS questionnaires. Patients will respond to TSES and NARS questionnaires. The survey will be conducted online.

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Ethics and dissemination: Ethical approval for the study was obtained by the Medical Ethics Commission of the University Medical Center (UKC) Maribor. Results will be published in a relevant scientific journal and communicated to participants and relevant institutions through dissemination activities and the ecosystem of the Horizon 2020 funded project HosmartAI (Grant No. 101016834).

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Study Protocol: A Cross-Sectional Survey on the Expectations and Attitude of Patients and Healthcare Professionals Towards the Use of Social Humanoid Robots in Nursing during Hospitalization

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Ethical Approval Date: 06th May 2021

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Estimated Start of the Study: September 2021

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Keywords: socially assistive humanoid robots, robots in nursing, social and ethical barriers, patient expectations and attitudes, artificial intelligence, health application

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Article summary

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Strengths and limitations of this study

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- A large and diverse study sample of patients and healthcare professionals, including physicians and nurses, will be recruited.
 - The study sample will include only subjects from Slovenia, which may lead to cultural bias and limit the generalizability of our results.
 - Data will be collected using self-report questionnaires only, which may lead to random or systematic misreporting.
 - The questionnaires that will be used in our study have previously been validated and used in several languages. Previous studies suggest that they are valid and reliable.
 - Our study will provide a broad assessment of attitudes, expectations and perceived barriers related to the use of humanoid social robots during hospitalization.

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Introduction

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Healthcare systems worldwide are striving to rise to the challenges that result from an aging population, the growth in chronic disease prevalence, the appearance of new viruses, burgeoning technical possibilities, and a rise of public expectations [1]. With the increasing economic burden of modern health, the Organization for Economic Co-operation and

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Development (OECD) estimates that up to 20% of health spending in Europe is spent on services that either do not deliver benefits or are even harmful, as they create additional costs and could be avoided by substituting them with (cheaper) alternatives with identical or greater benefits [2]. Technological developments in robotics and artificial intelligence (AI) could lead to improvements in many hospital processes. In fact, the robotic systems are being increasingly utilized to improve accuracy [3], to improve diagnosis and enable remote treatment [4], in supporting mental health and daily tasks [5,6], and in complementing the human workforce in auxiliary services [7]. Nursing and care, in particular, could gain much from the artificial systems' capacity to assist people with their daily living activities. Namely, nursing and care staff are a critical part of healthcare and make up the largest section of the health profession. According to the World Health Statistics Report, there are approximately 29 million nurses and midwives in the world [8,9], while current estimates suggest that additional 5.9 million nurses are needed worldwide [10]. However, there are multiple concerns related to integrating advanced technologies and assistive technologies in the healthcare sector. The more recognized ones include technical barriers and technological limitations, fairness and sustainability, accountability, acceptance, and negative preconceptions [11].

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Socially intelligent mobile robots have long been posited as a promising response to a chronic nursing shortage in the EU and US Health systems [12]. As physically and socially interactive technologies, SAHR present new opportunities for embodied interaction and active and passive sensing in this context. They have also been shown to psychologically impact individuals, affect group and organizational dynamics, and modify our concepts and experiences of work, care, and social relationships [13]. Although the systems exhibit robust,

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autonomous capabilities and initial concerns regarding physical safety around people have been at least partially addressed, the uptake of the technology is arguably slow. In addition to ethical considerations [14] related to decreased social contact, there are additional barriers related to acceptance, such as patients' stigmatization and fear of the dehumanization of society. The former is mostly related to non-acceptance from end-users [15] and the latter mostly to non-acceptance from healthcare professionals, nurses in particular [16,17]. In general, both relate to oversimplifying the complexity of nursing and care context. *"The implementation of a robotic system in nursing care must be seen as a complex intervention due to the number of involved stakeholders and their behaviors, the variability and number of outcomes and various interacting components."* [15:2]. Oversimplification in design may lead to unhelpful features, creating inconveniences and frustrations, preventing patients and professionals from recognizing the added value [18]. In some cases, robots may even be perceived as a local threat to their independence due to unfamiliarity and technical inexperience [19 - 21]. Furthermore, although healthcare professionals are facing high workloads and tend to recognize the potential value of care robots as an aid in "measuring/monitoring" (e.g., assessment of vital signs), "mobility/activity" (e.g., movement assistance) and "safety of care" (e.g., fall prevention) [22], they are still challenged in fully understanding, prioritizing, and integrating the robotic units into fundamental aspects of care [23,24].

SAHR in nursing can have a significant impact on the workload of nurses and the quality of hospital services. However, the barriers and challenges related to medical ethics (autonomy, beneficence, nonmaleficence, and justice), as well as other expectations and attitudes, have yet to be fully addressed and understood [11, 25]. A more anticipatory and contemporary

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8 position towards technology in nursing must be established with all stakeholders, especially
9 healthcare professionals and patients [26]. Most existing studies focus on long-term (elderly)
10 care or partial substitution of nursing activities rather than SAHRs as complimentary service.
11
12 The most frequently reported barriers fit in socioeconomic and ethical domains and are
13 focused on the implementation outcomes domain. The quality of reporting and quality of
14 evidence were low in most studies [23]. The proposed study will investigate i) general
15 acceptance of robots in the setting of nursing, ii) ethical and professional reservations, and iii)
16 functional (technological) expectations of healthcare providers and patients. The goal is to
17 gain a detailed and comprehensive insight into the current state of attitudes, expectations, and
18 ethical reservations regarding the use of SAHRs in nursing. This will allow us to develop
19 implementation strategies aligned with patients' and professionals' preferences. Moreover, the
20 study could reveal potential misconceptions about SAHRs and point to specific myths or fears
21 that should be addressed with future educational programs. Lastly, the results of the proposed
22 study will also reveal which patients and subpopulations of providers may need additional
23 information regarding the safety and potential benefits of SAHRs.
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Objectives and hypotheses

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45 The main objective is to assess expectations, attitudes, and ethical considerations
46 regarding the integration of SAHRs into the nursing and care workflow at the clinical center
47 in Maribor. With this study, we will evaluate the prevalence of generally recognized barriers
48 that could hinder the integration of SAHRs in the targeted institution. We will gain crucial
49 knowledge on how such SAHRs should be designed to match the complexity of the
50 environment and preferences of the target end-users (before their actual implementation).
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Overall, the study will address the following research questions:

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R1: What do healthcare professionals expect from socially assistive humanoid robots in hospital care?

R2: What do patients expect from socially assistive humanoid robots in hospital care?

R3: What are the main ethical reservations that may impact the acceptance of robotic units in hospital care in healthcare professionals?

R4: What is the general attitude of patients towards socially assistive humanoid robots in hospital care?

R5: How do employees and patients differ in their expectations regarding the use of socially assistive humanoid robots in hospital care?

R6: Which characteristics of healthcare professionals are related to their expectations and ethical reservations regarding the use of socially assistive humanoid robots in hospital care?

R7: Which characteristics of patients are related to their expectations and attitudes regarding the use of socially assistive humanoid robots in hospital care?

Moreover, based on previous literature [27,28], which investigated the role of age, education and other variables in the acceptance of socially assistive robots in different contexts, we have formed the following hypotheses, which concretize our expectations regarding the two correlational research questions (R6 and R7):

H1: Patients' attitudes towards socially assistive humanoid robots in hospital care are negatively related to their age, meaning that older participants exhibit less favorable attitudes.

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H2: Patients' attitudes towards socially assistive humanoid robots in hospital care are positively related to their level of education, meaning that participants with higher education level exhibit more favorable attitudes.

H3: Healthcare providers' opinion on ethical acceptability of socially assistive humanoid robots in hospital care is negatively related to their age, meaning that older participants find their use less acceptable.

H4: Healthcare providers' opinion on ethical acceptability of socially assistive humanoid robots in hospital care is positively related to their age, meaning that participants with higher education find their use more acceptable.

Methods

Design and setting

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The study is a cross-sectional survey evaluating expectations, attitudes, and ethical considerations related to the integration of SAHRs, as perceived by healthcare professionals and patients.

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The participating healthcare professionals employed in one of the hospitals in the region (Slovenia) will be asked to respond to a questionnaires' battery in a digital format, consisting of questions on their demographic characteristics, such as age, gender, and education level. To evaluate the SAHRs a pool of widely used questionnaires will be used [29]. The healthcare professionals will be asked to fill out the TSES [30], which was developed to measure users' expectations prior to encountering and interacting with a robot and which is often used as one of the indicators of acceptability. It can also offer insight into unrealistic ideas regarding the capabilities of robots. The scale consists of 10 items answered using a five-point Likert scale (1 – *Very low expectation*, 5 – *Very high expectation*). These items belong to two subscales,

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namely “capabilities” (e.g., “*I think I will be able to interact with the robot*”) and “fictional view” (e.g., “*I think the robot will have superhuman capacities*”). Both subscales generally exhibit good internal consistency (coefficient $\alpha = > .75$) [30]. Moreover, the healthcare professionals will also fill out the EAS [31], first developed to assess ethical issues in the use of robot-enhanced therapy with children with autism. In its original form, the scale consists of 12 items answered on a five-point Likert scale (1 – *Strongly disagree*, 5 – *Strongly agree*); approximately half of the items are directly focused on children with autism, and others are general. For the purposes of the proposed study, items specifically related to autism will be modified to be applicable in the more general healthcare context. Structurally, the scale consists of three subscales: ethical acceptability for use (5 items; e.g., “*It is ethically acceptable that social robots are used in healthcare*”), ethical acceptability of human-like interaction (4 items; e.g., “*It is ethically acceptable to make social robots that look like humans*”), and ethical acceptability of non-human appearance (3 items; e.g., “*It is ethically acceptable to make social robots that look like objects*”). All subscales generally exhibit good internal consistency (coefficient $\alpha = > .72$) [32]. Additionally, a few additional dichotomous questions will be posed to participants as well (e.g., “*Do you think the robot could answer patient’s questions about treatment?*”). The questionnaires will be digital, distributed to the healthcare professionals by the researchers.

The study will also involve inpatients from the clinical center in Maribor. Patients will be asked to answer questions on their demographic characteristics, such as age, gender, and education level. Similarly, to healthcare professionals, they will also respond to TSES [30]. However, since EAS is rather specific, as it tackles complex ethical issues, it is not as suitable for patients, who are less involved in the ethical aspects of social robots’ implementation. To

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keep the questionnaire battery short, we only plan to collect data that is highly relevant. As such, EAS will be substituted in the patients' sample with the NARS [33] questionnaire - a widely used and cited measure of negative attitudes towards robots, which was developed based on the analysis of participants' open responses regarding the robots. The scale consists of 14 items answered on a five-point Likert scale (1 – *Strongly disagree*, 5 – *Strongly agree*). The factor analyses revealed that NARS consists of three subscales, namely: negative attitudes toward situations of interaction with robots (6 items; e.g., "*I would feel uneasy if I was given a job where I had to use robots*"), negative attitudes toward social influence of robots (5 items; e.g., "*I would feel uneasy if robots really had emotions*"), and negative attitudes towards emotions in interaction with robots (3 items; e.g., "*I would feel relaxed talking with robots*"). Psychometric evaluations of NARS are rather extensive and support its use in various contexts [34]. Patients will respond to the questionnaires in a digital format. The questionnaires will be distributed by the hospital's staff using the hospital's tablets. Additional support will be offered if needed.

In both cases, a non-probability sampling method will be followed, i.e., all the eligible participants from the participating institutions will be invited to participate. The cross-sectional study is planned to begin in September 2021 and the data collection will last until the targeted sample sizes are reached for both populations. If we will not be able to reach the target sample size due to unforeseen challenges, the study will be closed after four months.

Table 1 summarizes the study design:

Table 1: Outline of the study design

<i>Employees in the medical institution</i>	
Design:	An electronic survey among healthcare professional

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Cohorts:	No a priori cohorts; instead, employees in the analyses will be divided according to their gender and occupation
Desired sample size:	500
Inclusion period:	Until the desired sample size is reached (max. 4 months after the beginning of the study)
Exclusion criteria:	None
Inclusion criteria:	Employees of participating medical institutions, between 18 and 65 years of age
Questionnaires:	EAS and TSES, demographic data, additional questions related to acceptance
Other requirements:	Willingness to participate
<i>Inpatients</i>	
Design:	An electronic survey among inpatients. Staff collects the responses using tablets. If needed, support of hospital's staff will be provided
Cohorts:	No a priori cohorts, instead, employees in the analyses will be divided according to their gender
Desired sample size:	500
Inclusion period:	Until the desired sample size is reached (max. 4 months after the beginning of the study)
Exclusion criteria:	Patients hospitalized at the pediatric clinic, department of psychiatry and the clinic for gynecology and perinatology
Inclusion criteria:	Hospitalized patients in the participating medical institution at the time of the survey, capable to sign the informed consent
Questionnaires:	NARS and TSES, demographic data, additional questions related to acceptance
Other requirements:	Willingness to participate

Participants

We plan to recruit 500 healthcare professionals between 18 and 65 years of age (although more than 1000 will probably have to be invited to reach this number). Besides the age requirement, another inclusion criterion for the healthcare professionals is that they need to be

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employed in one of the medical institutions in the region. There are no exclusion criteria for the healthcare professionals.

We estimate that more than 1000 patients will be invited to fill out the questionnaires, leading to the final sample size of about 500 patients aged 18 years or above. The inclusion criteria for the patients are that they need to be hospitalized in the clinical center during the study period, that they are willing to participate, and able to sign the informed consent. The patients hospitalized at the pediatric clinic, department of psychiatry, and the clinic for gynecology and perinatology will not be invited to participate. No information through which individuals could be identified will be collected; in other words, the study will be completely anonymous. Participants will be informed that participation is completely voluntary, and they can terminate their involvement at any time without any consequences. They will also receive the relevant information explaining the intent of the survey, its procedure, foreseen analyses, and dissemination strategy.

Ethical, legal and regulatory aspects

Ethical approval for this study was obtained from the Medical Ethics Commission of the UKC Maribor (UKCM-MB-KME-40/21). The study will not collect sensitive data. Data will be anonymized upon collection. Patients participate on a voluntary basis and sign the consent. The study group will be fully committed to respecting the highest ethical and legal standards.

Data storage and privacy

The study will not collect any personal identifying information, meaning that the data will already be anonymized at the collection point. The results of the study will be published, and data made available in digital form upon reasonable request. However, as a general rule,

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8 respect for fundamental rights to privacy and personal data, as set out in this document, is of
9 paramount importance to all partners and to the project.

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12 In view of this presumption and considering the different modes of flow of personal data
13 (including those categories of personal data that fall under sensitive data, as set out in Article
14 9 of the GDPR), the following compliance rules and management policies will apply. Among
15 personal data, we will collect information on gender, age, and level of education of patients,
16 and for employees, additional information on their occupation. The time span of the survey
17 will be used and not the exact date of the completed survey for the individual. Data will be
18 processed using descriptive statistics and appropriate inferential statistical tests.
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Management and reporting of adverse reactions

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31 We do not expect any adverse effects in the study. The only adverse event could be the
32 unwillingness of patients and staff to participate.
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Patient and Public Involvement

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38 Healthcare professionals of the participating medical institution were involved in the study
39 design. Patients were not involved in the study design. The results of the study will be
40 disseminated to the participants and public via publication of open access research papers and
41 dissemination channels of all participating institutions. These include local and social media,
42 website posts, and blog posts.
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Outcomes

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52 This study will examine the research questions and hypotheses to determine the prevalence of
53 various expectations, attitudes, and ethical reservations in two subsamples – patients and
54 employees. We are also interested in the relationship between expectations and attitudes of
55 patients and their age, gender, and education. Similarly, we are interested in the relationship
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between expectations and ethical reservations of employees, and their age, gender, education, and occupation. Table 2 summarizes the expected outcomes related to correlations and differences between subcohorts.

Table 2: Expected differences and correlations between sociodemographic variables and attitudes, expectations, and ethical reservations regarding SAHRs among employees and patients

Employee categories	Expected cohorts	Measuring tool
Age	Younger employees are more open to the idea of implementing a robot into medical care.	TSES and EAS Questionnaires (electronic form)
Gender	No expected difference in these groups.	
Education	We expect that employees with higher levels of education will be more open to the idea of implementing a robot into medical care.	
Occupation	Outcome uncertain.	
Inpatient categories	Expected cohorts	Measuring tool
Age	Younger patients are more open to the idea of implementing a robot into medical care.	TSES and NARS Questionnaires (electronic form)
Gender	No expected difference in the two groups.	
Education	We expect that patients with higher levels of education will be more open to the idea of implementing a robot into medical care.	

Data analysis and statistics

Sample size determination

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The sample size was determined based on various information sources, namely the observed sample sizes in previous similar studies, our selected tools, research questions and hypotheses (i.e., expected results), as well as the ratio between population and sample size.

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The sample sizes in previous studies normally vary between 50 to 300 participants [e.g., 35-38]. However, some of these studies explicitly mention that the generalizability of their results is limited due to a relatively low number of participants. As such, our goal is to overcome this limitation.

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Moreover, based on the selected tools, research questions, and hypotheses, we need a large enough sample to be able to detect relatively weak correlations between the measured constructs. For example, Heerink, 2011 [27] has found that the correlation between age and education, and attitudes towards the application of the robot are approximately $\pm .15$. Hence, the sample size calculation in the G*Power 3.1.9.7 software (two-tailed test, correlation = .15, $\alpha = .05$, $1-\beta = .80$) suggests the recruitment of at least 346 employees and 346 inpatients to achieve statistical significance (p -value) equal or below .05.

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Lastly, we want our sample to be as representative as possible (but data collection also needs to be feasible). For example, the main participating hospital employs approximately 3360 medical and non-medical staff members (approx. 600 medical doctors and 1500 healthcare workers). Using Israel's table [39] of sample sizes necessary for given combinations of population size, precision, confidence levels, and variability, this would suggest the recruitment of about 333 employees (given the $\pm 5\%$ precision). However, to further ensure a relevant sample of healthcare professionals, other hospitals from the region will also be invited to participate. The invitation will be carried out through already established research channels between the sponsor and centers in the region. As such, the population size is

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actually higher and this should also be reflected in our sample size. The population of patients is also quite large; the primary participating hospital is a 1316-bed facility and approximately 60,000 patients are treated annually.

Considering all the factors described above, we argue that approximately 500 employees and 500 patients should suffice for statistical inference as well as adequate generalizability of results.

Analysis

We will use the R 3.4.2 and IBM SPSS Statistics 26 programs for statistical analysis. Results with a p -value below .05 will be considered statistically significant. In the first steps, the missing values will be replaced (according to the logic of multiple imputation or using the “missForest” procedure). In addition, we will perform basic psychometric analyses, namely factor analysis and analysis of reliability as internal consistency (coefficient alpha). With a sufficient sample, the measurement invariance of the questionnaires used will also be checked. In accordance with the results of these preliminary analyses, the values of the parent dimensions (factor scores) will be calculated.

Following that, basic descriptive analyses will be performed (calculation of M and SD), and the normality of the distribution of the included variables and other assumptions of statistical tests, outlined below, will be checked. Since normality tests (such as the Kolmogorov-Smirnov test) are generally too sensitive in case of a relatively large sample size (and our hypothesized sample size may be considered as large), we will mostly rely on visual inspection, skewness, and kurtosis. Specifically, a general rule of thumb that suggests the use of parametric tests if skewness and kurtosis are between $-2,00$ and $2,00$ will be applied.

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Additionally, basic correlation analyses (Pearson's r) will be used to provide insight into the associations between variables. In cases where hypotheses assume the comparison of two or more independent groups, t -tests for two independent samples (e.g., to identify gender differences) and one-way analysis of variance analysis (ANOVA for independent groups, e.g., to identify differences between occupational groups) will also be used. In cases of correlation of the studied dependent variables, the MANOVA test (multivariate analysis of variance) will be used instead of the ANOVA test for independent groups.

Non-response

People tend to be more inclined to answer the questionnaire when they are familiar with the current subject. This situation might skew the prevalence estimates (regarding expectations, attitudes, ethical acceptability) found in our sample in case of substantial non-response. To evade considerable non-response among the patient population, healthcare professionals will inform patients regarding their value in the study even though they do not have experience with social robotic systems. Moreover, when necessary, the healthcare professionals will provide further assistance and explanation.

Declarations

Ethics approval and consent to participate

This study has been approved by the Medical Ethics Commission of the UKC Maribor (UKCM-MB-KME-40/21). The study will not collect sensitive data. Data will be anonymized upon collection. Informend patient consent is collected.

Consent for publication

Not applicable.

Availability of data and materials

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No sensitive data will be collected. Anonymized data collected during the study will be made available to other researchers upon reasonable request.

Competing interests

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The authors declare that they have no competing interests.

Funding

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Authors' contributions

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All authors conceptualized the study. IM and AB were in charge of the study design and wrote the original draft and the draft version of primary and secondary endpoints. VF, NK, TK, and MM were in charge of the inclusion/exclusion criteria and defined how the study would be carried out. US and NP were in charge of the definition of the data analysis methodology and the statistics, including sample size calculations. All authors contributed to background research. AB, VF, NK, TK, and MM were in charge of the ethics approval process. All authors contributed to the revision of the study. All authors read and approved the final manuscript.

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Not applicable.

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Study Protocol: A Survey Exploring Patients' and Healthcare Professionals' Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially Assistive Humanoid Robots in Nursing

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Study Protocol: A Survey Exploring Patients' and Healthcare Professionals' Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially Assistive Humanoid Robots in Nursing

Abstract

Introduction: Population aging, the rise of chronic diseases, and the emergence of new viruses are some of the factors that contribute to an increasing share of gross domestic product dedicated to health spending. COVID-19 has shown that nursing staff represents the critical part of hospitalization. Technological developments in robotics and artificial intelligence can significantly reduce costs and lead to improvements in many hospital processes. The proposed study aims to assess expectations, attitudes, and ethical acceptability regarding the integration of socially assistive humanoid robots (SAHR) into hospitalized care workflow from patients' and healthcare professionals' perspectives and to compare them with the results of similar studies.

Methods/Design: The study is designed as a cross-sectional survey which will include three previously validated questionnaires, the Technology-Specific Expectation Scale (TSES), the Ethical Acceptability Scale (EAS), and the Negative Attitudes towards Robots Scale (NARS). The employees of a regional clinical center will be asked to participate via an electronic survey and respond to TSES and EAS questionnaires. Patients will respond to TSES and NARS questionnaires. The survey will be conducted online.

Ethics and dissemination: Ethical approval for the study was obtained by the Medical Ethics Commission of the University Medical Center (UKC) Maribor. Results will be published in a relevant scientific journal and communicated to participants and relevant institutions through dissemination activities and the ecosystem of the Horizon 2020 funded project HosmartAI (Grant No. 101016834).

Ethical Approval Date: 06th May 2021

Estimated Start of the Study: December 2021

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Keywords: socially assistive humanoid robots, expectations, attitudes, ethical acceptance, artificial intelligence, health application

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Article summary

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Strengths and limitations of this study

- The study sample will include only subjects from Slovenia, which may lead to cultural bias and limit the generalizability of our results.
- Data will be collected using self-report questionnaires only, which may lead to random or systematic misreporting.
- A large and diverse study sample of patients and healthcare professionals, including physicians and nurses, will be recruited.
- The questionnaires that will be used in our study have previously been validated and used in several languages. Previous studies suggest that they are valid and reliable.
- Our study will provide a broad assessment of attitudes, expectations, and aspects of ethical acceptability related to the use of socially assistive humanoid robots during hospitalization.

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Introduction

Healthcare systems worldwide are striving to rise to the challenges that result from an aging population, the growth in chronic disease prevalence, the appearance of new viruses, burgeoning technical possibilities, and a rise of public expectations [1]. With the increasing economic burden of modern health, the Organization for Economic Co-operation and Development (OECD) estimates that up to 20% of health spending in Europe is spent on services that either do not deliver benefits or are even harmful, as they create additional costs and could be avoided by substituting them with (cheaper) alternatives with identical or greater benefits [2]. Technological developments in robotics and artificial intelligence (AI) could lead to improvements in many hospital processes. In fact, the robotic systems are being increasingly utilized to improve accuracy [3], to improve diagnosis and enable remote treatment [4], in supporting mental health and daily tasks [5,6], and in complementing the human workforce in auxiliary services [7]. Nursing and care, in particular, could gain much from the artificial systems' capacity to assist people and decrease the workload. Namely, nursing and care staff are a critical part of healthcare and make up the largest section of the health profession. According to the World Health Statistics Report, there are approximately 29 million nurses and midwives in the world [8,9], while current estimates suggest that additional 5.9 million nurses are needed worldwide [10]. However, there are multiple concerns related to integrating advanced technologies and assistive technologies in the healthcare sector. The more recognized ones include technical barriers and technological limitations, fairness and sustainability, accountability, acceptance, and negative preconceptions [11].

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8 Socially assistive humanoid robots (SAHR) have long been posited as a promising response
9 to a chronic nursing shortage in the EU and US Health systems [12]. As physically and
10 socially interactive technologies, SAHR present new opportunities for embodied interaction
11 and active and passive sensing in this context. They have also been shown to psychologically
12 impact individuals, affect group and organizational dynamics, and modify our concepts and
13 experiences of work, care, and social relationships [13]. Although the systems exhibit robust,
14 autonomous capabilities and initial concerns regarding physical safety around people have
15 been at least partially addressed, the uptake of the technology is arguably slow. In addition to
16 ethical considerations [14] related to decreased social contact, there are additional barriers
17 related to acceptance, such as patients' stigmatization and fear of the dehumanization of
18 society. The former is mostly related to non-acceptance from end-users [15] and the latter
19 mostly to non-acceptance from healthcare professionals, nurses in particular [16,17]. In
20 general, both relate to oversimplifying the complexity of nursing and care context. "*The*
21 *implementation of a robotic system in nursing care must be seen as a complex intervention*
22 *due to the number of involved stakeholders and their behaviors, the variability and number of*
23 *outcomes and various interacting components.*" [15:2]. Oversimplification in design may lead
24 to unhelpful features, creating inconveniences and frustrations, preventing patients and
25 professionals from recognizing the added value [18]. In some cases, robots may even be
26 perceived as a local threat to their independence due to unfamiliarity and technical
27 inexperience [19 - 21]. Previous research suggests that such negative perceptions are more
28 common among certain subgroups of the population, such as those that are older and less
29 educated [22,23]. Furthermore, although healthcare professionals are facing high workloads
30 and tend to recognize the potential value of care robots as an aid in "measuring/monitoring"
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(e.g., assessment of vital signs), “mobility/activity” (e.g., movement assistance) and “safety of care” (e.g., fall prevention) [24], they are still challenged in fully understanding, prioritizing, and integrating the robotic units into fundamental aspects of care [25,26].

SAHR in nursing can have a significant impact on the workload of nurses and the quality of hospital services. However, the barriers and challenges related to medical ethics (autonomy, beneficence, nonmaleficence, and justice), as well as other expectations and attitudes, have yet to be fully addressed and understood [11, 27]. A more anticipatory and contemporary position towards technology in nursing must be established with all stakeholders, especially healthcare professionals and patients [28]. Most existing studies focus on long-term (elderly) care or partial substitution of nursing activities rather than SAHRs as complimentary service. The most frequently reported barriers fit in socioeconomic and ethical domains and are focused on the implementation outcomes domain. The quality of reporting and quality of evidence were low in most studies [25]. The proposed study will investigate i) general attitudes of patients towards SAHR in the setting of nursing, ii) ethical acceptability among healthcare professionals, and iii) functional (technological) expectations of healthcare professionals and patients. The goal is to gain a detailed and comprehensive insight into the current state of attitudes, expectations, and ethical acceptability regarding the use of SAHRs in the Slovenian public healthcare context where the implementation of digital tools is riddled with challenges [29]. This will allow us to develop implementation strategies aligned with patients' and professionals' preferences. Moreover, the study could reveal potential misconceptions about SAHRs and point to specific myths or fears that should be addressed with future educational programs. Lastly, the results of the proposed study will also reveal

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8 which patients and subpopulations of providers, based on their demographic characteristics,
9 may need additional information regarding the safety and potential benefits of SAHRs.
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12 **Objectives and hypotheses**
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15 The main objective is to assess expectations, attitudes, and ethical acceptability
16 regarding the integration of SAHRs into the nursing and care workflow at the regional clinical
17 center. With this study, we will evaluate the prevalence of generally recognized barriers that
18 could hinder the integration of SAHRs in the targeted institution. We will gain crucial
19 knowledge on how such SAHRs should be designed to match the complexity of the
20 environment and preferences of the target end-users (before their actual implementation).
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29 Overall, the study will address the following research questions:
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31 *R1: What do healthcare professionals expect from SAHRs in hospital care?*
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33 *R2: What do patients expect from SAHRs in hospital care?*
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35 *R3: To what extent do healthcare professionals find the use of SAHRs in hospital care*
36 *ethically acceptable?*
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38 *R4: What is the general attitude of patients towards SAHRs in hospital care?*
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40 *R5: How do healthcare professionals and patients differ in their expectations regarding the*
41 *use of SAHRs in hospital care?*
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43 *R6: Which demographic characteristics of healthcare professionals (i.e., gender, age,*
44 *education, occupation) are related to their expectations and ethical acceptability regarding*
45 *the use of SAHRs in hospital care?*
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48 *R7: Which demographic characteristics of patients (i.e., gender, age, education) are related*
49 *to their expectations and attitudes regarding the use of SAHRs in hospital care?*
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Moreover, based on previous literature [22,23], which investigated the role of age, education and other variables in the acceptance of SAHRs in different contexts, we have formed the following hypotheses, which concretize our expectations regarding the two correlational research questions (R6 and R7):

H1: Patients' attitudes towards SAHRs in hospital care are negatively related to their age, meaning that older participants exhibit less favorable attitudes.

H2: Patients' attitudes towards SAHRs in hospital care are positively related to their level of education, meaning that participants with higher education level exhibit more favorable attitudes.

H3: Healthcare professionals' opinion on ethical acceptability of SAHRs in hospital care is negatively related to their age, meaning that older participants find their use less acceptable.

H4: Healthcare professionals' opinion on ethical acceptability of SAHRs in hospital care is positively related to their age, meaning that participants with higher education find their use more acceptable.

Methods

Design and setting

The study is a cross-sectional survey evaluating expectations, attitudes, and ethical acceptability related to the integration of SAHRs, as perceived by healthcare professionals and patients.

The participating healthcare professionals employed in the clinical center in Maribor (Slovenia) will be asked to respond to a questionnaires' battery in a digital format, consisting of questions on their demographic characteristics, namely age, gender, education level, and occupation. To collect information regarding the SAHRs, we will use two widely used

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questionnaires [30]. The healthcare professionals will be asked to fill out the Technology-Specific Expectation Scale (TSES) [31], which was developed to measure users' expectations prior to encountering and interacting with a robot and which is often used as one of the indicators of acceptability. It can also offer insight into unrealistic ideas regarding the capabilities of robots. The scale consists of 10 items answered using a five-point Likert scale (1 – *Very low expectation*, 5 – *Very high expectation*). These items belong to two subscales, namely “capabilities” (e.g., “*I think I will be able to interact with the robot*”) and “fictional view” (e.g., “*I think the robot will have superhuman capacities*”). Both subscales generally exhibit good internal consistency (coefficient $\alpha = > .75$) [31]. Moreover, the healthcare professionals will also fill out the Ethical Acceptability Scale (EAS) [32], first developed to assess ethical issues in the use of robot-enhanced therapy with children with autism. In its original form, the scale consists of 12 items answered on a five-point Likert scale (1 – *Strongly disagree*, 5 – *Strongly agree*); approximately half of the items are directly focused on children with autism, and others are general. For the purposes of the proposed study, items specifically related to autism will be modified slightly to be applicable in the more general healthcare context (only small modifications are needed, as the items capture ethical reservations regarding SAHRs that exist in various contexts). Structurally, the scale consists of three subscales: ethical acceptability for use (5 items; e.g., “*It is ethically acceptable that social robots are used in healthcare*”), ethical acceptability of human-like interaction (4 items; e.g., “*It is ethically acceptable to make social robots that look like humans*”), and ethical acceptability of non-human appearance (3 items; e.g., “*It is ethically acceptable to make social robots that look like objects*”). All subscales generally exhibit good internal consistency (coefficient $\alpha = > .72$) [33]. Additionally, a few additional dichotomous questions

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will be posed to participants as well (e.g., “*Do you think the robot could answer patient’s questions about treatment?*”). The questionnaires will be digital, distributed to the healthcare professionals by the researchers.

The study will also involve inpatients from the clinical center in Maribor. Patients will be asked to answer questions on their demographic characteristics, namely age, gender, and education level. Similarly to healthcare professionals, they will also respond to TSES [31]. However, since EAS is rather specific, as it tackles complex ethical issues, it is not as suitable for patients, who are less involved in the ethical aspects of SAHRs implementation. As such, EAS will be substituted in the patients’ sample with the Negative Attitudes towards Robots Scale (NARS) [34] - a widely used and cited measure of negative attitudes towards robots, which was developed based on the analysis of participants’ open responses regarding the robots. The scale consists of 14 items answered on a five-point Likert scale (1 – *Strongly disagree*, 5 – *Strongly agree*). The factor analyses revealed that NARS consists of three subscales, namely: negative attitudes toward situations of interaction with robots (6 items; e.g., “*I would feel uneasy if I was given a job where I had to use robots*”), negative attitudes toward social influence of robots (5 items; e.g., “*I would feel uneasy if robots really had emotions*”), and negative attitudes towards emotions in interaction with robots (3 items; e.g., “*I would feel relaxed talking with robots*”). Psychometric evaluations of NARS are rather extensive and support its use in various contexts [35]. Patients will respond to the questionnaires in a digital format. The questionnaires will be distributed by the hospital’s staff using the hospital’s tablets. Additional support will be offered if needed.

In both cases, a non-probability sampling method will be followed, i.e., all the eligible participants from the participating institution will be invited to participate. The cross-sectional

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study is planned to begin in December 2021 and the data collection will last until the targeted sample sizes are reached for both populations. If we will not be able to reach the target sample size due to unforeseen challenges, the study will be closed after four months. Table 1 summarizes the study design.

Table 1: Outline of the study design

<i>Healthcare professionals</i>	
Design:	An electronic survey among healthcare professionals
Cohorts:	No a priori cohorts; instead, employees will be divided according to their gender and occupation in the analyses
Desired sample size:	500
Inclusion period:	Until the desired sample size is reached (max. 4 months after the beginning of the study)
Exclusion criteria:	None
Inclusion criteria:	Employees of participating medical institution, between 18 and 65 years of age
Questionnaires:	EAS and TSES, demographic data, additional questions related to acceptance
Other requirements:	Willingness to participate
<i>Patients</i>	
Design:	An electronic survey among inpatients. Staff collects the responses using tablets. If needed, support of hospitals' staff will be provided
Cohorts:	No a priori cohorts, instead, patients will be divided according to their gender in the analyses
Desired sample size:	500
Inclusion period:	Until the desired sample size is reached (max. 4 months after the beginning of the study)
Exclusion criteria:	Patients hospitalized at the pediatric clinic, department of psychiatry and the clinic for gynecology and perinatology

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Inclusion criteria:	Hospitalized patients in the participating medical institution at the time of the survey, capable of signing the informed consent
Questionnaires:	NARS and TSES, demographic data, additional questions related to acceptance
Other requirements:	Willingness to participate

Participants

We plan to recruit 500 healthcare professionals between 18 and 65 years of age (although more than 1000 will probably have to be invited to reach this number). Besides the age requirement, another inclusion criterion for the healthcare professionals is that they need to be employed in the participating medical institution. There are no exclusion criteria for the healthcare professionals.

We estimate that more than 1000 patients will be invited to fill out the questionnaires, leading to the final sample size of about 500 patients aged 18 years or above. The inclusion criteria for the patients are that they need to be hospitalized in the clinical center during the study period, that they are willing to participate, and able to sign the informed consent. The patients hospitalized at the pediatric clinic, department of psychiatry, and the clinic for gynecology and perinatology will not be invited to participate. No information through which individuals could be identified will be collected; in other words, the study will be completely anonymous. Participants will be informed that participation is completely voluntary, and they can terminate their involvement at any time without any consequences. They will also receive the relevant information explaining the intent of the survey, its procedure, foreseen analyses, and dissemination strategy.

Ethical, legal and regulatory aspects

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Ethical approval for this study was obtained from the Medical Ethics Commission of the UKC Maribor (UKCM-MB-KME-40/21). The study will not collect sensitive data (e.g., data revealing racial or ethnic origin, sexual orientation, religious beliefs, etc.). Data will be anonymized upon collection. Patients participate on a voluntary basis and sign the consent.

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The study group will be fully committed to respecting the highest ethical and legal standards.

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Data storage and privacy

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The study will not collect any personal identifying information, meaning that the data will already be anonymized at the collection point. The results of the study will be published, and data made available in digital form upon reasonable request. However, as a general rule, respect for fundamental rights to privacy and personal data, as set out in this document, is of paramount importance to all partners and to the project.

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In view of this presumption and considering the different modes of flow of personal data (including those categories of personal data that fall under sensitive data, as set out in Article 9 of the GDPR), the following compliance rules and management policies will apply. Among personal data, we will collect information on gender, age, and level of education of patients, and for employees, additional information on their occupation. The time span of the survey will be used and not the exact date of the completed survey for the individual. Data will be processed using descriptive statistics and appropriate inferential statistical tests.

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Management and reporting of adverse reactions

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We do not expect any adverse effects in the study. The only adverse event could be the unwillingness of patients and staff to participate.

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Patient and Public Involvement

Healthcare professionals of the participating medical institution were involved in the study design (e.g., selection of relevant variables and questionnaires, method of data collection) via multidisciplinary workshops and electronic communication. Patients were not involved in the study design. The results of the study will be disseminated to the participants and public via publication of open access research papers and relevant dissemination channels. These include local and social media, website posts, and blog posts.

Outcomes

This study will examine the research questions and hypotheses to determine the prevalence of various expectations, attitudes, and ethical reservations in two subsamples – patients and employees. We are also interested in the relationship between expectations and attitudes of patients and their age, gender, and education. Similarly, we are interested in the relationship between expectations and ethical acceptability of employees, and their age, gender, education, and occupation. Table 2 summarizes the expected outcomes related to correlations and differences between subcohorts.

Table 2: Expected differences and correlations between sociodemographic variables and attitudes, expectations, and ethical acceptability regarding SAHRs among employees and patients

Employee categories	Expected results	Measuring tool
Age	Younger employees are more open to the idea of implementing a SAHR into nursing care.	TSES and EAS Questionnaires (electronic form)
Gender	No expected difference in these groups.	

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Education	We expect that employees with higher levels of education will be more open to the idea of implementing a SAHR into nursing care.	
Occupation	Outcome uncertain.	
Inpatient categories	Expected results	Measuring tool
Age	Younger patients are more open to the idea of implementing a SAHR into nursing care.	TSES and NARS Questionnaires (electronic form)
Gender	No expected difference in the two groups.	
Education	We expect that patients with higher levels of education will be more open to the idea of implementing a SAHR into nursing care.	

Data analysis and statistics

Sample size determination

The sample size was determined based on various information sources, namely the observed sample sizes in previous similar studies, our selected tools, research questions and hypotheses (i.e., expected results), as well as the ratio between population and sample size.

The sample sizes in previous studies normally vary between 50 to 300 participants [e.g., 36-39]. However, some of these studies explicitly mention that the generalizability of their results is limited due to a relatively low number of participants. As such, our goal is to overcome this limitation.

Moreover, based on the selected tools, research questions, and hypotheses, we need a large enough sample to be able to detect relatively weak correlations between the measured constructs. For example, Heerink, 2011 [22] has found that the correlation between age and education, and attitudes towards the application of the robot are approximately $\pm .15$. Hence,

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the sample size calculation in the G*Power 3.1.9.7 software (two-tailed test, correlation = .15, $\alpha = .05$, $1-\beta = .80$) suggests the recruitment of at least 346 employees and 346 inpatients to achieve statistical significance (p -value) equal or below .05.

Lastly, we want our sample to be as representative as possible (but data collection also needs to be feasible). For example, the main participating hospital employs approximately 3360 medical and non-medical staff members (approx. 600 medical doctors and 1500 healthcare workers). Using Israel's table [40] of sample sizes necessary for given combinations of population size, precision, confidence levels, and variability, this would suggest the recruitment of about 333 (given the $\pm 5\%$ precision) to 714 (given the $\pm 3\%$ precision) employees. The population of patients is also quite large; the primary participating hospital is a 1316-bed facility and approximately 60,000 patients are treated annually.

Considering all the factors described above, we argue that approximately 500 employees and 500 patients should suffice for statistical inference as well as adequate generalizability of results.

Analysis

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We will use the R 3.4.2 and IBM SPSS Statistics 26 programs for statistical analysis. Results with a p -value below .05 will be considered statistically significant. In the first steps, the missing values will be replaced (according to the logic of multiple imputation or using the “missForest” procedure). In addition, we will perform basic psychometric analyses, namely factor analysis and analysis of reliability as internal consistency (coefficient alpha). With a sufficient sample, the measurement invariance of the questionnaires used will also be

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8 checked. In accordance with the results of these preliminary analyses, the values of the parent
9 dimensions (factor scores) will be calculated.
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12 Following that, basic descriptive analyses will be performed (calculation of M and SD), and
13 the normality of the distribution of the included variables and other assumptions of statistical
14 tests, outlined below, will be checked. Since normality tests (such as the Kolmogorov-
15 Smirnov test) are generally too sensitive in case of a relatively large sample size (and our
16 hypothesized sample size may be considered as large), we will mostly rely on visual
17 inspection, skewness, and kurtosis. Specifically, a general rule of thumb that suggests the use
18 of parametric tests if skewness and kurtosis are between $-2,00$ and $2,00$ will be applied.
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20 Additionally, basic correlation analyses (Pearson's r) will be used to provide insight into the
21 associations between variables. In cases where hypotheses assume the comparison of two or
22 more independent groups, t -tests for two independent samples (e.g., to identify gender
23 differences) and one-way analysis of variance analysis (ANOVA for independent groups, e.g.,
24 to identify differences between occupational groups) will also be used. In cases of correlation
25 of the studied dependent variables, the MANOVA test (multivariate analysis of variance) will
26 be used instead of the ANOVA test for independent groups.
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29 ***Non-response***
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32 People tend to be more inclined to answer the questionnaire when they are familiar with the
33 current subject. This situation might skew the prevalence estimates (regarding expectations,
34 attitudes, ethical acceptability) found in our sample in case of substantial non-response. To
35 evade considerable non-response among the patient population, healthcare professionals will
36 inform patients regarding their value in the study even though they do not have experience
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8 with SAHRs. Moreover, when necessary, the healthcare professionals will provide further
9 assistance and explanation.
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Declarations

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Ethics approval and consent to participate

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This study has been approved by the Medical Ethics Commission of the UKC Maribor (UKCM-MB-KME-40/21). The study will not collect sensitive data. Data will be anonymized upon collection. Informed patient consent is collected.

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Consent for publication

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Not applicable.

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Availability of data and materials

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No sensitive data will be collected. Anonymized data collected during the study will be made available to other researchers upon reasonable request.

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Competing interests

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The authors declare that they have no competing interests.

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Authors' contributions

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8 All authors conceptualized the study. IM and AB were in charge of the study design
9 and wrote the original draft and the draft version of primary and secondary endpoints. VF,
10 NK, TK, and MM were in charge of the inclusion/exclusion criteria and defined how the
11 study would be carried out. US and NP were in charge of the definition of the data analysis
12 methodology and the statistics, including sample size calculations. All authors contributed to
13 background research. AB, VF, NK, TK, and MM were in charge of the ethics approval
14 process. All authors contributed to the revision of the study. All authors read and approved the
15 final manuscript.
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