

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>info.bmjopen@bmj.com</u>

BMJ Open

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

Journal:	BMJ Open
Manuscript ID	bmjopen-2021-054310
Article Type:	Protocol
Date Submitted by the Author:	08-Jun-2021
Complete List of Authors:	Mlakar, Izidor; University of Maribor Faculty of Electrical Engineering and Computer Science Kampič, Tadej; Univerzitetni Klinicni Center Maribor Flis, Vojko; Univerzitetni Klinicni Center Maribor, Vascualr Surgery Kobilica, Nina; Univerzitetni Klinicni Center Maribor, Vascular Surgery Molan, Maja; Univerzitetni klinični center Maribor Smrke, Urška; University of Maribor Faculty of Electrical Engineering and Computer Science Plohl, Nejc ; University of Maribor, Department of Psychology Bergauer, Andrej; Univerzitetni Klinicni Center Maribor, Vascular Surgery
Keywords:	QUALITATIVE RESEARCH, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE[™] Manuscripts

1	
2	
3	Study protocol: a cross-sectional survey on expectations and attitude of patients and
4	
5	healthcare professionals towards the use of social humanoid robots in nursing during
6	neartheare professionals towards the use of social numanoid robots in nursing during
7	hospitalization
8	hospitalization
9 10	
10	Izidor Mlakar ¹ , Tadej Kampič ² , Vojko Flis ² , Nina Kobilica ² , Maja Molan ² , Urška Smrke ¹ ,
12	
13	Nejc Plohl ³ , Andrej Bergauer ²
14	
15	
16	
17	¹ University of Maribor, Faculty of Electrical Engineering and Computer Science, Slovenia
18	
19	² University Clinical Center Maribor, Slovenia
20	
21	
22	³ University of Maribor, Faculty of Arts, Department of Psychology, Slovenia
23	
24	
25	
26	
27	
28	³ University of Maribor, Faculty of Arts, Department of Psychology, Slovenia
29	
30	
31	
32	
33	
34	
35	
36 27	
37	
38 39	
40	
40	
42	
43	Corresponding author: Izidor Mlakar, University of Maribor, Faculty of Electrical
44	
45	Engineering and Computer Science, Koroška cesta 46, 2000 Maribor, Slovenija; T: + 386 2
46	
47	220 7267; E-mail: izidor.mlakar@um.si
48	\sim
49	
50	
51	
52	
53	
54	

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

Abstract

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.

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 questionaries. Patients will respond to TSES and NARS questionaries. 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.

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.

BMJ Open

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

Ethical Approval Date: 06th May 2021

Estimated Start of the Study: September 2021

Keywords: robots in nursing, social robotic systems, nursing, social and ethical barriers,

patient expectations, artificial intelligence, health application

Article summary

Strengths and limitations of this study

- A substantial and diverse study population of patients and healthcare professionals including physicians, nurses, technologists and other staff.
- The cohort will include subjects from the region rather than country.
- Data will be collected based on subjective questionnaires, which may lead to information bias.
- The applied questionnaires have undergone widespread use in several languages, allowing a comparison between different populations, cultures, and contexts of use of SRS.
- Broad assessment of expectations and barriers to use of social robotic systems during hospitalization.

Introduction

Healthcare systems throughout the world are striving to rise to the challenges that result from an ageing population, the growth in chronic disease prevalence, 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, create additional costs and could be avoided by substituting (cheaper) alternatives with identical or greater benefits [2].

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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

 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]

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

BMJ Open

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

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

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

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

BMJ Open

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

H1: Patients' attitudes towards the robot are related to their age.

H2: Patients with higher reported level of education have statistically significantly more positive attitude towards the robot.

H3: The higher the education of the employee, the more he / she is in favor of the robot.
H4: There is a statistically significant difference in relation to the robot between the groups of healthcare employees according to their profession and patients they care for in daily routine.

H5: There is a statistically significant difference in relation to the robot between the groups of patients depending on their momentary status of dependence (i.e. disease/condition).
H6: There is a statistically significant difference in relation to the robot between the groups of patients depending on their duration of hospitalization.

ien

Methods

Design and setting

The study is a cross-sectional survey investigating the feasibility and technical and nontechnical considerations of integration of social robotic systems as perceived by healthcare professionals and patients in hospitals in the region.

The cross-sectional study will include at least 1,000 healthcare professionals and at least 500 inpatients answering to two questionnaires. The healthcare professionals of the hospitals in the region (Slovenia) will be asked to participate via an electronic survey and respond to TSES [21] and EAS [22] questionnaires. Based on age, gender, department (medical or support staff) and education, the initial attitude of healthcare employees before meeting the robot – nurse will be assessed.

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

Inpatients at University Clinical Center and Hospital (UKC Maribor) will be asked to respond

to TSES [21] and NARS23000 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 desi	gn
------------------------------------	----

Employees in the medical institution: UKC Maribor and other hospitals		
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	
Inpatients of UKC Maribor		
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		

BMJ Open

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

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	

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

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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

results will be compared with studies in similar settings in order to estimate cross-cultural differences.

Ethical, legal and regulatory aspects

The study group will be fully committed to respecting the highest ethical, fundamental rights and legal standards as recognized at European Union and international level, including the EU Charter of Fundamental Rights (2000 / c 364/01), the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), the European Code of Conduct for Research Integrity and the OECD Council Recommendations on Health Data Management. In addition, the project will be implemented in accordance with the Declaration of Helsinki and Taipei and the Convention for the Protection of Human Rights and Human Dignity in Biology and Medicine.

As a rule, all research activities are carried out on the basis of the following principles of bioethics to ensure the protection and dignity of patients:

- Autonomy: An individual's right to free choice has to be respected
- Non-maleficence: No harm must come to the patient.
- Beneficence: Procedures must be done with the intent of doing good.
- Justice: Risks and benefits must be correctly balanced

Researchers and any other person participating in the research will pay close attention to the standard of ethics and integrity of the research, taking into account the following moral constraints:

- **Reliability** in ensuring the quality of research, which is reflected in the design, methodology, analysis and use of resources.
- **Honesty** in developing, reviewing, reporting and communicating research in a transparent, fair, comprehensive and impartial manner.
- **Respect** for collaborators, research participants, society, ecosystems, cultural heritage and the environment.

BMJ Open

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

• **Responsibility** for research from idea to publication, for its management and organization, for training, supervision, mentoring and for wider influences.

Data storage and privacy

The study will not collect any personal information. 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.

In view of this presumption and taking into account 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. Anonymous survey regarding patient attitudes towards the robot in a hospital environment for the needs of the international project Horizon 2020 will be carried out for the preliminary needs of the project. For the most part, questionnaires with the Likert scale will be used, and among personal data we will only collect information on gender, age and level of education of patients, and for employees, an 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. The data will be anonymized at the collection point.

Management and reporting of adverse reactions

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

Patient and Public Involvement

Since the study is a survey, the patients' direct involvement in the study design was not applicable. The results of the study will be disseminated to the participants and public via

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

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

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

the patients and	employees

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

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

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

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 (Cronbach's 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. Specifically, 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

A tendency for people to be more inclined to answer the questionnaire when they are familiar with the current subject. This situation will inflate the prevalence estimate found in our sample in case of substantial non-response. To evade the non-respondent 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.

BMJ Open

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

Discussion

Technological developments in robotics and artificial intelligence can significantly reduce costs and lead to improvements in many hospital processes. Artificial intelligence and digital solutions are going to contribute to more efficient and automated work management processes and continuous training of healthcare professionals. Most recently, COVID-19 has shown us the need for understanding and coordination in dealing with new outbreaks. It tested the ability of the global health community to collaborate, share information, and rely on proven approaches to epidemics and in working with industry.

The aim of this study is to assess the feasibility of integration of the social robotic system into nursing and care during hospitalization. Social robotic systems are expected to be effective in integrated nursing care services, particularly in delivering 'other nursing services' and measuring/monitoring' [19]. The goal of such units is not to replace human contact but to improve quality of care and decrease the workload of healthcare professionals by delivering 'other nursing services' categorized as non-value-added nursing activities. However, major barriers related to such integration are associated with implementation outcomes, socioeconomic and ethical domains [14]. From both the patient and professional perspective they are realized as non-acceptance from end users due to unfamiliarity, manifestation either as technological fear threatening independence [28] or as a lack of confidence in professional use and in the safety of technology itself [29].

Thus, within this study both expectations and possible reservation will be collected from patients and professionals. The results of this study will be used to model the design of the social robotics systems that will be further evaluated in a clinical study implemented under

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

the umbrella of project H2020 project HosmartAI, Pilot 5: Assistive care in hospital: robotic nurse [30], delivered in UKC Maribor.

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. Explicit patient consent is not required.

Consent for publication

Not applicable.

Availability of data and materials

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

Competing interests

The authors declare that they have no competing interests.

Funding

This research project is partially funded by European Union's Horizon 2020 research and innovation program, project HosmartAI (grant agreement No. 101016834). The funding source approved the funding of project HosmartAI of which this study is a part of and ensured the funds for the implementation. The funding source had no role in the design of this study and will not have a role beyond progress monitoring and evaluation or influence the execution, analyses, interpretation of the data of this study, or decision to submit results.

Authors' contributions

BMJ Open

All authors contributed to securing the funding of the project. All authors conceptualized the study. IM wrote the original draft and the draft version of primary and secondary endpoints. All partners contributed to refine the study. All authors read and approved the final manuscript.

Acknowledgments

Not applicable.

References

- European Commission, The 2018 Ageing Report: Economic and Budgetary Projections for the EU Member States (2016–2070). 2018
- 2. OECD and European Commission, Health at a Glance: Europe 2018. 2018
- Khanna, O., Beasley, R., Franco, D., & DiMaio, S. (2021). The path to surgical robotics in neurosurgery. Operative Neurosurgery, 20(6), 514-520.
- Wang, J., Peng, C., Zhao, Y., Ye, R., Hong, J., Huang, H., & Chen, L. (2021).
 Application of a Robotic Tele-Echography System for COVID-19 Pneumonia. Journal of Ultrasound in Medicine, 40(2), 385-390.
- 5. Abdi, J., Al-Hindawi, A., Ng, T., & Vizcaychipi, M. P. (2018). Scoping review on the use of socially assistive robot technology in elderly care. BMJ open, 8(2), e018815.
- 6. Law, M., Sutherland, C., Ahn, H. S., MacDonald, B. A., Peri, K., Johanson, D. L., ...
 & Broadbent, E. (2019). Developing assistive robots for people with mild cognitive impairment and mild dementia: a qualitative study with older adults and experts in aged care. BMJ open, 9(9), e031937.

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

- Flynn, A. (2019). Using artificial intelligence in health-system pharmacy practice: finding new patterns that matter. American Journal of Health-System Pharmacy, 76(9), 622-627.
- Haddad, L. M., & Toney-Butler, T. J. (2019). Nursing shortage. In StatPearls [Internet]. StatPearls Publishing.
- Alexander, G. R., & Johnson Jr, J. H. (2021). Disruptive Demographics: Their Effects on Nursing Demand, Supply and Academic Preparation. Nursing Administration Quarterly, 45(1), 58-64.
- World Health Organization (WHO). (2020). The State of the world's nursing 2020: Investing in education, jobs and leadership. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf
- Richert, A., Schiffmann, M., & Yuan, C. (2019, July). A Nursing Robot for Social Interactions and Health Assessment. In International Conference on Applied Human Factors and Ergonomics (pp. 83-91). Springer, Cham.
- Clabaugh, Caitlyn, and Maja Matarić. "Escaping oz: Autonomy in socially assistive robotics." Annual Review of Control, Robotics, and Autonomous Systems 2 (2019): 33-61.
- Stokes, F., & Palmer, A. (2020). Artificial intelligence and robotics in nursing: Ethics of caring as a guide to dividing tasks between AI and humans. Nursing Philosophy, 21(4), e12306.
- Servaty, R., Kersten, A., Brukamp, K., Möhler, R., & Mueller, M. (2020).
 Implementation of robotic devices in nursing care. Barriers and facilitators: an integrative review. BMJ open, 10(9), e038650.

BMJ Open

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

- 15. Archibald, M. M., & Barnard, A. (2018). Futurism in nursing: Technology, robotics and the fundamentals of care. Journal of Clinical Nursing, 27(11-12), 2473-2480.
- Gombolay, M., Yang, X. J., Hayes, B., Seo, N., Liu, Z., Wadhwania, S., ... & Shah, J. (2018). Robotic assistance in the coordination of patient care. The International Journal of Robotics Research, 37(10), 1300-1316.
- Frennert, S., Aminoff, H., & Östlund, B. (2020). Technological Frames and Care Robots in Eldercare. International Journal of Social Robotics, 1-15.
- Hebesberger, D., Koertner, T., Gisinger, C., & Pripfl, J. (2017). A long-term autonomous robot at a care hospital: A mixed methods study on social acceptance and experiences of staff and older adults. International Journal of Social Robotics, 9(3), 417-429.
- Lee, J. Y., Song, Y. A., Jung, J. Y., Kim, H. J., Kim, B. R., Do, H. K., & Lim, J. Y. (2018). Nurses' needs for care robots in integrated nursing care services. Journal of Advanced Nursing, 74(9), 2094-2105.
- 20. Archibald, M. M., & Barnard, A. (2018). Futurism in nursing: Technology, robotics and the fundamentals of care. Journal of Clinical Nursing, 27(11-12), 2473-2480.
- Alves-Oliveira, P., Ribeiro, T., Petisca, S., Di Tullio, E., Melo, F. S., & Paiva, A. (2015, October). An empathic robotic tutor for school classrooms: Considering expectation and satisfaction of children as end-users. In International Conference on Social Robotics (pp. 21-30). Springer, Cham.
- 22. Krägeloh, C. U., Bharatharaj, J., Sasthan Kutty, S. K., Nirmala, P. R., & Huang, L. (2019). Questionnaires to measure acceptability of social robots: a critical review. Robotics, 8(4), 88.

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

- 23. Syrdal, D. S., Dautenhahn, K., Koay, K. L., & Walters, M. L. (2009). The negative attitudes towards robots scale and reactions to robot behaviour in a live human-robot interaction study. Adaptive and emergent behaviour and complex systems.
- 24. Chen, S. C., Jones, C., & Moyle, W. (2019). Health Professional and Workers Attitudes Towards the Use of Social Robots for Older Adults in Long-Term Care. International Journal of Social Robotics, 1-13.
- 25. Bartneck, C., Nomura, T., Kanda, T., Suzuki, T., & Kennsuke, K. (2005). A crosscultural study on attitudes towards robots.
- 26. Rantanen, T., Lehto, P., Vuorinen, P., & Coco, K. (2018). The adoption of care robots in home care—A survey on the attitudes of Finnish home care personnel. Journal of clinical nursing, 27(9-10), 1846-1859.
- 27. Hall, A. K., Backonja, U., Painter, I., Cakmak, M., Sung, M., Lau, T., ... & Demiris, G. (2017). Acceptance and perceived usefulness of robots to assist with activities of daily living and healthcare tasks. Assistive Technology.
- 28. Wu, Y. H., Wrobel, J., Cornuet, M., Kerhervé, H., Damnée, S., & Rigaud, A. S. (2014). Acceptance of an assistive robot in older adults: a mixed-method study of human-robot interaction over a 1-month period in the Living Lab setting. Clinical interventions in aging, 9, 801.
- 29. Conti, D., Cattani, A., Di Nuovo, S., & Di Nuovo, A. (2019). Are future psychologists willing to accept and use a humanoid robot in their practice? Italian and English students' perspective. Frontiers in psychology, 10, 2138.
- 30. H2020 HosmartAI, pilots: https://www.hosmartai.eu/pilot/, last visited June 2021.

BMJ Open

31. Krägeloh, C. U., Bharatharaj, J., Sasthan Kutty, S. K., Nirmala, P. R., & Huang, L.

(2019). Questionnaires to measure acceptability of social robots: a critical review. Robotics, 8(4), 88.

for occurrence on the terms of term

SPIRIT Checklist:

Item 1: Descriptive title identifying the study design, population,	Title is descriptive and identifies the study design, intervention and primary endpoint
interventions, and, if applicable, trial acronym.	
Item 2a: Trial identifier and registry	N/A
name. If not yet registered, name of	IN/A
intended registry. Item 3: Date and version identifier.	The content is highlighted under sections Ethical Approval Da
	and Estimated Start of the Study
Item 4: Sources and types of	The content is highlighted under section Declarations,
financial, material, and other	subsection Funding. A document highlighting more details ab
support.	the study including the official link to web page of the project
	the funding agency is given on page 15.
Item 5a: Names, affiliations, and	The content is highlighted under section Declarations,
roles of protocol contributors.	subsection Authors' contributions on page 15 of the manuscrip
Item 5b: Name and contact	N/A
information for the trial sponsor.	
Item 5c: Role of study sponsor and	The content is highlighted under section Declarations,
funders, if any, in study design;	subsection Funding
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.	
Item 5d: Composition, roles, and	N/A
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).	
Item 6a: Description of research	The content is highlighted under section Introduction, pages 4
question and justification for	6
undertaking the trial, including	V
summary of relevant studies	
(published and unpublished)	
examining benefits and harms for	
each intervention.	
Item 6b: Explanation for choice of	The content is highlighted under section Declargy d. ross (
1	The content is highlighted under section Background, page 6
comparators.	The content is highlighted and the Oliver in the
Item 7: Specific objectives or	The content is highlighted under section Objectives and
hypotheses.	hypotheses, page 6-7
Item 8: Description of trial design	The content is highlighted under section Methods subsection
including type of trial (e.g., parallel group, crossover, factorial, single	Study design, page 7-10

2		
3	group), allocation ratio, and	
4	framework (e.g., superiority,	
5	equivalence, non-inferiority,	
6		
7	exploratory).	
8	Item 9: Description of study	The content is highlighted under sections: Methods, pages 7-9;
9	settings (e.g., community clinic,	
10	academic hospital) and list of	
11	countries where data will be	
12	collected. Reference to where list of	
13	study sites can be obtained.	
14	Item 10: Inclusion and exclusion	The content is highlighted under section, Outcomes –
15	criteria for participants. If	Participants, page 9
16	applicable, eligibility criteria for	
17	study centres and individuals who	
18	will perform the interventions (e.g.,	
19	surgeons, psychotherapists).	
20	Item 11a: Interventions for each	The content is highlighted in Table 1. Outling of the study
21		The content is highlighted in Table 1: Outline of the study
22	group with sufficient detail to allow	design. Page 8
23	replication, including how and	
24	when they will be administered.	
25	Item 11b: Criteria for discontinuing	N/A
26	or modifying allocated	
27	interventions for a given trial	
28	participant (e.g., drug dose change	
29	in response to harms, participant	
30	request, or improving/worsening	
31	disease).	
32	Item 11c: Strategies to improve	The content is available under section Data analysis and
33	adherence to intervention protocols,	statistics, sub-section Non-response, page 13
34	and any procedures for monitoring	sutistics, sub section ron response, page 15
35	adherence (e.g., drug tablet return;	4
36		
37	laboratory tests).	
38	Item 11d: Relevant concomitant	N/A
39	care and interventions that are	
40	permitted or prohibited during the	
41	trial.	
42	Item 12: Primary, secondary, and	The content is highlighted under Outcomes, pages 11-12
42	other outcomes, including the	
43	specific measurement variable (e.g.,	
44	systolic blood pressure), analysis	
45 46	metric (e.g., change from baseline,	
	final value, time to event), method	
47 48	of aggregation (e.g., median,	
48	proportion), and time point for each	
49		
50	outcome. Explanation of the	
51	clinical relevance of chosen	
52	efficacy and harm outcomes is	
53	strongly recommended.	
54	Item 13: Time schedule of	The content is highlighted under Table 1: Outline of the study
55	enrolment, interventions (including	design. Page 8
56		
57		
58		

any run-ins and washouts),	
assessments, and visits for	
participants. A schematic diagram	
is highly recommended (see Figure	
1).	
Item 14: Estimated number of	The content is highlighted under Data analysis and statistic
participants needed to achieve	pages 12-13
study objectives and how it was	
determined, including clinical and	
statistical assumptions supporting	
any sample size calculations.	
Item 15: Strategies for achieving	The content is highlighted under Data analysis and statistic
adequate participant enrolment to	subsections Sample size and Non-response, pages 12-13
reach target sample size.	
[16-17] Methods: Assignment of	N/A
interventions (for controlled trials)	
Item 18a: Plans for assessment and	The content is highlighted under sections Methods and Da
collection of outcome, baseline, and	analysis and statistics, subsection Data Collection
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.	
Item 18b: Plans to promote	N/A
participant retention and complete	
follow-up, including list of any	
outcome data to be collected for	
participants who discontinue or	
deviate from intervention protocols.	
Item 19: Plans for data entry,	The content is highlighted under Methods, subsection Data
coding, security, and storage,	storage and privacy, pages 10,11
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.	
Item 20a: Statistical methods for	The content is highlighted under Data analysis and statistic
analysing primary and secondary	pages 12-13
outcomes. Reference to where other	P.0 12
details of the statistical analysis	
plan can be found, if not in the	
protocol.	
p1010001.	

2		
3	Item 20b: Methods for any	N/A
4	additional analyses (e.g., subgroup	
5	and adjusted analyses).	
6	Item 20c: Definition of analysis	N/A
7	population relating to protocol non-	
8		
9	adherence (e.g., as randomised	
10	analysis), and any statistical	
11	methods to handle missing data	
12	(e.g., multiple imputation).	
13	[21-23] Methods: Monitoring	N/A
14	Item 24: Plans for seeking research	The study has received ethical approval. This is highlighted
15	ethics committee/institutional	under Declarations, subsection Ethics approval and consent to
16	review board (REC/IRB) approval.	participate, page 15
17	Item 25: Plans for communicating	The content is highlighted under section Ethics and
18	important protocol modifications	dissemination, pages 2 and 3
19	(e.g., changes to eligibility criteria,	
20	outcomes, analyses) to relevant	
21	parties (e.g., investigators,	
22	REC/IRBs, trial participants, trial	
23	registries, journals, regulators).	
24	Item 26a: Who will obtain	The study will not collect sensitive data. The content is
25	informed consent or assent from	highlighted under section Participants, page 9
26	potential trial participants or	ingingited under section r articipants, page 9
27	authorized surrogates, and how (see	<u> </u>
28	Item 32).	
29	Item 26b: Additional consent	N/A
30 31	provisions for collection and use of	IV/A
32	participant data and biological	
33		
34	specimens in ancillary studies, if	
35	applicable.	
36	Item 27: How personal information	No personal information will be collected during the study. This
37	about potential and enrolled	is highlighted under section Data storage and privacy, page 10
38	participants will be collected,	
39	shared, and maintained in order to	
40	protect confidentiality before,	
41	during, and after the trial.	
42	Item 28: Financial and other	The content is highlighted under section Declarations, page 15
43	competing interests for principal	
44	investigators for the overall trial	
45	and each study site.	
46	Item 29: Statement of who will	The content is highlighted under section Declarations, page 15.
47	have access to the final trial dataset,	
48	and disclosure of contractual	
49	agreements that limit such access	
50	for investigators.	
51	Item 30: Provisions, if any, for	N/A
52	ancillary and post-trial care, and for	
53	compensation to those who suffer	
54	harm from trial participation.	
55	Item 31: Dissemination policy	N/A
56	Term 51. Dissemination policy	
57		
58		
50		

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
28
29
30
31
32
33
34
35
36
37 38
38
39
40
41
42
43
44
45
46
47
48
49

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

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

Journal:	BMJ Open	
Manuscript ID	bmjopen-2021-054310.R1	
Article Type:	Protocol	
Date Submitted by the Author:	27-Dec-2021	
Complete List of Authors:	Mlakar, Izidor; University of Maribor Faculty of Electrical Engineering and Computer Science Kampič, Tadej; Univerzitetni Klinicni Center Maribor Flis, Vojko; Univerzitetni Klinicni Center Maribor, Vascualr Surgery Kobilica, Nina; Univerzitetni Klinicni Center Maribor, Vascular Surgery Molan, Maja; Univerzitetni klinični center Maribor Smrke, Urška; University of Maribor Faculty of Electrical Engineering and Computer Science Plohl, Nejc ; University of Maribor, Department of Psychology Bergauer, Andrej; Univerzitetni Klinicni Center Maribor, Vascular Surgery	
Primary Subject Heading :	Nursing	
Secondary Subject Heading:	Health services research, Patient-centred medicine, Surgery	
Keywords:	QUALITATIVE RESEARCH, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT	

SCHOLARONE[™] Manuscripts

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

Izidor Mlakar¹, Tadej Kampič², Vojko Flis², Nina Kobilica², Maja Molan², Urška Smrke¹,

Nejc Plohl³, Andrej Bergauer²

¹University of Maribor, Faculty of Electrical Engineering and Computer Science, Slovenia

² University Clinical Center Maribor, Slovenia

³ University of Maribor, Faculty of Arts, Department of Psychology, Slovenia

Corresponding author: Izidor Mlakar, University of Maribor, Faculty of Electrical Engineering and Computer Science, Koroška cesta 46, 2000 Maribor, Slovenija; T: + 386 2 220 7267; E-mail: izidor.mlakar@um.si

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

Abstract

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.

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 questionaries. Patients will respond to TSES and NARS questionaries. 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).

BMJ Open

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

Ethical Approval Date: 06th May 2021

Estimated Start of the Study: September 2021

Keywords: socially assistive humanoid robots, robots in nursing, social and ethical barriers,

patient expectations and attitudes, artificial intelligence, health application

Article summary

Strengths and limitations of this study

- 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.

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

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

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].

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,

Page 5 of 23

BMJ Open

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

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

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

position towards technology in nursing must be established with all stakeholders, especially healthcare professionals and patients [26]. 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 [23]. The proposed study will investigate i) general acceptance of robots in the setting of nursing, ii) ethical and professional reservations, and iii) functional (technological) expectations of healthcare providers and patients. The goal is to gain a detailed and comprehensive insight into the current state of attitudes, expectations, and ethical reservations regarding the use of SAHRs in nursing. 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 which patients and subpopulations of providers may need additional information regarding the safety and potential benefits of SAHRs.

Objectives and hypotheses

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

BMJ Open

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

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.

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

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

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.

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 questionaries 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,

BMJ Open

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

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

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

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

Employees in the medical institution	
Design:	An electronic survey among healthcare professional

BMJ Open

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

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
Inpatients	
Design:	An electronic survey among inpatients. Staff collects the responses using tablets. If needed, support of hospital's staff will is 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

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

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,

Page 13 of 23

BMJ Open

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

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.

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.

Management and reporting of adverse reactions

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

Patient and Public Involvement

Healthcare professionals of the participating medical institution were involved in the study design. 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 dissemination channels of all participating institutions. 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

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

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

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

patients

Data analysis and statistics

Sample size determination

BMJ Open

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

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., 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.

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.

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

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

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.

BMJ Open

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

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

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

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

Competing interests

The authors declare that they have no competing interests.

Funding

This research project is partially funded by European Union's Horizon 2020 research and innovation program, project HosmartAI (grant agreement No. 101016834). The funding source approved the funding of project HosmartAI, of which this study is a part, and ensured the funds for the implementation. The funding source had no role in the design of this study and will not have a role beyond progress monitoring and evaluation or influence the execution, analyses, interpretation of the data of this study, or decision to submit results.

Authors' contributions

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 statics, 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.

Acknowledgments

Not applicable.

References

2
2
2
4
3 4 5 6 7 8 9 10 11
6
7
, 0
0
9
10
11
12
12
13
14
15
16
17
10
18
19
20
21
22
14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
23
24
25
26
27
27
28
29
30
31
32
32 33
34 35 36 37
35
36
27
37 38
39
40
41
41
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

23		BMJ Open	
	Study	y 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	
	1.	European Commission, The 2018 Ageing Report: Economic and Budgetary	
		Projections for the EU Member States (2016–2070). 2018	
	2.	OECD and European Commision, Health at a Glance: Europe 2018. 2018	
	3.	Khanna, O., Beasley, R., Franco, D., & DiMaio, S. (2021). The path to surgical	
		robotics in neurosurgery. Operative Neurosurgery, 20(6), 514-520.	
	4.	Wang, J., Peng, C., Zhao, Y., Ye, R., Hong, J., Huang, H., & Chen, L. (2021).	
		Application of a Robotic Tele-Echography System for COVID-19 Pneumonia. Journal	
		of Ultrasound in Medicine, 40(2), 385-390.	
	5.	Abdi, J., Al-Hindawi, A., Ng, T., & Vizcaychipi, M. P. (2018). Scoping review on the	
		use of socially assistive robot technology in elderly care. BMJ open, 8(2), e018815.	
	6.	Law, M., Sutherland, C., Ahn, H. S., MacDonald, B. A., Peri, K., Johanson, D. L.,	
		& Broadbent, E. (2019). Developing assistive robots for people with mild cognitive	
		impairment and mild dementia: a qualitative study with older adults and experts in	
		aged care. BMJ open, 9(9), e031937.	
	7.	Flynn, A. (2019). Using artificial intelligence in health-system pharmacy practice:	
		finding new patterns that matter. American Journal of Health-System Pharmacy,	
		76(9), 622-627.	
	8.	Haddad, L. M., & Toney-Butler, T. J. (2019). Nursing shortage. In StatPearls	
		[Internet]. StatPearls Publishing.	
	9.	Alexander, G. R., & Johnson Jr, J. H. (2021). Disruptive Demographics: Their Effects	
		on Nursing Demand, Supply and Academic Preparation. Nursing Administration	

Quarterly, 45(1), 58-64.

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

 World Health Organization (WHO). (2020). The State of the world's nursing 2020: Investing in education, jobs and leadership. Retrieved from

https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf

- 11. Papadopoulos, I., Koulouglioti, C., Lazzarino, R., & Ali, S. (2020). Enablers and barriers to the implementation of socially assistive humanoid robots in health and social care: a systematic review. BMJ open, 10(1), e033096.
- Richert, A., Schiffmann, M., & Yuan, C. (2019, July). A Nursing Robot for Social Interactions and Health Assessment. In International Conference on Applied Human Factors and Ergonomics (pp. 83-91). Springer, Cham.
- Clabaugh, Caitlyn, and Maja Matarić. "Escaping oz: Autonomy in socially assistive robotics." Annual Review of Control, Robotics, and Autonomous Systems 2 (2019): 33-61.
- 14. Stokes, F., & Palmer, A. (2020). Artificial intelligence and robotics in nursing: Ethics of caring as a guide to dividing tasks between AI and humans. Nursing Philosophy, 21(4), e12306.
- Servaty, R., Kersten, A., Brukamp, K., Möhler, R., & Mueller, M. (2020). Implementation of robotic devices in nursing care. Barriers and facilitators: an integrative review. BMJ open, 10(9), e038650.
- 16. Archibald, M. M., & Barnard, A. (2018). Futurism in nursing: Technology, robotics and the fundamentals of care. Journal of Clinical Nursing, 27(11-12), 2473-2480.
- 17. Gombolay, M., Yang, X. J., Hayes, B., Seo, N., Liu, Z., Wadhwania, S., ... & Shah, J. (2018). Robotic assistance in the coordination of patient care. The International Journal of Robotics Research, 37(10), 1300-1316.

BMJ Open

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

- Pirhonen, J., Lolich, L., Tuominen, K., Jolanki, O., & Timonen, V. (2020). "These devices have not been made for older people's needs"–Older adults' perceptions of digital technologies in Finland and Ireland. Technology in Society, 62, 101287.
- Frennert, S., Aminoff, H., & Östlund, B. (2020). Technological Frames and Care Robots in Eldercare. International Journal of Social Robotics, 1-15.
- 20. Hebesberger, D., Koertner, T., Gisinger, C., & Pripfl, J. (2017). A long-term autonomous robot at a care hospital: A mixed methods study on social acceptance and experiences of staff and older adults. International Journal of Social Robotics, 9(3), 417-429.
- 21. Wu, Y. H., Wrobel, J., Cornuet, M., Kerhervé, H., Damnée, S., & Rigaud, A. S. (2014). Acceptance of an assistive robot in older adults: a mixed-method study of human–robot interaction over a 1-month period in the Living Lab setting. Clinical interventions in aging, 9, 801.
- Lee, J. Y., Song, Y. A., Jung, J. Y., Kim, H. J., Kim, B. R., Do, H. K., & Lim, J. Y. (2018). Nurses' needs for care robots in integrated nursing care services. Journal of Advanced Nursing, 74(9), 2094-2105.
- Archibald, M. M., & Barnard, A. (2018). Futurism in nursing: Technology, robotics and the fundamentals of care. Journal of Clinical Nursing, 27(11-12), 2473-2480.
- 24. Conti, D., Cattani, A., Di Nuovo, S., & Di Nuovo, A. (2019). Are future psychologists willing to accept and use a humanoid robot in their practice? Italian and English students' perspective. Frontiers n psychology, 10, 2138.
- 25. Feil-Seifer, D., & Matarić, M. J. (2011). Socially assistive robotics. IEEE Robotics & Automation Magazine, 18(1), 24-31.

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

- 26. Vandemeulebroucke, T., de Casterlé, B. D., & Gastmans, C. (2018). The use of care robots in aged care: A systematic review of argument-based ethics literature. Archives of gerontology and geriatrics, 74, 15-25.
- 27. Heerink, M. (2011). Exploring the influence of age, gender, education and computer experience on robot acceptance by older adults. In 2011 6th ACM/IEEE International Conference on Human-Robot Interaction (HRI) (pp. 147-148). IEEE.
- 28. Andtfolk, M., Nyholm, L., Eide, H., Rauhala, A., & Fagerström, L. (2021). Attitudes toward the use of humanoid robots in healthcare—a cross-sectional study. AI & SOCIETY, 1-10.
- 29. Krägeloh, C. U., Bharatharaj, J., Sasthan Kutty, S. K., Nirmala, P. R., & Huang, L. (2019). Questionnaires to measure acceptability of social robots: a critical review. Robotics, 8(4), 88.
- 30. Alves-Oliveira, P., Ribeiro, T., Petisca, S., Di Tullio, E., Melo, F. S., & Paiva, A. (2015, October). An empathic robotic tutor for school classrooms: Considering expectation and satisfaction of children as end-users. In International Conference on Social Robotics (pp. 21-30). Springer, Cham.
- 31. Krägeloh, C. U., Bharatharaj, J., Sasthan Kutty, S. K., Nirmala, P. R., & Huang, L. (2019). Questionnaires to measure acceptability of social robots: a critical review. Robotics, 8(4), 88.
- Peca, A.; Coeckelbergh, M.; Simut, R.; Costescu, C.; Pintea, S.; David, D.;
 Vanderborght, B. Robot enhanced therapy for children with autism disorders: Measuring ethical acceptability. IEEE Technol. Soc. Mag. 2016, 35, 54–66

BMJ Open

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

- 33. Syrdal, D. S., Dautenhahn, K., Koay, K. L., & Walters, M. L. (2009). The negative attitudes towards robots scale and reactions to robot behaviour in a live human-robot interaction study. Adaptive and emergent behaviour and complex systems.
- 34. Nomura, T., Suzuki, T., Kanda, T., & Kato, K. (2006, July). Altered attitudes of people toward robots: Investigation through the Negative Attitudes toward Robots Scale. In Proc. AAAI-06 workshop on human implications of human-robot interaction (Vol. 2006, pp. 29-35).
- 35. Chen, S. C., Jones, C., & Moyle, W. (2019). Health Professional and Workers Attitudes Towards the Use of Social Robots for Older Adults in Long-Term Care. International Journal of Social Robotics, 1-13.
- Bartneck, C., Nomura, T., Kanda, T., Suzuki, T., & Kennsuke, K. (2005). A crosscultural study on attitudes towards robots.
- 37. Rantanen, T., Lehto, P., Vuorinen, P., & Coco, K. (2018). The adoption of care robots in home care—A survey on the attitudes of Finnish home care personnel. Journal of clinical nursing, 27(9-10), 1846-1859.
- 38. Hall, A. K., Backonja, U., Painter, I., Cakmak, M., Sung, M., Lau, T., ... & Demiris, G. (2017). Acceptance and perceived usefulness of robots to assist with activities of daily living and healthcare tasks. Assistive Technology.

39. Israel, G. D. (1992). Determining sample size.

BMJ Open

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

Journal:	BMJ Open
Manuscript ID	bmjopen-2021-054310.R2
Article Type:	Protocol
Date Submitted by the Author:	02-Mar-2022
Complete List of Authors:	Mlakar, Izidor; University of Maribor Faculty of Electrical Engineering and Computer Science Kampič, Tadej; Univerzitetni Klinicni Center Maribor Flis, Vojko; Univerzitetni Klinicni Center Maribor, Vascualr Surgery Kobilica, Nina; Univerzitetni Klinicni Center Maribor, Vascular Surgery Molan, Maja; Univerzitetni klinični center Maribor Smrke, Urška; University of Maribor Faculty of Electrical Engineering and Computer Science Plohl, Nejc ; University of Maribor, Department of Psychology Bergauer, Andrej; Univerzitetni Klinicni Center Maribor, Vascular Surgery
Primary Subject Heading :	Nursing
Secondary Subject Heading:	Health services research, Patient-centred medicine, Surgery
Keywords:	QUALITATIVE RESEARCH, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE[™] Manuscripts

2	
2	Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'
4	Study Protocol. A Survey Exploring Fatients and Heatthcare Protessionals
5	Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially
6 7	Expectations, interfaces, and Ethical Receptaisinty Regarding the Integration of Sociary
8	Assistive Humanoid Robots in Nursing
9	
10	Izidor Mlakar ¹ , Tadej Kampič ² , Vojko Flis ² , Nina Kobilica ² , Maja Molan ² , Urška Smrke ¹ ,
11	
12 13	Nejc Plohl ³ , Andrej Bergauer ²
14	
15	
16	
17	¹ University of Maribor, Faculty of Electrical Engineering and Computer Science, Slovenia
18 19	
20	² University Clinical Center Maribor, Slovenia
21	3 University of Mariley Frenches of Anter Demonter and of Developing Classes
22	³ University of Maribor, Faculty of Arts, Department of Psychology, Slovenia
23 24	
24 25	
26	
27	
28	
29 30	
30	
32	³ University of Maribor, Faculty of Arts, Department of Psychology, Slovenia
33	
34	
35 36	
37	
38	
39	
40	
41 42	
43	Corresponding author: Izidor Mlakar, University of Maribor, Faculty of Electrical
44	Engineering and Commuter Science, Kanstle casts 46, 2000 Mariban Slovenija, T. + 286.2
45	Engineering and Computer Science, Koroška cesta 46, 2000 Maribor, Slovenija; T: + 386 2
46	220 7267; E-mail: izidor.mlakar@um.si
47 48	220 7207, E-mail. 121dol.makai@um.si
49	
50	
51	
52	
53 54	
55	

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 questionaries. Patients will respond to TSES and NARS questionaries. 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

BMJ Open

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

Keywords: socially assistive humanoid robots, expectations, attitudes, ethical acceptance,

artificial intelligence, health application

Article summary

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.

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

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].

BMJ Open

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

Socially assistive humanoid robots (SAHR) 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, 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]. Previous research suggests that such negative perceptions are more common among certain subgroups of the population, such as those that are older and less educated [22,23]. Furthermore, although healthcare professionals are facing high workloads and tend to recognize the potential value of care robots as an aid in "measuring/monitoring"

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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

(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

BMJ Open

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

which patients and subpopulations of providers, based on their demographic characteristics, may need additional information regarding the safety and potential benefits of SAHRs.

Objectives and hypotheses

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

R1: What do healthcare professionals expect from SAHRs in hospital care?

R2: What do patients expect from SAHRs in hospital care?

R3: To what extent do healthcare professionals find the use of SAHRs in hospital care ethically acceptable?

R4: What is the general attitude of patients towards SAHRs in hospital care?

R5: How do healthcare professionals and patients differ in their expectations regarding the use of SAHRs in hospital care?

R6: Which demographic characteristics of healthcare professionals (i.e., gender, age, education, occupation) are related to their expectations and ethical acceptability regarding the use of SAHRs in hospital care?

R7: Which demographic characteristics of patients (i.e., gender, age, education) are related to their expectations and attitudes regarding the use of SAHRs in hospital care?

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially

Assistive Humanoid Robots in Nursing

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

BMJ Open

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

questionaries [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

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

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

BMJ Open

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially

Assistive Humanoid Robots in Nursing

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.

Healthcare professionals	
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
Patients	
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

Table 1: Outline of the study design

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially

Assistive Humanoid Robots in Nursing

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

BMJ Open

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

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. 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, 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.

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.

Management and reporting of adverse reactions

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

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

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

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.	

patients

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially

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 Expected results Measuring tool categories Age Younger patients are more open to the idea of TSES and NARS implementing a SAHR into nursing care. Ouestionnaires (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.

Assistive Humanoid Robots in Nursing

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,

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

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

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

BMJ Open

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

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. 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

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially

Assistive Humanoid Robots in Nursing

with SAHRs. 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

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

Competing interests

The authors declare that they have no competing interests.

Funding

This research project is partially funded by European Union's Horizon 2020 research and innovation program, project HosmartAI (grant agreement No. 101016834). The funding source approved the funding of project HosmartAI, of which this study is a part, and ensured the funds for the implementation. The funding source had no role in the design of this study and will not have a role beyond progress monitoring and evaluation or influence the execution, analyses, interpretation of the data of this study, or decision to submit results.

Authors' contributions

BMJ Open

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

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.

Acknowledgments

We would like to thank mrs. Simona Majhenič, mag. prev., for proof and language editing.

References

- European Commission, The 2018 Ageing Report: Economic and Budgetary Projections for the EU Member States (2016–2070). 2018
- 2. OECD and European Commission, Health at a Glance: Europe 2018. 2018
- Khanna, O., Beasley, R., Franco, D., & DiMaio, S. (2021). The path to surgical robotics in neurosurgery. Operative Neurosurgery, 20(6), 514-520.
- Wang, J., Peng, C., Zhao, Y., Ye, R., Hong, J., Huang, H., & Chen, L. (2021).
 Application of a Robotic Tele-Echography System for COVID-19 Pneumonia. Journal of Ultrasound in Medicine, 40(2), 385-390.
- 5. Abdi, J., Al-Hindawi, A., Ng, T., & Vizcaychipi, M. P. (2018). Scoping review on the use of socially assistive robot technology in elderly care. BMJ open, 8(2), e018815.

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially

Assistive Humanoid Robots in Nursing

- Law, M., Sutherland, C., Ahn, H. S., MacDonald, B. A., Peri, K., Johanson, D. L., ... & Broadbent, E. (2019). Developing assistive robots for people with mild cognitive impairment and mild dementia: a qualitative study with older adults and experts in aged care. BMJ open, 9(9), e031937.
- Flynn, A. (2019). Using artificial intelligence in health-system pharmacy practice: finding new patterns that matter. American Journal of Health-System Pharmacy, 76(9), 622-627.
- Haddad, L. M., & Toney-Butler, T. J. (2019). Nursing shortage. In StatPearls [Internet]. StatPearls Publishing.
- Alexander, G. R., & Johnson Jr, J. H. (2021). Disruptive Demographics: Their Effects on Nursing Demand, Supply and Academic Preparation. Nursing Administration Quarterly, 45(1), 58-64.
- World Health Organization (WHO). (2020). The State of the world's nursing 2020: Investing in education, jobs and leadership. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/331673/9789240003293-eng.pdf
- 11. Papadopoulos, I., Koulouglioti, C., Lazzarino, R., & Ali, S. (2020). Enablers and barriers to the implementation of socially assistive humanoid robots in health and social care: a systematic review. BMJ open, 10(1), e033096.
- Richert, A., Schiffmann, M., & Yuan, C. (2019, July). A Nursing Robot for Social Interactions and Health Assessment. In International Conference on Applied Human Factors and Ergonomics (pp. 83-91). Springer, Cham.

21 of 24	BMJ Open
	Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'
	Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially
	Assistive Humanoid Robots in Nursing
	13. Clabaugh, Caitlyn, and Maja Matarić. "Escaping oz: Autonomy in socially assistive
	robotics." Annual Review of Control, Robotics, and Autonomous Systems 2 (2019):
	33-61.
	14. Stokes, F., & Palmer, A. (2020). Artificial intelligence and robotics in nursing: Ethics
	of caring as a guide to dividing tasks between AI and humans. Nursing Philosophy,
	21(4), e12306.
	15. Servaty, R., Kersten, A., Brukamp, K., Möhler, R., & Mueller, M. (2020).
	Implementation of robotic devices in nursing care. Barriers and facilitators: an
	integrative review. BMJ open, 10(9), e038650.
	16. Archibald, M. M., & Barnard, A. (2018). Futurism in nursing: Technology, robotics
	and the fundamentals of care. Journal of Clinical Nursing, 27(11-12), 2473-2480.
	17. Gombolay, M., Yang, X. J., Hayes, B., Seo, N., Liu, Z., Wadhwania, S., & Shah, J.
	(2018). Robotic assistance in the coordination of patient care. The International
	Journal of Robotics Research, 37(10), 1300-1316.
	18. Pirhonen, J., Lolich, L., Tuominen, K., Jolanki, O., & Timonen, V. (2020). "These
	devices have not been made for older people's needs"-Older adults' perceptions of
	digital technologies in Finland and Ireland. Technology in Society, 62, 101287.
	19. Frennert, S., Aminoff, H., & Östlund, B. (2020). Technological Frames and Care
	Robots in Eldercare. International Journal of Social Robotics, 1-15.
	20. Hebesberger, D., Koertner, T., Gisinger, C., & Pripfl, J. (2017). A long-term
	autonomous robot at a care hospital: A mixed methods study on social acceptance and
	experiences of staff and older adults. International Journal of Social Robotics, 9(3),
	417-429.

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

- 21. Wu, Y. H., Wrobel, J., Cornuet, M., Kerhervé, H., Damnée, S., & Rigaud, A. S. (2014). Acceptance of an assistive robot in older adults: a mixed-method study of human–robot interaction over a 1-month period in the Living Lab setting. Clinical interventions in aging, 9, 801.
- 22. Heerink, M. (2011). Exploring the influence of age, gender, education and computer experience on robot acceptance by older adults. In 2011 6th ACM/IEEE International Conference on Human-Robot Interaction (HRI) (pp. 147-148). IEEE.
- 23. Andtfolk, M., Nyholm, L., Eide, H., Rauhala, A., & Fagerström, L. (2021). Attitudes toward the use of humanoid robots in healthcare—a cross-sectional study. AI & SOCIETY, 1-10.
- 24. Lee, J. Y., Song, Y. A., Jung, J. Y., Kim, H. J., Kim, B. R., Do, H. K., & Lim, J. Y. (2018). Nurses' needs for care robots in integrated nursing care services. Journal of Advanced Nursing, 74(9), 2094-2105.
- 25. Archibald, M. M., & Barnard, A. (2018). Futurism in nursing: Technology, robotics and the fundamentals of care. Journal of Clinical Nursing, 27(11-12), 2473-2480.
- 26. Conti, D., Cattani, A., Di Nuovo, S., & Di Nuovo, A. (2019). Are future psychologists willing to accept and use a humanoid robot in their practice? Italian and English students' perspective. Frontiers n psychology, 10, 2138.
- 27. Feil-Seifer, D., & Matarić, M. J. (2011). Socially assistive robotics. IEEE Robotics & Automation Magazine, 18(1), 24-31.
- 28. Vandemeulebroucke, T., de Casterlé, B. D., & Gastmans, C. (2018). The use of care robots in aged care: A systematic review of argument-based ethics literature. Archives of gerontology and geriatrics, 74, 15-25.

BMJ Open

1	Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'
2	Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially
3	Expectations, Attitudes, and Etincal Acceptability Regarding the Integration of Sociary
4 5	Assistive Humanoid Robots in Nursing
6	
7 8 9	29. Cuzak G. and Cvirn M. (2021). Digitalno zdravstvo v Sloveniji/Digital health in
10 11	Slovenia. Farmacevtski vestnik, 1, 3-9.
12 13 14	30. Krägeloh, C. U., Bharatharaj, J., Sasthan Kutty, S. K., Nirmala, P. R., & Huang, L.
15 16	(2019). Questionnaires to measure acceptability of social robots: a critical review.
17 18 19	Robotics, 8(4), 88.
20 21	31. Alves-Oliveira, P., Ribeiro, T., Petisca, S., Di Tullio, E., Melo, F. S., & Paiva, A.
22 23 24	(2015, October). An empathic robotic tutor for school classrooms: Considering
24 25 26	expectation and satisfaction of children as end-users. In International Conference on
27 28	Social Robotics (pp. 21-30). Springer, Cham.
29 30 31	32. Krägeloh, C. U., Bharatharaj, J., Sasthan Kutty, S. K., Nirmala, P. R., & Huang, L.(2019). Questionnaires to measure acceptability of social robots: a critical review.
32 33	Robotics, 8(4), 88.
34 35	10000103, 0(4), 00.
36 37	33. Peca, A.; Coeckelbergh, M.; Simut, R.; Costescu, C.; Pintea, S.; David, D.;
38 39 40	Vanderborght, B. Robot enhanced therapy for children with autism disorders:
40 41 42	Measuring ethical acceptability. IEEE Technol. Soc. Mag. 2016, 35, 54–66
43 44 45	34. Syrdal, D. S., Dautenhahn, K., Koay, K. L., & Walters, M. L. (2009). The negative
45 46 47	attitudes towards robots scale and reactions to robot behaviour in a live human-robot interaction study. Adaptive and emergent behaviour and complex systems.
48 49	35. Nomura, T., Suzuki, T., Kanda, T., & Kato, K. (2006, July). Altered attitudes of
50 51 52	people toward robots: Investigation through the Negative Attitudes toward Robots
53 54	Scale. In Proc. AAAI-06 workshop on human implications of human-robot interaction
55 56 57	(Vol. 2006, pp. 29-35).
58 59 60	

Study Protocol: A Survey Exploring Patients' and Healthcare Professionals'

Expectations, Attitudes, and Ethical Acceptability Regarding the Integration of Socially Assistive Humanoid Robots in Nursing

- 36. Chen, S. C., Jones, C., & Moyle, W. (2019). Health Professional and Workers Attitudes Towards the Use of Social Robots for Older Adults in Long-Term Care. International Journal of Social Robotics, 1-13.
- 37. Bartneck, C., Nomura, T., Kanda, T., Suzuki, T., & Kennsuke, K. (2005). A crosscultural study on attitudes towards robots.
- 38. Rantanen, T., Lehto, P., Vuorinen, P., & Coco, K. (2018). The adoption of care robots in home care—A survey on the attitudes of Finnish home care personnel. Journal of clinical nursing, 27(9-10), 1846-1859.
- Hall, A. K., Backonja, U., Painter, I., Cakmak, M., Sung, M., Lau, T., ... & Demiris, G. (2017). Acceptance and perceived usefulness of robots to assist with activities of daily living and healthcare tasks. Assistive Technology.

40. Israel, G. D. (1992). Determining sample size.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml