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# Effects of interactive digital assistance on patients and hospital staff

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 15/02/2022 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 24/02/2022 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 03/12/2025 | Other | |

**Plain English summary of protocol**
Background and study aims
We are currently witnessing a significant workforce shortage in the healthcare context, leading to overworked hospital staff and suboptimal patient care. As traditional approaches alone may not be able to tackle this problem sufficiently, there is a need for innovative solutions. This study tests the effects that one such solution, the use of socially assistive robots, has on a wide array of patient- and staff-related outcomes.

Who can participate?
Vascular or thoracic surgery patients in the participating clinical centre, or nursing and physiotherapeutic employees working in either of these two wards.

What does the study involve?
The study involves nursing education and physiotherapy provided in a traditional manner (by staff) and gamified nursing education and physiotherapy provided by a socially assistive robot. All participating patients will receive education from both sources. The socially assistive robot will also be available throughout patients' participation in the study for additional interactions.

What are the possible benefits and risks of participating?
While the researchers cannot guarantee that the interventions will help all participants, it is hoped that receiving education from both sources will help patients better understand the selected information and exercises. Moreover, the researchers believe that the deployment of a socially assistive robot may reduce the workload of employees working in the two selected wards.
The researchers do not foresee any potential for significant distress or adverse events, as participants will sign the informed consent before the beginning of their participation. However, it is possible that the presence of a socially assistive robot will lead to slight discomfort, especially in the earlier stages of their deployment. Participants who will feel distressed for any reason will be able to withdraw their consent or/and get individualized support.

Where is the study run from?
University Clinical Centre Maribor (Slovenia)

When is the study starting and how long is it expected to run for?
October 2021 to June 2024

Who is funding the study?
Horizon 2020

Who is the main contact?
1. Dr Izidor Mlakar
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# Contact information

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Principal investigator

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### Type(s)
Scientific

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# Additional identifiers

# Study information

## Scientific Title
Effects of interactive digital assistance on engagement and perceived quality of care of surgery patients and self-efficacy and workload of staff

## Acronym
IDA

## Study objectives
Hypotheses:
H1: Patients will exhibit higher levels of patient engagement after being subjected to gamified nursing education and general/respiratory physiotherapy (delivered by a socially assistive robot) compared to levels at the beginning of the study.
H2: Patients will exhibit higher levels of perceived quality of medical care after being subjected to gamified nursing education and general/respiratory physiotherapy (delivered by a socially assistive robot) compared to levels at the beginning of the study.
H3: Patients will exhibit equal or higher levels of patient engagement after being subjected to a gamified nursing education (delivered by a socially assistive robot) compared to levels after receiving nursing education and general/respiratory physiotherapy via traditional human interaction.
H4: Patients will exhibit equal or higher levels of perceived quality of care after being subjected to a gamified nursing education (delivered by a socially assistive robot) compared to levels after receiving nursing education and general/respiratory physiotherapy via traditional human interaction.
H5: Employees will exhibit higher self-efficacy during the use of a socially assistive robot compared to levels before the deployment of a socially assistive robot.
H6: Employees will exhibit a lower workload during the use of a socially assistive robot compared to levels before the deployment of a socially assistive robot.

Research questions:
RQ1: What percentage of non-urgent communication will be taken up by a socially assistive robot?
RQ2: How much of the employees' time will be saved by human-robot interactions?
RQ3: How much extra time of interaction will be provided to patients by using a socially assistive robot?
RQ4: How do the variables listed above correlate with patient- and staff-related outcomes?
RQ5: To what extent are patients satisfied with user experience concerning the use of a socially assistive robot?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 15/12/2021, Medical Ethics Commission (University Medical Center Maribor, Ljubljanska ulica 5, 2000 Maribor, Slovenia; +386 (0)2 321 2489; eticna.komisija@ukc-mb.si), ref: UKC-MB-KME-76/21

## Primary study design
Interventional

## Study design
Single-centre interventional study employing a within-subjects design with counterbalancing

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Engagement and perceived quality of care of vascular and thoracic surgery patients, and self-efficacy and workload of nursing and physiotherapeutic employees

## Interventions
The study will be performed in multiple iterations, in 1-week intervals, followed by a 1-week washout period between each iteration. In other words, the researchers will repeat the study (that lasts 1 week) as many times as needed to obtain the desired sample size. Furthermore, each repetition will be followed by a 1-week period when the study will not be performed to be able to recruit new patients who have not already participated in the study.

Surgery patients will participate in the study over the period of 5 days (1 week, excluding weekends). They will first be informed about the study procedures and fill out the baseline questionnaires, followed by two randomly ordered test conditions (each of the test conditions will last two days). The test conditions will include nursing education and general/respiratory physiotherapy delivered either by a human or a socially assistive robot. The robot will also be available for additional assistance during all 5 days.

Hospital staff will fill out the questionnaires before the first introduction of a socially assistive robot and then again after the end of the first iteration. The same protocol will be carried out thrice during the course of the study (1) before and after the first iteration, 2) again after 1 year, and 3) again right before and after the last iteration).

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Not provided at time of registration

## Primary outcome(s)
1. Patient engagement (a patient-related outcome) measured using the Patient Health Engagement scale at baseline (T1), at the end of the first test condition (T2), and at the end of the second test condition (T3)
2. Perceived quality of care (a patient-related outcome) measured using the Perceived Quality of Medical Care scale at baseline (T1), at the end of the first test condition (T2), and at the end of the second test condition (T3)
3. Self-efficacy (a staff-related outcome) measured using the New General Self-Efficacy Scale at baseline (T1) and at the end of the first iteration (T2), before and after the iteration that will happen at a 1-year mark (T3 and T4), and right before and after the last iteration (T5 and T6)
4. Workload (a staff-related outcome) measured using Nasa Task Load Index at baseline (T1) and at the end of the first iteration (T2), before and after the iteration that will happen at a 1-year mark (T3 and T4), and right before and after the last iteration (T5 and T6)

### Key secondary outcome(s)
1. Percentage of non-urgent communication taken up by the social robot, recorded automatically throughout the study period
2. Time saved by human-robot interaction, recorded automatically throughout the study period
3. Extra time of interaction provided to patients, recorded automatically throughout the study period
4. User experience (patients) measured using the User Experience Questionnaire at the end of the study period (T3)
5. Ratings of each of the two types of nursing and physiotherapy education (patients), measured with self-construed items at the end of the first test condition (T2), and at the end of the second test condition (T3)

### Completion date
30/06/2024

## Eligibility

### Key inclusion criteria
Patients:
1. Patients admitted to a vascular surgery or a thoracic surgery ward for an elective (non-emergency) procedure in the participating hospital
2. Aged 18 years or above
3. Willing to participate in the study

Employees:
1. Nursing and physiotherapy staff working on either the vascular surgery or the thoracic surgery ward in the participating hospital
2. Aged 18 years and above
3. Signed a consent form

### Participant type(s)
Health professional, Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
All

### Total final enrolment
40

### Key exclusion criteria
Patients:
1. Emergency patients
2. Patients already enrolled in other studies
3. Patients with dementia, special needs or appointed guardians
4. Patients allocated to an intensive step-down unit and/or regimen

There are no exclusion criteria for employees

### Date of first enrolment
01/06/2022

### Date of final enrolment
31/05/2024

## Locations

### Countries of recruitment
Slovenia

### Study participating centre
**University Clinical Centre Maribor**
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## Sponsor information

### Organisation
University Clinical Centre Maribor

### ROR
https://ror.org/02rjj7s91

### Organisation
University of Maribor

### ROR
https://ror.org/01d5jce07

# Funder(s)

### Funder type
Government

### Funder Name
Horizon 2020

### Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location

# Results and Publications

### Individual participant data (IPD) sharing plan
Anonymized participant-level data can be retrieved by contacting Dr Izidor Mlakar (Izidor.mlakar@um.si). The researchers are willing to share anonymized raw data with researchers for use in meta-analyses or for other research-related purposes (with no time restriction). They are not willing to share data for commercial purposes under any circumstances. They would also like to note that participants will be made aware of how the data will be used, stored and shared in the informed consent form.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 30/04/2025 | 08/05/2025 | Yes | No |
| Results article | | 02/12/2025 | 03/12/2025 | Yes | No |
| Protocol article | | 17/10/2022 | 04/11/2022 | Yes | No |