A Digital Health Intervention for Stress Relief in Perioperative Care: Clinical Study

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Objectives: Main objective: A personalized intervention of patients* stress and anxiety based on the combined use of standard measures (e.g. questionnaires) and advanced tools (smart watch sensors, mHealth app and VR) through a radical Artificial...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49898

Source
ToetsingOnline

Brief title
CARINAE

Condition

- Other condition

Synonym
Anxiety, Stress

Health condition

Stress Management

Research involving
Human

Sponsors and support

Primary sponsor: Salumedia Labs
Source(s) of monetary or material Support: Funded by the sponsor

Intervention

Keyword: Digital Health, Perioperative Care, Stress management

Outcome measures

Primary outcome

For assessing the main objective of the study, a personalized stress and anxiety intervention based on technologies and artificial intelligence will be performed to patients and caregivers belonging to intervention group from the enrolment to the follow up at 14 days after the operation. The objective of this personalized intervention will be to gather quantitative information to better understand individualized experiences of patients undergoing major surgeries and also experiences of their caregivers. Moreover, barriers and facilitators for the adoption of the CARINAE solution perceived by patients, caregivers and healthcare professionals will also be examined. This personalized intervention will be based on mental health and technology acceptance theoretical framework based on previous works (Mohr et al., 2014). The personalized intervention will be recorded upon the consent of the participant. During the personalized intervention, the research team through an automatic AI-algorithm will analyse the performance in order to provide personalized contents. This analysis will target subjective experiences, perceived challenges and barriers related by the participants, including the sentiment analysis for positive and negative perceptions of specific topics and

the whole CARINAE solution.

Secondary outcome

For assessing the secondary objectives, the following study parameters will be used:

• Patients* and caregivers* self-reported stress will be measured by a Visual Analogue Scale (VAS) for stress measurement at enrolment (baseline), at admission for surgery, at hospital discharge, and 2 weeks after the surgery.

• Patients* self-reported pain will be measured by a Visual Analogue Scale (VAS) for pain measurement at enrolment (baseline), at admission for surgery, at hospital discharge, and 2 weeks after the surgery.

• Patients* health-related quality of life (HRQoL) will be measured by the evolution of the EQ-5D-3L questionnaire at enrolment, admission for surgery and at clinical discharge.

• Patients* emotional status will be measured at enrolment (baseline), at admission for surgery, at hospital discharge, and 2 weeks after the surgery.

• Patients* and caregivers* mental wellbeing will be measured at enrolment and 2 weeks after the surgery by means of the SWEMWBS questionnaire.

• Patients* and caregivers* self-efficacy will be measured at enrolment and 2 weeks after the surgery by means of the GSE-SF questionnaire.

• Patients* activation status will be measured by means of the Patient Activation Measure short form (PAM-13) self-reported questionnaire at enrolment, admission for surgery and 2 weeks after the surgery.

• Data on patients* medication use will be gathered at enrolment and 2 weeks after surgery by pulling this information from the patient*s Electronic Health

Record (EHR).

• Patients* length of hospital stay will be measured in natural days from admission to surgery to hospital discharge.

• Data on patients* health outcomes (post-operative complications, re-operations and mortality) will be measured 2 weeks after the surgery by pulling this information from the patient*s EHR.

Usability will be checked per phase: pre-hospital, hospital stay, and post-hospital. For those participants allocated to the intervention group and healthcare professionals involved in the care management of these participants, the following metrics will be used:

• Subjective overall patient satisfaction: If the patient likes using the system as scale 1-10

• Evaluation of patient satisfaction with the solution:

- Ability to be carried by the patient, to be light and non-intrusive.

- Ease of learning: how fast a patient who has never used the solution can accomplish basic tasks, even for patients with limited digital skills.

- Memorability: after using the solution, if the patient can remember enough to use it effectively in the future.

• Evaluation of health care professionals' experience

• Net Promoter Score (NPS): measures customer experience and provides the core measurement for customer experience management programs.

Reliability will also be measured regarding the ability to have the potential to accommodate lacks of connectivity, ability to transfer data into the Health Information System (if applicable), and ability to avoid

single-point-of-failure.

Study description

Background summary

Preventing pre-surgical stress can help patients achieve positive outcomes on health and wellbeing. However, very few patients receive adequate stress relief support prior to a surgical procedure. Provision of education and information about the surgery can be a crucial component of the preoperative experience and is inversely related to levels of preoperative anxiety. However, resource constraints make face-to-face education sessions untenable, in view of cost considerations and time investment by trained health personnel. Interventions based on ICT, geared towards increasing familiarity with surgical procedures and hospital environments have been shown to help patients feel informed about possible benefits and risks of available treatment options. Virtual Reality (VR) can offer patients an immersion experience in the perioperative environment. VR interventions can be helpful in empowering patients and enhancing a more positive experience. However, available applications focus only on providing informative content, neglecting the importance of patient empowerment with a more robust educational curriculum.

Study objective

Objectives:
Main objective: A personalized intervention of patients* stress and anxiety based on the combined use of standard measures (e.g. questionnaires) and advanced tools (smart watch sensors, mHealth app and VR) through a radical Artificial Intelligence-assisted approach to the empowerment of the patient's psychological adaptation to a major life event such as surgery.
Secondary objectives: This study will also analyse the impact that CARINAE may have on the following clinical outcomes in patients undergoing major surgeries:
• Self-reported stress levels along the patient journey.
• Self-reported pain levels along the patient journey.
• Health-Related Quality of Life (HRQoL).
• Emotional status.
• Mental wellbeing.
• Self-efficacy.
• Activation status: patient knowledge, skill, and confidence for self-management.
• Medication use
• Total length of hospital stay and length of postoperative stay
• Postoperative complications, re-operation and mortality.

Besides, the CARINAE solution will also be assessed by healthcare professionals, and patients and caregivers allocated to the intervention group, in terms of usability, subjective satisfaction, and overall experience.

Study design

This is a prospective mixed-methods (qualitative-quantitative) multi-centric randomized controlled trial with two groups: control group (N>=30; 6 per clinical site) and intervention group (N>=30; 6 per clinical site). The minimum total number of participants has been fixed in 60 subjects (30= intervention group and 30=control group).
The maximum total participants* number has been established in 250 subjects (125=intervention group; 25 per clinical site and 125= control group; 25 per clinical site).

Intervention

Patients randomly assigned to intervention group will be exposed to the use of CARINAE for 4 months approximately, a patient-centred digital health support program. This program delivers the following non-medicinal interventions to the patients:
• Personalised patient-centred health education program to improve patient*s disease and recovery self-management skills.
• Artificial Intelligence-based behaviour change program to promote healthier lifestyle habits.
• Personalised mental well-being support program to improve patient*s ability to cope with emotional disturbances such as stress and anxiety.
• A collaborative digital support platform to enable information exchange between patients, caregivers, and healthcare professionals.
This program is delivered to patients and caregivers as an mHealth application (smartphone app) and an immersive environment with a VR device. Healthcare professionals will be able to access the collaborative digital support platform through a web application.

Main study parameters/endpoints:
For assessing the main objective of the study, a personalized stress and anxiety intervention based on technologies and artificial intelligence will be performed to patients and caregivers belonging to intervention group from the enrolment to the follow up at 14 days after the operation. The objective of this personalized intervention will be to gather quantitative information to better understand individualized experiences of patients undergoing major surgeries and also experiences of their caregivers.
For assessing the secondary objectives, the following metrics will be used:
• Patients* and caregivers* self-reported stress will be measured by a Visual Analogue Scale (VAS) for stress measurement at enrolment (baseline), at admission for surgery, at hospital discharge, and 2 weeks after the surgery.

• Patients* self-reported pain will be measured by a Visual Analogue Scale (VAS) for pain measurement at enrolment (baseline), at admission for surgery, at hospital discharge, and 2 weeks after the surgery.
• Patients* health-related quality of life (HRQoL) will be measured by the evolution of the EQ-5D-3L questionnaire at enrolment, admission for surgery and at clinical discharge.
• Patients* emotional status will be measured at enrolment (baseline), at admission for surgery, at hospital discharge, and 2 weeks after the surgery.
• Patients* and caregivers* mental wellbeing will be measured at enrolment and 2 weeks after the surgery by means of the SWEMWBS questionnaire.
• Patients* and caregivers* self-efficacy will be measured at enrolment and 2 weeks after the surgery by means of the GSE-SF questionnaire.
• Patients* activation status will be measured by means of the Patient Activation Measure short form (PAM-13) self-reported questionnaire at enrolment, admission for surgery and 2 weeks after the surgery.
• Data on patients* medication use will be gathered at enrolment and 2 weeks after surgery by pulling this information from the patient*s Electronic Health Record (EHR).
• Patients* length of hospital stay will be measured in natural days from admission to surgery to hospital discharge.
• Patients* length of postoperative stay will be measured in natural days from surgery day to hospital discharge.
• Data on patients* health outcomes (post-operative complications, re-operations and mortality) will be measured 2 weeks after the surgery by pulling this information from the patient*s EHR.
Usability will be checked per phase: pre-hospital, hospital stay, and post-hospital. For those participants allocated to the intervention group and healthcare professionals involved in the care management of these participants, the following metrics will be used:
• Subjective overall patient satisfaction: If the patient likes using the system as scale 1-10
• Evaluation of patient satisfaction with the solution:
o Ability to be carried by the patient, to be light and non-intrusive.
o Ease of learning: how fast a patient who has never used the solution can accomplish basic tasks, even for patients with limited digital skills.
o Memorability: after using the solution, if the patient can remember enough to use it effectively in the future.
• Evaluation of health care professionals' experience
• Net Promoter Score (NPS) will be used to measure customer experience and provides the core measurement for customer experience management programs.
• Reliability (only intervention group) will be measured via:
o Ability to have the potential to accommodate lack of connectivity.
o Ability to transfer data into the Health Information System (if applicable).
o Ability to avoid single-point-of-failure.

Study burden and risks

The burden associated to this study is minimal, as all study visits have been scheduled to coincide with routine care visits. During these study visits, participants will be asked to complete a set of questionnaires that will take as much as 30 minutes to complete. For participants allocated to intervention group, they will receive an mHealth-based behavioural intervention delivered through a mobile app installed in their own mobile and a VR headset that participants can use at their convenience. This study expects to recruit minors as participants as one of the surgical cases addressed (scoliosis surgery) is usually delivered to the paediatric population. The behavioural intervention will be delivered according to both the participant profile and already validated contents and recommendations for stress management in perioperative care and, therefore, there is no risk associated to this intervention. CARINAE does not have any severe side/adverse effect associated to its use. However, on some occasions (occurs in less than 1 in 10 people), when using the virtual reality headset for the first time participants may experience dizziness, headache, and/or motion sickness.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Patients planned for one of the selected surgery types:
o Cardiopulmonary bypass (CPB) surgery (Maastricht UMC+)
o Coronary artery bypass surgery (Maastricht UMC+)
o Cardiac valve replacement (SAS, Maastricht UMC+)
o Prostate, kidney, and bladder cancer surgery (INRCA)
o Hip and knee replacement (HSJD; Parc Tauli)
o Maxillofacial surgery (HSJD)
o Orthognathic surgery (HSJD)
o Scoliosis (HSJD)
• Signed informed consent (by patient or legal guardian in paediatric cases).
• Patients >= 18 years old
• Patient owns a smartphone with Android version 4.4 or above.
• Patient (or legal guardian/caregiver in paediatric cases) is able to demonstrate basic digital literacy (e.g. knows how to communicate through instant messaging apps or similar).

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Dementia.
• Pregnant women.
• Categorized > ASA IV.
• Inability to understand the local language.
• Allergic to dedicated wearable material (stainless steel and silicone).
• Currently enrolled in a different clinical trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-11-2021
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	CARINAE: A digital therapeutics platform for stress management
Registration:	No

Ethics review

Approved WMO

Date:	17-11-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78333.068.21