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A study protocol to develop and test an e-health intervention in follow-up service for intensive care survivors' relatives

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Abstract

Background: The negative impact on long-term health-related outcomes among relatives of critically ill patients in the intensive care unit (ICU) has been well described. High-quality ICU specialized follow-up care, which is easily accessible with digital innovation and which is designed by and with relevant stakeholders (i.e., ICU patients' relatives and nurses), should be considered to reduce these impairments in the psychological and social domains.

Aim: The programme's aim is to develop and test an e-health intervention in a follow-up service to support ICU patients' relatives. Here, the protocol for the overall study programme will be described.

Study Design: The overall study comprises a mixed-methods, multicentre research design with qualitative and quantitative study parts. The study population is ICU patients' adult relatives and ICU nurses. The main outcomes are the experiences of these stakeholders with the newly developed e-health intervention. There will be no predefined selection based on age, gender, and level of education to maximize diversity throughout the study programme. After the participants provide informed consent, data will be gathered through focus groups ($n = 5$) among relatives and individual interviews ($n = 20$) among nurses exploring the needs and priorities of a digital follow-up service. The findings will be explored further for priority

[†]The ICNaVEN-study group are listed in Acknowledgements.

Clinical trial registration: Will follow after publication of the protocol in the Dutch clinical trial registry, available at <https://clinicaltrialregister.nl/en>

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considerations among members of the patient/relative organization (aiming $n = 150$), which will serve as a basis for digital prototypes of the e-health intervention. Assessment of the intervention will be followed during an iterative process with investigator-developed questionnaires. Finally, symptoms of anxiety and depression will be measured with the 14-item Dutch version of the 'Hospital Anxiety and Depression Scale', and symptoms of posttraumatic stress will be measured with the 21-item Dutch version of the 'Impact of Events Scale-Revised' to indicate the effectiveness of digital support among ICU patients' relatives.

Relevance to Clinical Practice: The e-health intervention to be developed during this research programme can possibly bridge the gap in integrated ICU follow-up care by providing relevant information, self-monitoring and stimulating self-care among ICU patients' relatives.

KEYWORDS

e-health, follow-up service, intensive care unit, nurses, post-intensive care syndrome – family

1 | INTRODUCTION

Health-related quality of life and the long-term consequences of critical illness are gaining more attention from healthcare providers and policy makers.¹ Between 30% and 70% of intensive care unit (ICU) survivors experience physical, cognitive and mental health-related problems after discharge.^{2,3} These impairments are collectively known as post-intensive care syndrome (PICS).⁴ For patients' relatives, ICU admission can also be a stressful event.⁵ As a result, they are at risk of developing psychological distress, such as symptoms of posttraumatic stress disorder (PTSD) (35%–57%), anxiety (15%–25%) and depression (5%–36%) up to 6 months after the ICU discharge of their loved one.⁶ These impairments are collectively referred to as PICS-Family (PICS-F).⁷ Both ICU survivors and their relatives deserve adequate support with knowledge and competences of ICU professionals and a well-defined place in follow-up care.⁸

1.1 | Background

Factors that might trigger PICS-F are, among others, the erratic course of the patients' condition, the severity and duration of the ICU admission and a lack of adequate information during and after the ICU admission.^{9,10} The COVID-19 pandemic has further increased the burden of relatives because of undesirable physical distance and visiting restrictions.^{11–13} An integrated follow-up service might include written and digital information, support from a multidisciplinary ICU follow-up team, offering peer support groups, structured care coordination and navigation through first-line professional treatment.^{8,14} Without integrated and structured follow-up services, symptoms of PICS and PICS-F are barely recognized and supported, thus leading to inadequate prevention and treatment. Diagnosis and treatment of PICS and PICS-F symptoms are the domain of first-line healthcare professionals, such as general

What is known about the topic

- Long-term consequences of critical illness might have a health-related impact in the psychosocial domain on ICU survivors and their relatives.
- Both groups deserve adequate follow-up support with knowledge and competence of ICU professionals.

What this paper adds

- Current ICU follow-up services could further improve the support of ICU survivors and their relatives with personalized e-health intervention(s).
- The e-health intervention to be developed during the research programme, which is described in this study protocol, could possibly bridge the gap in ICU follow-up care by providing relevant information and by stimulating self-care among ICU survivors' relatives.

practitioners, physiotherapists, dieticians and psychologists. However, high-quality ICU specialized follow-up care, easily accessible with digital innovation and designed by and with all stakeholders (i.e., ICU patients' relatives and nurses), should be considered for implementation.¹⁵

Several initiatives have been explored to formalize ICU follow-up services for ICU survivors, aiming to reduce and, ideally, prevent symptoms of PICS.^{16–18} However, a major shortcoming is that interventions during follow-up care for ICU patients' relatives are not standardized or structurally implemented.^{14,19} Personally addressed, comprehensive and practical information provided by ICU nurses offers a solid ground for evidence-based person-centred (after)care and might prevent the relatives' insecurity and stress.^{20,21} This information can prepare them for the upcoming

situation at home, their (new) role of caregiver, an emotional loss in (temporary) changes in the personality of their loved one, and their own emotional vulnerability. Therefore, nurse-led support for ICU patients and their relatives should be included in the design of standardized ICU follow-up.^{22,23}

1.2 | E-health and digitization in ICU follow-up care

Because of digitization, new technologies, and the 24 h economy, individuals want and are stimulated to increase their self-management at the times and places that best suit them.²⁴ As a result, the demand for healthcare is changing, and tailored delivery of care should become available in line with individuals' wishes.^{25,26} The acute care domain could respond to these societal changes with smart digital innovation of care processes to maintain and enhance high-quality, accessible, available and affordable follow-up care.^{16,27}

Furthermore, in a recent integrative review of interventions using digital technology to promote family engagement in the adult ICU, Shin et al.¹⁵ recommended collaborating in a close and iterative process with these stakeholders to develop future innovations. However, knowledge on how to collaboratively develop an e-health follow-up intervention for ICU patients' relatives, including the perspectives of all stakeholders, is still in its infancy.

2 | AIMS AND OBJECTIVES

The aim of the study is to develop and test an e-health intervention in a follow-up service to support ICU patients' relatives. This goal will be achieved with perspectives from these relatives as well as ICU nurses through four work packages (WPs) with study objectives and consequential research questions (Table 1). Here, the protocol for the overall study programme is described.

3 | DESIGN AND METHODS

This study adopts a mixed-methods multicentre research design in five ICUs in the Netherlands. The main outcome of the study programme is the experience of ICU patients' relatives and ICU follow-up nurses with the newly developed e-health intervention. In addition, long-term health-related impairments, such as symptoms of depression, anxiety and posttraumatic stress, will indicate the effectiveness of the digital support. A timeline and flow chart for the WPs in the study programme are provided in Figure 1. This protocol publication follows the SPIRIT guidance.²⁸

The 'Centre for eHealth Research and Disease Management' (CeHRes)-roadmap is a development approach for e-health interventions. This roadmap serves as an evidence-based method to create value-adding and sustainable e-health technologies.²⁹ It incorporates both a person-centred design and a business modelling focus. The

CeHRes-roadmap is a combination of consulting the users throughout the design and pre-testing process and creating an optimum fit between technology, organizational procedures and organizational resources. Therefore, to successfully design and implement e-health interventions, stakeholders (i.e., ICU patients' relatives and the ICU follow-up team) should be involved in the development process. This method of action research enhances compassionate, person-centred relationships with all stakeholders and is focused on high-quality outcome measures.³⁰ Therefore, a participatory approach will guide the integrative methods in which ICU patients' relatives and professionals are essential partners from the start of design thinking through pilot testing until the implementation of the e-health intervention (Figure 2).

3.1 | The four work packages

- WP1 aims to describe the needs and priorities of digital follow-up services through individual and focus group interviews among ICU patients' relatives. The results will be checked in a broader context with an investigator-developed questionnaire spread among volunteers of the Foundation Family and patient Centred Intensive Care (FCIC). This member check will voice the priorities of former ICU patients' relatives.
- WP2 aims to explore the perspectives of ICU nurses in follow-up services on digital support and their roles regarding ICU patients' relatives with individual interviews to learn from their opinions and ideas for e-health, followed by a questionnaire at two consecutive time points related to their role and work environment. Providing compassionate, personalized and excellent quality follow-up service requires vital professionals with profound coping skills to meet the inherently demanding ICU environment. Nurses who design and utilize nurse-led interventions in daily follow-up care might grow in their professional and personal competencies, take on leadership roles and expand their nursing knowledge.
- WP 3 aims to develop and pilot-test the e-health intervention in a participatory approach with iterative feedback rounds among ICU patients' relatives and the ICU follow-up team.
- WP4 aims to explore the effects of the e-health intervention on health-related outcomes among ICU patients' relatives in a pre- and post-measurement with validated questionnaires.

3.1.1 | Aimed intervention

Based on the results from WP1 and WP2, the e-health intervention will be developed during this study in WP3. This intervention should bridge the gap in integrated ICU follow-up care through self-monitoring of psychosocial health, providing information and stimulating selfcare. Psychoeducation,³¹ which in this study programme means providing (1) information about psychological symptoms and (2) easily accessible tips for self-managing emotional turbulence, might

TABLE 1 Overview of objectives and research questions per work package in the study programme.

| Work package objective | Research questions | Study methods | Preparation | Expected time frame |
|---|--|---|---|---|
| 1 To describe the needs in the development of an e-health intervention in nurse-led follow-up service from the perspectives of ICU patients' relatives | 1.1 What are the informational and supportive needs in follow-up service among ICU patients' relatives? | 1.1.1 Focus group interviews ($n = 5$ at minimum) among ICU patients' relatives (aiming for 6–8 participants, preferred an in-person session) | Topic list and accordingly a semi-structured interview guide | Start in April 2022 with a pilot ($n = 7$ participants), followed with a focus group in each study setting from January through April 2023 |
| | | 1.1.2 Individual in-person interviews with non-Western participants ($n = 6$ at minimum) | Topic list and semi-structured interview guide as much as possible similar to focus group interview | Start in November 2022, ongoing until June 2023 |
| | 1.2 Which e-health interventions could align with the preferences of ICU patients' relatives? | 1.2 Member check through a convenience sample of participants among volunteers of Foundation Family and patient Centred Intensive Care (FCIC) ($n = 200$) | Development of questionnaire based on literature, preliminary results from focus groups, and expert opinion of the research team. This will be short, 20 items and 10 min to complete maximum | Start data gathering from April through July 2023 |
| 2 To explore perspectives of ICU nurses in follow-up service on digital support and their roles regarding ICU patients' relatives with respect to their job resources | 2.1 Which enablers and barriers influence the ability to take the role as a nurse in follow-up service regarding digital ICU support? | 2.1 Individual interviews ($n = 2$ per study setting) | Interview guide based on expert opinion from researchers. A test will be done by researchers for comprehensiveness on one follow-up nurse | Start March through July 2023 |
| | 2.2 What is the effect of a nurse-led e-health intervention on autonomy, job satisfaction and vitality among ICU follow-up nurses? | 2.2 Survey among ICU nurses in follow-up service ($n = 10$) and ICU nurses (aiming for $n = 150$ in all included study settings) | A questionnaire composed of validated measuring instruments, repeated in two consecutive time points | Timepoint September 1, 2023; timepoint September 2, 2024; and timepoint September 3, 2025 |
| 3 To develop and pilot-test an e-health intervention in nurse-led follow-up service and to explore the reported experience measures in ICU patients' relatives and nurses' perspectives | 3.1 What are the experiences with the developed e-health intervention among all stakeholders? | 3.2 A participatory approach with iterative qualitative feedback rounds until a concept version of the application will be agreed. | In-person and online inspiration sessions will be held to test the concepts, to work on adaptations, and to gather opinions on expected usefulness of the application | Aiming for November 2023 through March 2024 |
| 4 To determine the impact of the developed e-health intervention through ICU patients' relatives health outcomes in a pre- and post-measurement | 4.1 What is the long-term (up to 1 year) impact of the developed e-health intervention on quality of life, satisfaction with care and symptoms of depression, anxiety and PTSD in ICU patients' relatives? | 4.1 A pre- and post-quantitative measurement with validated questionnaires | Survey composed of validated measuring instruments | Start September 2023 through September 2025 |
| | 4.2 What are the long-term (up to 1 year) social burden outcomes related to increased use of medical care, return to work and reduced financial income in ICU patients' relatives? | A pre- and post-measurement with validated questionnaires | Survey composed of validated measuring instruments | Start September 2023 through September 2025 |

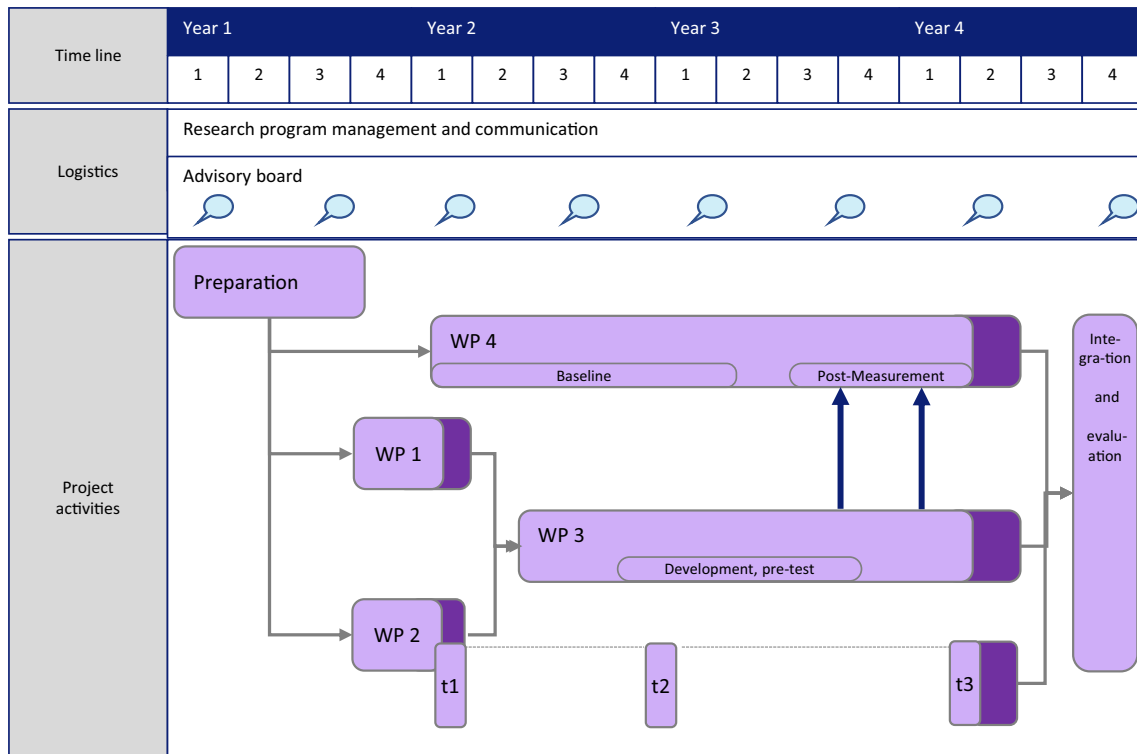
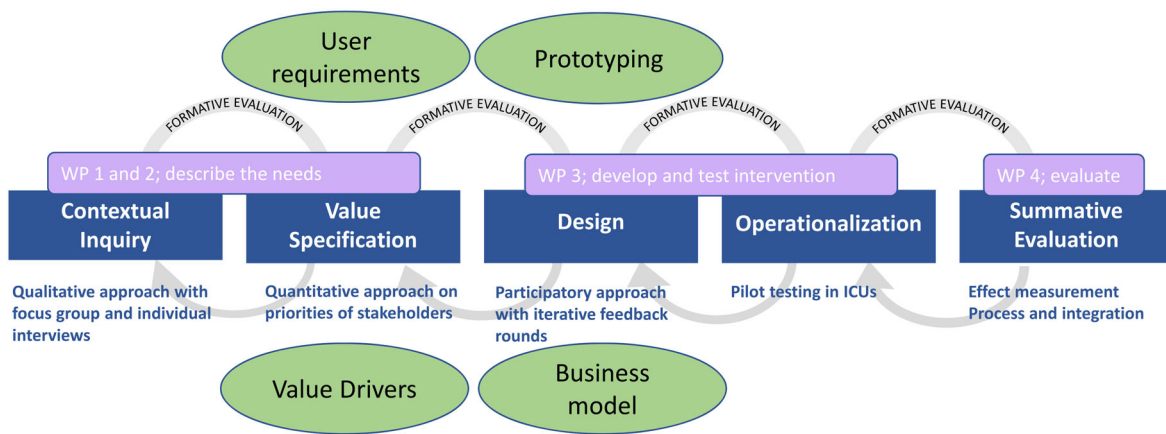


FIGURE 1 Summary and flowchart for the work packages in the study programme. t = time period; t1 February 2023, t2 February 2024, t3 February 2025. WP, work package. WP1 To describe the needs in the development of an e-health intervention. WP2 To explore perspectives of ICU nurses in follow-up service on digital support and their roles. WP3 To develop and pilot-test the e-health intervention. WP4 To determine the impact in a pre- and post-measurement.



CEHRES ROADMAP

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FIGURE 2 Integrative approach of CeHRes roadmap and study programme. WP, work package.

enlarge supportive care, such as reducing insecurity and finding peer support.

3.2 | Setting and sample

A university medical centre in the Netherlands, with over 44 operational-level three ICU beds that provide a full spectrum of monitoring

and life support technologies³² and more than 3000 admissions per year, is the lead centre of this study. This ICU is part of a regional consortium, a group of ICUs working together to provide quality care and perform research. Previous studies, including ICU follow-up with specific virtual reality for ICU patients,³³ have been conducted in this consortium. All ICUs in the consortium will be invited to join the study programme, with the aim of having at least four participating hospitals.

3.2.1 | Participants

The study population consists of ICU patients' relatives from joined hospitals (WP1, WP3 and WP4). All follow-up nurses from included ICUs will be approached for participation (WP2 and WP3).

3.2.2 | Inclusion and exclusion

An ICU patient's relative must meet all of the following criteria to be eligible to participate in the study programme:

- ICU stay of their loved one longer than 48 h of mechanical ventilation.
- Age above 18 years.
- Sufficient knowledge of the Dutch language (which means reading, discussing, and understanding relevant information about the study aspects and the questionnaires).
- Present during the ICU stay and considered a legal representative at the time of admission.

Relatives with unknown contact details will be excluded from participation in this study.

ICU follow-up nurses must spend dedicated work time of at least 4 h/week in follow-up service to be eligible to participate in the study programme.

3.2.3 | Recruitment and informed consent

The eligible respondents will be recruited by the local study coordinators. There will be no predefined selection based on age, gender, level of education or cultural background to maximize diversity in the study group, data gathering and analysis. No financial compensation will be offered for participation. Furthermore, members of the Dutch Foundation FCIC, including patient organization IC Connect, will be invited to participate through the organization's newsletters and social media channels (WP1 and 3).

All eligible participants will be informed about the study verbally by a follow-up nurse and by a postal letter generally sent by the study centre. Personal data will be retrieved of the electronic health records from former ICU patients. Interested participants will receive at least 24 h to consider their participation, and they can approve until the set dates of study activities. Because the intervention is noninvasive and is associated with low risks, as previously assessed by the institutional review board, this period is considered justified. Consent for participation will be given through a written informed consent form.

3.2.4 | Ethical considerations

The study protocol has been approved by the Medical Ethics Committee (MEC-2022-0153). This study will be conducted according to the

principles of the Declaration of Helsinki, 64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013, and in accordance with the Dutch Medical Research Involving Human Subjects Act. The study will comply with the Netherlands Code of Conduct for Scientific Practice from the Association of Universities in the Netherlands. Participation in this study is on a voluntary basis. If relatives do not wish to participate, they can withdraw without specifying why.

This particular area of research may be a confronting issue for participants. ICU patients' relatives are vulnerable, and even voluntary participation in the study might evoke negative flashbacks of the ICU admission of their loved one. This possibility will be taken into account by allowing the relatives to share their own experiences when completing the questionnaires. They choose what to reveal, and they are not required to answer.

Previous studies have shown that comparable respondents usually characterize their participation as helpful and not harmful.³⁴ Furthermore, information about supporting services will be included in the participant information form and at the beginning of the survey. This method was used in a previous study among bereaved relatives and worked well.¹³ The general practitioner of the participants will not be informed about the participation in this study, because of the negligible consequences that need professional support. In case a relative experiences health-related symptoms after participation in the study, the coordinating investigator (psychologist and ICU nurse), a clinical psychologist, the ICU follow-up teams and an independent specialist will be available for professional support.

3.3 | Data collection and outcomes

Recruitment starts in April 2022 with a pilot focus group meeting and will be ongoing for the whole programme until approximately June 2025. Data will be collected in consecutive qualitative and quantitative rounds at different time points (Figure 1).

3.3.1 | Qualitative study procedures

In WP1, focus groups ($n = 5$, one per setting), which will include 6–10 participants among ICU patients' relatives. In WP2, individual interviews among ICU follow-up nurses will ideally be held in person to observe nonverbal attitudes, facial expressions and interaction, if applicable. Prior to all qualitative meetings, the research group will create a topic list and a semi-structured interview guide based on the literature and their own experiences. Two researchers with expertise in qualitative research and ICU care will lead all meetings. The reflexivity of the researchers, which means their prior experiences, assumptions and beliefs in this study domain, might influence the research process. Therefore, reflexivity will be included in detail when reporting the study findings. Interview data will be audiotaped, transcribed verbatim and pseudonymously archived.

3.3.2 | Quantitative study procedures

The surveys are constructed as online questionnaires and will be sent to the participants via a personal and safe digital link via email. Data management will be established in Castor[®], a safe software package to gather and archive quantitative data, with digital reminders to non-responders at 2 and 4 weeks after the first approach. A data management plan will be used for a complete description of maintaining privacy rules, confidentiality and data storage. In WP1, a convenience sample of participants, aiming for 200 responses, will be established. In WP2, a minimum of two participants per setting will be sought. In WP4, a minimum of 160 participants is needed (see power calculation).

3.3.3 | Study outcomes and measurement instruments

All outcomes and measurement instruments are presented in Table 2.

3.4 | Data analysis

3.4.1 | Qualitative data

The NVivo12[®] software programme will be used for qualitative analysis of data. Thematic analysis will be used as a theoretical method, providing clear steps to categorize and report the data that are

TABLE 2 Overview of study outcomes and measurement instruments.

| Main study outcomes | |
|--------------------------|--|
| WP1 | <ul style="list-style-type: none"> Needs and priorities in e-health among relatives of ICU patients |
| WP2 | <ul style="list-style-type: none"> Person-centred Nursing Care among follow-up nurses: The Person-Centred Practice Inventory-Staff questionnaire (PCPI-S) is used to measure the delivery of person-centred care. This is a 59-item validated 5-point Likert scale, including constructs as context and shared decision-making, that maps specifically to the theoretical framework for person-centred practice and provides a generic measure of person-centeredness.³⁵ |
| WP3 | <ul style="list-style-type: none"> Experiences of all stakeholders with the newly developed e-health intervention which is to be developed during the study in participatory feedback rounds |
| WP4 | <ul style="list-style-type: none"> Symptoms of anxiety and depression; measured with the Dutch version of the 'Hospital Anxiety and Depression Scale' (HADS), that includes to 7 items on the subscales tapping 'Anxiety' and 'Depression', respectively.^{36,37} These subscales are reliable and valid measures of mental health status with items concerning symptoms of psychological well-being. Scores range from 0 to 21, categorized as 'normal' (0-7); 'mild' (8-10); and 'moderate to severe' (11-21). The HADS is not used as a diagnostic criterion. Symptoms of posttraumatic stress; measured with the 21-item Dutch version of the 'Impact of Events Scale-Revised' (IES-R).³⁸ This measuring instrument is used worldwide to self-report the frequency of intrusive and avoidant phenomena after a variety of traumatic experiences. The reliability of the Dutch version of the IES is adequate across the various stressors.³⁹ Scores range from 0 to 88, categorized as 'low risk' (0-11); 'moderate risk' (12-32); and 'high risk' (≥33). The IES-R is not used as a diagnostic criterion. |
| Secondary study outcomes | |
| WP1 | <ul style="list-style-type: none"> Satisfaction and experiences with follow-up care which can be answered on an investigator-developed questionnaire with a Likert scale from 0 (Not at all) to 4 (A lot). |
| WP2 | <ul style="list-style-type: none"> Job autonomy among follow-up nurses is measured with five items on a three point scale (no; yes, sometimes; yes, regularly) based on the Job Content Questionnaire.^{40,41} Job satisfaction is measured with one item: 'Altogether, how satisfied are you with your work?' The responses range from 1 (very dissatisfied) to 5 (very satisfied). The Practice Environment Scale of the Nursing Work Index is the most widely used measure to gauge the state of nursing practice environments.^{42,43} It is the only measure recommended by several organizations promoting quality health care. The 15-item questionnaire uses responses ranging from 1 (= strongly disagree) to 4 (= totally agree). Vitality is measured with four items from the original 36-item Short Form Health Survey (SF-36).⁴⁴ The total summed score of four items that refer to the past 4 weeks: 'Did you feel full of liveliness?', 'Did you have a lot of energy?', 'Did you feel worn out?', and 'Did you feel tired?'. The answers are rated on a six-point scale from 1 (= constantly) to 6 (= never).⁴⁵ Higher scores indicating a better subjective vitality |
| WP4 | <ul style="list-style-type: none"> Symptoms of health-related problems; measured with the 36-item RAND-36. The RAND-36 is a self-reported measure of health status. The RAND-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed to a 0-100 scale on the assumption that each question carries equal weight. The sections are; vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning and mental health.⁴⁶ These are not used as diagnostic criterion. Caregivers' strain; measured with the Carer Strain Index (CSI) measures the perspectives of relatives related to care provision including elements of emotional adjustment, social issues, physical and financial strain.⁴⁷ Each question is given 1 point. A score of 7 or greater is the generally accepted cut-off point for a high level of stress. An investigator-developed questionnaire regarding the use of medical care, satisfaction and experiences with follow-up care which can be answered on a Likert scale from 0 (Not at all) to 4 (A lot). |

BOX 1 Five steps in qualitative data analysing.

Two researchers will read the transcripts (Step 1: Familiarize with the data). Each of them will develop a structured analysis framework that consists of preliminary codes (Step 2: Generating initial codes). After that, they will compare their frameworks to reach consensus on codes and themes. Next, one researcher will code the transcripts line by line according to this framework (Step 3: Searching for themes). When coding is finished and the code 'other' is used, the two researchers will discuss these codes and rename them into a new or existing codename best reflecting the contents of the otherwise uncategorised text fragment (Step 4: Reviewing themes). After coding is finished, the cohesion and interrelations between codes will be analysed by the two researchers through mind mapping (Step 5: Defining and relating themes). An expert in qualitative research will support the process of analysis and reporting of data.⁴⁷

found.⁴⁸ To determine essential themes in the needs assessment (WP1) and nursing roles (WP2), an accurate reflection of the content of the dataset is needed. Inductive analysis will be applied to find themes without pre-existing conceptions from the researchers.⁴⁹ The researchers will follow previously described steps in their analysis, shown in Box 1.⁵⁰ To ensure credibility, theoretical data saturation will be sought and decided upon by discussion with the principal investigator (MvM).^{48,49}

3.4.2 | Quantitative data

Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp) version 28.0 or higher will be used for quantitative data analysis. The scores will be analysed based on the original data and, when available, according to established cut-offs. Spearman correlations and a linear mixed regression model with random subject effects to analyse trajectories over time will be used for the longitudinal data, with the correlations assessed between previously addressed time points. In cases of lack of normality, the non-parametric longitudinal approach will be implemented.

Demographic variables (e.g., gender, age and educational level) and outcome measures (e.g., anxiety, depression, posttraumatic stress, caregiver strain, medical use, satisfaction and experiences with care) will be reported as descriptive statistics (e.g., means, medians or proportions, as appropriate). A Student's *t*-test will be used to present noticeable differences between the baseline (18 months) and post-measurement (8 months) group. In addition, time as the within-subject factor (baseline versus post-measurement) will be used to conduct repeated measure analysis of variance. Cohen's *d* will be calculated to

present effect sizes, if applicable. All tests will be bilateral, and significance will be defined as $p < .05$. A statistician will be consulted for the final approval of data analysis.

3.4.3 | Power calculation for WP4

As far as known, this study is the first of its kind for which no previous literature was found to define the expected effect estimate. Derived from a follow-up study measuring the effects of virtual reality glasses on the reduction of PTSD in patients, for which a Cohen's *d* effect size of 0.77 was found,³³ a clinically meaningful Cohen's *d* effect size of 0.55 (medium effect) might be anticipated in ICU patients' relatives. Assuming a loss-to-follow-up of 20%, in total, 160 participants should be included in this study based on a two-sided alpha of 0.05 and a power of 0.80. This means 80 relatives in the baseline group and 80 relatives in the post-measurement group. This number is expected to be achieved within 12 months in each study setting.

4 | DISCUSSION

Currently, there is limited understanding of the impact of PICS-F among ICU relatives.⁵¹ It is essential to develop and test novel interventions to reduce long-term health-related impairments. In addition to inpatient follow-up contact through a multidisciplinary ICU team, e-health innovations might provide applicable solutions to self-monitor symptoms of PICS and PICS-F with an easy, user-friendly and inexpensive method. For noninteractive digital information in ICU healthcare, numerous resources of variable quality with readily accessible medical data and comprehensible videos on PICS, PICS-F and related topics have been offered internationally and in the Netherlands.⁵² Current ICU follow-up services could further improve the support of ICU patients and their relatives with personalized e-health intervention(s).

E-health has been defined as 'the application of both digital information and communication to support and/or improve health and healthcare'.⁵³ Conscious choices will be made about how, why, and for whom the e-health intervention can be tailored to the needs of the target group. A member consultation in 2020 by the foundation FCIC has led to the drafting of a patient-driven knowledge agenda.⁵⁴ Based on patient journeys, knowledge gaps were converted into feasible research questions and prioritized. The top-three research themes included (1) reliable and valid screening for PICS; (2) understanding the epidemiology of PICS-F; and (3) determining the effectiveness of an innovative e-health platform for psychosocial follow-up.⁵⁴

It is unknown which e-health interventions best meet the needs of ICU patients' relatives. Innovative strategies during the COVID-19 pandemic have shown digital possibilities for providing information and supportive care.²⁷ Web-based interventions, such as video conferencing and text messages, have been alternatives to providing interhuman contact, information and support.^{55,56} Virtual reality could have great potential in the clinical ICU environment.^{33,57} E-health

applications, such as integrated health apps and home self-monitoring, might be beneficial for individuals who can proactively check their health by means of regularly completed short digital questionnaires recording expected symptoms, thus raising awareness or reducing deterioration through timely professional support. This new approach, including a patient dashboard to signal problems, has been applied in diverse settings (frail elderly, patients with depression) with a positive effect on active participation.⁵⁸ This fact might offer a starting point for e-health in ICU follow-up.

4.1 | Strengths and limitations

A strength of this extensive study programme is the joint development of digital innovation by relevant stakeholders, with their experiences as the main outcomes. However, there are some shortcomings to acknowledge. First, generalization of the results might be limited because of the predominance of the ICU settings being in a confined area in the Netherlands. Second, the time and involvement of ICU follow-up nurses might be restricted by a high workload. Third, it might be questionable if e-health in ICU follow-up services is going to be used by the target group. It not only requires appropriate solutions in terms of access and presentation, but appropriate implementation strategies should also be considered. Fourth, because of the confined knowledge of digital possibilities, another similar intervention might have been developed that is already or is almost on the market. For all of these limitations, the research team will be open to collaboration, both national and international.

4.2 | Relevance to clinical practice

The results of the research programme described in this study protocol could lead to a more tailored approach in clinical ICU practice supporting patients' relatives through integrated stepped care with the right (digital and/or professional) support at the right place and the right time. Successful development and national implementation of digital support could reorganize healthcare systems and provide financial support for ICU follow-up services. Because of an increase in understanding and awareness of PICS and PICS-F, the gained knowledge could be incorporated into practice guidelines and into the existing curricula of vocational and bachelor nurse students.

5 | CONCLUSION

This study programme will contribute to closing the knowledge gap in the long-term follow-up of ICU patients' relatives. The e-health intervention to be developed during this research programme can possibly bridge the gap in integrated ICU follow-up care by providing relevant information, self-monitoring, and stimulating self-care among ICU patients' relatives. This intervention might lead to less quality of life loss and a reduction of healthcare costs.

AUTHOR CONTRIBUTIONS

MMCVm developed the initial idea of the intervention and is the grant holder and coordinating investigator of the study. MMCvM, EJOK, JvB, and JML defined the methods of the study. MMCvM, EJOK, and JML drafted the study protocol. The ICNaVEN-study group provided comments on the protocol. MMCvM, EJOK, JvB, JML critically revised the protocol. All authors agreed on the final version of the manuscript.

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DATA AVAILABILITY STATEMENT

Anonymized data gathered and analysed during the study will not be available publicly because of legal and ethical restriction. These will be freely available at a reasonable request to any scientist wishing to use them for non-commercial purposes as well as text and photo material of the developed intervention. The results of the study programme will be disseminated to healthcare professionals, health services authorities and the public via presentations at national and international meetings and published in peer-reviewed journals. A lay summary of the results will be written and shared with the Dutch ICU patient organization and made available to participants on request.

ETHICS STATEMENT

The research protocol for this study has been approved by the Medical Ethics Committee (MEC-2022-0153).

PATIENT CONSENT STATEMENT

Not applicable for this research protocol.

PARTICIPANTS RECRUITMENT

Start in November 2022 and ongoing through 2025.

PERMISSION TO REPRODUCE MATERIAL FROM OTHER SOURCES

Not applicable for this study.

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