A clinical field study aimed at Digitally identifying and minimizing stressors at the Palliative care workplace by measuring stress continuously through wearable sensors (DiPa): Study Design

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Abstract

Background: Nursing in palliative medicine combines primary patient care with the special challenges of this medical field, e.g., handling the processes of dying, grief, and death. These cause high stress levels and burden on the nursing staff, fostering early drop-outs of working life because of physical or psychological disorders like burnout.

Objective: DiPa is a prospective study which investigates the feasibility of measuring the burden and its causes in palliative care using methods of subjective and objective stress detection. Based on these results, stress-reducing interventions are to be deduced and evaluated. In this paper, we present our study protocol.

Methods: The nursing staff of an inpatient university palliative hospital ward gathered data over 6 weeks. Each was equipped with a smart wrist band and a smartphone which continuously measures physiological and ambient parameters throughout their working days. These objective data were enriched by subjective measurements: a questionnaire at the beginning of the study, which assessed multiple potential stressful situations and constellations in the private and working environment, and ecological momentary assessments (EMA) during the workday, which were prompted by scanning near-field communication (NFC) tags placed at different locations on the ward. The ongoing data analyses will be processed by using computer algorithms partly programmed specifically for this study and partly drawn from existing libraries, such as toolboxes for neurophysiological signal processing for Python. Comparisons between subjective and objective measures and group comparisons between variables of interest will be made using inferential statistics, including regression analyses and analyses of variance. Data analysis using machine learning algorithms will be implemented once sufficient data will have been gathered.

Results: As of April 2024, 12 of 18 nurses of the Palliative Care Unit consented to participate in our study.

Conclusions: The DiPa study aims at testing the feasibility of measuring and merging subjective and objective stress parameters in a palliative care nurses. Clinical Trial: The DiPa study has been registered in the German Register for Clinical Studies on February 10th, 2021 (DRKS, ID DRKS00024425A).

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Abstract

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Keywords: Stress; distress; palliative care; nurse; burden; burnout; wearable sensors; digitalization

Introduction

Background

Chronic and severe diseases gain importance and require a sufficient medical treatment and well-educated specialists in the field to provide medication, help with personal hygiene and offer counselling conversation. In 2020, a number of 1.7 million nursing staff worked in nursing and elderly care in Germany [1], which reflects a growing shortage of skilled workers in view of the aging population. The reasons are manifold but those found in the working environment include the three-shift system, time pressure and heavy physical and emotional burden, leading to dissatisfaction or even leaving the profession [2,3]. These factors can be found in almost all hospital departments but aggravate in areas with a high level of physical and interpersonal care. Palliative medicine is one of these particularly sensitive areas.

Palliative Medicine

Palliative medicine is specialized in the treatment of people who suffer from critical diseases like advanced cancer or higher-grade cardiac, renal or lung diseases with limited life expectancy. Not only medical care but also psycho-social and spiritual aspects in the interaction between nursing staff and the patients and/or their relatives render palliative care a challenging discipline, all in all with the aim to improve the quality of life in the last months and weeks of the patients' lives. The main tasks of nursing staff in the palliative field include life support for the terminally ill and relieving their suffering from common severe symptoms. These include pain, shortness of breath or nausea, but anxiety and depression also occur with a high prevalence, which Sewtz et al. [4] could show in a study.

Burden in Palliative Caregiving

Palliative nurses face the many stressors mostly anyone or any nurse can face at work (like interruptions, time pressure, interpersonal conflicts or working in shifts, as mentioned above) but also additional stressors that are unique when taking care of patients that are terminally ill or close to dying (see Table 1, adapted to [5]). It is an immanent part of the job that physicians and palliative nurses are confronted with the end of a patient's life and with patients and relatives facing this stage. Even though nurses in this field choose this sensitive job after careful consideration, it still is an emotional burden to cope with the dying and death of patients for 54-68 % of nurses in palliative care [5], which is moderated by circumstances (e.g., age of the patient, torments).

Table 1: These are examples of potential stressors in a Palliative Care Unit (PCU).

Team-associated Factors	Patient-associated Factors	Structural Factors	Personal Factors
Staff fluctuation among physicians on the PCU	Young patients' age	Understaffing	Ethical conflicts
Lack of support	High care effort due to symptoms (e.g., wounds, nausea, breathlessness, restlessness)	High amount of documentation	The feeling of being overwhelmed
Lack of appreciation by other professional groups	Insufficient symptom control (therapy resistant pain, insatiable bleeding)	Inadequate education of patients and relatives about the palliative setting by the referring doctor	High expectation of one's own work

Only a few studies have investigated this topic [5–11]. Diehl et al. [10] surveyed and compared strains and resources in 149 nurses (34.5 % response rate) working in the field of palliative care (in either hospitals, hospices or outpatient care in Germany). In their study, more than half of the nursing activities were perceived as heavy burdens, including transferring patients, time pressure, having to care for too many patients per day, handling patients with severe symptoms or dealing with grief and death. Being surrounded by these topics every working day, nurses are at risk for psychiatric disorders which can accumulate in a burnout syndrome in 15-20 % among palliative nurses in home care [11,12].
Clinicians and researchers demand more studies, as it has been urged in the systematic review of burnout syndrome in palliative care by Pereira et al. [9]. Further evaluations of palliative care nurses throughout Europe could ensure a better positioning of any results in the transnational context of the palliative care area and reveal further deficits in the care structures [8].

DiPa Study

The DiPa study was conceptualized to use **di**gital technologies ("Di") to assess the working conditions and burden on nurses in **pa**lliative settings ("Pa"). The study is a joint project of the Fraunhofer IGD Rostock and the Rostock University Medical Centre (UMR) and funded by the State Office for Health and Social Affairs Mecklenburg-Western Pomerania. The study aims at the identification of correlations between measured objective physiological parameters and subjective perceptions of stress in everyday situations in the PCU. Therefore, the proof of the feasibility of identifying stressors in palliative care and of measuring stress reactions with wearable devices is needed as the primary goal. With these initial results, stressors and stress shall be reduced by developing preventive measures.

Physiological Stress Model

To explain our rationale for using wearable devices to measure stress in humans, the physiological stress model is presented. The autonomic nervous system is responsible for all vital functions, regulating breathing, digestion and the cardiovascular system as well as influencing the heart and glands [13]. The ANS is divided into the sympathetic and parasympathetic nervous systems, which often act antagonistically (ibid.). While the sympathetic nervous system is activated by stress, the

parasympathetic nervous system supports resting states. ‘Stress’ occurs when the demands of the environment exceed the individual's ability to cope [14]. It is defined as an individual’s reaction to burden and is caused by triggers that are called ‘stressors’.
Three phases of the physiological reaction can be distinguished, which were first described as part of the ‘general adaptation syndrome’ by Hans Selye [15]: the first phase is called “alarm phase” and appears immediately after the stimulus.
The sympathetic nervous system reacts to a stressor by releasing catecholamines like noradrenalin and adrenalin from the adrenal medulla [16] and, simultaneously, ACTH from the cortical part [17]. Chodan et al. [18] describe in their paper how the different physical changes interact during the alert: the muscles require oxygen for the oxidation of glucose and fat into energy. To provide this surplus of oxygen, the breathing rate and the heart rate increase. Empirical knowledge and experiences in handling data from biomedical parameters gathered with wearable devices has been accumulated in prior studies [18–20]. Especially the heart rate and heart rate variability have been identified as valid stress markers [21,22].
To facilitate chemical reactions to provide energy, i.e., the oxidization of glucose and fat, the body temperature rises. At the same time, to protect the body from overheating, the sweat glands are also targeted by the sympathetic nervous system (SNS), increasing the skin conductance and lowering the skin resistance, which can be measured between two electrodes placed onto the skin [23]. Thus, measuring sweat secretion is an important method to investigate the activity of the SNS and to determine stress reactions.
Directly after the alarm phase, the “resistance phase” ensures and is biochemically characterized by an increased cortisol liberation. Cortisol passes through the blood-brain barrier to the hippocampus, which then lowers the activity of the HTPA via negative feedback mechanisms. This serves to regulate the stress reactions and to prevent exhaustion of the stress hormones.
Only in chronic stress (e.g., when the available resources are insufficient to relieve stress or when the stressor is present over a long period of time), a third phase, “exhaustion phase”, follows with symptoms of exhaustion and a dangerous weakening of the immunological system [24].

Methods

Study Design

To assess the working conditions and burden on nurses in palliative settings, preliminary tests were executed to investigate the functionality and user experience, including the handling in a hospital environment and resistance to the hospital’s disinfection routines.
The study design (Figure 1), a prospective cross-sectional approach with continuous measurements throughout each workday, allows for assessing both the current manifestation of stressors and current level of perceived stress load both objectively and subjectively. Participants will be split into groups, and each group will conduct the measurements for 6 weeks, thus expanding the span of the measurement across all participants (to increase the time frame depicted in the data) while individual participants are not burdened with the additional workload for longer than necessary.

FIGURE 1

Apparatus

The stress level will be measured both objectively (physiological stress reaction) and subjectively (appraisal of the perceived stress in Ecological Momentary Assessments, EMAs). Possible stressors are also identified both in the subjective perception via questionnaires and objectively by matching physiological stress responses to concurrent ambient conditions, such as noise, interruptions, or

specific activities. Additionally, we will compare the objective stress levels to the daily staffing, occupancy level and other daily changing factors of an hospital ward.
To this end, a combination of wearable and ambient sensors was put together that can measure the physiological (objective) stress reaction as well as possible stressors (stress causes). The prototypical setup consists of a smart wristband, a smartphone, NFC tags, and Raspberry Pis® equipped with microphones to record interruptions (incoming telephone calls) and unexpected tasks (calls from patients). The setup can be seen in Figure 2 and Figure 3. At the end of the study, it will be possible to characterize a normal working day of a palliative caregiver more precisely in terms of the physical and psychological stress. The perceived burden will be correlated with the bed occupancy, the number of patient admissions, discharges and decease per day as well as the influence of the duty roster design (including the staffing) and the frequency of interruptions by telephone or a patient's bell.

FIGURE 2

The results of measured electrodermal activity (EDA), heart rate (HR) and skin temperature should provide information of a sympathetic nervous system reaction to stress [13]. All these parameters are recordable with the research wristband Empatica E4. Thus, to measure the physiological stress reaction, we will take recourse to the commercially available E4 wristband by Empatica Inc. [25]. The E4 wristband possesses a PPG sensor and two electrodes to measure the galvanic skin response at the wrist. It will be used to measure the pulse, heart rate variability (HRV), electrodermal activity (EDA), and body temperature (surface). The automatic data pre-processing will be bypassed since this would require sending the sensitive data to an alien server. To circumvent these international servers for reasons of data protection, the code of the E4 has been altered, allowing the extraction of raw data. Raw data is then sent to the smartphone, which is also part of the study's setup, and stored on the phone's memory until transferred to a local server. The E4 has no display and thus, provides no feedback to the participants that could interfere with or distort the measurement. LED lights provide the necessary feedback on the functionality of the wristband, and additional feedback on functionality (and connectivity) is given in the corresponding smartphone application.
In addition to the LED light, allowing event marking – i.e., a real-time annotation –, as the tapping deposits a record in the session file. The record includes the time of the button press (expressed as Unix timestamp in UTC), which is synchronized with the initial time of the corresponding session. Feedback on the button press is given both visually (illuminating the LED light) and audibly (beeping). The button press was used for two purposes, a) for logging an event of subjectively perceived stress (a single button press) and b) for logging the event of disinfecting one's hands (as this can alter the EDA; two consecutive button presses).

FIGURE 3

To assess possible stressors, NFC tags (Figure 2c) have been programmed and have been placed in numerous positions at the ward. The NFC tags will be used to log the activity of the participants, such as NFC tags placed onto the doors of the nine patient rooms to log when a subject will enter or leave a specific patient room. Other activities which will be logged include the beginning and ending of meetings (medical rounds, daily, weekly, and monthly team meetings, and daily handovers at the beginning or end of a shift), the beginning and ending of conversations with patients and/or their relatives, and relaxation.
Furthermore, not only by pressing the wristband button, as mentioned above, a stressful event can be marked, also scanning the NFC tags will offer the possibility to communicate a challenging situation by providing the possibility to enter a short description of the current event by using a HUAWEI smartphone P30 lite. This smartphone hanging by a cord around the participants' necks and can be

stored conveniently in their gowns' pockets with the microphone poking out (compare Figure 2) is also used to measure the ambient noise.
Lastly, two types of interruptions will be measured, each with a microphone attached to a Raspberry Pi® 4 Model B. The first kind is the interruption by telephone calls, e.g., outsiders calling to reach patients or to retrieve information about the patients such as family physicians or calls from within the hospital, e.g., calling about referrals. The second kind of interruption is a distress call (from a patient) or an emergency call (from a fellow nurse or physician), both broadcast through the hospital ward's bell system.

Two types of questionnaires will be used to assess the subjective stress levels. An extensive study questionnaire with 137 items (101 of which asked for specific stressors) will be handed out at the beginning of the study. It inquires about the subjectively perceived frequency and the subject's rating of different stressors (i.e., how often does this event take place and how stressful does one find it). A multiplication of the two parameters allows for an evaluation of the perceived stress. While an event can be labelled as very stressful, it is not necessarily a meaningful stressor if it rarely ever occurs. Thus, a stressful event that seldom takes place or a frequent event which barely stresses the subject are both considered less harmful than an event that is both frequent and (moderately or highly) stressful. The study questionnaire was designed specifically for this study by a psychologist and a nurse with longstanding work experience, incorporating known stressors from the literature as well as stressors mentioned in a survey carried out at a palliative ward and an outpatient palliative care facility.
In addition, the Maslach Burnout Inventory (MBI) [26] will be handed out to assess further burdens (or possible sequelae of the stress). It is a standard questionnaire that will allow for inter-study comparisons of this study's findings with the literature.
In addition to these two questionnaires that will only be filled out once at the beginning of the measurements, the subjective stress level will also be assessed throughout the workday accompanying the continuous ambulatory measurements using ecological momentary assessments (EMAs). EMAs are short questionnaires asking for self-reports that document the perceived subjective experience of stress at a certain moment, i.e., a *momentary* appraisal of their *current* stress level [27]. The questionnaires will pop up on the participants' smartphones whenever an NFC tag will be scanned that indicates the end of an activity (e.g., end of rounds, leaving a patient room, end of a meeting, end of speaking with a patient or his or her relatives) asking, for example, "How stressed do you feel right now?" with a continuous slider from 0% to 100%, labelled in increments of 20%. In addition, the questionnaire can also be accessed at any time by scanning a designated NFC tag called "open questionnaire". Additional EMAs pop up when the setup will be put on at the beginning of a shift (greeting the participant, asking for the subjective sleep quality of the night before and for the current stress level) and when the setup will be shut down at the end of the shift (asking for the current stress level, how many patients were looked after throughout the day, and wishing a pleasant recreational time).

Sample and Recruitment

The PCU of the University Medicine Rostock with its currently 14 beds is the largest PCU in Mecklenburg-Western Pomerania. Thirteen full-time nurses and five part-time nurses are employed, working in a three-shift system. For the "DiPa" study, all eighteen nurses working in the PCU of the Rostock University Medical Centre, partly being specialized in palliative care, were invited in December 2020 to participate in the study by presenting the procedure and aims of the project in a lecture as well as in a written inquiry. Each was partaking in the measurement for six weeks allowing for a total measurement duration of three months.
A power analysis was not conducted as the population was prespecified (N = 18), rendering the need

for an accruing sample. Twelve nurses agreed to participate resulting in a participation rate of 66.7 %.

Patient and Public Involvement

Patient involvement is not directly part of our study design because of focusing on nursing staff in palliative care. However, analogous to patients our study participants are included in selected questions when creating the study design. As an example, preliminary tests could be used to compare measuring instruments with different measuring methods with regard to their wearing comfort and manageability. Furthermore, before starting the measurements, the nursing staff were shown a list of possible stressors in their work area. Anyone who had an additional suggestion could add it anonymously to this list. After the study design has been further developed, the study was presented to the potential participants in an on-site presentation, as already mentioned above. There was also the opportunity for answers and questions. Each nurse is free to take part in the study after having detailed knowledge of the study objective and carrying out the measurements on a daily basis.
The public is included in the study to the extent that several notices on the ward draw attention to the study and thus take away the fear of the new technology from patients and their relatives.

Procedure

After enrolment, each participant will receive a thorough instruction on how to use the technical equipment. On the same day, each participant will be interviewed separately to define their expectations and attitudes towards the DiPa study. Interviews will be conducted by UMR staff who are not involved in the study i.e., a research assistant or a member of the central research center of the UMR. The answers will be recorded during the interview and transcribed afterwards to allow for an evaluation by independent raters to reduce bias and to ensure data privacy. In addition, the participants will fill out the questionnaire on their perception of stressors and stress, including patient-associated stressors, working environment, team-associated stressors, resources etc..
Participants will be instructed to conduct the measurements during every shift. At the beginning of the shift, the participants will gather their equipment from their locker, put on the wristband and pick up the smartphone. By turning on the wristband, a digital questionnaire will appear automatically on the smartphone’s display, welcoming the participant and asking for the current stress level as well as the sleep quality of the previous night. There will also be the possibility for further free-text annotations. Participants will then store the smartphone in the pocket of their scrubs and begin their workday.
Participants will be instructed to use the smartphone to scan the corresponding NFC tag whenever entering a patient’s room. To this end, a green NFC tag with an arrow has been placed on each patient room door. This event will thus be recorded on the smartphone. Analogously, a red NFC tag will have to be scanned when leaving the room. This will not only record the event but will also prompt a short questionnaire which will be displayed on the smartphone’s screen and which will ask for the current stress level including a free text space.
Special recurring processes on the PCU like daily visits, weekly and daily team meetings attended by nurses and physicians as well as patient interviews have their own individual NFC tags denoting its start and its end, respectively.
Simultaneously to the data recording by the wristband and smartphone the study team collected and analyzed data about the nurses, e.g. how many worked at the ward per shift, with how much working experience in years and if they had the additional designation “palliative care nurse” as we expected an influence of the working load for each participant. The second focus were patient-associated factors, especially the average, minimum and maximum of patient’s age or the number of occupied

beds per day. Because the PCU treats many critical ill patients with life-limiting diseases we also thought it could be important to analyze the count of deaths per day.

Data Analyses

Every participant will receive a pseudonym so that data from the different sources (interviews, questionnaires, physiological data from the E4, EMAs from the smartphone) can be grouped. Raw data analyses and analyses of data on an individual level will be conducted by the Fraunhofer IGD, an institution which is independent of the UMR hospital, ensuring data privacy. The UMR will receive the pre-processed, averaged data for further evaluation processes.
The raw data will be collected with the Empatica E4 device and stored in CSV files. Each parameter will be sampled at the maximum available rate provided by the Empatica E4 firmware:

- Inter beat intervals (IBI) sampled at $\frac{1}{64}$ s
- Blood volume pressure (BVP) sampled at 64 Hz
- Electrodermal activity (EDA) sampled at 4 Hz
- Temperature sampled at 4 Hz
- Acceleration sampled at 32 Hz.

All parameters will be stored with a Unix timestamp to allow a proper selection of intervals.
The EDA data will be decoupled by applying the NeuroKit2 Python library so that the tonic component (skin conductance level or SCL) and the phasic component (skin conductance response or SCR) can be extracted.
Since the Empatica E4 wrist band saves inter beat intervals only when the signal quality is sufficient, IBI data can include missing values. The IBI data will be used to determine the heart rate variability and heart rate by applying the following equation: $HR = \frac{60\,s}{IBI}$
The acceleration data will be fused to a three-dimensional vector by applying the following equation: $vector = \sqrt[2]{x^2 + y^2 + z^2}$
All algorithms for data extraction are currently being written in Python by applying Jupyter Notebooks and the Pandas, Numpy, SciPy, Matplotlib, NeuroKit2 libraries.
Descriptive and inferential statistical analyses will be applied. For stress detection analysis, all stress events marked with a button press will be identified and windows surrounding this event will be extracted and averaged, leading to one value per stress event per participant. Analogously, the windows surrounding a scan of the NFC tag "relaxation" and the baseline windows will be extracted and averaged as well. Weighted ANOVAs for correlated samples will be computed to compare the stressful events and the baseline for each physiological parameter.
To examine the predictability of experiencing stress, the subjective ratings given in the EMA will be used as ground truth. Surrounding the EMA, data windows will be extracted from the data of each physiological parameter. A linear regression will be computed with the subjective stress level (EMA) as the dependent variable and entering the means of the physiological variables (HR, HRV, tonic EDA, phasic EDA, temperature, and acceleration) as independent variables. Artificial intelligence approaches will be used to analyse the data where appropriate.
With the data of daily occupancy with patients and the total count of nurses at the same day we will able to calculate the relationship between these two variables. The value can be used to be compared to the minimum occupation according to the Recommendation of the German Society for Palliative Medicine (DGP) on staffing in palliative wards [28] of 1.4 nurses per patient.

Results

At submission of this article, the devices have been assembled and the stationary equipment on the ward has been put into place (e.g., the server, the NFC tags). Data assessment algorithms are currently being programmed. Recruitment to the trial has been finished with a total of 12 participants having signed the written consent form by June 12th, 2021. The measurements have been initialized by giving out the first questionnaires; data assessment is ongoing.

Discussion

Potential Outcomes and Impact

To our knowledge, the DiPa project is the first innovative project addressing the burden on nursing staff in palliative care using wearable devices for objective data in combination with subjective measurement instruments such as questionnaires. This project aims to measure the feasibility of generating data with the above-mentioned technology and to merge the results. With the generated results, structural processes can be questioned and adjusted, if necessary, to reduce stress and its impact. These interventions will be part of further studies.

Ethics and Dissemination

The ethics committee of the University of Rostock consented to the study with a positive vote on December 18th, 2020. The DiPa study has been registered in the German Register for Clinical Studies on February 10th, 2021 (DRKS, ID DRKS00024425A). Data protection will be ensured by providing participants with their own lockers to store their devices, by gathering data using pseudonyms only and by analysing raw data at the Fraunhofer IGD exclusively (sharing only group means with the UMR which employs the participants). We aim to publish data and summary findings in academic journals and at conferences.

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Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Abbreviations

ACTH: Adrenocorticotropic hormone
ANOVA: Analysis of variance
ANS: Autonomic nervous system
BVP: Blood volume pressure
DGP: German Society for Palliative Medicine
DiPa: Digitally identifying and minimizing stressors at the Palliative care
DRKS: German Register for Clinical Studies

EDA: Electrodermal activity
EMA: Ecological momentary assessments
HR: Heart rate
HRV: Heart rate variability
HTPA: Hypothalamic–pituitary–adrenal axis
IBI: Inter beat intervals
IGD: Institute for Computer Graphics Research
JMIR: Journal of Medical Internet Research
LED: Light-emitting diode
MBI: Maslach Burnout Inventory
NFC: Near-field communication
PCU: Palliative Care Unit
SCL: Skin conductance level
SCR: Skin conductance response
SNS: Sympathetic nervous system
UMR: University Medical Centre Rostock
UTC: Universal Time Coordinated

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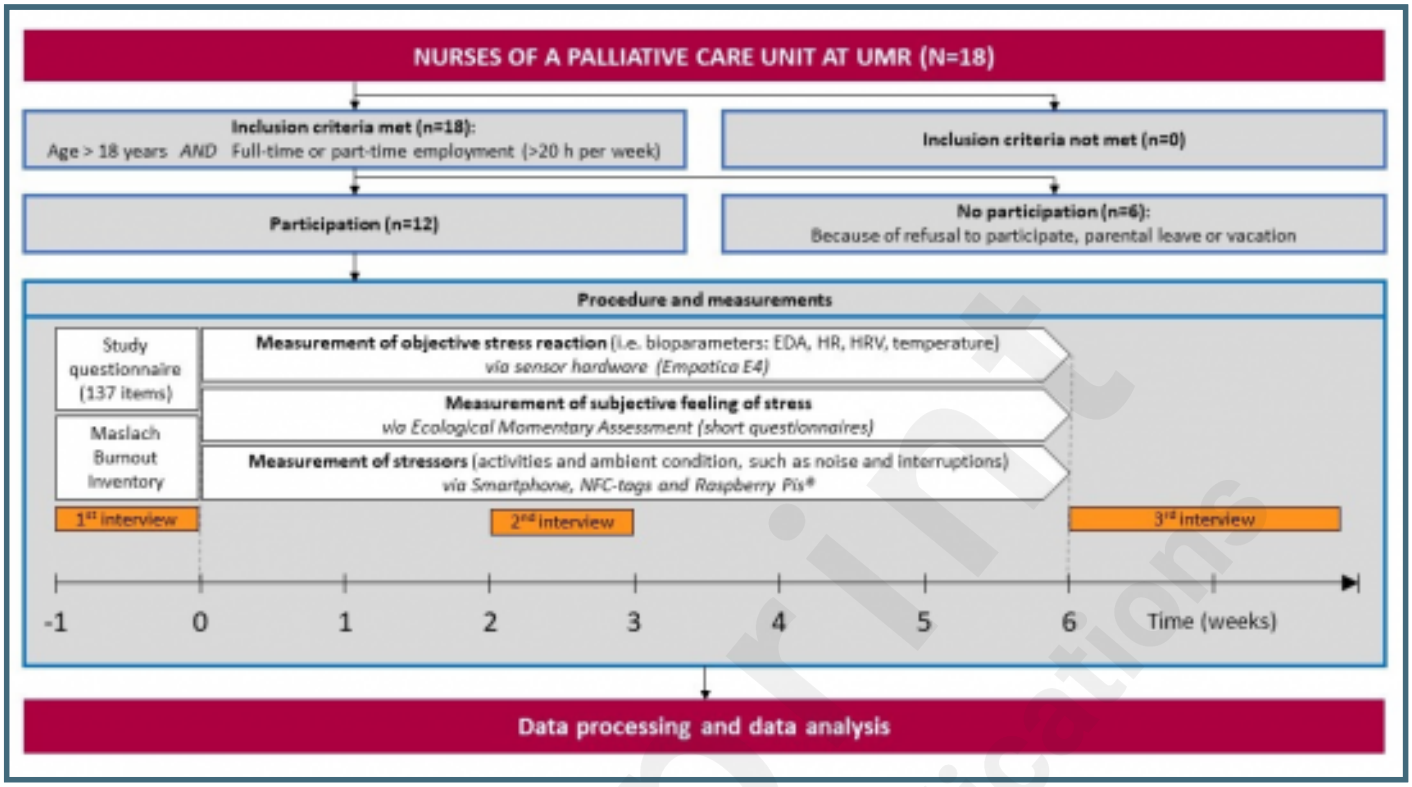
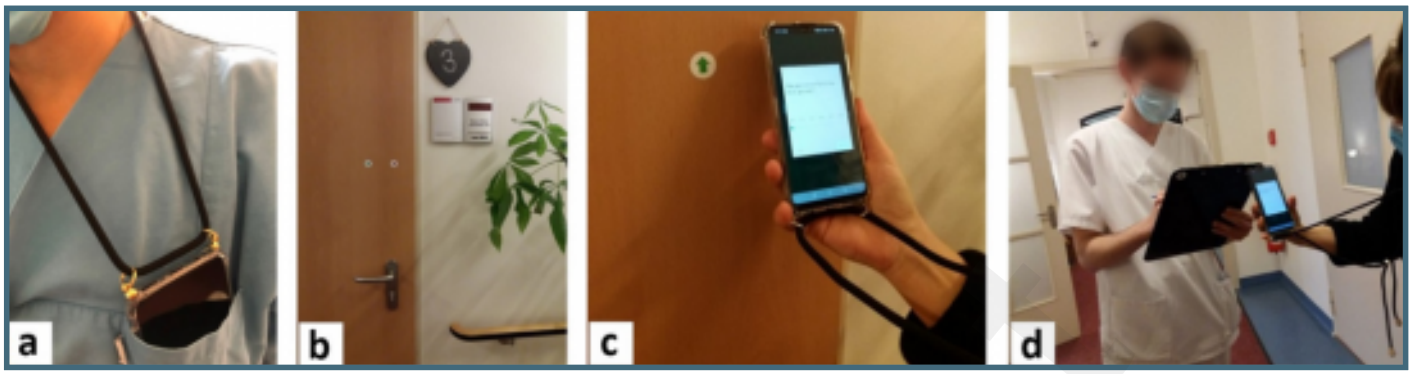
Supplementary Files

Figures

The study design is shown here.



To assess possible stressors, NFC tags have been programmed and placed in numerous positions at the ward.



Electrodermal activity (EDA), heart rate (HR) and skin temperature were recorded with the research wristband Empatica E4.