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DISSERTATION

The Charité Dome, a device to improve patients with dementia's stay and non-contact measurement of vital signs and movement in emergency departments

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Vorwort

Die vorliegende Dissertation enthält bereits veröffentlichte Ergebnisse einer eigenen vorausgegangenen Publikation:

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Inhaltsverzeichnis

Abstract (English)

Background

Agitation is common in geriatric patients with cognitive impairment, e.g. in patients with dementia (PWD), who are admitted to an emergency department (ED). Monitoring of vital signs and enhanced movement as indicators of upcoming agitation is essential in these patients during their stay in the ED. Since PWD rarely tolerate fixed monitoring devices, a novel developed non-contact monitoring system (NCMSys), measuring pulse/heart and respiratory rate as well as movement, might represent an appropriate alternative.

Aim of this feasibility study was to test the reliability and validity of the NCMSys and the tent-like "Charité Dome" (ChD), attached to patients´ bed and aimed to shelter PWD from the ED environment. Effects of the ChD on wellbeing and agitation of PWD were investigated.

Methods

In the pre-study, the ChD's first prototype's usability was evaluated. For the main feasibility studies, the appropriately modified ChD and the NCMSys were attached to patient's bed. First, tests on technical reliability, validity and safety issues of NCMSys and ChD were performed with six healthy volunteers. Subsequently, a feasibility study evaluating the reliability of the NCMSys with and without the ChD was performed in an ED and on a geriatric-gerontopsychiatric ward. Wellbeing and patients' emotions were assessed by medical staff, relatives and patients themselves with a structured observation protocol and questionnaire. PWD inclusion criteria were age ≥ 55 years, a dementia diagnosis and a written consent. Exclusion criteria were acute life-threatening situations and a missing consent.

Results

The pre-study confirmed the usability and safety of the ChD. NCMSys measurements of pulse/heart rate, movement and sound emissions were reliable and valid, whereas patient movements affected respiratory rate measurements. For the feasibility study 18 patients (ED: 8 geriatric-gerontopsychiatric ward: 10 patients) were included, nine males and nine females; mean age: 77.4 (55–93) years. 13 were PWD. The ChD did not impact patients' vital signs or movements in the main study setting (1 hour without, 1 hour with ChD). However, 54% of the PWD (7/13) and most of the patients without dementia (4/5) benefited from its use regarding their agitation and overall wellbeing.

Conclusions

The results of this feasibility study encourage a future controlled clinical trial with geriatric ED patients, including PWD. This should evaluate if our concept of non-contact measurement of vital signs and movement complemented by the ChD helps to detect and prevent upcoming agitation in this vulnerable patient group in the ED.

Abstract (Deutsch)

Hintergrund

Unruhe ist eine häufige Begleiterscheinung bei geriatrischen Patient*innen mit kognitiven Beeinträchtigungen, z.B. bei Menschen mit Demenz (*Patients with Dementia*, PWD), die in eine Notaufnahme (*Emergency Department*, ED) eingeliefert werden. Die Überwachung von Vitalparametern und gesteigerter Bewegung als Indikator für aufkommende Unruhe ist bei diesen Patient*innen während ihres Aufenthalts in der Notaufnahme von wesentlicher Bedeutung. Da PWD am Körper befestigte Überwachungsgeräte selten tolerieren, könnte ein neu entwickeltes kontaktloses Überwachungssystem (*Non-Contact Monitoring System*, NCMSys), welches Puls/Herz- und Atemfrequenz sowie Bewegungen misst, eine geeignete Alternative darstellen.

Ziel dieser Machbarkeitsstudie war es, die Reliabilität und Validität eines NCMSys und der zeltartigen „Charité-Haube“ (*Charité Dome*, ChD), welche am Patient*innenbett befestigt wird und PWD vor der unübersichtlichen und verwirrenden ED-Umgebung abschirmen soll, zu testen. Darüber hinaus wurden die Auswirkungen der ChD auf das Wohlbefinden und die Unruhe bei PWD untersucht.

Methoden

In der Vorstudie wurde die Bedienungsfreundlichkeit des ersten Prototyps der ChD bewertet. Für die Machbarkeitsstudien wurden beide Geräte am Patient*innenbett befestigt. Zunächst wurden Tests zur technischen Zuverlässigkeit und Validität sowie Sicherheitsfragen von NCMSys und ChD mit sechs Proband*innen durchgeführt. Eine Machbarkeitsstudie zur Bewertung der Reliabilität des NCMSys mit und ohne ChD wurde im realen Umfeld einer ED und einer geriatrisch-gerontopsychiatrischen Station durchgeführt. Das Wohlbefinden und die Emotionen der Patient*innen wurden von medizinischem Personal, Verwandten und den Patient*innen selbst mit einem strukturierten Beobachtungsprotokoll und einem Fragebogen beurteilt. PWD-Einschlusskriterien waren ein Alter von mindesten 55 Jahren, eine Demenzdiagnose und die schriftliche

Einwilligung. Ausschlusskriterien waren eine akut lebensbedrohliche Situation und eine fehlende Einwilligung.

Ergebnisse

In der Vorstudie wurde die Gebrauchstauglichkeit und Sicherheit der ChD bestätigt. Herzfrequenz, Bewegung und Schallemissionen wurden durch das NCMSys zuverlässig gemessen und waren valide, während Patient*innenbewegungen die Atemfrequenzmessungen beeinflussten. In die Machbarkeitsstudie wurden 18 Patient*innen eingeschlossen, neun Männer und neun Frauen; Durchschnittsalter: 77,4 (55–93) Jahre, von denen 13 PWD waren. Die ChD hatte keinen Einfluss auf die Vitalfunktionen der Patient*innen oder deren Bewegungen in unserer Studienumgebung (1 Stunde ohne, 1 Stunde mit ChD). 54% der PWD (7/13) und die meisten Patient*innen ohne Demenz (4/5) profitierten von ihrer Verwendung in Bezug auf ihre Unruhe und das allgemeine Wohlbefinden.

Schlussfolgerungen

Die Ergebnisse dieser Machbarkeitsstudie legen eine zukünftige kontrollierte klinische Studie bei geriatrischen ED-Patient*innen, einschließlich PWD, nahe. Diese soll bewerten, ob das Konzept der berührungslosen Messung von Vitalfunktionen und Bewegung in Kombination mit der ChD dazu beitragen kann, aufkommende Unruhe bei dieser gefährdeten Patient*innengruppe in der Notaufnahme frühzeitig zu erkennen und zu verhindern.

1 Introduction

1.1 Patients with dementia in hospital

Dementia is a growing problem for societies all over the world. In 2019 Alzheimer's Disease International estimates that there are over 50 million people living with dementia globally, a figure set to increase to 152 million by 2050, as populations age (World Alzheimer Report, 2019).

Neuropsychiatric symptoms (NPS) of dementia or behavioural and psychological symptoms of dementia (BPSD), e.g. psychomotoric and verbal agitation, aggression, depression, anxiety, delusions, hallucinations, apathy and disinhibition (van der Linde et al., 2012; Brazil et al., 2013; Bedrosian and Nelson, 2013) occur in estimated 90-98% of these patients at some point in the course of the disease (O'Neil et al., 2011; Lyketsos et al., 2011). A stay in hospital is a threatening situation for PWD, because they are suddenly removed from their familiar surroundings and attachment figures (Clissett et al., 2013). Unable to cope with that overstimulating situation of hectic hospital routine, unknown and unclassifiable background noise and glaring neon lamps, PWD tend to be more agitated and delirious and more willing to run away which enhances their risk of falls and injuries as well as getting lost (George et al., 2013). Discomfortable over- or understimulation in general is a frequent condition in these patients, called sensoristasis (Kovach, 2000). Once hospitalized, PWD and the concerned medical staff suffer from PWD' lack of understanding and therefore missing cooperation in their treatment. It makes their therapy an especially difficult task to fit in hospital routine with scarce time and staff resources. Often, the only possibility to deal with these patients is to administer sedating medication with often hazardous side effects or their fixation with belts (Sadowsky and Galvin, 2012).

These conditions result in mostly negative consequences and worse outcomes, longer hospital stays, higher mortality rates and increased functional decline for PWD in hospital compared to patients without dementia (Dewing and Dijk, 2016; Draper et al., 2011). The ED's processes are particularly inappropriate for PWD because of its even intensified level of stress, noise, hectic and lack of staff (George et al., 2013).

1.2 Approaches to improve patients with dementias' stays in hospital

There are approaches to improve PWDs' stays in hospital: Some hospitals have organized voluntary visiting, which is a logistical challenge with sometimes several calls for

availability of visitors, but with good results concerning the well-being of the PWD (Pritchard et al., 2021).

There is evidence for preventive efficacy of non-pharmacological treatments like structured music therapy or sensory intervention (touch and others) as well as their recommendation as the preferred first-line treatment approach to NPS of renowned medical organizations like the American Geriatrics Society or the American Association for Geriatric Psychiatry (Kales et al., 2014). Recent studies are more careful in the outcomes and state behavioural improvements only during the interventions and short-term (Sanchez et al., 2013). These treatments are rarely used in real-world clinical settings, e.g. as EDs (Kales et al., 2014). The main reason is lack of training and experience of the staff with these techniques or missing equipment (Cohen-Mansfield et al., 2013). Also, in need of quick amelioration of NPS or BPSD, pharmacological treatment is still the method of choice *(*Magierski et al., 2020). There are few hospital studies regarding that topic yet which shows the difficulty to implement non-pharmacological interventions there (Livingston et al., 2014).

To better deal with PWD in clinical settings, low-level non-pharmacological interventions could be a suitable approach. These could be communicational training for hospital staff or clear optical structuring of corridors or rooms, e.g. arrows pointing to the bathroom (Kales et al., 2014).

The amelioration of PWD' treatment in hospitals, including EDs, is not only a question of ethics. Their presumably shorter stays, if treated appropriately, could also lead to a considerable reduction of costs for the whole public health sector (Vetrano et al., 2014).

1.3 Agitation in patients with dementia

As mentioned above, agitation (a state of extreme arousal characterized by altered psychomotoric activity) is often observed in PWD (van der Linde et al., 2012) and arises from a variety of underlying causes, e.g. infection or medication toxicity. Thus, it is a warning signal indicating health deterioration and potential danger for the patient (George et al., 2013). Therefore, it is important for professional caregivers and hospital staff to recognize and objectively measure agitation at an early stage in both nursing homes and hospitals.

1.4 Development of non-contact measurement system (NCMSys)

Agitation is often accompanied by a change of vital signs (Qiao et al., 2014), thus, several devices are used to monitor pulse/heart and respiratory rate as well as blood oxygen saturation. Commonly used measurement devices require the use of e.g. adhesive electrodes or finger clips. While these devices work well in patients without neuropsychiatric symptoms, monitoring is difficult in agitated patients, e.g. PWD. They tend to tear electrodes and similar devices off their body, not understanding their function or just feeling uncomfortable (George et al., 2013). Non-contact measurement of vital signs could help to monitor agitated patients adequately and remotely. If a system immediately recognised agitation, it could prevent dangerous situations and thus improve patients' care and safety. A system working with no need for attending staff permanently present like it is de facto often the case for PWD, could unburden concerned staff and lead to considerable cost savings for the public health sector (Brink and Schierz, 2006).

Already existing methods for that purpose are different kinds of skin measurements for pulse/heart and respiratory rate like photoplethysmography (Aarts et al., 2013), time-lapse-imaging (Takano and Ohta, 2007) and thermal imagery (Garbey et al., 2007). Radar systems (Kagawa et al., 2012) or sensors integrated in "smart clothes" (Teichmann et al., 2014), mats (Tanaka et al., 2002; Ohashi et al., 2008) or from bedside (Zaffaroni et al., 2013) allow conclusions on pulse/heart and respiratory rates. Actigraphy, although not non-contact, has been used to measure agitated behaviour in PWD using wrist-worn actigraphs and shows some evidence of correlation with incidences of agitation (Khan et al., 2018). Multi-modal sensors seem to help in building better classifiers to identify agitation in PWD in comparison to a single sensor (Khan et al., 2019). These methods are in early testing stages and are not used in clinical routine yet.

In contrast to vital signs, there are no devices in clinical use to objectively measure agitation. Especially changes of movement and verbal expression as signs of agitation are difficult to register at an early stage. Different psychological rating scales like the Cohen Mansfield Agitation Inventory (CMAI) (Koss et al., 1997), the Positive and Negative Syndrome Scale Excited Component (PANSS-EC) and the Agitation-Calmness Evaluation Scale (ACES) (Meehan et al., 2002) are currently in use to assess PWD or patients' agitation. These tests are complex and too time-consuming to implement them in hospital routine with time and staff pressures, especially in an emergency

department (George et al., 2013). Thus, a more holistic, non-contact measurement combining movement, verbal expression and vital signs is needed.
We developed a non-contact measurement system (NCMSys) combining optical, acoustic and movement sensors. Furthermore, a tent-like construction ("Charité Dome", ChD), attached to a patient´s bed and aimed to shelter PWD from the busy ED environment was developed. We investigated the technical reliability and validity of NCMSys and the ChD in healthy test persons before performing a feasibility study of the combined system in PWD (Kroll et al., 2020).

1.5 The idea and the road to the development of a device to shelter PWD in EDs

The research project began with a practical project that Ms. Kroll carried out during her postgraduate studies in Design Thinking, an innovation methodology, at the School of Design Thinking in Potsdam in cooperation with the ED of the Berlin Charité Campus-Benjamin-Franklin (CBF).
The challenge of the practical project was to improve the situation of people with dementia in the ED. This challenge results from the following problem: PWD are often admitted to an ED due to an acute medical problem and/or trauma. Dependent on triage category, crowding situation and the need for diagnostic and therapeutic procedures, the length of stay in the ED may last six to eight hours and even longer. During that time in an unknown and very busy surrounding, PWD often become more and more agitated, start to ask for (already passed away) relatives, scream or try to run away, mostly without knowing where to go. Thus, they may develop a delirium.
The project team started with an intensive phase of research in old people's and nursing homes, discussions with researchers and PWDs' relatives, as well as internships by day and by night in the CBF's ED.
The team developed a concept of shielding persons with dementia from the overwhelming surroundings in emergency departments with the help of a convertible cover for hospital beds, the then-called Heimat-Haube (Home Dome). At that time, the concept comprised a multimedia installation, that allowed to watch personal pictures, e.g. old photographs or films or to listen to preferred music or sounds from nature via an USB stick or the pre-installed program and smell preferred odors via an aroma diffuser. The possibility of bringing or choosing the preferred stimuli led to the familiarity aspect mentioned in its name Heimat-Haube, feeling a bit like at home, even in an unknown surrounding like a hospital. This installation was inspired by the concepts of Multi-Sensory Environment and Snoezelen, approaches successfully used by ergotherapists to

calm or activate persons with dementia (Livingston et al., 2014). In the further development, these complementary elements for sensory stimulation had to be postponed due to legal requirements ("Conformité Européenne", CE certification) necessary for the ethics committees to approve the upcoming studies. In first interviews nursing staff indicated their positive thoughts of the multi-media installation and particularly the personalization, assuming a calming effect for confused PWD by consuming familiar media.

Starting from that concept, a very early "prototype" of the device was built and presented to members of the ED staff. The presentation led to the decision to start a research project, mainly coordinated, organized, and conducted by Lisa Kroll together with the ED team at the Charité Campus Benjamin Franklin.

1.6 Objectives

Due to the difficult situation for patients with dementia in EDs, the missing devices to shelter PWD from the ED surrounding and to measure upcoming agitation by non-contact monitoring as described above, the present thesis had the following objectives:

1) Development of a safe device (Charité Dome, ChD) to shelter patients from their surroundings in overly stressful hospital situations, such as in the ED;
2) Development of a non-contact monitoring system (NCMSys) to measure vital parameters and movement reliable and valid as signs of agitation in patients with dementia.
3) Feasibility study ("proof of principle") of the combined use of the ChD and NCMSys in an ED and gerontopsychiatric ward aiming to reduce discomfort and agitation of PWD, thus, enhancing wellbeing of these patients.

2 Methods

The development and testing of the ChD was carried out in different stages. After the recruitment of cooperation partners, a pre-prototype was designed (2.1), its suitability and further requirements were tested in a pre-clinical setting (2.2). After designing the main prototype, it was applied in a clinical setting without and with the newly developed NCMSys, complemented by a standardized external observation of emotions (feasibility study, 2.3).

2.1 Development of the Charité Dome (ChD)

2.1.1 Cooperation partners and design of a first pre-prototype

Project partners with experience in the field of shielding constructions and telemedicine were chosen to identify requirements and to build a shielding device which was later named Charité Dome (ChD). Besides the CBF´s ED, the Gesslein GmbH, a baby carriage company and the iDoc Institute for Telemedicine and Health Communication were selected as cooperation partners.

Several interviews with the ED staff and on-site operations revealed basic requirements of the ChD. Based on these criteria a rudimentary pre-prototype was built in cooperation with the Gesslein GmbH. At that point the pre-prototype had not to meet the strict requirements of the Medical Devices Act yet or had to fulfill all the features of the planned prototype but was close to the actual ChD in terms of size and handling. The pre-prototype consisted of a roof section that is slid onto the bed trapeze with the fastening device downwards and screwed tightly. The three panels for the head section and the right and left sides of the bed were attached with push buttons. The ChD had a white colour.

2.1.2 Testing of the ChD pre-prototype in a pre-study with medical staff and volunteers

Step 1: The first step of the pre-study focused on testing the installation and use of the ChD concerning usability, manageability, practicability, stability and safety. Over a period of two weeks in October 2011, nursing staff and doctors were asked to simulate and protocol typical hospital situations at a bed with a pre-installed ChD and a voluntary student as test person.

Test person and medical staff were instructed, supervised during the whole pre-study and results were documented. A special focus of the pre-study was given to:

a) The risk of injury for patient and staff (does one get "caught" by the ChD?).

b) The obstruction of patient care processes by ChD.
c) The stability of the attachment of the ChD (how easily can it be torn off, e.g. in case of an emergency?).

Step 2: At this step four test persons and four ED nurses and doctors took part. First, test persons lied in a normal hospital bed without examination for 30 minutes. After filling out a questionnaire a caregiver mounted the ChD to the hospital bed. The application time was measured. The test persons lied in the bed beneath the ChD for another half hour. He/she then completed the well-being questionnaire. The caregiver filled out the usability questionnaire.
In addition, typical hospital situations were simulated by nursing staff while test persons lied beneath the ChD. All necessary materials for the simulated hospital situations were provided: Blood pressure monitor, cannulas, side table, dishes/cutlery/drinking cups, second bed (to perform transfer), bedpan, diaper, leg in plaster simulation (external splinting).
Simulated hospital situations were:

1) Blood pressure measurement: The nurse approached the bed and measured the test person's blood pressure.
2) Cannulation or blood sampling: The nurse approached the bed and simulated cannulation/blood sampling and attached the infusion bag to the trapeze.
3) Access in an emergency situation, e.g. cardiac arrest: the test person simulated an emergency situation and the nurse resuscitated the subject.
4) Serving food with side table: The nurse moved the side table to the subject's bed and put it in a position that allowed the subject to eat and drink.
5) Washing or positioning/transferring the patient: The caregiver approached the bed and simulated washing the subject and positioning him/her. He/she then transferred him/her to another hospital bed. Care had to be taken here to ensure that the test person did not actively assist.
6) Fulfilling the test person's toilet request (bedpan, diaper): The nurse approached the bed and placed the bedpan under the test person. He/she then put a diaper on the dressed subject.
7) Standing up of the test person (additional simulation of plaster leg or arm, i.e. physical limitation) without the help of the nurse: The test person first tried to stand up without a simulated plaster leg. Then a simple plaster leg simulation was attached

to him/her and he/she tried to stand up with it. The same was repeated with an arm in plaster.

8) Moving the bed through hospital hallways: The nurse was told to move the bed from one room to another without any further instructions whether to pull or to push it and if the ChD should be changed for that purpose.

Afterwards, the test persons filled out a well-being questionnaire, and the caregivers filled out a usability questionnaire. Additionally, they were being watched during their interaction with the ChD and interviewed afterwards. Finally, the results were analyzed.

2.1.3 CE certification/ Failure Mode and Effects Analysis (FMEA) of the ChD

The prototype was CE certified. Therefore, the following requirements were conducted and organized, among others: records of the verification and validation measures of the software and usability, the instructions for use (“Gebrauchsanweisung”) and a clinical evaluation (“Klinische Bewertung”, a detailed literature research).

This clinical evaluation resulted in the following: The core element of the ChD’s value proposition, calming of PWD through shielding and additional sensory stimulation, can be partially proved by best practice and the clinical data found. Clinical trials are planned to obtain data regarding the effectiveness of the ChD. Potential risks have been reduced to an acceptable level. The use of the ChD in clinical studies seems reasonable within the scope of its intended purpose and can serve the well-being of its users.

Furthermore, technical data sheets for the components of the ChD, compliance with various safety standards through test reports on flame resistance according to EN 1021-1 and -2 as well as skin compatibility according to EN ISO 10993-5 for the textile material, further information about the product and corresponding responsibilities were created.

These tests were carried out in July 2012 with the support of a research team from the department of Human Factors Engineering and Ergonomics from the Technical University of Berlin (Dr. Maria Stahl, Prof. Dr. Wolfgang Friesdorf). A process and risk analysis workshop was held including a usability analysis for the CE certification with all project partners and medical specialists, resulting in a detailed Failure Mode and Effects Analysis (FMEA) (“Evaluation der Gebrauchstauglichkeit")

For this purpose, a detailed application scenario for preparing and arranging the ChD on the bed, its use, cleaning and storage was developed. Afterwards, every process

and sub-process of the scenario was analyzed concerning its Potential Failure Modes, the Potential Failures' Effects and Causes, as well as the Occurrence, Severity and and Detection Rating.

Amongst others, the process analysis identified the following requirements:

1) Easy transport and installation of the ChD (by one person at best)
2) Its use shall not endanger the patient in any way (e.g. by falling parts, danger of strangulation, non-toxicity of material in case of being sucked on)
3) The communication of caregiver and patient shall not be hindered by the ChD.
4) Easy de-installation in case of an emergency
5) Simple and complete cleaning by wipe disinfection

The most important failure modes were

1) ChD's unauthorized manipulation by strangers during the study
2) Limitation of caregivers's treatment (patients' care) by the ChD or the short time delay of demounting the ChD in case of an emergency
3) The patients' feeling of being restricted by the ChD

The FMEA detected several minor ergonomic deficits. The instruction of nursing staff concerning these deficits can compensate them partially. Nevertheless, the identified deficits need to be resolved prospectively to improve the ChD's usability.

2.1.4 Consideration of nursing home's interests in the development of the ChD

To include first-hand experiences from the staff in nursing homes during the development of the ChD, two members of the development team (L. Kroll and B. Kujumdshieva-Böhning, iDoc) observered processes in the Kursana Pflegeheim, talked to staff and considered the questions and concerns about the ChD project. The overall feedback was positive. Staff pointed to the importance of avoiding a permanent media exposure, which would probably lead to more irritated PWD. For PWD bound to bed, the concept of "bringing them life to their bedside" would be of special interest. For further consideration, nursing staff emphasized PWDs' widespread initial rejection of everything new. On the other hand, integrating the ChD would require a phase of adaptation and learning from nursing staff themselves as well.

For the use in nursing homes, the aspect of single or double rooms is important due to the possibly different tastes, e.g. of music/sound.

The pre-tests and discussions with geriatrics, psychologists and emergency room hospital staff approved the ChD's concept.

2.2 Development of a non-contact monitoring System (NCMSys) and testing in a pre-clinical setting with and without the ChD

To investigate the ChD's effects on patients with and without dementia regarding their vital signs (pulse/heart and respiratory rate), their psychomotoric and verbal agitation (number of motions, sound emission) and mood in a real-life hospital setting a non-contact monitoring system (NCMSys) was developed, then combined with the ChD. After tests with healthy volunteers focussing on technical aspects of the NCMSys, the system was combined with the ChD, to prove the effect of the ChD in a clinical setting. In the clinical setting this was complemented by a standardized external observation of emotions.

Testing of the technical features of the NCMSys was performed by the Charité and an iDoc team in October and November 2012 at the iDoc Institute for Telemedicine and Health Communication in Potsdam/Berlin, Germany. The feasibility study was performed by the study team headed by L. Kroll from January to July 2013 in the ED of the Charité Universitätsmedizin Berlin at the CBF and the geriatric-psychiatric department of the Oberhavel Kliniken Hennigsdorf (OHK).

The local ethics committee of the Charité Universitätsmedizin Berlin (EA4/040/12 and EA4/070/12) and the ethics committee of Brandenburg (EA4/070/12) approved this approach in accordance with data privacy protection regulations.

2.2.1 Volunteers for testing the NCMSys

Six healthy volunteers selected from different age groups (22-82 years; 4 women and 2 men) were included consecutively as test persons. Inclusion criteria were legal age and the agreement to wear the standard monitoring electrodes. Exclusion criteria were acute or chronic diseases. In compliance with the Helsinki declaration, the written consent of the test persons was obtained after they had been informed.

2.2.2 Technical details of the NCMSys

Test persons were connected to a monitor (model MP5, Philips, Amsterdam, The Netherlands) to measure the heart and respiratory rate ("standard monitoring"). This established monitoring method was compared to a new approach of combined measurement ("non-contact measurement") of:

1) an optical movement sensor detecting the physical expression of the test person (Mini-Webcam, Conrad Electronics SE, Hirschau, Germany).
2) an acoustic sensor (ME32, Olympus Imaging Europa GmbH, Hamburg, Germany) that was installed to record potential verbal expression.
3) a sensor mat integrated into the test person's mattress measuring the pulse/heart and respiratory rate and the movement activity of the test person (SafeBed IP system, Emfit® Ltd, Vaajakoski, Finland). The sensor responds to small pressure changes caused by patient's ballistocardiographic (BCG) and respiration movements and calculates the named parameters from the output voltage signal.

The latter two sensors are necessary since PWD often scream and/or nervously move as sign of their (upcoming) agitation.

Regarding the different components of the NCMSys, the following hypotheses were defined before the study started:

1) The pressure- and movement-sensitive sensor mat supplies qualitatively comparable data to conventional pulse/heart and respiratory rate measuring devices.
2) The optical motion sensor allows reliable conclusions to be drawn about the movement and restlessness of the person being monitored.
3) The recording of acoustic signals (noise level recording) works reliably.
4) The data obtained can be put into a coherent relationship to one another and result in a meaningful overall picture.

2.2.3 Pre-clinical testing of the NCMSys without and with the ChD

All vital signs, movements, and noise (ambient and from the test persons) were recorded simultaneously. A specialized software (iDoc-Studiendatenbank, iDoc-Institut, Potsdam/Berlin, Germany) with a user-friendly interface collected and visualized the recordings of all connected devices. All recorded data were synchronously merged.

The study was conducted in a room equipped with constant lighting conditions and a standard hospital bed (see figure 1A). As stated above, there were three different ways of measurement: the standard cable-connection to monitors that requires electrodes and probes tolerance, the sensor mat integrated into the test person's mattress (see figure 1D) with no direct body contact and the completely non-contact and independent audio and movement sensor system (see figure 1C). The measures were performed during two hours per test person. After the first hour, there was a change of experimental set-up. The ChD was installed on the bed to shield the test persons from

acoustic and other external influences from the room allowing a potentially different comparison measurement (see figure 1B).

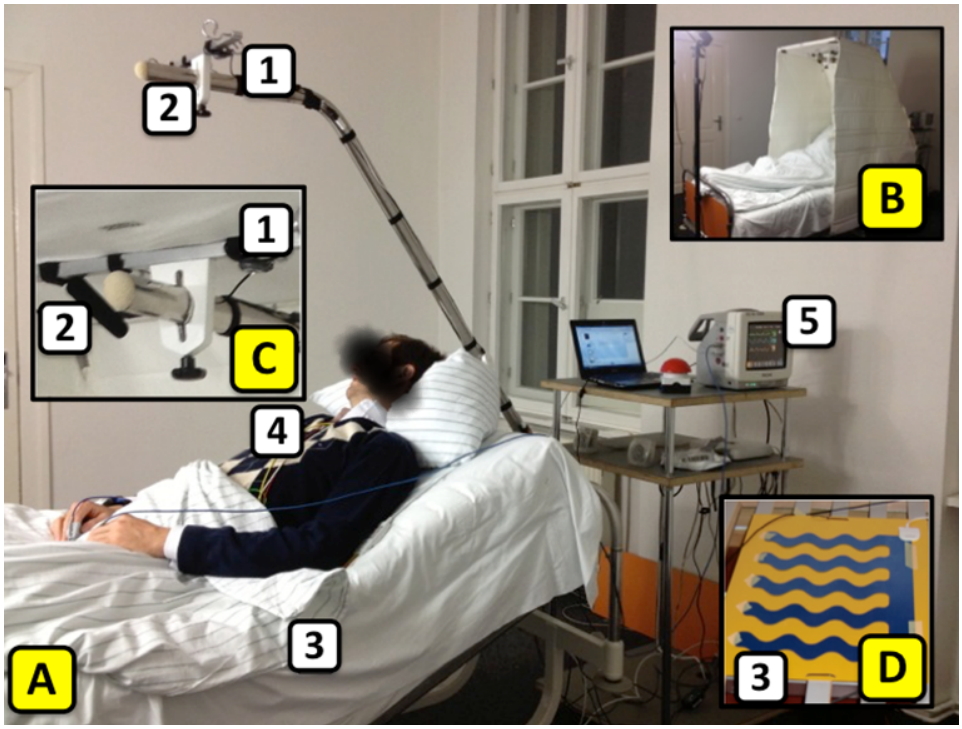

Figure 1. Arrangement of the non-contact measurement system (NCMSys) and the Charité Dome (ChD). (**A**) NCMSys without and (**B**) with the ChD during the feasibility study: (**1**) visual and (**2**) acoustic sensor (enlarged illustrated in (**C**); (**D**) sensor mat and (**3**) its location (**4**) ECG electrodes; (**5**) monitor. Taken from Kroll et al., 2020.

Different sorts of sounds, e.g. those of a dentist's drill, construction noise or (rock and pop) music recorded backward, were played in regular intervals to simulate an unpleasant soundscape. After five minutes of silence, there were two twenty-minute sections of sound with a ten-minute break of silence in between and another five minutes of silence in the end. On the one hand, this provided a standardized acoustical surrounding. Furthermore, this was of importance to test the reliability of the sound recording. The acoustic sensor was equilibrated with the iDoc-unit system (see figure 2). On the other hand, playing unpleasant sounds was an attempt to test if a measurable change of agitation occurred. Measurement and the test persons' comments regarding the noise and their well-being were recorded.

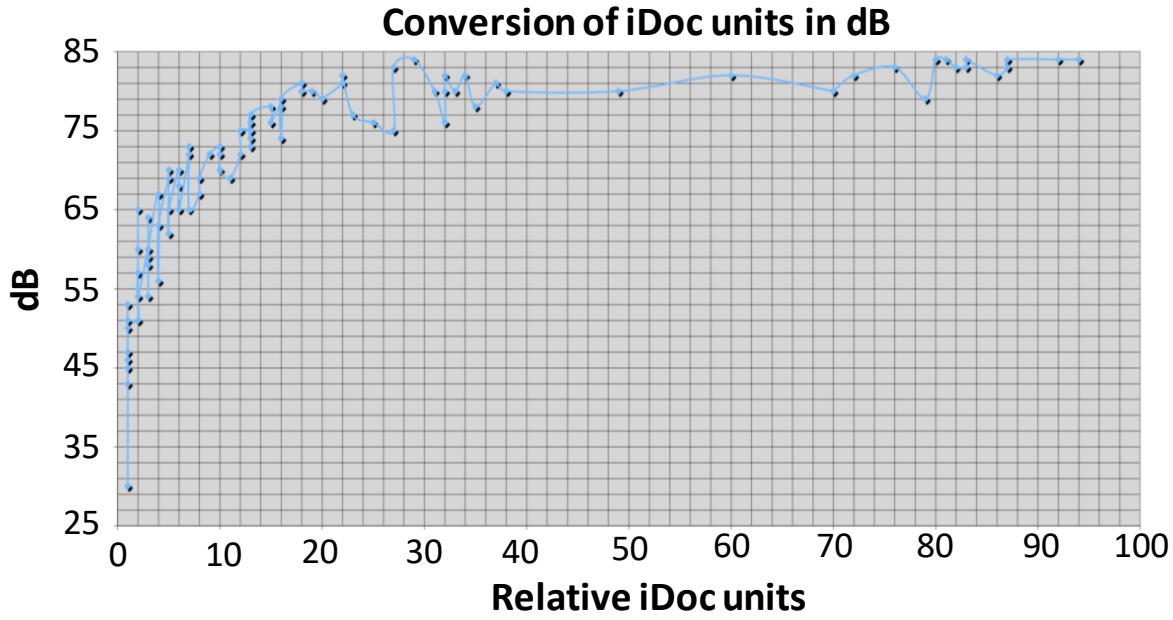

Figure 2. Exemplary depiction of recorded sounds and their conversion into analysable units by iDoc. Sound levels were measured with a Samsung Galaxy S3 device (App "Sound Meter", ver. 1.4.7).

A screenshot of the software visualizes the different parameters that were measured (Figure 3). The denomination of the optical sensor's measurement is *number of motions*, the one of the sensor mat *activity*. They both refer to movement.

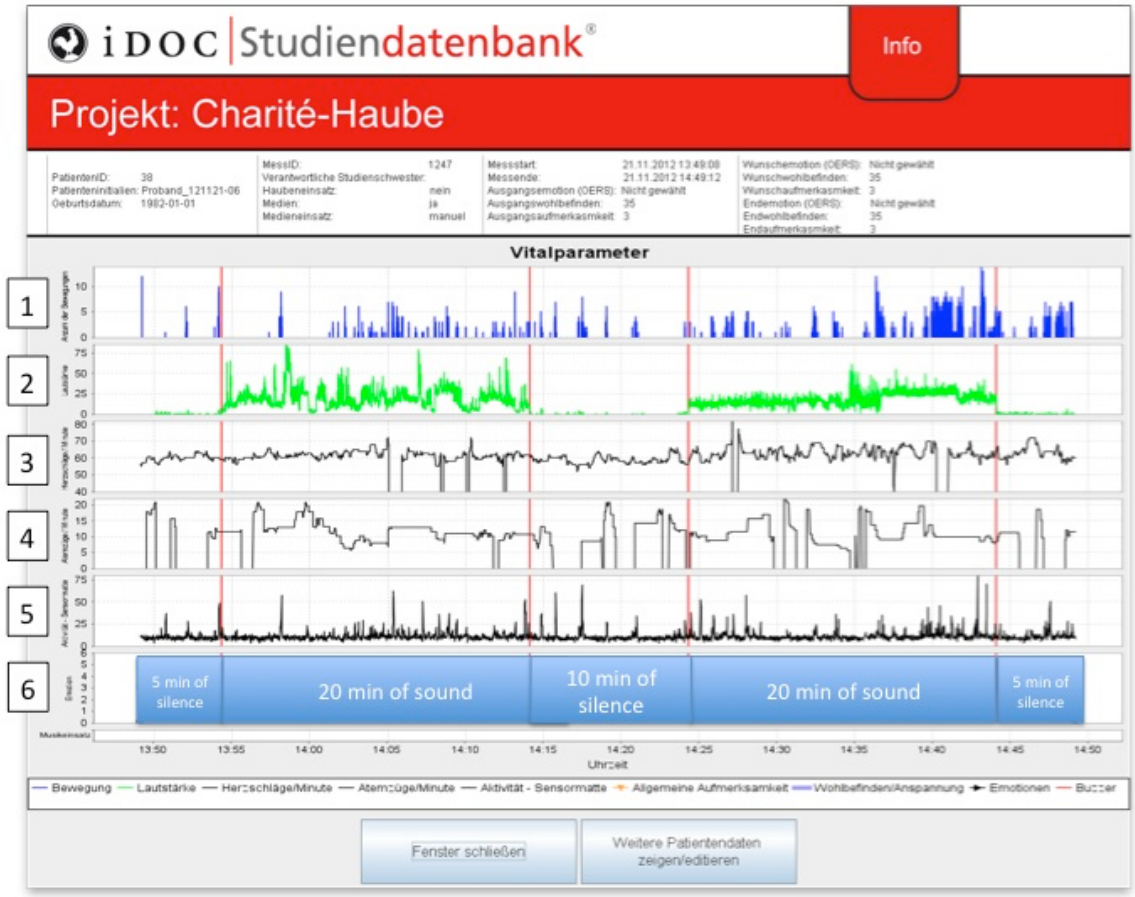

Figure 3. Screenshot of the iDoc software user interface. **1** number of motions; **2** sound intensity; **3** pulse/heart rate per minute; **4** respiratory rate per minute; **5** activity; **6** timeline. Taken from Kroll et al., 2020.

The recorded data of the pulse/heart and the respiratory rate coming from the standard measurement device MP5 were compared to the results recorded by the sensor mat. The sensor mat's measurement of movement was compared with the data of the optical movement sensor. The measurement of sound had no comparison device. Table 1 illustrates the devices and parameters used in the experimental setting (Kroll et al., 2020).

Table 1. Devices and parameters used in the experimental setting.

	MP5 monitor (Philips)	Sensor mat (Emfit)	Movement sensor (Conrad)	Acoustic sensor (Olympus)	Decibel measurement device (Smart tools)
Heart / pulse rate	x	x			
Respiratory rate	x	x			
Movements		x	x		
Sound				x	x*

*calibration in pre-test to avoid background noise.

2.2.3.1 Refining of certain measurements by the NCMSys

To refine data collection of the sensor mat, test persons were instructed to turn in regular intervals into different positions (data not shown). They were lying on their back, on their abdomen and on the sides. In the latter two positions recording of vital signs (pulse/heart and respiratory rate) was difficult, thus, for the main test of our study these movements were omitted for focus reasons. Nevertheless, movements were detected. In addition, the thickness of test persons' clothes as an influencing factor of the measurements was investigated. Thick winter clothing of the test persons complicated the sensor mat's measurement; therefore, test persons were asked to not wear them. With a light hospital gown, the measurement worked better, but patients' clothing is a given factor. This might limit the application.

In addition, the acoustic sensor was adjusted to different expressions of the human voice from whispering to screaming by different measurements of the sound quality.

2.3 Testing (feasibility study) of the ChD in a clinical setting using the NSMSys to measure vital signs (pulse/heart and respiratory rate), movements and sounds, complemented by standardized external observation of emotions

2.3.1 Patients

18 patients were included consecutively, therefrom eight patients of the ED of the CBF and ten patients of the specialised geriatric-psychiatric department of the OHK. Nine males and nine females were included. The mean age of the subjects was 77,4 years, ranging from 55 to 93 years. Three patients of the emergency department additionally to their acute medical issue and all nine patients of the geriatric-psychiatric department were PWD. For PWD inclusion criteria were being aged 55 years or over, a dementia diagnosis by Mini Mental Status Examination (MMSE) and assessment through General Deterioration Scale (GDS) as well as the patients or their legal guardians' written consent in compliance with the Helsinki declaration after they had been informed. Exclusion criterion was any kind of comorbidity that made lying impossible. For patients without dementia, inclusion criteria were being aged 18 years or over and the agreement to be examined. Exclusion criteria were an acute life-threatening disease (corresponding to Manchester Triage System red), an acute psychiatric disease (corresponding to Mini International Neuropsychiatric Interview M.I.N.I.) and a missing ability for consent, withdrawal of consent and strong agitation during measurement.

2.3.2 Conduction of the study

The two-centre study was conducted on the one hand in the ED at the CBF during a normal hospital routine day with changing lighting conditions and background noise and fluctuating patients that were lying in bed or sitting, as well as relatives and medical staff. On the other hand, it took place in the patients' rooms or the observation room of the OHK geriatric-psychiatric department. The measurements were performed during two hours per patient. During the first hour the patient was lying in a standard hospital bed equipped with the NCMSys to measure movement, sound emission and pulse/heart and respiratory rate. During the second hour the bed was additionally equipped with the ChD (see figure 4).

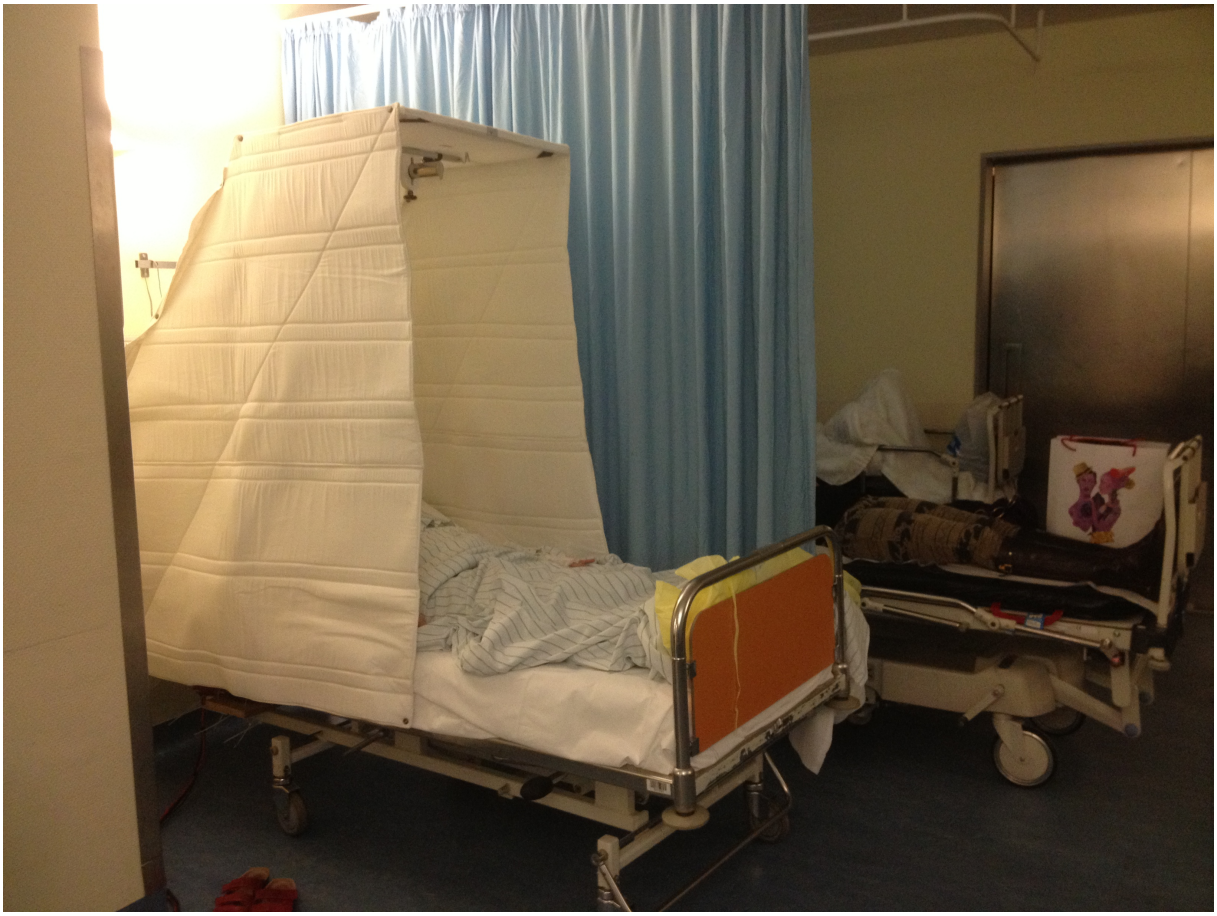

Figure 4. ChD during the feasibility study in the ED. Shown is a standard hospital bed with a mounted ChD. Taken from Kroll et al., 2020.

To identify changes in the NCMSys measurement curves that can be referred to nursing treatment or conversation as such, the nursing and study staff were instructed to press a so-called buzzer when entering the examination room. This marked an event in the recording curves, which was provided with a brief comment about the type of event. In retrospect, it was thus possible to determine the times at which the nursing

staff was in the room and thereby influenced the results. Other incidents that caused an abnormality in the measurement curves, such as falling asleep, coughing of the test person or loud street noise through the window, were also marked and commented on in this way.

Additionally, the patients without dementia and – if present – the relatives of the PWD in the ED at the CBF were asked to fill in a standardized form regarding their state of mood and agitation three times. The form was based on the Observed Emotion Rating Scale (OERS) (Lawton et al., 1996) with easily identifiable facial expressions (see figure 5). The form was filled in three times: before the measurement started, after the first hour in the regular hospital bed without ChD, and after the second hour in the bed equipped with ChD.

Patientennummer_____Geburtsdatum_____Datum_____Vor__Zwischen__Nach__

Vorhandensein der folgenden Stimmungen	0	Sehr stark	Stark	Ziemlich stark	Etwas	Kaum	Gar nicht
Freude 1		0	0	0	0	0	0
Ärger 2		0	0	0	0	0	0
Ängstlichkeit/ Angst 3		0	0	0	0	0	0
Traurigkeit 4		0	0	0	0	0	0
Allgemeine Aufmerksamkeit 5		0	0	0	0	0	0

Figure 5. Modified OERS as used in the study. 0 existence of the following emotions, ranging from very strongly to not at all; **1** pleasure; **2** anger; **3** anxiety/fear; **4** sadness; **5** general alertness.

For PWD, the study staff entered their evaluation of the patients' mood and emotions on a touch screen interface (see figure 6) in the same interval. This interface was based on the OERS and the Dementia Mood Picture Test (DMPT) (Tappen and Barry, 1995), complemented by the parameter for well-being (calmness)/stress (agitation) (Kroll et al., 2020).

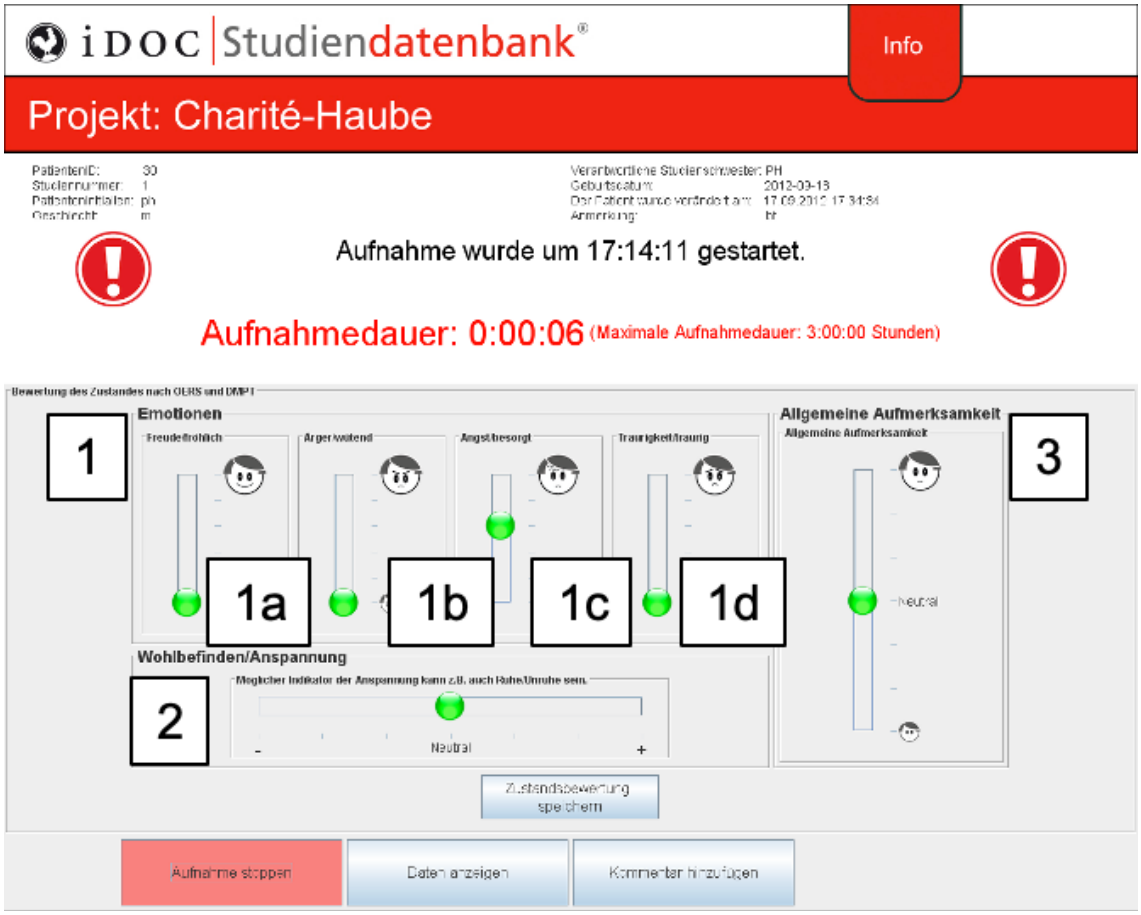

Figure 6. Screenshot of iDoc Software used to evaluate the patients' mood and emotions. 1 Emotions **1a** Pleasure; **1b** Anger; **1c** Fear; **1d** Sadness (There could only be selected one emotion out of the four.); **2** Wellbeing/Stress; **3** General attention (for the parameters Wellbeing and Attention: 3 equivalents neutral state, less than 3a negative condition). Taken from Kroll et al., 2020.

In addition, ergonomic questionnaires were filled out by the study staff for each testing to enable continuous improvement of ergonomics (not shown).

2.4 Statistical analysis

Spearman correlations were performed to analyse differences between measurements of pulse/heart rate and respiratory rate by standard monitoring and NCMSys. Effects of the ChD on pulse/heart rate, respiratory rate, the activity values, and the number of motions were analysed by multiple t tests using the Holm-Sidak method, with alpha=5.000%. All statistical calculations were performed with the SPSS Software (Version 23.0).

3 Results

3.1 Usability of ChD's installation and use

After Ms. Kroll's completed an "internship" in the CBF´s ED, the following discussions led to some modifications regarding the design and size of the ChD's. E.g., the sides of the ChD had to be extended to form an enclosed space inside the ChD. Furthermore, the length of the sides of the ChD had to be adjusted, since they should not touch the floor even when the hospital bed was set at the lowest possible height, thus hindering bed transport by dragging on the floor or being caught on the bed wheels.

3.1.1 Results from test persons' point of view concerning ChD's set-up, its effects and hospital simulations

The test persons preferred lying in a bed equipped with ChD. Comments included that it was comfortable and had a calming and (positively) soporific effect. In addition, a sensation of warmth was also indicated, as well as the welcomed effect that the ChD comfortably limits the field of vision. Test persons liked the lighting conditions (less glaring) and the better privacy protection – especially the fact that no one could look at them from their back without them noticing it. The protective effect could even be more pronounced by a larger ChD. One test person suggested a roller blind to close the ChD's front side. There were wishes to better shield noise, for different color/lighting options and a less chemical smell. While the ChD was mounted, test persons disliked the rocking at their bed. All test subjects trusted the ChD's stability. One remark praised the better protection from strangers' gaze while fulfilling the toilet request.

3.1.2 Results from nursing staff's point of view

a) Set-Up of the ChD

Nursing staff perceived the set-up of the ChD to be relatively simple. However, a second person's help in real-life would be recommended to ensure a fast procedure. Thus, nursing staff asked for a one-person-solution. A suggestion was a solution like a baby carriage convertible top, that can be handled with one hand. However, this solution is not suitable for the ED because of the necessity of the trapeze to be demounted. The trapeze would interfere with the attachment e.g. of infusion bags.

The presented solution to fix the sides of the ChD to the roof by snap buttons was assessed as intuitive ("like a tent for camping"). For caregivers of smaller size, the attachment of the panels was difficult, also the weight of the panels was perceived as

too high for some of them. Folding the panels was perceived as hard, the material was too stiff. Some nurses trusted while others doubted the ChD's stability, especially with aggressive PWD trying to tear it off. There was the wish for different colours, for example a soft yellow, with hospital's dominance of white.

b) Simulation of hospital situations with mounted ChD

1) Blood pressure measurement worked well: nurses stood underneath the ChD next to the test person, because the walls are flexible. The rollable measuring box could also stand underneath. Here, there were remarks that the typical bent over posture of routine nurse activities could be aggravated by the ChD. Tall nurses could by mistake lean against the ChD's roof section and break it. Other nurses stood outside the ChD which also worked well. Nurses remarked the difficulty of measurement with a non-cooperative patient.
2) Simulation of cannulation worked well; the infusion bag could easily be attached to the trapeze.
3) For accessing the test person in the case of an emergency, the whole construction must be removed which takes a lot of time. Therefore, for patients with a high risk of an emergency, nursing staff would not recommend the use of the ChD.
4) For delivering food with a side table, two versions were performed satisfactorily: Some nurses put the table underneath the ChD, some removed one side panel for a better range of movement.
5) Washing or positioning/transferring of the patient was perceived to be more complicated, because the space was limited underneath the ChD. There were remarks of standing too close to the test person, which was perceived as unpleasant, especially when imagining an aggressive PWD trying to hit the nurse with no possibility to turn away. When asked to remove one side panel to be able to step aside, some nurses did not like that option because of the additional time required. In case of a heavy or non-cooperative patient, two nurses transfer patients from one bed to the other, here, removing at least one side panel seems inevitable.
6) Fulfilling the test person's toilet request worked well, taking place in the middle of the bed, which is only partly covered by the ChD.
7) Standing up of the test persons worked well, but test persons were young, fit students. With an additional simulation of leg or arm in plaster, i.e. physical limitation, it was more difficult. The test persons and nursing staff were concerned on the one hand that PWD could mistake the panels for solid walls and could lean against

them or hold onto them to pull themselves up. On the other hand, if patients wished to leave the bed, they could feel restricted by the panels.

8) When asked to move the bed, caregivers followed different approaches. Some pulled the bed walking backwards themselves – with limited overview of where to go – for the test person to be forward-facing. Others pushed the bed forward holding it at the head section and trying to look around the ChD. The bar was hard to hold then, with the panel lying over it. Other nurses were folding the panel up to be able to see where they were going. The panel was in the way then because it was not attached to the roof section. When rolling the back panel up, it did not fall and hinder the sight. One caregiver was disturbed by the ChD in maneuvering the bed and would prefer not to transfer a bed with ChD. Others perceived it as not hindering the transport. Here, conflicting interests of spacious interior for patients and the need for nursing staff to maneuver the bed in narrow hallways were identified. Some nursing staff imagined the ChD construction to scare some PWD because of its shaking when being pushed through the hospital halls.

Additionally, one caregiver presumed it being difficult to mount safety bed rails to a bed equipped with ChD. Another general remark was the lack of visibility of the PWD lying under the ChD, which would result in a necessity for intensified surveillance (“I have to go to the foot section of the bed to see how the patient is doing.”) In this context, there was the wish for a spy film, where patients could be seen from outside, but could not look outside themselves, feeling protected. This solution was declined for data protection reasons. As a compromise, some nurses wished for a window at head level, maybe with a cover, that could be lifted.

As mentioned above, most nurses did not intend the ChD’s use for instable patients. If it was used, the necessity of quick access in the case of an emergency and the need to fold the side cover instead of tearing it off – which is difficult because of the strong push buttons and would take too much time – led to another push button in the middle of the roof to attach the folded side there.

The ChD needs to offer the possibility to be transferred from one bed to the other for flexibility reasons. Some nurses therefore stated they would not install it to a bed with a patient lying inside but prepare it and put the patient in it afterwards. That means increased effort concerning the hospital beds’ preparation if a patient forced to be lying for medical reasons than uses two beds.

Some nurses presumed the ChD to be more suitable for nursing homes than for hospitals.

3.1.3 Considering of the experiences for the design of the actual ChD prototype

After analysis of the interviews the results and suggestions were discussed with Gesslein Kinderwagen Fabrik, which then used them directly for the further development of the actual ChD prototype.
Finally, e.g. push buttons were used to attach the side covers to the roof section according to patients' and nursing staff needs. Other tested options to fix the sides had been Velcro fastener and magnets, the first being difficult to clean (hair and other materials easily get caught in Velcro), the second being a risk for interfering with electronic devices. Also, push buttons proved to be the strongest solution against being teared off by patients. This was an important requirement, as PWD according to experience tend to pull things in their reach or try to pull themselves up by holding onto things.

3.2 Reliability and validity of non-contact monitoring of pulse/heart and respiratory rate, movement and sound in healthy test persons by the NCMSys

3.2.1 Measurement of pulse/heart and respiratory rate – sensor mat vs. monitor

To evaluate the non-contact measurement of pulse/heart and respiratory rate, the signals of the sensor mat were compared to those recorded by the monitor.
As shown in figure 7A, there was a clear correlation for the first hour of pulse/heart rate measurement between the reference monitor and the sensor mat in all six test persons (R^2=0,874). During the second hour with the ChD the results were similar (R^2=0,608) (see figure 7B), thus pointing to the reliability of contact free pulse/heart rate measurement by the sensor mat.
For the respiratory rate the results are shown in figures 7C and 7D: While there was a clear correlation between the values measured by the MP5 monitor and the sensor mat during the first hour (R^2=0,840) (see figure 7C), this was not seen during the second hour (R^2=0,062) (see figure 7D).

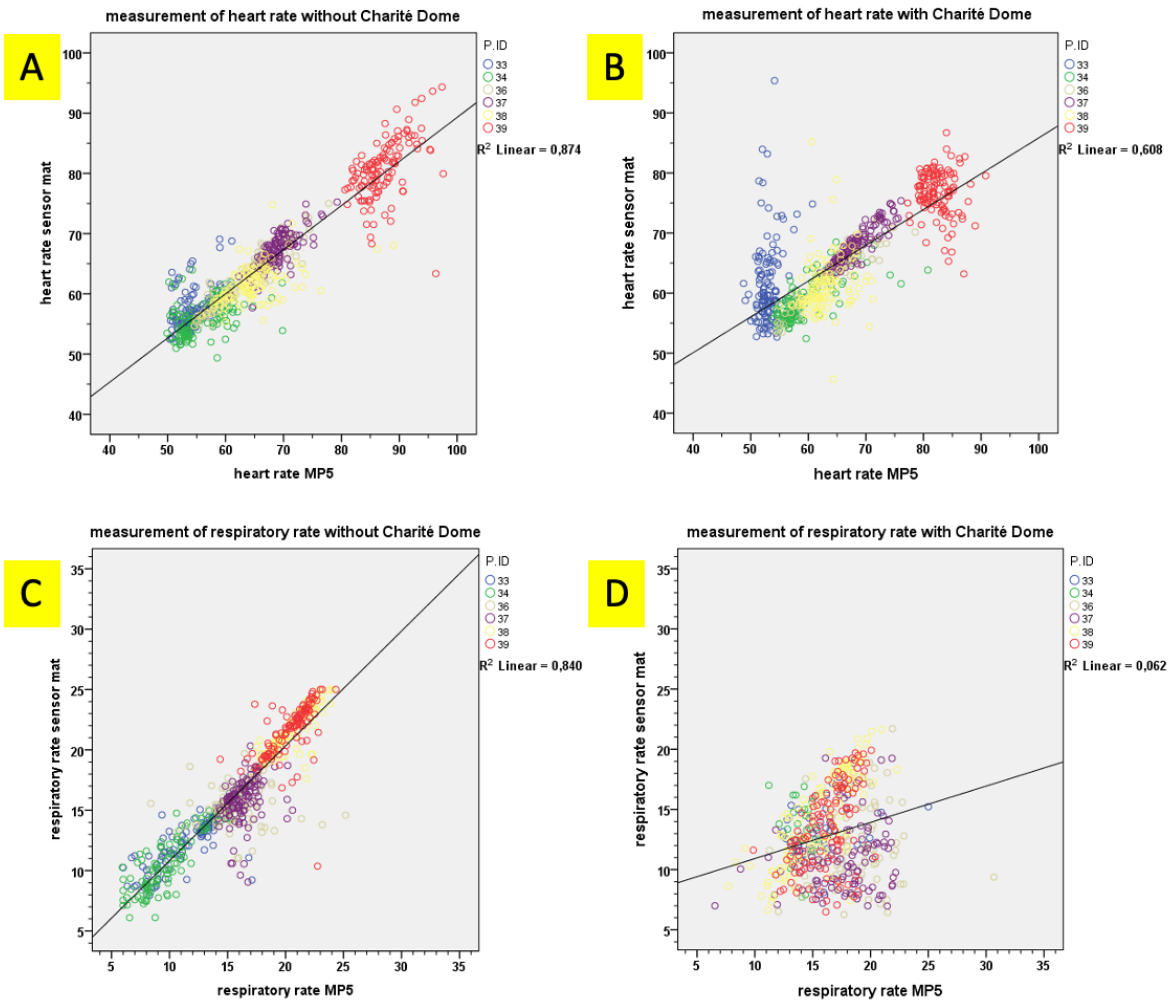

Figure 7. Correlations of non-contact measurement Emfit sensor mat vs. MP5. (**A**) measurement of pulse/heart rate without ChD; (**B**) measurement of pulse/heart rate with ChD; (**C**) measurement of respiratory rate without ChD; (**D**) measurement of respiratory rate with ChD.

3.2.2 Measurement of movement – visual sensor vs. sensor mat

The visual sensor and the sensor mat registered changes in movement. Figure 3 shows a representative example of the registered changes in movement curves of the visual sensor (number of motions, line 1) and the sensor mat (activity, line 5) during a one-hour period with a healthy test person lying in bed. A clear correlation of these measurements was not detected (see fig. 8). Depending on the kind of changes in movement, e.g. just moving hands over or under the covers, registration by the visual sensor was not always paralleled by registration of the sensor mat, pointing to complementarity of both systems, each one covering different ranges. This was even more pronounced when examining patients.

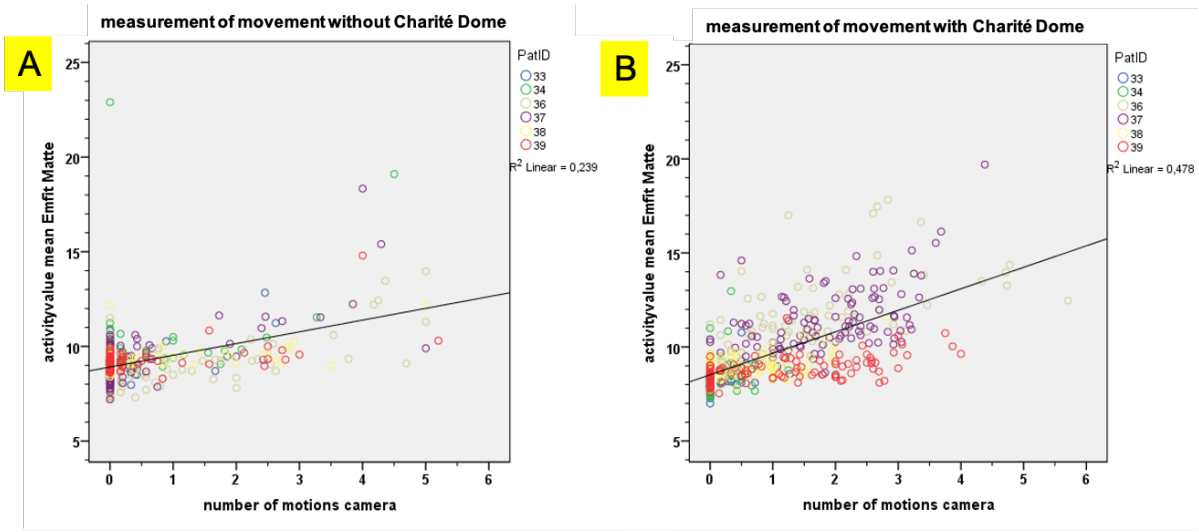

Figure 8. Correlations of non-contact measurement Emfit sensor mat vs. camera. (**A**) measurement of movement without ChD; (**B**) measurement of movement with ChD.

3.2.3 Reliability of the acoustic sensor and sound test

The acoustic sensor registered the sound reliably with only little perturbation and artifacts. As shown in figure 9 for both hours of test persons 33 and 34, the sound was recorded parallel (left: first hour, right: second hour). The same sound pattern was found for the other test persons (data not shown).

The test persons were not disturbed by the unpleasant sounds in a way that their vital signs or agitation level changed. Nevertheless, according to six of six test persons' comments, the sounds were unpleasant.

The measurement with a sound level meter did not reveal any significant acoustic shielding by the ChD. This did not change significantly when using a modified prototype with thicker, reinforced walls. Storage and transport with the thicker sides turned out to be more complex and cumbersome. Thus, the previous prototype with thinner walls was further used. Nevertheless, the test persons felt noise shielded when the ChD was placed over them. Interestingly, the subjective effect of shielding occurred even when measurably no noise was kept out by the ChD (Kroll et al., 2020).

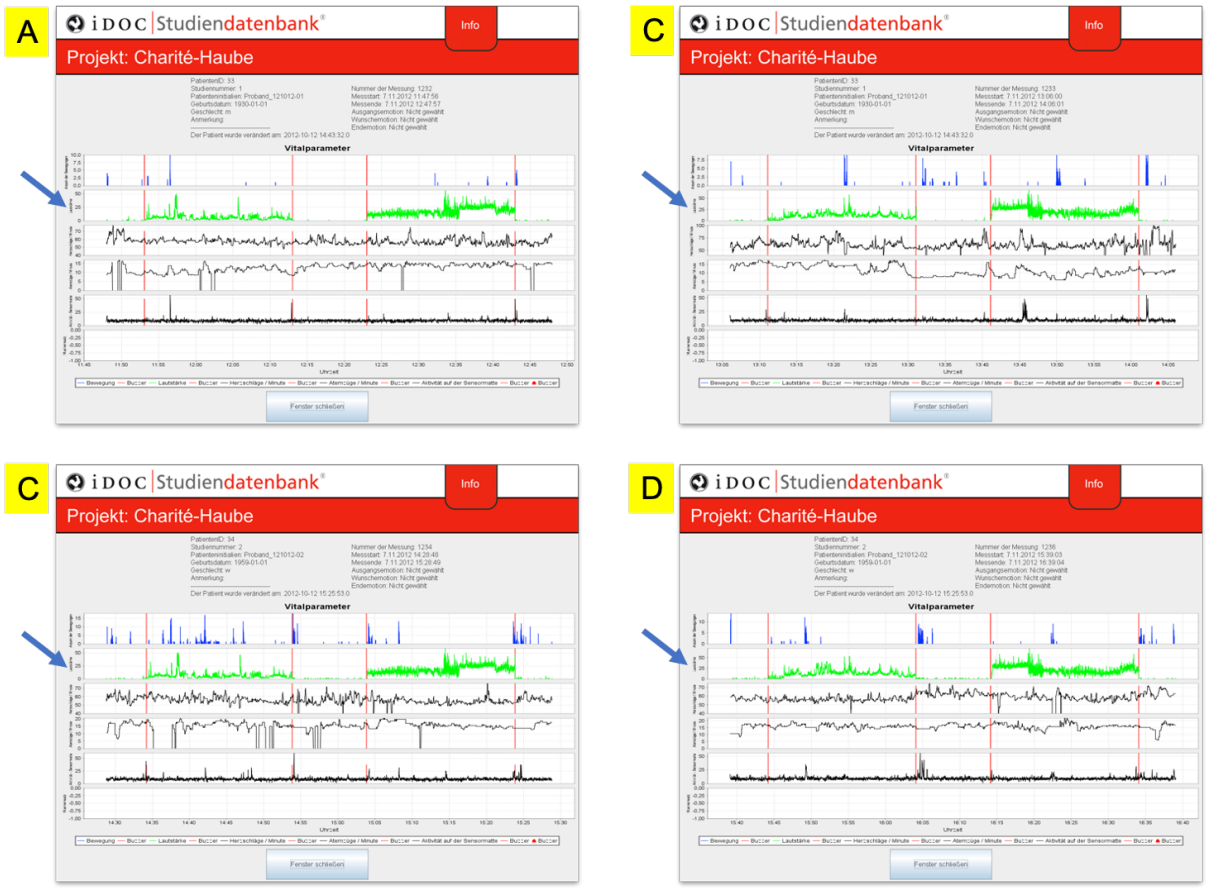

Figure 9. Screenshots of software user interface depicting sound registration (green curves). (**A**) Screenshot test person 33, registration first hour, without ChD, (**B**) Screenshot test person 33, registration second hour, with ChD, (**C**) Screenshot test person 34, registration first hour, without ChD, (**D**) Screenshot test person 34, registration second hour, with ChD.

3.3 Effects of the ChD on patients – measured by the NCMSys and assessed by staff, patients themselves and relatives

From 19 patients one patient had to be excluded after the monitoring started due to missing cooperation, resulting in 18 patients to be evaluated. Throughout the test of the ChD, the NCMSys monitored reliably with only little perturbations and dropouts.

No significant changes in sound emissions, pulse/heart rate and movements were measured by the NCMSys when comparing the one hour spent without and with the ChD (data not shown). However, analysis of the assessment by the attending staff in the ED and geriatric-gerontopsychiatric ward, by patients themselves and by relatives pointed to positive effects on patients' mood by assessing emotion, wellbeing, and alertness (results are summarized in Table 2).

The self-evaluation forms that the five patients without dementia and one dementia patient's wife filled out in the ED of at the CBF revealed that half of that group would prefer lying in a bed equipped with ChD while others preferred a normal hospital bed.

Five of the six patients noted an increase, one a decrease of pleasure, two each noted a decrease of fear and two a decrease of sadness.

Amelioration was perceived by higher levels of joy, general alertness, and wellbeing. Some patients snuggled into the panels of the ChD, others were calmer in their physical agitation. Deterioration was mirrored by decreases of mood, alertness, and wellbeing. Being restricted and having limited sight were reasons to dislike the ChD (deterioration).

The observation results concerning mood and emotions on the geriatric-gerontopsychiatric ward during the 1 hour without and 1 hour with the ChD showed in 5/10 patients amelioration, 4/10 showed deterioration, whereas there was no change in 1/10 patients (Kroll et al., 2020).

Table 2. Effects of the ChD on patients' mood rated by staff, patients themselves and relatives (summarized). The assessment is based on the Observed Emotion Rating Scale and the Dementia Mood Picture Test.

	Amelioration	No change	Deterioration
Emergency Department – Patients without Dementia	**4**	**–**	**1**
Emergency Department – Patients with Dementia	**2**	**1**	**–**
Geriatric-gerontopsychiatric Ward	**5**	**1**	**4**

4 Discussion

4.1 Usability of ChD's installation and use

Taken together, the ChD prototype was accepted by test persons and medical staff and was conceived a possibly appropriate device to shield PWD in EDs and thus, alleviate their situation. It was improved according to the requirements of test persons and medical staff. And finally, after a successful "failure mode and effects analysis", focusing on safety it was approved to be used in the feasibility study with patients in the ED and the geriatric-gerontopsychiatric ward (CE certification).

An advantage of the ChD turned out to be the limited amount of space it required. Especially in the ED, the available space for beds is often limited. Bed curtains also provide a certain private sphere, though the sheltering effect of the ChD is much more distinctive. However, there are no data till now to proof that and a respective experimental comparison might be considered in follow-up studies.

4.2 Reliability and validity of NCMSys

Our NCMSys was developed to measure upcoming agitation in PWD and thus, to verify potential positive effects of the ChD on agitation of PWD.

We demonstrated a good correlation for the measurement of pulse/heart rate (Emfit sensor mat and monitor) – independent from test-persons' or PWDs' position and the setup of the ChD – and a good recording quality of the acoustic sensor. The measurement of movement by the sensor mat and the visual sensor pointed to a complementary measurement to cover different kinds of movements. Thus, measurement of pulse/heart rate, recording of the acoustic sensor and movement showed reliable and valid results. In contrast, the correlation results for the measurement of respiratory rate (sensor mat and monitor) were not satisfactory.

None of the already existing non-contact methods to measure vital signs is established in hospital routine yet. Amongst others this is due to their complexity, the necessity to wear a device or their sensitivity to interferences caused by movements.

Wearable methods like smart clothes must be worn continuously, which is difficult in a hospital situation with frequent change of hospital gown and the need of quick access to the patients' chest in the case of an emergency. However, they have the advantage of not limiting patients' mobility (Teichmann et al., 2014). A visible bedside device used e.g. for sleep apnoe studies (Zaffaroni et al., 2013) might be removed or damaged by agitated patients.

Actigraphs can record patients' movements that allow conclusion on their agitation but require wearing them irremovably – though PWD usually want to remove unknown or incomprehensible devices fixed to their body. So far, another constraint was that this method did not transfer data immediately so that an alarming function was not possible, and a retrospective analysis was necessary (Nagels et al., 2006). But further developments focus on systems with "sensing technology, smartwatches, tablets, and data analytics to detect and predict agitation in PWD" in time (Anderson et al., 2021), thus, such systems may be integrated in the future.

Patients' movement makes reliable non-contact measurement of vital signs difficult. This can be seen in non-contact pulse/heart rate monitoring using camera photoplethysmography (Aarts et al., 2013). Darker skin tones and changing lighting conditions are also common challenges for photoplethysmographic measurements (Kumar et al., 2015). Camera monitoring can detect motions as cause of artefacts, being an advantage to non-visual measurements not delivering this information (Tarassenko et al., 2014). Radar systems also face the difficulty of irregular motions such as limb movement during sleep that can be mixed with respiration and heartbeat signals (Kagawa et al., 2012). Time-lapse imaging even has the restriction of only working properly when the examined patient respects calmness (Takano and Ohta, 2007).

In contrast to the good results for the pulse/heart rate measurements, the correlation of respiratory rate differed strongly between the two test hours. During the second test hour, neither the sensor mat nor the monitor, the standard instrument for that purpose, recorded the respiratory rate constantly. Apparently, a moving or turning test person made it even harder to measure respiratory rate continuously. The latter is a known problem, e.g. during the use of sensor mats for continuous measurements, e.g. in intensive care units, unless the patients are asleep or sedated (Ohashi et al., 2008). Therefore, we cannot recommend non-contact measurement of respiratory rate in this setting being in line with other findings, that to date, non-contact monitoring of respiratory rate is not well-engineered for applications in general (Zaffaroni et al., 2013). However, monitoring of respiratory rate is essential, particularly in the ED. New technical systems were published recently (Becker et al., 2017; Madsen et al., 2016; Iwashita et al., 2021), but need further evaluation in the setting "PWD in the ED".

Most of the test persons remarked that the better privacy protection due to the ChD during the second hour made them move more freely. However, this cannot be seen in the measurement curves. This might be the reason why a lot of drop-outs

complicated the analysis during the second hour for both, monitor and sensor mat. At the same time, the appliance in an authentic hospital situation will have to deal with varying levels of activity of the patients.
Another possibility for the limited correlation is the ChD itself. Its influence on the respiratory rate must be examined in further studies.
The partially good correlation of sensor mat's and visual sensor's measurement of movement makes it a promising method to detect and measure agitation (test person 36 and 37, see figure 8). It showed to be reasonable for the here tested sensor mat and visual sensor to complement each other for monitoring movement: The sensor mat covers pressure-full whole-body movements like turning, while the visual sensor also covers smaller movements like fiddling fingers above the blanket. The latter could be an expression of increasing nervousness and agitation and might be ignored and overlooked with sensor mat's measurement of movement alone or by solely measuring vital signs.
The reliability of the sound recording allows us to measure sound from a patient and thereby indicate a growing agitation. Differences in the sound measurements' curves despite the standardized acoustic surrounding are due to ambient noise. Here it is arguable if the acoustic sensor needs to be even more directional in its recording.
In a study by Suzuki et al., test persons were exposed to stressful audio stimuli that increased the heart rate (Suzuki et al., 2008). Thus, the missing influence of unpleasant noises on the vital signs in our study might be due to not reaching a specific threshold of pain in the test persons.
Taken together, the here presented test system of sensor mat, visual and acoustic sensor has the advantage of being relatively robust against movements-induced disturbances. Furthermore, the NCMSys has the advantage of an easy and quick installation (and deinstallation) on a standard hospital bed, a precondition in busy EDs. This enables the NCMSys to fit better in the clinical setting than the other measurement systems described above. Nevertheless, the velocity of technical development will enable the application of new and smaller systems. But also, these systems will need to be evaluated before use in the clinical surrounding (Kroll et al., 2020).

4.3 Measurement of agitation in patients (with dementia)

The general difficulty in measuring agitation is the presumption that an increase of any of the possibly measured parameters equivalents an increase of agitation. In some cases, this is even wanted because the base level is unhealthily low, e.g. in apathetic

PWD, where an increased movement is desired. Animation could thus be mistaken for agitation. On the other hand, there are patients with a high base level of motion that could trigger an agitation alarm, a function which is intended for the future. Such a function would enable an immediate reaction to treat upcoming agitation. Probably because of this ambiguity, there is no established gold standard for agitation yet.

Because of individual base levels of pulse/heart rate as well as movements or sound emission, a person, e.g. a nurse, a physician or a relative, will be necessary in the introductory phase of our measurement system to define these levels to detect changes. It is important to calibrate the system in a way, that single strong amplitudes like e.g. a patient scratching his neck hectically (movement) or a cup falling down and bursting (sound) does not trigger the alarm. Only altered amplitudes of a certain continuity should trigger an alarm. It is furthermore essential to easily switch off the intended alarm function in case a physician or nurse interacts with the patient to avoid false alarm. Once calibrated, the system should work with no need for continuously attending staff.

The preventive feature of this measurement system is of general interest for all care and hospital situations of dementia and other diseases that include agitation. It can also be of interest for patients without dementia regarding the discomfort many of them experience during conventional full-cable measurement (Poh et al., 2010). Furthermore, to avoid skin irritation, the use of electrodes may not desirable (Teichmann et al., 2014).

It is conceivable, that the visual and acoustic sensor system could also monitor whole rooms to allow patients' mobility like recent studies suggest (Wan-Tai et al., 2020). In this setting, too, an alarm could warn the responsible staff in case of – again individually defined – excessive amplitudes. This would be a cost-effective system, constructed from easily available components (Kroll et al., 2020).

4.4 Effects of the ChD on patients

During the two-hour setting (1h without, 1h with the ChD), no changes of vital signs were detected by the NCMSys, neither in the healthy test persons nor in the patient group. This might be due to the short period of measurement and especially due to the heterogeneity of the studied patients. The patients on the geriatric-gerontopsychiatric ward were mobile, whereas ED patients were mainly lying in bed because of acute medical problems. The differentiation of PWD with acute medical issues and long-term patients in their need for being shielded and monitored became obvious. Future studies

should focus on the latter patient group, which then should be monitored by our system for the whole time of their stay in the ED. However, for some PWDs the ChD even had an agitation promoting effect. Therefore, a close observation at the beginning of the lying-beneath-the-ChD-phase in future studies is needed to identify those patients.

More than half of the PWDs and most of the patients without dementia lying beneath the ChD experienced beneficial effects in terms of emotion, wellbeing and alertness, according to the nursing staffs' or their relatives' evaluation. Thus, the ChD might be suitable counteracting upcoming agitation. Since "hard-fact" data such as vital signs are very rare for this patient group, comparable studies showed, that for measuring the success of non-pharmaceutical implementations PWD's experience and carers' assessment could be more meaningful than such data sets (Goldberg et al., 2013). We here confirm this assumption with our data regarding the ChD, which are mainly based on the assessment of health care professionals, relatives and patients themselves.

According to the self-evaluation forms in the CBF, the reasons for preferring a normal hospital bed instead of the bed equipped with ChD were bad smell (patient suffering from flatulence), claustrophobic feelings – although there were also patients who had feared this and were pleasantly surprised when it was not the case – fear of heat accumulation or the wish to have an overview over the surroundings. The reasons to prefer the bed with ChD were reassurance through better privacy protection and better lighting conditions (dimmed neon lights).

Irrespective of their personal preference, five of the six patients rated the ChD with the highest or second highest school grade acknowledging its function and purpose. During the first hour (without ChD) in CBF some patients' moods declined, probably because of the stressful setting with lying in the hectic and confusing waiting room. Better privacy protection can be of interest not only for PWD but also for different kinds of patient groups e.g. those including agitation without underlying dementia and/or delirium.

Future developments should take into account that the ChD could be personalised with e.g. sensory stimulation/intervention like favourite music, sounds from nature like waves or birds as well as colour therapy like the ergotherapeutic approach Snoezelen uses. Via USB or a pre-installed software with different choices, it might be a future feature of the ChD, since structured music therapy and sensory intervention are proven to reduce agitation in PWD (Livingston et al., 2014).

Sufficient training for hospital staff will be necessary to really institutionalize the ChD. Otherwise, it risks the fate of other non-pharmacological interventions not being used despite their known benefit (Kales et al., 2014).

In the busy surrounding of an ED PWD and their special needs are often overlooked. ChD would be an indicator of dementia ("We have to pay special attention on him.") – this visual information would be seen as an additional advantage for nursing staff although special labeling such as patients' names is relevant to data protection law, representing a conflict between patient safety and data protection.

The use of the adverse effect-free ChD to reduce agitation potentially leads to a reduction of secondary threats (e.g. falls) and self-threatening behaviour like running away. The ChD thereby might reduce the necessity of sedative medication and fixation.

Calming down agitated PWD, e.g. allowing the patient group of so-called wanderers to have a rest, is often necessary. Further, a close supervision of PWD requires the limitation of their radiuses. Many wards and some specialised dementia departments follow an activating care concept, as declining physical activity has detrimental effects on cognition and behaviour in these patients (Scherder et al., 2010). Even worse, PWD are often kept in bed unnecessarily, which can lead to medical complications like hospital acquired pneumonia, thromboembolism, or pressure ulcers (Thornlow et al., 2009).

Altogether, the ChD could be a helpful device for enhancing some patients' well-being and thus, safety in the ED and other locations, such as different hospital wards or nursing homes, while others would not benefit from its use.

Implementing the ChD (with or without further NCMSys) will have to deal with these differing individual needs of PWD in different settings (ED vs. geriatric ward etc.), and thus, must be considered in further studies (Kroll et al., 2020).

4.5 Limitations of the study

Only a few patients were included in our feasibility study, therefore the population is too small to include a detailed statistical analysis. Further, the test times were rather short and were restricted to daytime. The assessments of amelioration and deterioration were estimated by experienced nursing staff in a non-standardized manner. Therefore, an individual "human factor" cannot be excluded. Furthermore, even the few patients in the ED were studied under more "quiet" conditions, although extrinsic factors causing further stress for patients – beside their acute medical problem – could not be excluded completely. Thus, there might be a bias in the estimated grade of wellbeing

of patients in our setting. Having in mind a potential translation of our approach into the clinical routine, more patients and a less artificial study setting (e.g. a real-life, but defined ED surrounding during the whole time of patient's stay in the ED) need to be considered in a future controlled clinical trial (Kroll et al., 2020).

4.6 Conclusion

The combined concept of the presented NCMSys to detect pulse/heart rate, changes in movement and sound emission complemented by the ChD might be suitable to detect upcoming agitation, e.g. due to delirium, and to prevent further deterioration in older patients with cognitive impairment, including PWD, bound to bed in the ED. This concept may help to ameliorate quality of care, e.g. by less demand for sedating medication, and may result in shorter in-hospital stays of these patients (Yeh and Ouyang, 2012). Furthermore, this may lead to cost reductions for the public health sector (Olsen et al., 2016) without reduction of quality of care. Future studies will focus on further technical and design development of the NCMSys and the ChD, respectively, including a valid non-contact detection of respiratory rate. The results of our feasibility study support the initiation of a controlled clinical trial to evaluate if our system ameliorates level of care of older patients with cognitive impairment, especially PWD, in an ED. Such a trial must take the legal and ethical issues into account, and finally, it must be emphasized, that a technical solution only can complement, but never replace personal care of this very vulnerable group of patients in the ED (Kroll et al., 2020).

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Eidesstattliche Versicherung / Anteilserklärung

„Ich, Lisa Kroll, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: **The Charité Dome, a device to improve patients with dementia's stay and non-contact measurement of vital signs and movement in emergency departments**
– Forschungsarbeit zur Charité-Haube, einem beruhigender Bettaufsatz, um Menschen mit Demenz den Aufenthalt in Rettungsstellen zu erleichtern und zur kontaktlosen Messung von Vitalparametern und Bewegung selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.
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Ich versichere ferner, dass ich die in Zusammenarbeit mit anderen Personen generierten Daten, Datenauswertungen und Schlussfolgerungen korrekt gekennzeichnet und meinen eigenen Beitrag sowie die Beiträge anderer Personen korrekt kenntlich gemacht habe (siehe Anteilserklärung). Texte oder Textteile, die gemeinsam mit anderen erstellt oder verwendet wurden, habe ich korrekt kenntlich gemacht.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der untenstehenden gemeinsamen Erklärung mit dem/der Erstbetreuer/in, angegeben sind. Für sämtliche im Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE (International Committee of Medical Journal Editors; www.icmje.og) zur Autorenschaft eingehalten. Ich erkläre ferner, dass ich mich zur Einhaltung der Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis verpflichte.

Weiterhin versichere ich, dass ich diese Dissertation weder in gleicher noch in ähnlicher Form bereits an einer anderen Fakultät eingereicht habe.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer unwahren eidesstattlichen Versicherung (§§156, 161 des Strafgesetzbuches) sind mir bekannt und bewusst."

Datum Unterschrift

Ausführliche Anteilserklärung

Kroll L, Böhning N, Müßigbrodt H, Stahl M, Halkin P, Liehr B, Grunow C, Kujumdshieva-Böhning B, Freise C, Hopfenmüller W, Friesdorf W, Jockers-Scherübl M, Somasundaram R. Non-contact monitoring of agitation and use of a sheltering device in patients with dementia in emergency departments: a feasibility study. BMC Psychiatry. 2020;20(1):165.

Die Auswertungen und die Aufbereitung der gewonnenen Datensätze aus den Studien „Pilotstudie zur Validierung von nicht invasiven Messgeräten zur Messung von Vitalparametern und Erfassung von Unruhe/Bewegung bei klinisch gesunden Probanden sowie Patienten der Notaufnahme“ sowie der „Charité-Haube-Machbarkeits-Studie“ wurden im oben genannten Artikel zusammengefasst und veröffentlicht. Die Konzeption der vorliegenden Publikation erfolgte maßgeblich durch Frau Kroll unter Supervision von Prof. Somasundaram. Frau Kroll schrieb die erste ausführliche Fassung des Manuskripts. Die für Einleitung, Methodik und Diskussion benötigte Literaturrecherche übernahm sie vollständig. Die aus der Diskussion mit den Co-Autor*innen entstandenen Anpassungen sowohl der statistischen Analysen als auch der Manuskriptgestaltung realisierte Frau Kroll eigenverantwortlich. Beide Abbildungen in der Publikation (Abbildung 1 auf Seite 3, Abbildung 2 auf Seite 4) sowie die Tabelle auf Seite 6 wurden von Frau Kroll konzipiert, erstellt und angepasst. Die Finalisierung des Manuskripts sowie die Erstellung einer revidierten Manuskriptversion im Rahmen des Revisionsprozesses erfolgte maßgeblich durch Frau Kroll in späterer Absprache mit den Co-Autor*innen.

Datum Unterschrift

Lebenslauf

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

Komplette Publikationsliste

Kroll L, Böhning N, Müßigbrodt H, Stahl M, Halkin P, Liehr B, Grunow C, Kujumdshieva-Böhning B, Freise C, Hopfenmüller W, Friesdorf W, Jockers-Scherübl M, Somasundaram R. Non-contact monitoring of agitation and use of a sheltering device in patients with dementia in emergency departments: a feasibility study. BMC Psychiatry. 2020;20(1):165. Impact Factor: 2,666.

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