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Bringing research into a closed and protected place – the development and implementation of a complex clinical intervention project in an ICU

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INTRODUCTION

How can intervention studies in complex health care environments be conducted especially in units which are protected and to which other hospital staff and visitors have no immediate access? What research methods are suitable for studying spatial meanings or the impact of interiors and equipment in a specific room such as a patient room in an intensive care unit (ICU)? This article focuses on these questions, taking as its starting point an intervention study performed in a general ICU in a regional hospital. The intervention aimed to examine whether an ICU patient room refurbished according to an evidence-based design could promote and accelerate patient health, recovery and wellbeing compared to an ordinary ICU patient room. The purpose of his actual paper is to describe the theoretical underpinnings, ethical and methodological aspects applicable when carrying out complex intervention research in an ICU and further to provide guidance for intervention research carried out in closed and superficial environments that constitutes high-tech settings. The term “closed” here refers to the fact that an ICU is literally closed as visitors need to announce their presence in advance by making an appointment with the ward staff. To gain admission to an ICU a doorbell has to be rung and the errands stated. Visits to patients ordinarily need to be agreed with the staff and the fact that the unit is locked often surprises relatives who have usually never previously visited an ICU^{1,2}. A part from the worries caused by the critical event and the illness the ICU environment often appears strange and frightening to those close to the patient. For this reason and many other special circumstances an ICU appears a complicated place in which to perform research. Craig and co-workers³ emphasize the importance of detailed reporting of complex intervention studies to enable replication, evidence synthesis and wider dissemination of received experiences. This article focuses on an intervention process concerning physical environment in an ICU thus contributing to knowledge about research in settings that are technologically dense and complex and complicated to gain access to.

The idea – a complex clinical intervention

Planning and performing intervention research has been described as a process. The most frequently cited and utilized model is the Medical Research Council’s (MRC) framework for design and evaluation of complex interventions⁴. This process was originally described as evolving in five phases where the first phase is preclinical and theoretical and the following phases are modelling, exploratory trial, randomized control trial and long-term implementation. The framework has been revised^{3,5} and currently a linear process and

experimental design are not always applied. Qualitative approaches have been added together with emphasis on adjustment of the intervention to a local context. The phases of the process evolve in close interaction – expressed in the updated version as; development, assessing of feasibility and evaluation. The framework guides both medical and nursing projects, see ^{3,6,7}, and consequently the actual project as well as the structure for this paper.

BACKGROUND

What is regarded as a complex intervention that both improves and has important consequences for health and what does complex mean in this context. According to ^{3,5} a complex intervention contains a set of several interventions or components that need to be understood and evaluated (Box 1.). An other dimension is ⁸ the length of the intervention process, e.g. when an intervention is implemented over a long time, as was the case in our project. We consider research in ICUs in general as having great complexity due to the critical illness of the patient and their heavy dependency on staff and equipment. Protection of patient vulnerability, integrity and the limited possibility of obtaining autonomous and informed consent to participation mean that the researcher has to be particularly sensitive to the ethics involved ⁹. Spatial problems related to a setting with advanced machinery and equipment and high staff ratios with the resulting narrow spaces, limit the researcher's physical space for collecting data.

Please Insert Box 1.

We believe that the components: 1) patients dependency and vulnerability, 2) the critical event and 3) the high-tech environment, further contribute to the complexity of interventions in ICUs. Caring activities and treatment in high-tech surroundings represent such an area. Patients who are critical ill and their loved ones are seen as vulnerable research subjects ^{9,10}. The planning and carrying out of a complex intervention in this context is challenging and demands a well-developed combination of experience in the field and competence among the research team. The first phase in the intervention process is preclinical, in that it has to do with the theoretical rational for the study ^{3,8}.

Developing an intervention: The theoretical phase

The theoretical framework is seen as important, especially when researchers represent different traditions and paradigm of knowledge ^{3,5}. Our research team represented scholars from the caring sciences, architecture, design and work- environment medicine. Introductory discussions were aimed at establishing a common theoretical perspective and basic values. These were identified and negotiated to be a caring science perspective, a framework grounded within the concepts of health geography, healing environments and evidence-based design.

A caring science perspective

A caring science perspective is based in human science and existential philosophical traditions. The idea of natural caring (latin: caritas) rests on the idea that caring is the very essence of humanity and a basic foundation for human existence ¹¹⁻¹³. Core values are mercy, compassion and love towards the other. Caring also involves nourishing the other, both physically and spiritually. The philosopher Julia Kristeva ¹⁴ expresses the meaning of care through stating that caritas is endless and grows within relationships. Caritas is like a treasure that is not lost even if it is given away. On the contrary, it will grow because receiving care breeds the desire in the receiver to give back. Professional caring is an honest commitment and response ¹³ to these “natural values” of care in that it involves a promise and a response by virtue of the professionals’ capacity in having scientific knowledge, skill and receiving payment for caring. In the Nordic countries a caring science perspective is seen as neutral with regard to professional roles, but is considered the ideal/foundation and guide in nursing research, education and clinical practice. Professional care is always related to place and space ^{15,16} and as our research hypothesis was based on the idea that an environment could be conducive to healing, staff efficiency, patient safety and wellbeing we added a geographical perspective.

Health geography

The concept of geography originates from a positivism paradigm, as it has its roots in the exact measuring and depicting of geographical landscapes. More recent geographical research developed into the discipline of cultural geography and further into a wide field of human geographies ¹⁷ often using a phenomenological approach. When studying professional health care environments and peoples’ experiences of place and space concepts such as medical, health and/or nursing geography have been used. According to Andrews and Kitchin ¹⁸ places are not only containers for people’s activities but result of complex interactions, i.e. people

“make” places and places make and affect people in a certain way, either positively or negatively. The present project focused on place- and space-sensitive issues ¹⁵ and thus examined what makes a good ICU patient room, conducive to treatment, care and recovery. We also gathered knowledge about how staff, patients and their close ones related dynamically to spaces and places c.f. ^{10,19}. We consider the meaning of the concept of place being related to location and spatiality, whereas space is related to how people experience the meaning of places that they inhabit ²⁰.

Healing environments and evidence-based design

The main purpose of a hospital building (latin: hospitium; guesthouse) is to offer a place and protection for people and their activities. This protection is directed to aspects of climate and unwanted activities, such as intrusions of various kinds. Healthcare buildings incorporate different kinds of rooms, each with a specific function. From a patient perspective, a patient room can be regarded as a temporary home for the receiving of medical and nursing treatment and care, while at the same time being a place in which to dwell and recover. But it can also be a room associated with worries, experiences of /inflicted/ pain, and feelings of unfamiliarity, suffering and death. Healthcare buildings are extremely complex and not well studied, as the time spent in a hospital or an institution is much shorter than in a home. The concepts “healing environment” ^{21,22} and “healing architecture” ²³ contains elements of the design and construction of health environments that are social, psychological, spiritual, physical and functional in a supportive way regarding illness, recovery and health. It also refers to places and spaces that are designed based on evidence and are simultaneously sustainable as being effective and conducive to better experiences for patients and their loved ones. A health environment/building should also be safe and attractive to staff so that they will continue to work there and contribute to the caring processes ²⁴. Evidence-based design has evolved as a new research field focusing on the impact of architecture on health environments. Ulrich ²⁴ uses the concept as a guide to healing environments as a way of integrating knowledge from various research disciplines, i.e. to base decision-making about health surroundings and architecture on the best available evidence.

Literature review – obtaining existing evidence

The final part of the preclinical phase is inevitably a systematic literature review. This step constitutes an essential phase in identifying existing evidence ³, in evaluating and reflecting on findings and on the methods used in previous research. The outcomes of a literature review

guide the planning and development of the intervention, provide guidance about active aspects of interventions but also guide decisions concerning methodological design. The result of the literature search of international databases should be brought together, discussed and documented in order to form a research draft. This draft then serves as the basic data needed for writing research proposals. Our review revealed evidence that impacted on patients' health and recovery to sounds, light, sleep deprivation and risk of developing ICU delirium. Consequently, when designing the intervention room in the ICU, interests was focused on the light system, sound and interior design. We also extended the design to involve enhancement of patient's view of natural scenery. At this stage the project had received funding for a further two doctoral students, i.e. a total of three, focusing light, sound and the interior ICU room respectively.

Developing the intervention: The modelling (and building) phase

The intervention comprised four parts: Rebuilding a two-bed patient room with sound absorbent walls, installing a cyclic light system and "plain" design with moderate colors and comfortable furniture using ecological, sustainable materials. "Plain" design meant that nursing and medical equipment, such as documents, gloves and technical devices were moved or concealed. The intention was to study any possible effects on patients' health and recovery when compared to patients cared for in an ordinary two-bed patient room. In the modelling phase we carried out a pilot study where sound measurements from all patient rooms in the actual ICU and future intervention settings were studied, both by technical means and from patient narrations ^{25,26}. In addition to identifying various outcomes we also learnt and tested methodological issues (Johansson^a) et al. in progress) including how to move in an ICU patient room in a sensitive way, how to adapt measuring instruments and how to synchronize the research work with ongoing treatments and staff activities.

Modelling presents a progressive and operative phase with processes that move in parallel. A research draft was presented to the senior hospital administrator who gave permission for implementation of the intervention within the hospital's general ICU. A national organisation (Considerate Care®) was then contacted and an application to join their education programme in leading projects in refurbishing healthcare buildings was accepted. Considerate Care is an official agency which acts to stimulate sustainable design within the Swedish public sector. At this time the research team consisted of a small group of nursing researchers and one doctoral student. In order to meet the educational requirements concerning members of a project group

an invitation was sent to the actual ICU's two ward sisters and an architect specializing in the construction of hospital buildings was also engaged. When working with intervention research it is the utmost importance to create a well-informed and motivated team ⁸ with diverse competencies and interests, who can act as gate keepers and agents when the time comes to launch the intervention. The next step was to enlarge the research group to form a multi-professional team with scholars sharing a common interest in caring for patients in high-tech care environments and in architecture. Thus, scholars representing the school of textiles, architecture and work & environmental medicine joined the group. Who bears the responsibility for a project has to be clearly stated; the nursing research section assumed accountability as we had access to the research field. Processes in the modelling and building phase also need to be documented. This is extremely important for handling problems and decisions that come up during the process, when writing applications for funding and later for the publication of scientific reports. Consultants, manufacturers, managers and hospital's representatives also need to be contracted. Here we recommend consulting the universities' or hospital's legal department about establishing legal agreements with each contributing party. Such documents will help to make clear future decisions and commitments about data and research findings.

A working plan should be established and documented (Box 2) including a schedule for the meetings for the research team. A small steering group can work more effectively – our advice is also to establish a larger reference group of people representing various disciplines and professions.

Insert Box here

As a last step in our modelling phase a meeting was held to create ideas, inspiration and vision among the research team. A mix of people with special knowledge of and interest in design, healthcare and research were invited to a half-day seminar. Finally, an author and consultant in Feng Shui (academic level) were contracted. An additional doctoral student in architecture and representatives from three specially chosen companies in the healthcare technological business and technological textile production were invited to collaborate in the modelling and building phase. Together we approached the manager of the hospital building and presented drawings for the refurbishment of one two-bed patient room in the ICU, created by the architects within the group but modelled and negotiated in the research team. The plan and drawings were approved and the renovation and building of the room followed.

Insert Image 1 here.

Developing the intervention: methodological design and implementation phase

The idea of performing the actual intervention was guided by the aim to develop and evaluate innovative solutions that could improve care conditions, the physical environment and recovery for patients, next of kin and professionals in everyday ICU practice. The active components were a cyclic light system, sound absorbents and interior design. The idea of caring based primarily on the patient perspective formed the core of evaluation of intervention outcomes. Eriksson ²⁷ state that evidence in the caring sciences can be sought using both quantitative and qualitative research methods – in so far as the research problem is something that concerns the idea of caring. The fact that people being cared for in ICUs are fragile calls for a combination of research methods ⁹. As ICU delirium or syndrome is a well-known problem in ICU care ^{28,29} all patients treated in the intervention and control room were scored daily for this phenomenon, using the CAM-ICU instrument ²⁹ and in some cases the OBS scale ¹⁰ to show if the ICU patient was awake and fully aware of the situation, not too tired, anxious or in too much pain to consent to participation.

In more detail, we approached patients' situation concerning the sound environment using data collection methods such as sound pressure measurements in dB(A) (Bruel & Kjaer 2260), instruments directed to discerning delirium incidents such as CAM-ICU ²⁹ and an observations guide ³⁰. We also interviewed the patients ^{25,26} and these data were subjected to phenomenological-hermeneutical analysis ³¹. As ICU nurses' knowledge of sound and noise has been described earlier as weak ³² we decided to investigate this situation on a general basis concerning Swedish ICU caring teams (Johansson^b) et al. submitted 2014). Data were therefore collected from physicians, ICU nurses and enrolled nurses in ICUs that were not included in the intervention study. We used a validated web-based questionnaire ³² addressed to 133 physicians, 914 ICU nurses and enrolled nurses (n=1047). A total of 305 people responded. Supplementary data were collected by means of open-ended interviews that were subjected to qualitative content analysis. This design gave us a more holistic view of the sound element and a basis for further research.

Polit and Beck ⁸ stress the importance of a design being based on an intervention theory that clearly states what must be done to achieve the desired outcomes. Moreover, it is a good idea to develop separate designs for each study included as they have their own purpose.

When designing studies about the cyclic light system³³ we also collaborated with researchers in environmental psychology and used their validated instruments for light experiences (SMB® BELUPP®, Küller, 1993, Küller and Laike, 1998). Baseline measurements were carried out by lighting technicians in the two rooms concerning illuminance, luminance and radiance using a Hagner S1 Universal Photometer and an AVASpec-2048-USB2, a spektro-radiometer with software AvaSoft 7.5.3 for measuring of irradiance. During their stay in the intervention room and the control room patients were provided with an Actiwatch® (Philips, Actiwatch Sectrum Plus). The watch is worn on patients' wrists like an ordinary watch –but registers time, light exposure and patient movements. According to the manufacturer the latter are to be seen as a reflection of the patient's wakeful-ness or sleeping and have been used for this end in previous studies^{34,35}. However, we used Actiwatch® data to indicate whether the patient was quiet and peaceful mood. Follow-up interviews were performed with patients after their discharge to a general ward, using a semi-structured interview guide.

Basic data, such as demographic data, medical and pharmacological treatment, patients' length of stay, disease and severity of illness, were received continuously via the ICU's ordinary digital record system. Special arrangement had to be made, as in Sweden all material must be anonymous when removed from the ICU. A code key was therefore kept under lock and key in the unit. When designing studies directed to examining the interiors of ICU patient rooms an overall perspective was taken by one of the doctoral students. The aim was to present an overall and qualitative description of experiences of the ICU patient room as lived by patients, their close ones and staff^{10,19,36}. The methodological approaches employed were phenomenology and phenomenological-hermeneutics. The data collection, i.e. qualitative research interviews³⁷ took place in the actual ICU and another two general ICUs in order to achieve a deeper understanding of place and place as lived when critical illness is involved. During the data collection processes the application of photo-voice methodology^{38,39} was developed for ICU research (Olausson et al. 2014, submitted).

ETHICAL CONSIDERATIONS

Patients in need of critical care are among the most of people beings due to the severity of their illness, unconsciousness, reduced autonomy and confinement to bed etc. They are situated under an existential threat where they have to put their bodies and life into the hands of others⁴⁰. Vulnerable people are often excluded from taking part in research^{41,42} because of concerns related to their fragility and the problem of the risk of burdening them and causing

them harm. The researcher in such situations therefore, becomes the voice of the vulnerable and responsible for illuminating and displaying this existential threat in a reflective and critical way. Liamputtong⁹ warns that deliberately excluding vulnerable people from research causes even more harm. On the contrary, researchers need to develop sensitive methods that give vulnerable people better opportunities to participate in research.

The actual intervention project has been assessed by the University Research Ethics Board (no 695-10). When recruiting participants for the respective studies Swedish laws and regulations are stated, according to the Helsinki Declaration (<http://codex.vr.se/>) of 1964 but amended several times since. The consent process should include strategies to minimize the risk of harm and discomfort, the right to receive full information and the right to withdraw from the study without giving any reason⁸. All participants received written and oral information about the study. They also signed a consent form. The responsibility for obtaining informed consent was delegated in our intervention project to two doctoral students, a research assistant nurse and two representatives among the ICU staff (gate-keepers). We recommend this practice as patients are admitted to the ICU around the clock and there is a risk that asking for the patient's consent will be forgotten due to staff's high workload. Some staff also may feel uncomfortable asking about consent when patients are in an exposed situation and under existential stress.

A note was attached to the staff clipboard explaining about the study and several oral presentations were held at staff meetings. As patients in ICUs are critically ill, often unconscious or confused due to pharmacological treatments they might be unable to consent. The recruiting process may allow the family to consent. We used a process consent⁸, meaning that in some cases relatives gave informed but vicarious consent on behalf of the patients. We then obtained consent from the patient after recovered and were in a communicative and stable state before their data were processed. Liamputtong⁹ uses the expression "ethics-as-process-approach". The term has guided our programme in terms of regarding the research process as an ongoing and negotiated process.

Piloting and assessing feasibility

After the official opening of the intervention room a period was set for the staff to adjust to the new working environment. When the environment in the ICU patient room was changed, it became evident that safety is built on the idea that all equipment is kept in the same place. An introductory period is very important for maintaining patient safety as the staff had to

move in the room in a different way, the storage of equipment was new and the technology was adapted in new ways. The first patients who were chosen for admission to the new room were in need of post-operative care, i.e. in need of less advanced care.

Using feasibility studies is one way to prepare for a full-scale study without risking ⁸ full-scale failure concerning personal and economic costs. We therefore included a feasibility study (Johansson^a), Knutsson, Lindahl, Öberg, Persson-Waye & Ringdal, in progress) in the programme.

Evaluating and reporting of the intervention

Some proximal, ⁸ i.e., immediate, outcomes can be presented. The sound levels in the patient room – LAF max levels – are shown to exceed 55dB for 70–90% of the registered time ^{25,26}. Only small differences between night and day values were reported, which put the patients in an uncontrollable situation impossible to escape from, regarding noise levels. As we consider that nurses play a vital role in developing an environment, another study (Johansson^a) et al. in progress) aimed to scrutinize this aspect of the problem. The knowledge and suggestions of the ICU staff about sound environment improvements showed that the theoretical aspect of their knowledge was somewhat weak but their practical awareness and actions were good. Our studies concerning interior design show that these aspects have a great impact on caring, from the patients', loved ones' and ICU nurses' perspectives. The high-tech character, narrow spaces and the heavy presence of various health professionals in the patient room is often taken for granted. Organizational responsibility concerning the design of rooms and the effects on the care given in them seemed to be unclear. Findings that focus on the lighting environment in the intervention room are limited as data collection is still proceeding. However, a group of invited visitors who assessed the intervention and control rooms differed significantly in their evaluation of hedonic tone, favoring the intervention lighting³³. Patients' recovery will be evaluated in relation to the room in which they were cared for i.e., the refurbished or the ordinary room.

REFLECTIONS

We argue that there is an urgent need to critically reflect on and articulate the issue concerning improvement of ICU patient rooms to create safer, more humane and healing atmosphere. Cyclic light, sound absorbents, interior design and a view to the scenery may be aspects that can contribute to this.

Even if experimental design is most often used in intervention studies, there may be ethical and medical objections to using randomisation ⁵. Here, “best available” methods should be accepted and adapted to contextual conditions. Our aim was to perform randomised trials when comparing the outcomes in the intervention and control room respectively, but we were forced to deviate from randomisation of sample sizes in the two rooms due to staffing ratios, the patients’ severe illness and security. Polit and Hungler ⁸ state that there is a consensus about using mixed methods when doing complex intervention research.

One challenge when carrying out complex intervention research in the ICU –is that staff are not used to having researchers around in clinical practice, and did not want the research to be a burden to the patients or the relatives or, in some cases, to themselves. Polit and Beck ⁸ report problems with staff, managers and administrators who see no need to create or implement interventions and therefore do not want to participate or do not understand what is expected from them. The authors claim that the research team needs to “own” such questions as these problems are a part of the programme and the fact that an intervention’s success relies on actions being taken by human resources such as policy makers, various facilitators and gate-keepers. Such relationships need to be continuously maintained. The doctoral students were in time incorporated into the unit’s team spirit and were often consulted by staff about various research issues. Such events could be seen as a distal outcome ⁸ or behaviour and knowledge that develop over time as the project proceeds. Initially the staff was very motivated to take part in the sound measurement but were also afraid of being bugged/wiretapped. This issue gave rise to several extra meetings and information that this fear was groundless and not the focus of the study. We believe that one distal outcome, therefore, became increased awareness of sound environment in the actual unit. Clarke ⁴³ emphasises the importance of reflecting on intervention research designs with regard to how and which components comprising the whole intervention should be understood and what power is built into the components, both as parts and as a whole. Our main components were sound, light and interiors. These components are complex to implement and evaluate concerning outcomes, both in terms of parts and a whole, as they are integrated and inseparable in creating the atmosphere in a room. It is too early today to give a clear definition of the power they exercise on care practice. However, we have noticed an increased awareness among the staff concerning the impact of these components on the everyday care as well as on the understanding of research as an important issue, i.e. the need for evidence-based practice ^{27,44}.

We recommend the use of audit trails ⁴⁵ to retain clarity, keep up with general decisions made and consultants and expert's contracts. The Feng Shui expert held a lecture at the unit for staff and the research team and also wrote three reports during the modelling phase that was very inspiring. Good theoretical, practical understandings of the essence of caring in ICUs and good communicative competence in updating and filling staff with enthusiasm are also valuable qualities. It is probably an advantage if the clinical research team is completed with a post-doctorate researcher as there are many problems that have to be solved ad hoc. One such problem is adapting and installing technological and digital equipment for data collection along side the huge amount of machinery that is already used for medical treatment in an ICU patient room. The hospital environment has been discussed in a broad sense and here researchers have stressed the importance of involving the staff. When exploring the concept of sustainability ⁴⁶ in relation to nursing and hospital buildings the authors claim that the ultimate goal is an environment that is not harmful to current and future generations. When strategic building plans among the 64 Norwegian hospitals were examined ⁴⁷ few gave guidance for aesthetic dimensions, which points to a certain knowledge gap within this field. Data collection in such a complex context as an ICU is time-consuming and a good time schedule therefore counteracts the risk of weakness in the research process arising from the small sample. Our project plans to continue with the study of how family interaction and comfort can be promoted during the critical event and how safety in the rooms and during transfers (radio-therapy department, operation theatre etc.) that the patient is subjected to the caring period, can be enhanced.

CONCLUSIONS

Complex interventions are sparse in nursing studies, especially in an ICU context ^{6,8}. As ICU care is costly and a healing environment conducive to health may shorten a patient's length of stay and recovery time these aspects are important for further research from a humanistic and caring perspective. A combination of methodological approaches, good contact with the clinical field, recurring opportunities for reporting and the exchange of information, communication within the research team and funding are all of vital importance for this to occur.

Box 1. MRC's description of the definition of the term complex intervention.

The concept complex intervention refers to:

- number and interactions between components that form the project,
- number and difficulty of behaviours among those who deliver and receive the intervention,
- number of groups or organisational levels that are involved,
- number and variability of outcomes and lastly,
- degree of flexibility or tailoring of the intervention

(MRC complex intervention guide, 2006).

Box 2. Schedule describing the modelling phase

- Analysis of needs for an intervention ICU patient room

- Priority of needs:

to create a healing environment conducive to the health of the patients, next of kin and staff

to create an intervention room that is safe, functional and aesthetically attractive

to reduce the negative effects of ICU environments, such as delirium, depression and sensory overload

to develop scientific knowledge about what aspects of ICUs or high-tech surroundings affect health and recovery in a positive way to achieve shorter patients' length of stay, less staff turn-over and notification of illness

to collaborate multidisciplinarily with the goal of developing new sustainable methods and products .

- Analysis of sustainability

Survey and examination of material used in the ICU intervention room.

- Summary of main findings from analyses

- Visions for the future

Image 1. Drawing made by architect Maria Berezecka, Chalmers Dept. Architecture.

Image 1. The artificial headboard fixed to the wall, lit by the cyclic light system.

Image 2. Patients' view of natural scenery.

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