Clinical Cross-over Trial, testing Dynamic Air Mattresses

Assessment of pressure injury risk and mattress functionality

NCT number: NA
Sunnaas Rehabilitation Hospital, Departments of Spinal Cord Injury, Multi-trauma, Neurology and Burns,
January 1st 2022

Content

Preface Testbed and Tidewave

Innovation at Sunnaas Rehabilitation Hospital (SunHF) has a main focus on better health services and methods of treating patients. With an increasing amount of development and innovation projects connected to private or public businesses, SunHF decided to set up a service that could facilitate the cooperation between business and the hospital. Thus, Testbed was created as an arena where business and health care can work together to test, develop and implement new products, services, methods, and organizational solutions.

In 2019, Tidewave R&D and SunHF began discussing the prospect of assessing the newly developed Tidewave turning mattress (Tidewave). The development of Tidewave is based on a systematic review on the role of repositioning in the prevention of pressure injury (2018)[1], in addition to a pressure test performed by the Norwegian Research Center[2] (NORCE 2018/19). Patients at SunHF are potential users of this turning mattress, and it are therefore important candidates to test the mattress with focus on the product`s quality regarding functionality and pressure injury (PI) prevention. One of the patient groups that would potentially benefit from the matrass is individuals with spinal cord injuries, which is also one of the main patients groups at the hospital. In the trial, Tidewave will be compared with the recommended CuroCell® 4 AD (CuroCell) mattress to investigate the quality of the product with in particular focus on individuals with spinal cord injury (SCI).

January 1st 2022

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Introduction

Sunnaas Rehabilitation hospital delivers acute rehabilitation to patients suffering from newly acquired injuries related to the spinal cord, as well as to the muscular and skeletal structure. The acute rehabilitation takes place from the departments focusing on spinal cord injury sequelae (RMS), and the department of multi trauma, neurology and burns (MNB). Newly injured individuals are admitted from the acute care hospital as soon as they are ready and in a condition to start their multidisciplinary rehabilitation program. In 2019, 82 patients, with a mean age of 56 years, received their acute rehabilitation at one of these two facilities. The mean length of stay was 71 days. After the rehabilitation, 63 (77%) of the patients were discharged to home, 8 (10%) to other hospitals, 7 (8%) to private rehabilitation facilities and 4 (5%) to nursing homes[3]. Individuals with paralysis and individuals recovering after multiple trauma has increased risk of pressure injury (PI) development, compared to individuals not suffering such injuries or diseases[4-6]. This is due to lack of sensibility, reduced or lack of voluntary mobility and areas of the skin being exposed to unfavourable moisture from sweating and incontinency[7-9]. Individuals with PI are often hospitalized over increased time-periods and are exposed to an increased number of outpatient consultations related to PI treatment and follow-up[10]. PI causing infection can potentially expose patients to life-threatening conditions[8,9]. PI can also cause increased pain, tension and sleep deprivation. PI prevalence assessments performed at RMS and MNB in 2019 indicated that a major portion of the hospitalized patients were at risk of having a PI, and that 29% of the examined population at the two departments had a PI. This finding confirmed the importance and value of risk reducing intervention. The assessment also elaborated that the PIs occurred at areas of the body that are exposed to pressure over time, whilst in a supine position, e.g. such hips, buttock and heels. A long-time supine position demands a need for manual turning and, thus a waking of the individual during the night if the mattress is a standard static version. On the other hand, dynamic air mattresses are widely in use today, focusing on a variation in pressure, and thus a reduced need of position change during the imbedded time lap. Even though these mattresses reduce the need for manual turning, they do not eliminate the problem for individuals who are not capable of managing the position change on their own, and some individuals require position change assistance every second hour. The European Pressure Ulcer Advisory Panel's (EPUAP) 2019 guidelines[11] recommend an average of position change every second to forth hour. Further, they advise individuals at risk of PI development to be positioned in a 30-degree sideways posture[11].

Dynamic air mattresses represent a variation of quality, related to pressure variation of the mattress to prevent PIs. This pressure variation is due to automatic air change offered by an automatic air pump system. However, the noise generated by the pump could disturb the sleep, causing a decrease in quality of life over time.

Technical information regarding the mattresses

The intervention mattress, **Tidewave,** is a dynamic air mattress which automatically turns the patient from side to side with a maximum angle of 30 degrees at each side, over the course of a maximum of 180 minutes. When inflated, the mattress shape and retains a cradle formation, which in favour of increasing comfort and safety for the patient. The cradle shape provides a 10% increase in pressure distribution, in comparison to traditional posture alteration. In addition, the mattress provides a pressure relief caused by the continuous movement of the individual. The mattress is designed to be comfortable, increase sleep quality and reduce the amount of manual position changes required from the nursing staff. The mattress has three variations of weight recommendations, ranging upwards to a maximum of 150 kilos. The mattress has been tested in nursing homes, in individuals` homes and hospitals. The Norwegian Medicines Agency (NO918491775/0941-55297) has approved the mattress, and the mattress conforms to the European Regulation 2017/745, with a risk class 1 as per rules in Annex VIII. The developer, Tidewave R&D, started mass production of the product in October 2020.

The control mattress, **CuroCell® 4 AD,** is a dynamic mattress providing pressure variation and in prevention and treatment of PIs, this can be utilized. The mattress is functional and provides satisfying comfort for the individual. The removable bedsheet isdocumented to have a high hygiene standard, and is designed to allow moisture to pass through, reducing the risk of moisture related injuries to the skin. The mattress offers a variety of attributes, such as a heel function that reduces strain on exposed/sensitive heels. Recommended weight ranges from 0 – 200 kg. The mattress is in Sunnaas Rehabilitation hospital currently used as first of choice mattress to individuals at risk of PI development.

Contamination procedures

The hospital has established and implemented cleaning and disinfection procedures in accordance with current national regulations. These procedures will be followed throughout the project. This is especially important in contamination-related situations.

The purpose of the study

To compare an intervention mattress and a regular care mattress in relation to occurrence of pressure-relief, experienced sleep comfort, pain and quality of life in the participants. Further, to examine resources needed to assist in position change of the participants, as well as physical strain for the nurses.

Troubleshooting

Compare the Tidewave turning mattress (intervention mattress) to the CuroCell® 4 AD (control mattress) in relation to;

1) Development of PI risk
2) Noise disturbance, pain, quality of life, quality of sleep, general bedrest comfort.
3) Functionality in terms of daily use, such as getting dressed and repositioning to and from the bed.
4) Resource use in staff members with focus on amount of required manual position changes during the day, as well as number of staff members required for each manual position change, and the level of physical exertion required from the hospital staff to perform the position changes.

Material and Methods

Research design

To conduct a prospective cross over testing, with ten participants from the group of patients at the two acute rehabilitation departments.

A feasibility study was in advance of the main trial completed. The results from the feasibility trial supported the choice of inclusion and exclusion criteria regarding safety in the participants while testing the mattresses. Acceptable pressure limits were set, based on the findings in the feasibility study, as well as evidence-based knowledge regarding level of pressure and risk of PI[12]. The feasibility study was performed between May 4th to 7th 2021.

Based on the results from the feasibility study, relevant validated and custom-made questionnaires were chosen to get the needed information regarding the participants` experience being bed rested on the mattresses. Custom-made questionnaires regarding experienced strain, resource use and physical exertion in the group of staff members was

developed. As well as two semi-structured questionnaires, focusing on in-depth knowledge of the participants' and the staff members` experience with the mattresses, respectively.

Selection of participants

Three to four weeks after admission to the RMS or MNB departments, between September 2021 and December 2022, ten participants will be included in the study. Participants included in the trial will suffer from SCI, neurological disease with paralysis or multi trauma. All with the consequence of decreased self-dependency and mobility, and thus lack of independency in position change in bed. The selection of candidates will be by the project nurse, based on the inclusion criteria, and in accordance with the responsible physician at the department. The duration for each participant will be 14 days, seven days on each of the mattresses. The project nurse will contact potential participants in person, provide oral information about the study, hand out written project information, as well as an invitation to participate.

Power calculation

The sample size calculation is based on the Insomnia Severity Scale (ISS) validation study by Morin et al (2011)[13]. The hypothesis is that the sleep will improve when using the intervention mattress, as compared to the control mattress. However, the expectation is a low improvement, due to the low period of time the intervention mattress will be in use. Thus, the sample size calculation will be based on what is denoted a "slight improvement", defined by Morin et.al. as an improvement on 4.6 points on the ISS scale[13]. Based on this effect, a power of 0.8 and a significance level of 0.05, will need eight participants, given the set assumptions regarding variation (SD = 4.5, taken from Morin et. al). Thus, we include 10 participants to tolerate some drop- outs.

Inclusion citeria

- $\geq$ 18 years of age
- SCI, neurological disease with paralysis or multi trauma, all with lack of independency in position change in bed Hospitalized for primary rehabilitation in either the RMS or the MNB department
- Requires manual position change
- Medically approved for the participation by the patient's physician
- Able to consent to participate
- Psychically and cognitively able to properly answer the questionnaires

- Speaks/understands Norwegian language

Exclusion criteria

- Ongoing PI upon admission to the hospital
- External fixation, except use of neck-collar
- Body weight surpassing the mattress limits
- Pressure testing indicating a worse result than the set pressure limit
- The participant has a planned leave of absence during night time, during the test-period

Procedure

To secure safe use of the intervention mattress, a noise-test and a pressure assessment test of the mattresses has been performed in advance of the research project. A pressure limit is defined, based on current evidence based knowledge regarding pressure injury risk. If this limit is exceeded during the project period, the participant will be excluded from further testing, due to a potential increased risk of pressure injury development.
An Xsensor mat[14] will be used in all pressure assessments. Written and oral information regarding the project will be given. The participants will give a written consent before inclusion. The regular care mattress, used as control in this trial, is considered one of the best pressure relieving mattresses available in Norway, and this mattress is the mattress of choice when the patient is admitted to the spinal cord unit for post-acute rehabilitation. Due to the randomized cross over design of the study, the start mattress will be chosen according to the randomization. The test-period will start with one of the mattresses for seven days, and then change back to the other mattress after seven days. This to secure a best possible objective comparison between the two mattresses. The study will be open labelled, because it will be impossible to mask the mattresses due to different designs. Ten participants will be included. Baseline data regarding gender, age, level and severity of the spinal injury, together with pressure injury associated dysfunction, like increased sweat, bladder and bowel incontinency, will be collected immediately after inclusion. Further, information of comorbidity previous to the injury or disease, including cardiovascular disease, embolisms or diabetes mellitus, will be registered. Pressure monitoring will be performed before start up, and validated questionnaires will be used in assessing pressure injury risk, pain and quality of life (QoL). After seven days use of the first mattress, new data will be collected, by means of validated forms regarding pressure injury occurrence, pain occurrence, noise from the mattress devices,

sleeping wellness and participant satisfaction. Custom made forms regarding resource use in the nursing staff, especially at night and in relation to position change, will be collected, together with data regarding physical strain in the staff. In-depth interviews will be performed on one participant and one nurse.

The participant will then change to the second mattress and use the mattress for seven days. Then a new data collection will be performed, similar to the questionnaires used in the first mattress. In-depth interviews will be performed in one participant and one nurse.

Collection of data and assessment instruments

At every shift during the project period, the nurses will check for pressure wounds, and mark identified pressure wounds on a pressure injury body-map. At every shift the nurses will also use a custom made form to register resources needed in each position changing of the patient, the number of times the position is changed, as well as the level of physical strain in the nurses. At the end of each of the two the test periods, the participants will register their QoL, bedrest comfort, sleep-wellness, pain and satisfaction in the test period.
One participant and one nurse will be asked to participate in in-depth interviews regarding experienced quality in use and in managing each of the mattresses.

Demographic data

Will be retrieved from the electronic patient record (EPR), and include gender, age, height and weight, injury-related information, time between the occurrence of the SCI as well as known injury-related risks, related to PI.

Primary Outcome Measure

Pressure Injury risk.

Assessment of PI risk will be performed via the Braden scale[15]. Every morning an evening any PI occurrence will be performed according to the NPIAP, 2019 Clinical Practice Guideline[16], and any new mark/PI will be noted and rated on a severity scale ranging from 1 to 4. The location of the mark/PI will be marked on a body map chart, displaying the location of the mark/PI.

Secondary Outcome Measures

Health related quality of Life (HRQoL) regarding overall well-being, physical well-being and psychological well-being. Assessment will be performed using the spinal cord injury quality

of life basic data set (SCI QoL BDS)[17]. Assessment will be performed at baseline, at change of mattress and at end of study.

Sleep wellness assessment will be performed, using the Insomnia Severity Index (ISI)[18]. Assessment will be performed at baseline, at change of mattress and at end of study.

Experienced pain when using the two mattresses will be assessed by using the Brief Pain Inventory (BPI)[19]. Assessment will be performed at baseline, change of mattress and at end of study.

Satisfaction in participants will be assessed using a custom-made Likert scale where 1 is completely dissatisfied and 5 is totally satisfied. Assessment will be performed at baseline, at change of mattress and at end of study.

Satisfaction in staff will be assessed as resource-use, counting the number of personnel needed, number of manual turnings required/level of required support during daytime/night-time, and physical strain in the nursing staff, using a custom made Likert scale where 1 is worst possible strain and 5 is no strain at all. Assessment will be performed at baseline, at change of mattress and at end of study.

A custom made semi-structured interview guide has been conducted, asking more details of the experienced quality in use and in managing the mattress.

Ethical considerations

The patient will be excluded from the study if risk of increased PI is apparent during the pre-test pressure mapping. The risk is determined by the pre-set pressure measurement limit.

The project will follow the national regulations regarding approval, collection and handling of sensitive data. Privacy regulations will be followed. The Tidewave mattress was approved by the Norwegian Medicines Agency (SLV) November 25th 2020, (NO918491775/0941-55297) and evaluated not to be included in the Ethical Committee`s (REK) area of responsibility, January 15th 2021 (229188), and by the Patient Ombudsman at Sunnaas Rehabilitation hospital, September 16th 2021. Written and oral information will be given to all invited participants, and the participants have the right to withdraw from the project without giving any reason for the withdrawal.

Data processing

All data will be anonymized and stored at the hospital's encrypted data server. This is in line with the Norwegian privacy and data protection legislation. The data be available solely to individuals connected to the project. Any privacy information that can identify participants will be stored separately from the rest of the data. The letter of consent and the answers to the

questionnaires will be stored in a secure research cabinet. The keys to the cabinet are be stored securely. The data will be deleted 15 years after the conclusion of the study. Latest date of deletion is 1st of September 2037.

Consumer perspective

An experienced consumer and two representatives from the Norwegian Spinal Cord Injury Association (LARS) will participate in the study, to ensure the quality of the procedures and make sure the actions are performed in an ethically suitable manner.

Insurance

The participants in the study are insured via the hospital`s insurance program.

Milestones

WHEN	WHAT
Week 15, 2021	Feasibility
Week 36, 2021	Preparation
Week 39, 2021	Start Inclusion
Week 26, 2022	Start data processing
Weeks 33, 2022	Start writing study article
Week 50, 2022	Submitting article

Economy

Tidewave is funding the study as well as providing the required equipment and services for the pressure assessments. Sunnaas Rehabilitation hospital has the ability to purchase the equipment after the conclusion of the study. The researchers will perform all tests, data punching and analyses. The researchers will write a final report to Tidewave. The researchers will write and submit an article to a peer-reviewed journal, based on the results from the study.

Project organization

The managers from the Innovation department, Clinic, Clinical departments and Research department will represent the management group. The project group is responsible for the

planning and follow-up through of the project. The project group consists of nurses, physicians, occupational therapists and physiotherapist. All members with thorough knowledge of PI, PI prevention and pressure measurement.

The expanded project group will be invited to project meetings before the project initiates, and every second to third month afterwards.

Group	Department	Members	Assignment
Management	Clinic	**Kathi Sørvig**	Clinic manager and project owner.
	Research	**Anne Catrine Trægde Martinsen**	Research director.
	Innovation	**Sveinung Tornås**	Manager of the Innovation department
			Manager of the RSM department
	Clinic	**Birgitte Dahl**	
			Manager of the MNB department
	Clinic	**Christine Mol Slettenes**	
Project-group (co-authors)	Research	Ingebjørg Irgens	Project leader, guide in the data collection, analysis, report/article,
	Innovation	Lene Mosberg	Testbed coordinator
	Clinic	Tina Kopseng	Pressure measurement
	Clinic	Anne Birgitte Flaaten	Pressure measurement
	Unit of skills	Gro Marianne Eriksen	Overall project nurse
	MNB	Hanne Karlstrøm-Bjørnstad (RN)	Project nurses in the departments
		Anne Innerdal (NA)	
	RMS	Jeanine Paulsbo (RN)	
		Sarah Amey Pedersen (NA)	

Reference group	Consumer association	**LARS;** Morten Lind Sonja Brinsky	Inputs related to development of the protocol, interview guide Communicate status and decisions/recommendations, bilaterally.
	Peer-consultant	Gunhild Bottolfsen	Forthcoming input, and participation in the feasibility test
	RMS	Philip Bilberg	Follow-up in the departments.
	Tidewave	Nina Fagerheim Åmodt Bjørn Sebastian Lorentzen	Representatives from Tidewave

Dissemination

The results will be presented in the form of a report, as well as presented in national, and international professional meetings/conferences. An article will be submitted to peer-reviewed, international journals.

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