Videoconferencing for Follow-Up of Pressure Injury

Period Prevalence, Risks, Treatment and Financial Consequences

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TABLE OF CONTENTS

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LIST OF PAPERS

This thesis is based on the following papers:

PAPER I

Irgens I, Hoff JM, Jelnes R, Alexander M, Stanghelle JK, Thoresen M, Rekand T. Spinal cord injury and development of pressure ulcers during acute rehabilitation in Norway; a retrospective multi-center study. Spinal Cord 2020;58:069–1079. https://doi.org/10.1038/s41393-020-0465-z.

PAPER II

Irgens I, Midelfart-Hoff J, Jelnes R, Alexander M, Stanghelle JK, Thoresen M, Rekand T. Videoconferencing in pressure injury: results from a randomized controlled telemedicine trial in patients with spinal cord injury. JMIR Form Res 2022;6(2):e27692. https://doi.org/10.2196/27692.

PAPER III

Irgens I, Kleven L, Hoff JM, Jelnes R, Alexander M, Stanghelle JK, Rekand T. Cost-utility analysis and environmental outcome of videoconference in pressure injury. A randomized controlled trial in individuals with spinal cord injury. Submitted.

SUMMARY

Background The occurrence of pressure injury (PI) and risk factors related to the PI development among people with spinal cord injury (SCI) in Norway are unknown. Barriers and challenges related to transportation, climate, and costs may have an impact on the follow-up services for people in need of specialized, long-term services related to PI treatment. New ways of providing satisfactory and safe follow-up are needed.

Aims The aims of paper I were to estimate the prevalence of PI and to identify risk factors for PI during acute rehabilitation in a group of people with a newly acquired SCI in Norway.
In paper II the main aim were to examine the health-related quality of life (HRQoL) in patients with SCI in a randomized controlled trial (RCT). Secondary aims were to investigate PI healing, experienced satisfaction, safety and patient-empowerment related to the follow-up.
In paper III the main aim was to perform a cost-utility analysis (CUA) alongside the RCT, taking a healthcare perspective. Quality-adjusted life years (QALYs) was the outcome measure. The QALY combines the length of life and the quality of that life into a single index, which allows for comparisons of effectiveness between the treatment groups. Secondary aims were to conduct an environmental evaluation with outcomes regarding transportation related costs and environmental emissions.

Methods The electronic medical record of all persons acquiring a SCI between 2004 and 2014, and who were admitted to one of the three Norwegian spinal cord units for acute rehabilitation were examined. The period prevalence of PI, as well as possible risk factors for PI during acute rehabilitation were investigated based on a retrospective epidemiologic design.
The participants in the RCT were randomly allocated to an outpatient regular care group (RCG) and an outpatient regular care group with additional videoconference (VCG), in a one-year follow-up. The patients were recruited between 2016 and 2019. Main outcome in the RCT was HRQoL, calculated from the EQ-5D-5L, the SF-36 and the international spinal cord injury quality of life basic data set. The percentage change in ulcer volume from baseline to end of follow-up was used to monitor the healing. Experienced satisfaction, safety and patient-empowerment were collected at end of follow-up.
The CUA compared the costs and outcomes of RCG and VCG. The outcome measure was quality-adjusted life years (QALYs), derived from the generic questionnaire EQ-5D-5L. The results were presented as an incremental cost-effectiveness ratio (ICER), which is the

difference in costs between the two groups, divided by the difference in effects (QALYs). HRQoL were collected at baseline and end at end of study, while costs were collected at each consultation. Transportation costs and greenhouse gas emission were calculated at each consultation.

Results The cross-sectional study included 1012 eligible individuals, 742 men (73%) and 270 women (27%). Mean age at injury was 48 years (standard deviation [SD], 19 years). The period prevalence of PI in the population was 16% (95% confidence interval [CI], 0.14–0.19). Identified associations with PI were completeness of the SCI (odds ratio [OR] = 0.1), being injured abroad (OR = 2.4), bowel dysfunction (OR = 13), bladder dysfunction (OR = 9.2), comorbidity, e.g. diabetes mellitus type 1 (OR = 7.9), diagnosed depression (OR = 3.8) and concurrent traumatic brain injury (OR = 1.7), need for ventilator support (OR = 3.0) as well as drug abuse (OR = 3.0). Individuals aged 15–29 years had higher odds of PI compared with middle-aged individuals (45–59 years). There were 56 participants included in the RCT, 28 in each group. Of these 27 participants in the VCG and 26 in the RCG completed the study. Three participants died. The results showed no significant differences in HRQoL in the two groups (*P* values ranged from 0.09 to 0.88), or PI healing (p= 0.32). A Kaplan-Meier plot with a log-rank test regarding time to healing did not show any significant difference between the two groups. No significant differences were found regarding experienced satisfaction, safety or patient-empowerment.

The CUA estimated a mean cost of € 8819 per patient in the VCG and € 3607 in the RCG, with 0.1 QALYs gained in favour of the VCG. The ICER was € 52 120 per QALY gained. No significant differences were found regarding transportation costs or emission of greenhouse gases in the two groups.

Conclusion The period prevalence of PI during acute care rehabilitation after SCI in Norway was 16%. Several risk factors were identified as having an impact on the odds of acquiring a PI. No significant differences were identified in the two groups in the RCT in terms of HRQoL, healing, satisfaction, safety or patient-empowerment. The VCG costs € 5212 more for an additional 0.1 QALYs, giving an ICER of € 52 120 per QALY. No significant differences were found regarding transportation related costs, or emission of greenhouse gases in the two groups.

SAMMENDRAG

Bakgrunn Forekomsten av trykkskader blant personer med en nylig ervervet ryggmargskade (RMS) i Norge er ikke kjent. Det foreligger heller ikke kunnskap om risikofaktorer for utvikling av trykkskader i populasjonen. Begrensninger og utfordringer knyttet til reisevei, klima og kostnader kan påvirke oppfølgingstilbudet til personer som er avhengige av langtidsoppfølging fra spesialisthelsetjenesten på grunn av trykkskader. Det er behov for å finne nye, tilfredsstillende og trygge måter å tilby oppfølging på.

Mål med studien I artikkel I var hovedmålet å undersøke forekomsten av trykkskader. Sekundærmål var å undersøke faktorer som kan påvirke utviklingen av trykkskader under primær-rehabiliteringsoppholdet i den norske populasjonen av personer med ryggmargsskade (RMS).
Artikkel II var en randomisert kontrollert studie (RCT) der hovedmålet var å evaluere helserelatert livskvalitet (HRQoL) til pasienter med RMS og trykkskader som fikk ulike polikliniske oppfølgingstilbud. Sekundærmål var kartlegging av sårtilheling og deltagernes opplevelse av tilfredshet, trygghet og brukermedvirkning i de to gruppene.

I artikkel III utførte vi en kostnad-effekt analyse (KEA) med utgangspunktet i en RCT, med kvalitetsjusterte leveår (QALYs) som effektmål. Sekundærmål var å undersøke transportrelaterte kostnader og utslipp av drivhusgasser i gruppene.

Metode Periodisk prevalens av trykkskade, samt risikofaktorer for trykkskadeutvikling ble undersøkt retrospektivt. Epidemiologiske data ble innsamlet fra den elektronisk pasientjournalen til alle som pådro seg ryggmargskade i tidsrommet 2004 til 2014, og som ble innlagt til primærrehabilitering ved en av de tre norske spinalenhetene.

Pasientene i RCT'en fikk enten tradisjonell poliklinisk behandling (RCG) eller tradisjonell poliklinisk behandling supplert med videokonferanse konsultasjoner (VCG), i et tidsperspekiv på ett år. Pasientene ble rekruttert i perioden 2016 til 2019. Hver deltager ble fulgt opp til trykkskaden var tilhelet eller i maksimalt 12 måneder. I studien ble det gjort en sammenligning av HRQoL og sårtilheling i de to gruppene. Helserelatert livskvalitet ble målt ved hjelp av de to generiske instrumentene, EQ-5D-5L, SF-36, samt spørreskjemaet fra «The International Spinal Cord Injury Quality of Life Basic Data set» ved start og studieslutt.

Prosentvis endring i sårstørrelse fra start til studieslutt ble brukt for å monitorere sårtilheling. Tilfredshet, trygghet og brukermedvirkning i oppfølgingen ble registrert ved studieslutt.

Vi utførte en kostnad-effektanalyse (kostnad-per-QALY analyse) som sammenlignet kostnader og effekter mellom de to behandlingsalternativene, i et helsetjenesteperspektiv. Effektmålet i analysen var kvalitetsjusterte leveår (QALYs), basert på spørreskjemaet EQ-5D-5L. QALYs kombinerer tid levd i en tilstand med den helserelaterte livskvaliteten, omregnet til en indeksverdi (mellom 0-1), som gjør at man kan sammenligne effekten mellom de to gruppene. Resultatet er presentert som en IKER (inkrementell kostnadseffektivitets ratio), som er forskjellen i kostnader mellom de to gruppene, delt på forskjellen i effekt (QALYs). HRQoL ble innhentet ved baseline og oppfølgingsslutt, dog ikke senere enn 12 måneder etter baseline. Kostnader ble innhentet ved hver konsultasjon. Transportkostnader og utslipp av drivhusgasser ble registrert ved hver konsultasjon.

Resultat Tverrsnittstudien inkluderte 1012 personer, 742 menn (73 %) og 270 kvinner (27 %). Gjennomsnittsalder ved ryggmargsskade var 48 år (standardavvik [SD], 19). Periodisk prevalens av trykkskade var 16 % (95 % konfidensintervall [KI] = 0.14- 0.19). Trykkskadeassosiasjoner var komplett ryggmargskade (Odds ratio [OR]= 0.1), ryggmargskade ervervet utenfor Norge (OR= 2.4), funksjonsforstyrrelser i tarm (OR= 13) og blære (OR= 9.2), samt komorbiditet som diabetes mellitus type 1 (OR= 7.9) og diagnostisert depresjon (OR= 3.8). I tillegg var det økt odds for trykkskade om ervervet ryggmargsskade og samtidig traumatisk hjerneskade (OR= 1.7). Behov for ventilasjonsstøtte økte også oddsen for trykkskade (OR= 3.0), det samme gjorde regelmessig misbruk av vanedannende/ illegale preparater (OR= 3.0). Personer i aldergruppen 15- 29 år hadde høyere odds for trykkskade, sammenlignet med gruppen av middelaldrende (45- 59 år).

Femtiseks deltakere ble inkludert i den randomisert kontrollerte studien, 28 i hver av gruppene. Av disse fullførte 27 deltagere i VCG og 26 deltakere i RCG. Tre pasienter døde. Det ble ikke funnet noen signifikant forskjell i helserelatert livskvalitet i de to gruppene (p-verdier mellom 0.09 og 0.88). Det ble heller ikke funnet noen signifikant forskjell mellom gruppene med hensyn til sårtilheling (p= 0.32). Et Kaplan-Meier plot med log-rank test for tid til tilheling, viste ingen signifikant forskjell i de to gruppene. Det ble ikke funnet signifikante forskjeller vedrørende tilfredshet, trygghet eller brukermedvirkning i gruppene.

KEA estimerte en gjennomsnittskostnad på € 8819 per pasient i VCG og € 3607 i RCG, med en forskjell på 0.1 QALYs i favør VCG. Dette resulterte i en IKER på € 52 120 per QALY.

Det ble ikke funnet noen signifikante forskjeller mellom gruppene når det gjaldt transportkostnader, eller utslipp av transportrelaterte drivhusgasser.

Konklusjon: Periodisk prevalens av trykkskader i løpet av primæroppholdet etter ryggmargskade var 16%. Flere risikofaktorer som påvirker oddsen for å pådra seg en trykkskade ble funnet. Det ble ikke funnet signifikante forskjeller mellom de to oppfølgingsgruppene i den randomisert kontrollerte studien når det gjaldt HRQoL, tilheling, tilfredshet, trygghet eller brukermedvirkning. Kostnad-per QALY analysen vist at VCG kostet € 5212 mer, og gav en økning på 0.1 QALYs når VCG ble sammenlignet med RCG. Dette medførte en IKER på € 52 120 per QALY. Det ble ikke funnet signifikante forskjeller i transportrelaterte kostnader eller utslipp av drivhusgasser i de to gruppene.

ABBREVIATIONS

AIS	American Spinal Injury Association (ASIA) Impairment Scale
ANOVA	Analysis of variance
ASIA	American Spinal Injury Association
C	Cervical segments of the spinal cord
CE-plane	Cost-effectiveness planeCEAC Cost-effectiveness acceptability curve
CI	Confidence interval
CUA	Cost-utility analysis
EMR	Electronic medical record
EQ-5D-5L	European Quality of Life 5 Dimensions 5 Level Version
HRQoL	Health-related quality of life
ICER	Incremental cost-effectiveness ratio
ICF	International Classification of Function and Disability
ISCI-QoL-BDS	International Spinal Cord Injury Quality of Life basic dataset
L	Lumbar segments of the spinal cord
N/n	Number
NTSCI	Non-traumatic SCI
OR	Odds ratio
QALYs	Quality-adjusted life-years
QoL	Quality of life
PI	Pressure injury
PU	Pressure ulcer
RCT	Randomized controlled trial
S	Sacral segments of the spinal cord
SCI	Spinal cord injury
SCU	Spinal cord unit
SD	Standard deviation
SF-36	The Short Form (36) Health Survey
SPSS	Statistical Package for the Social Sciences
T	Thoracic segments of the spinal cord
TIMES	Tissue, infection, moisture, edge, surrounding skin
TSCI	Traumatic SCI
UN	United Nations
WHO	The World Health Organization

DEFINITION OF THE CENTRAL CONCEPTS

AIS A: complete injury. No sensory or motor function is preserved in the sacral segments S4-5.

AIS B: sensory incomplete. Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-5 (light touch or pin prick at S4-5 or deep anal pressure) AND no motor function is preserved more than three levels below the motor level on either side of the body.

AIS C: motor incomplete. Motor function is preserved at the most caudal sacral segments for voluntary anal contraction OR the patient meets the criteria for sensory incomplete status (sensory function preserved at the most caudal sacral segments S4-5 by light touch, pinprick or deep anal pressure), and has some sparing of motor function more than three levels below the ipsilateral motor level on either side of the body. Less than half of key muscle functions below the single neurological level of injury have a muscle grade ≥3.

AIS D: motor incomplete. Motor incomplete status as defined above, with at least half (half or more) of key muscle functions below the single neurological level of injury having a muscle grade ≥3.

AIS E: normal. If sensation and motor function as tested with the International Standards for Neurological Classification of Spinal Cord Injury are graded as normal in all segments, and the patient had prior deficits, then the AIS grade is E. Someone without an initial SCI does not receive an AIS grade.

Care at home (follow-up at home, treatment at home). Treatment performed via telemedicine solutions with the patient and the district nurses located in the patient's home and the specialized health care professionals at the outpatient clinic.

Cost-utility analysis (CUA). A calculation of the ratio between cost and effects, with quality-adjusted life years (QALYs) as the outcome. The QALYs captures both life years gained and improved health-related quality of life as a result of the treatment/intervention. The QALYs in the study was measured prospectively by using the questionnaire EQ-5D-5L. The result of the CUA are presented as an incremental cost-effectiveness ratio (ICER), interpreted as how much more an intervention cost per QALYs gained.

Evidence-based guidelines. Clinical practice guidelines developed by using research findings that have been graded for scientific strength.

HRQoL. Health-related quality of life (HRQOL) is an individual's or a group's perceived physical and mental health over time. Different scales are used to describe the HRQoL.

> **EQ-5D-5L.** EuroQuality of life, 5 dimensions, 5 labels. A self-rating form, comprises five dimensions of health, each with five labels of possible answers. Describes the patient's health state.
>
> **SF-36.** The 36-Item Short Form Survey is an outcome measure instrument regarding self-reported measure of health. It comprises 36 questions that cover eight domains of health.
>
> **ISCIQoLBDS.** The International Spinal Cord Injury Quality of Life Basic Data Set. Consists of 3 variables rated on a scale ranging from 0 (completely dissatisfied) to 10 (completely satisfied).

Paraplegia. Impairment or loss of motor and/or sensory function in the lower extremities due to damage of the neural elements within the thoracic, lumbar, or sacral segments of the spinal cord.

Pressure Injury. A localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction

Regular care. On-site consultations at the outpatient wound clinic, telephone consultations from the participant`s home to the wound clinic, and ambulatory visits to the patient`s home by the wound team.

Quality-adjusted life years (QALYs). See Cost-utility analysis (CUA).

Tetraplegia: Impairment or loss of motor and/or sensory function in all four extremities due to damage of the neural elements within the cervical segments of the spinal cord.

Video conference. Synchronous live, videoconferencing in real time, using a PC with camera at the wound clinic and a laptop with a mobile webcam at the patient's location. Encrypted communication channels are used to protect privacy of the participants.

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

Number	Text	Comments
1	Diagnoses with a potential for spinal cord injury	Used in paper I
2	The electronic medical record mapping form	Used in paper I
3	The pressure injury questionnaire	Used in relation to papers I and II
4	The multidisciplinary wound record form	Used in paper II
5	The cost assessment form	Used in paper III
6	The satisfaction form	Used in paper II
SUPPLEMENTARY MATERIALS		
1	The Consolidated Standards of Reporting Trials (CONSORT) guidelines	Included in Paper II
2	The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)	Included in Paper II
3	The Template for Intervention Description and Replication (TIDieR) checklist and guide	Included in Paper II
1	Identification, valuation and quantification of the different cost elements used in the cost-utility analysis	Included in paper III
2	Resource use, total consultations and mean costs (including direct and indirect cost) in both groups	Included in paper III
3	Number of consultations and personnel in both groups	Included in paper III
4	Comparison of the accurate transportation costs in the two groups	Included in paper III
5	A modelled scenario comparing the transportation costs in videoconference consultations only, and on-site consultations only	Included in paper III

1. INTRODUCTION

People who acquire a spinal cord injury (SCI) [1] are faced with a wide range of functional concerns and limitations [2, 3]. Pressure injury (PI) [4] contributes to further loss of function and is a cause of readmission to hospital after discharge from acute care rehabilitation [2, 5-7]. Thus, the availability and quality of the medical care offered should include effective follow-up, meeting the needs of the person regarding equality of the health care service provided and regardless of the geographic location of the health care receivers and providers [8-14]. Transportation can worsen the condition, or even cause new PIs to develop. Further, financial implications related to transportation can be a barrier to receiving the necessary treatment [2, 5, 15]. In this setting, remote PI follow-up at home via telemedicine represents an innovative method of delivering treatment, preventative measures, and self-care rehabilitation for the person in need of specialized health care service, and may also contribute to local health care provision [9]. This facilitates nationwide, equal health care services with proper treatment at the right place and the right time.

There is a lack of knowledge regarding pressure injury (PI) occurrence and follow-up in the Norwegian population of people with spinal cord injury (SCI). The current thesis reports on epidemiologic findings of a retrospective cross-sectional study regarding the occurrence of PI and risk factors associated with PIs in people with an SCI. Further, the thesis presents the results of a randomized controlled trial (RCT) focusing on health related quality of life (HRQoL) in people living with a PI, healing of the PI and the cost-utility when an additional treatment is implemented in the follow-up. An investigation of telemedicine as a method of offering effective treatment at the right place and the right time, interaction with the patient and the district nurses in the process, as well as efficient use of outpatient health care services has been emphasized [16].

In the following chapters, gaps in the current knowledge are recognized. A framework and aims for the thesis are provided, including clarifications of the terms used and the background information needed to establish a theoretical basis and the clinical motivation for the study. The methods and results are described, followed by a discussion of the findings and implications for future research.

2. BACKGROUND

The goals of rehabilitation are to optimize the functional level and reduce disability in individuals with health conditions in interactions with their environment [17]. The World Health Organization (WHO) summarizes that “rehabilitation services should be integrated into and between primary, secondary and tertiary levels of health systems and a multidisciplinary rehabilitation workforce should be available. Further, financial resources should be allocated to rehabilitation services to implement and sustain the recommendations on service delivery” [17, 18]. SCI is a complex condition that requires close interaction between health care professionals and the individual to be able to identify and map problem areas, and set goals for treatment and rehabilitation. Complicating conditions, such as PI, demand even more interaction [2, 6, 19-23].

2.1. Rehabilitation

Rehabilitation is defined as “a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment” [18].

The goals of rehabilitation are to improve the functional level, decrease secondary morbidity and enhance health-related quality of life [18]. The International Classification of Functioning, Disability and Health [24], more commonly known as the ICF model (Figure 1), is the WHO’s contextual framework for measuring health and disability at both individual and population levels. The model focuses on body impairments related to the condition and on limitations in activity and restrictions in participation, involving personal and environmental factors affecting the outcome [25] (Figure 1).

Rehabilitation supports the individual to become as independent as possible regarding everyday activities. Rehabilitation enables participation in education, work, leisure time and important life roles, such as family care, by addressing underlying conditions, such as PI, improving the individual’s everyday functioning, adjusting for limitations, and supporting the individual to master difficulties, e.g. moving around [18]. The ICF framework conceptualizes functioning as a “dynamic interaction between a person's health condition, environmental factors and personal factors” [24]. Here, the ICF framework is used to demonstrate new and innovative ways of interaction and cooperation between the patient, specialized health care providers and local district nurses regarding health-related quality of life (HRQoL) and PI treatment.

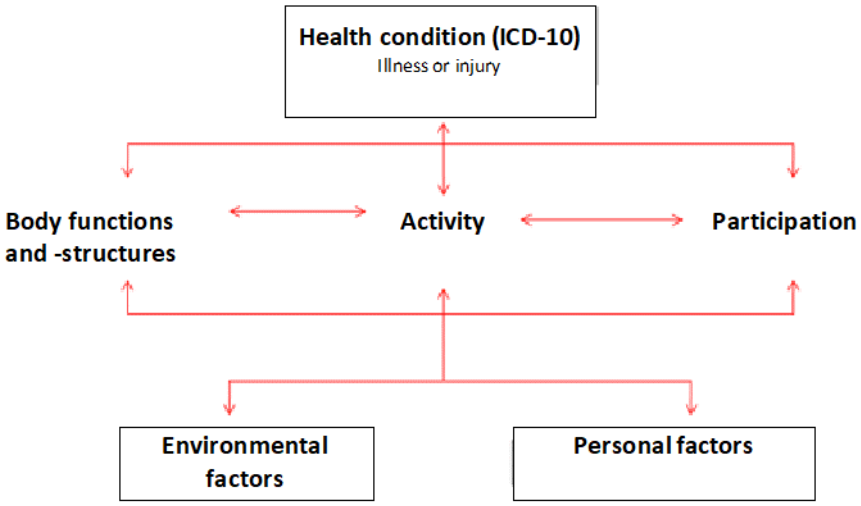


Figure 1. The International Classification of Function model. The World Health Organization's International Classification of Functioning is a tool to map health and disability in a contextual framework. Reproduced from the European Commission-europa.eu, 2021 [18].

2.1.1. ICF in a multidisciplinary approach

In Norway, spinal cord units (SCUs) have the responsibility for life-long follow-up for individuals with SCI [26, 27]. Post-injury rehabilitation involves a multidisciplinary approach, involving the appropriate professionals needed for specific issues [28, 29], such as the multidisciplinary wound care team, focusing on healing and prevention of PIs. Norrfalk [29] summarize multidisciplinary team work as activities that involve the efforts of individuals from a number of disciplines. These efforts are disciplinary-orientated and, although they may impinge upon clients or activities dealt with by other disciplines, they approach them primarily through each discipline relating to its own activities [30]. The approach involves timely and anticipatory communications, engaging in interactive problem solving, and ability to translate technologic findings to people who are untrained in the techniques that are used.

When pressure damage has occurred, measures must be taken to limit the scope and the PI heals. Having the necessary knowledge and competency allows care providers to take care of the consumer's needs, treat and guide them, as well as guide colleagues. All health care professionals who see naked skin must be able to recognize the red marks that indicate that a PI is developing, and relevant professional groups must be familiar with the general procedures for evaluating and treating PIs. The ICF model assists the multidisciplinary team in conducting good, comprehensive mapping and assessment of SCI and PI factors. This

applies to both positive and limiting factors and provides insight into potential issues that contribute to PIs. Local health care providers, such as district nurses, are also part of the rehabilitation process and are involved in rehabilitation from an early stage. However, there is a lack of knowledge regarding organization of collaborative care, at least in the Norwegian population of people with SCI and PI. In the current study, the ICF framework is used to define and limit the actions required to manage and optimize PI follow-up in those with SCI (Figure 2).

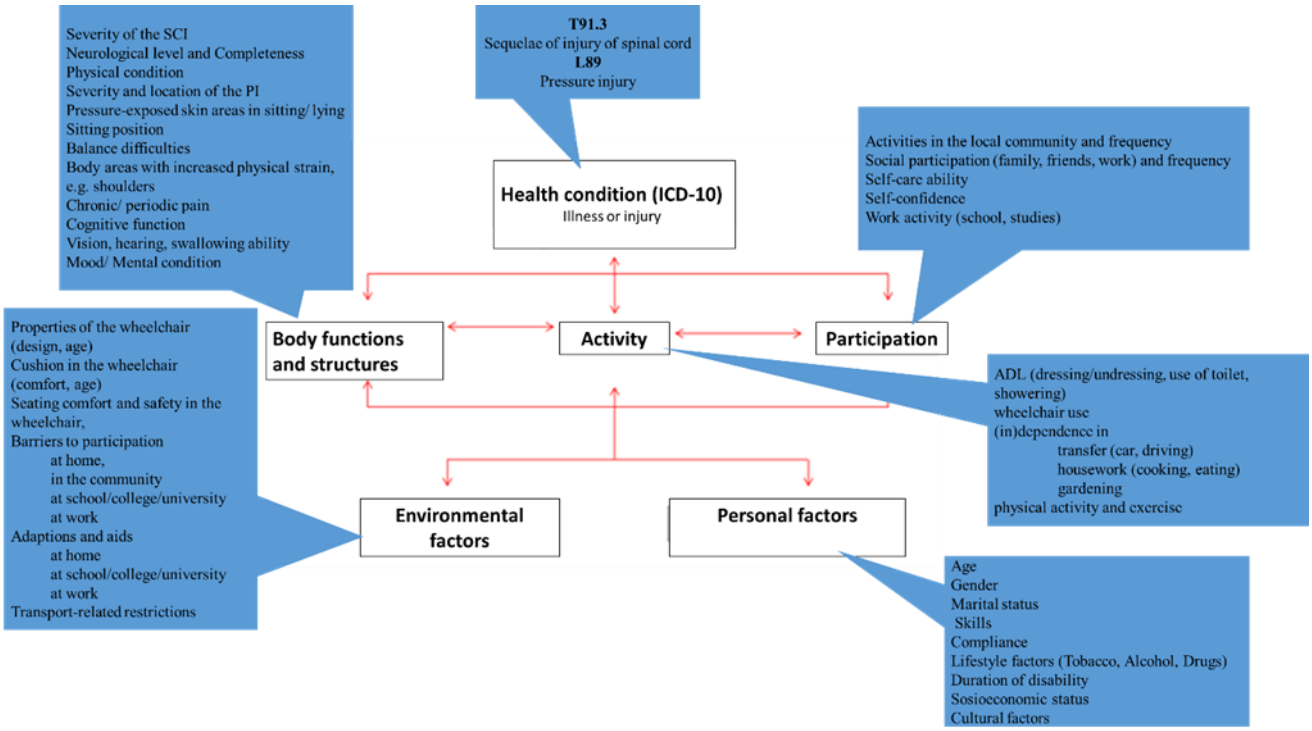


Figure 2. The International Classification of Function framework used to focus on cooperation between the multidisciplinary wound care team, the local care providers and the patient in the follow-up of spinal cord injury (SCI) and pressure injury (PI). Reproduced from the European Commission-europa.eu, 2021 [18], and modified by the author, 2022.

2.2. Spinal cord injury

2.2.1. Definition and classification

SCI is temporary or permanent damage in motor, sensory, and/or autonomic function below the site of an injury to the spinal cord [1]. The damage may be traumatic due to falls, traffic accidents, occupational and sports accidents, or non-traumatic, due to underlying pathology such as infection, arteriosclerotic disease, a tumour or degeneration [25].

The cervical (C) segments are C1 to C8, the thoracic (T) segments T1 to T12, the lumbar (L) segments L1 to L5 and the sacral (S) segments S1 to S5. The higher up the spinal cord the lesion occurs, the more extensive the range of impairments will be. An injury to the spinal cord at the cervical segments will cause tetraplegia, resulting in sensory and motor loss (paralysis) in the arms, trunk and legs below the site of the spinal damage. An injury from segment T1 and below will cause paraplegia, resulting in sensory and/or motor loss in the trunk and legs [25] (Figure 3). Injury in the sacral segments will interfere with bowel, bladder and sexual function. If the injury is above the sixth thoracic segment, autonomic control will be impaired, affecting the cardiovascular and bronco-pulmonary systems, as well as urinary, gastrointestinal, sexual, and thermoregulatory functions [32].

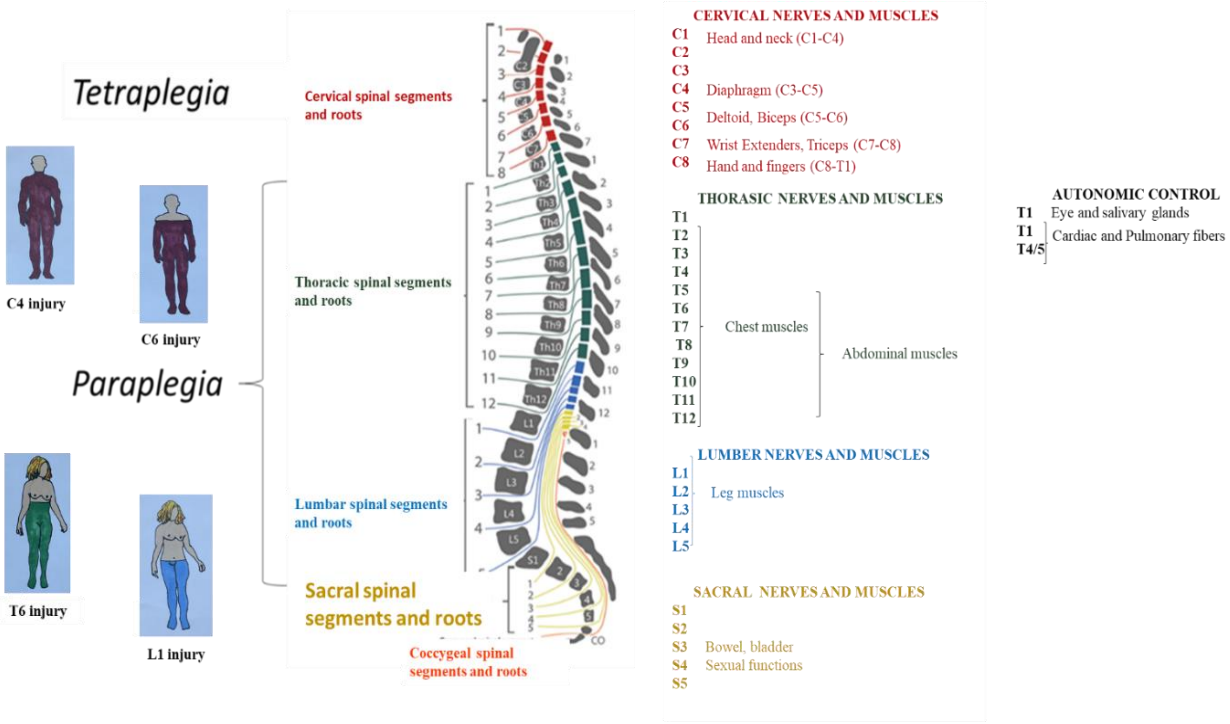


Figure 3. The human spinal cord. Neurological segments, roots, and muscles according to the different segments. Reproduced from CompatCath and NeuroGen Brain & Spine and modified by the author.

An international classification for the level and severity of SCI has been developed [33-35]. The motor function in five key muscles in the upper limbs, together with five key muscles in the lower limbs, determines the motor impairment. Sensory impairment is determined by the ability to identify touch and pain in all segments of the body. However, the sensory function in the two lower sacral segments determines whether the injury is sensory complete (no sensation) or incomplete (some sensation). Even though some sensory or motor function,

including the sacral segments S4-S5, may be preserved below the level of injury in incomplete SCI, the SCI is no less serious and can still result in severe impairments [33]. The recommended international classification is used to describe the severity of SCI in this thesis.

2.2.2. Incidence and prevalence

The number of individuals living with an SCI is estimated to be about 27.04 million (confidence interval [CI], 24.98 to 30.15 million) [36]. In 2012, the number of individuals living with SCI in Norway was estimated to be between 1500 and 2500 [37]. However, the actual number of individuals with non-traumatic SCI (NTSCI) is not known, because unlike people with traumatic SCI (TSCI), acute rehabilitation after NTSCI is less well defined [26]. Table 1 shows the incidence and characteristics of those who sustain an SCI globally and in Norway.

Table 1. Incidence and characteristics of those who sustain a spinal cord injury globally and in Norway

	Globally	**Norway**	
		TSCI	**NTSCI**
Incidence per year	5 to 196 per million population	11.4 to 15.9 per million person-years	7.7 to 10.4 per million persons-years
Number per year	250 000 to 500 000	100 to 120 according to the Norwegian Spinal Cord Registry	
Male-to-female ratio	About 2:1 (adults)	3:1	3:2
Age at injury (years), mean (SD)	43 years	47 (19)	55 (17)

Data from refs. [6, 36, 38-40].

TSCI, traumatic spinal cord injury; NTSCI, non-traumatic spinal cord injury; SD, standard deviation.

2.3. Pressure injury

2.3.1. Definition and categorization

Several different terms are used to describe pressure-related damage to the skin or the underlying tissue: pressure ulcer, pressure soar, bed soar and decubitus. However, the term

pressure injury (PI) is recommended to cover all aspects of the condition [21]. The definition of PI is as follows:

> A pressure injury is a localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction [4].

PIs are categorized with numbers from 1 to 4, depending of the severity of the tissue damage. There is also an unstageable category and one category with suspected deep tissue damage (Figure 4) [4, 41].

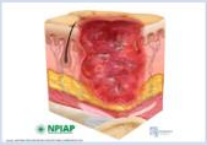
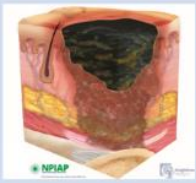
Categorization	Description	Illustration
1	Intact skin with non-blanchable redness of a localized area. Darkly pigmented skin may not have visible blanching, but it`s color may differ from the surronding skin.	
2	Partial thickness loss of dermis, presenting as a shallow open wound with a red/ pink wound bed, without slough. It may also present as an intact or open/ruptured serum-filld or serosanguineous blister.	
3	Full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon or muscle are not exposed. Some slough may be present. Undermining and tunnelling may be included.	
4	Full thickness tissue loss with exposed bone, tendon or muscle. Sloughe or eschar may be present. Undermining and tunnelling are often included.	
Unstagable	Full thickness tissue loss in which actual depth of the wound is completely obscured by slough and/or eschar in the wound bed.	
Suspected Deep Tissue Injury	Purple or maroon localized area of discolored, intact skin , or blood-filled blister due to damage of underlying tissue due to pressure and/or shear.	

Figure 4. Categorization of pressure injuries, according to the European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2019 [4]. Illustrations are reproduced with permission from NPIAP.

SCI causes disability and associated conditions, including PI [2, 6, 25, 38, 42]. These consequences do not result from the condition but from inadequate medical care and rehabilitation services, from barriers in the physical and social environments, as well as barriers within the rules and regulations regarding rehabilitation [25]. Common conditions experienced by people with SCI include neurogenic bladder and bowel dysfunction, spasticity, metabolic and cardiovascular disorders, which may contribute in the development of PIs [25]. Treatment and prevention of associated conditions are important, because they affect the well-being, self-esteem, self-management and HRQoL of individuals with SCI [2, 3, 6, 36, 42-46].

2.3.2. Spinal cord injury and pressure injury

PI is a common and feared complication associated with many conditions, including SCI (Figure 5) [19, 47-49]. In 2013, a systematic review concluded that overall, there is no single factor that can explain the risk of PI, but rather a complex interplay of factors that increase the probability of the development of a PI [22]. The risk factors have been summarized as follows:

> Some intrinsic risk factors are diseases and illnesses, like spinal cord injury, diabetes mellitus, vascular disease, renal failure and hearth disease, as well as factors like smoking, malnutrition and some medication, like immunosuppressive drugs. Prolonged immobility and contractures are other intrinsic factors, while extrinsic risk factors are hardness of the surface the person is lying on, e.g. the hardness of the mattress, poor skin hygiene, lack of fitting of prostheses and orthoses, lack of educated personnel at nursing homes, and compliance of the person at risk [50].

Paralysis, with varying degree of loss of skin sensation, combined with loss of underlying muscle mass and loss of protection against external pressure, increase the risk of developing skin wounds. This constitutes a threat to individuals with SCI. Moisture makes the conditions even worse [6, 51, 52]. Many direct and indirect risk factors are described [20, 22, 53], Figure 5 shows some of the known risk factors for the development of a PI, but there is a lack of knowledge regarding the occurrence of these factors and their contribution to the development of PI in the Norwegian population of people with SCI.

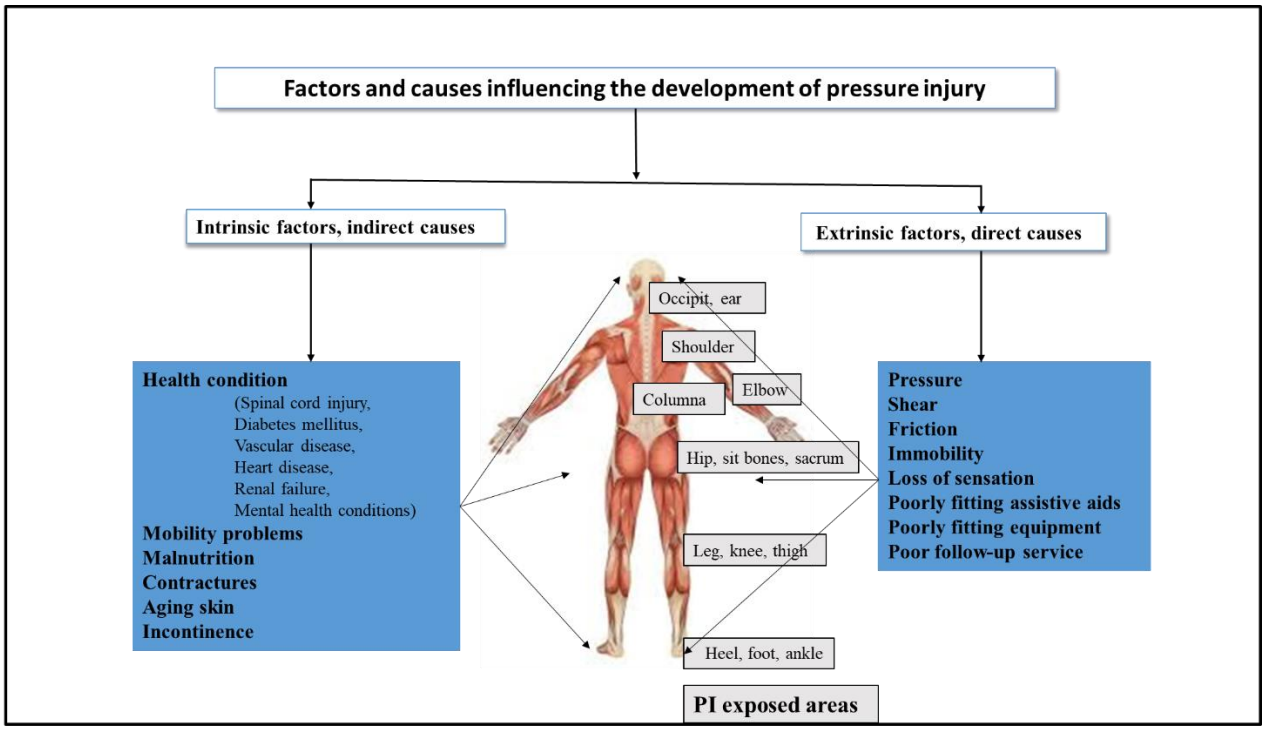


Figure 5. Factors and causes contributing to the development of pressure injury. Illustration from Boyko, TV. et.al. [50].

The global incidence of PI among individuals with SCI is unknown; the prevalence varies between 35% and 80% [6, 54]. Studies have found the prevalence of PIs in acute care hospitals in Norway to be about 18%, and the occurrence in home care and nursing homes varies between 16% and 48% [55-57]. However, the total percentage of those who develop such wounds is most likely higher, especially in high-risk groups, such as individuals with SCI, patients with hip fracture and patients in the intensive care unit [6, 22, 42, 51, 52, 54, 56-58]. The incidence and prevalence of PIs in the Norwegian population with SCI is not known [59]. Better knowledge of the occurrence of PI among people with SCI in Norway is important to get information on the severity of the condition to help plan for better follow-up for this group of people in the future.

2.4. The cost of pressure injury

Previous research regarding the costs associated with PIs are inconsistent regarding the indicators used in the different studies [60, 61], thus, there are few studies that can reliably provide comparable costs [62]. Research indicates that the costs associated with the condition are considerable [6, 60, 63], but there seems to be a lack of updated information on the costs

of PIs among those with SCI [36, 64]. In addition to the financial impact, PIs also affect patient morbidity, mortality, and HRQoL [21, 36, 44, 52, 65]. Early treatment can shorten the duration and the costs, and thus contribute to economic and human savings [61, 63-66]. We believe there is potential for improvement in the human and financial costs but there is a lack of knowledge regarding the consequences of PI follow-up among those with an SCI [59].

2.5. Telemedicine

2.5.1. Definition

Several names are in use for remote health care services, e.g. telemedicine, telehealth, mHealth and telerehabilitation. In this thesis, telemedicine is used to describe the technical and digital health service solutions used in remote follow-up. Telemedicine can be defined as

> The investigation, monitoring, and management of patients and education of patients and staff using systems, which allow access to expert advice and patient information, no matter where the patient or relevant information is located [67].

2.5.2. Digital solutions

Telemedicine involves the use of digital tools in health care services [68], and the solutions can be organized according to the performance of the service, as well as the modalities and technology in use (Figure 6).

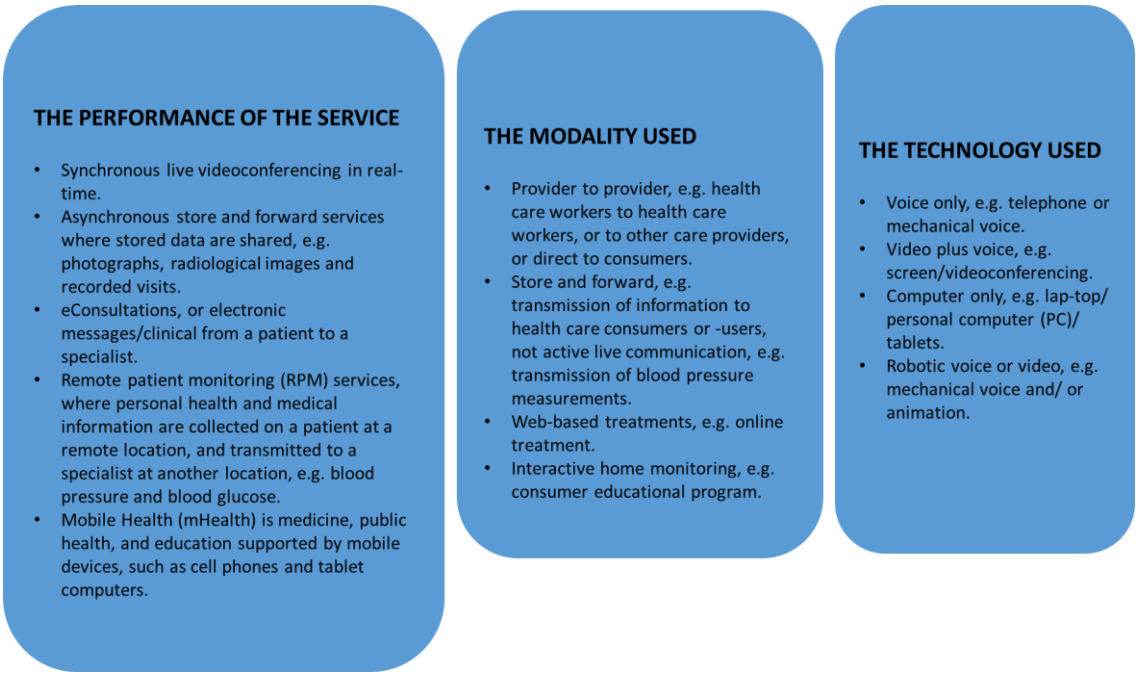


Figure 6. An example of how to organize the different telemedicine solutions in use.

In this thesis, additional synchronous real-time live videoconferencing between multidisciplinary health care providers at the SCU and patients and district nurses in the municipalities are investigated because there is a lack of knowledge on how this cooperation is working out in remote follow-up of people with SCI and PI [59]. There is a particular lack of knowledge regarding cooperation when the follow-up is organized with a focus on the patient. The specialized health professionals at the SCU and the district nurses develop an integrated, multidisciplinary culture that better captures the patient's needs with regard to activity and participation [24, 28], and as implemented in the Norwegian Coordination Reform [16]. This can be described as empowering the patient to be an active participant in handling their own condition through increased knowledge about the condition and treatment options [69-71]. However, there is a lack of knowledge on patient empowerment among those with SCI and PI [59].

2.5.3. Telemedicine follow-up and patient empowerment

Patient empowerment places great demands on the health care professionals and the organization of the health care services offered [69]. Telemedicine makes it possible to ensure interaction between all levels of care providers needed for successful long-term follow-up, and it enables the patient to be at the centre of the cooperation, because telemedicine solutions, e.g. videoconferencing, make provider(s)-to-patient and provider(s)-to-provider(s) interactions possible. People with SCI and PI are often hospitalized for long periods, and they need frequent outpatient care to treat and to monitor the PI [2, 42, 46, 51]. Some people have to travel long distances to get to a hospital and this can worsen their condition or cause new ulcers to develop [5]. Videoconferencing is a suitable tool to include in the ICF framework regarding PI follow-up [68, 72-77]. By using videoconferencing, the multidisciplinary team at the SCU can be involved in remote visits in the patient's home to treat and guide, as well as educate the patient and the district nurses in PI prevention [68]. Remote videoconference follow-up regarding PI issues can facilitate involving the patients in the decision-making and management of their condition to a greater extent, giving them more choice and control over their own health and care [70, 71]. There is a lack of knowledge regarding such cooperation, therefore this study focuses on patient empowerment.

2.5.4. Telemedicine and the coordination reform

The Norwegian coordination reform states that appropriate treatment at the right place and at the right time should be provided through comprehensive and coordinated health care services

that are adapted to the individual consumer [16]. Good quality treatment involves safe and secure services that are effective, coordinated and interact. The patients have the possibility to be engaged in and have an influence on their own treatment, and the health and care resources are utilized in a proper manner. In addition, the health care service should be available and fairly distributed [69, 78]. The Norwegian Minister of Health and Care emphasized this in the Annual Hospital Speech in 2015:

> I expect managers to use all available sources to understand the quality of the service for which they are responsible, and to take action to improve the quality where necessary. This applies to both patient-experienced quality, as well as to the quality of the health care service offered. Further, it applies to an efficient consumption of the service [79].

2.5.5. Telemedicine and costs

Some research has been published regarding telemedicine and costs [80-83]. However, there is a lack of studies looking into cost-utility outcomes related to remote PI follow-up for people with SCI [84]. Further, it is not possible to direct compare previous results due to inconsistent use of indicators in previous studies on telemedicine [22, 62, 68, 82, 83, 85]. Jennett et al. highlighted a lack of consistency in the use of socio-economic indicators in previous research, making comparison of the different studies difficult, although the results seem to favour telemedicine solutions [62]. In this project, we wanted to investigate the financial aspects of offering telemedicine as a treatment option, focusing on existing cost-utility evidence and knowledge in the data collection and analyses, and reporting the results in compliance with recommended health economic standards [86].

2.5.6. Telemedicine and sustainability

People with SCI need to be cognizant of the resources they have available to manage their health and activities of daily living [87]. Telemedicine follow-up services can help maintain a person's ability to take an active role after discharge from the SCU. Living in the community is an important concept regarding these activities, provided that adequate and appropriate assistance is available [25, 87]. Telemedicine is an environmentally friendly, patient friendly and cooperation friendly tool in health care. Digital technology, such as telemedicine, also has a high political priority as a strategy to achieve the Sustainability Development Goals set by the United Nations [88-90]. Telemedicine follow-up can provide good cooperation and a proper health care service, no matter the geographic location of the person receiving the service [16, 27, 68, 72, 84, 91]. Remote follow-up allows people living in rural areas or areas

at a distance from the nearest specialized hospital to receive health care, without environmental pollution through transportation-related emissions, at least as long as people have access to digital technology [92]. It is reported that as many as 5.3 billion (67%) of the global population (7.9 billion) are unique mobile users, 4.9 billion (62%) are internet users, and 4.6 billion (58%) are active on social media [92]. The global urbanization rate is 57%, indicating that 43% of the population in the world live in more or less rural areas [92], many of them with limited access to health care services and facilities [93]. Thus, this study investigates how to facilitate proper knowledge transfer, prevention and treatment despite distance, geographic or climatic barriers, and to contribute to proper use of the health care and environmental resources [16, 83, 93].

2.6. Knowledge gaps and rationale of this thesis

The number of people with SCI and PI in Norway and the effect of PI on the well-being and HRQoL in the population are unknown. Further, no studies have been performed to increase our knowledge about the risk factors and their contribution to the development of PI in the population.

There are no studies on the use of telemedicine for the long-term follow-up of people with SCI and PI focusing on HRQoL and healing, and knowledge is missing regarding interactions and cooperation between the patient and the health care providers.

In Norway, there is no knowledge regarding the costs and human outcomes of telemedicine follow-up of people with SCI and PI.

These knowledge gaps have contributed to the rationale and aims of this study project.

3. AIMS OF THE STUDY

Based on the knowledge gaps and the rationale of this thesis, the overall aim of the project was to explore the period prevalence and potential risk factors for PI and to investigate the efficiency, applicability and cost-utility of telemedicine in the treatment of PI.

The aims addressed in the three papers of this thesis are as follows:

Paper I: To explore the period prevalence of PI and potential risk factors for PI in individuals with a newly acquired SCI during the period between admission to and discharge from the Norwegian SCU in the time period 2004 to 2014.

Paper II: To study the effect of videoconference in addition to regular care, compared to regular care in the treatment of PI, in terms of HRQoL and healing, patient empowerment and satisfaction with the follow-up.

Paper III: To evaluate the cost-utility of videoconference in addition to regular care, compared to regular care alone. Comparison of the transport related costs and environmental impact of the treatment were secondary outcomes.

4. MATERIALS AND METHODS

The thesis consists of two studies, from which three papers have been generated. Study 1 is a retrospective, cross-sectional study on people who acquired a TSCI or NTSCI between 2004 and 2014 and had their acute rehabilitation at one of the three SCUs in Norway. Study 2 is a randomized controlled trial (RCT), consisting of a selection of participants from study 1 plus participants identified via the outpatient wound clinics at two of the three SCUs. A cost-utility analysis (CUA) was conducted alongside the RCT. The cross-sectional study has generated paper I, and the RCT generated papers II and III. Details regarding the materials and methods used in the overall research project are provided in this chapter. Figure 7 shows the flowchart of the two studies and their papers.

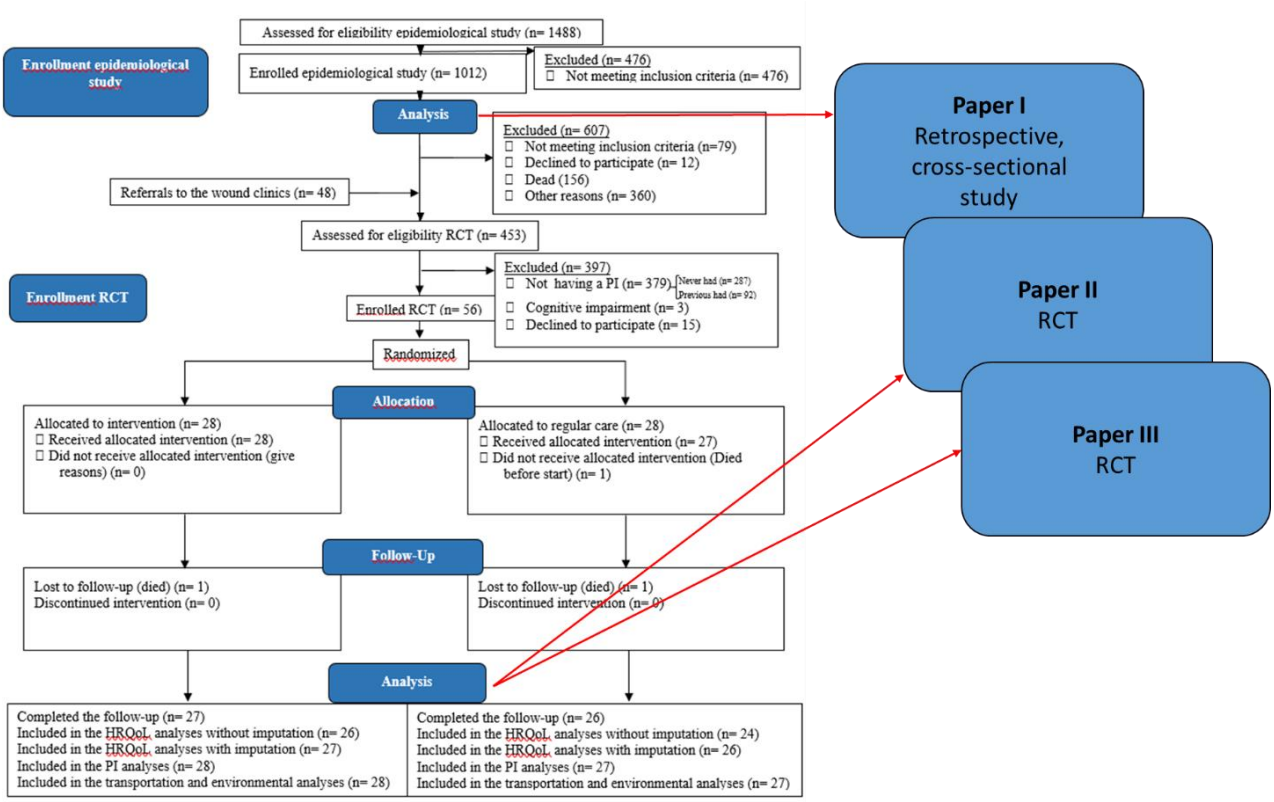


Figure 7. The CONSORT 2010 flow diagram [94] of the study and the analyses used in the three papers included in the thesis. HRQoL, health-related quality of life; PI, pressure injury; RCT, randomized controlled trial.

4.1. Study design

Data for this this thesis were extracted from the Norwegian SCUs, located at Haukeland University Hospital in Bergen, St. Olav's University Hospital in Trondheim, and Sunnaas Rehabilitation Hospital, near Oslo (paper I) and from Haukeland University hospital and Sunnaas Rehabilitation hospital (Paper II and III). Figure 8 gives an overview of the design in the three papers in the thesis.

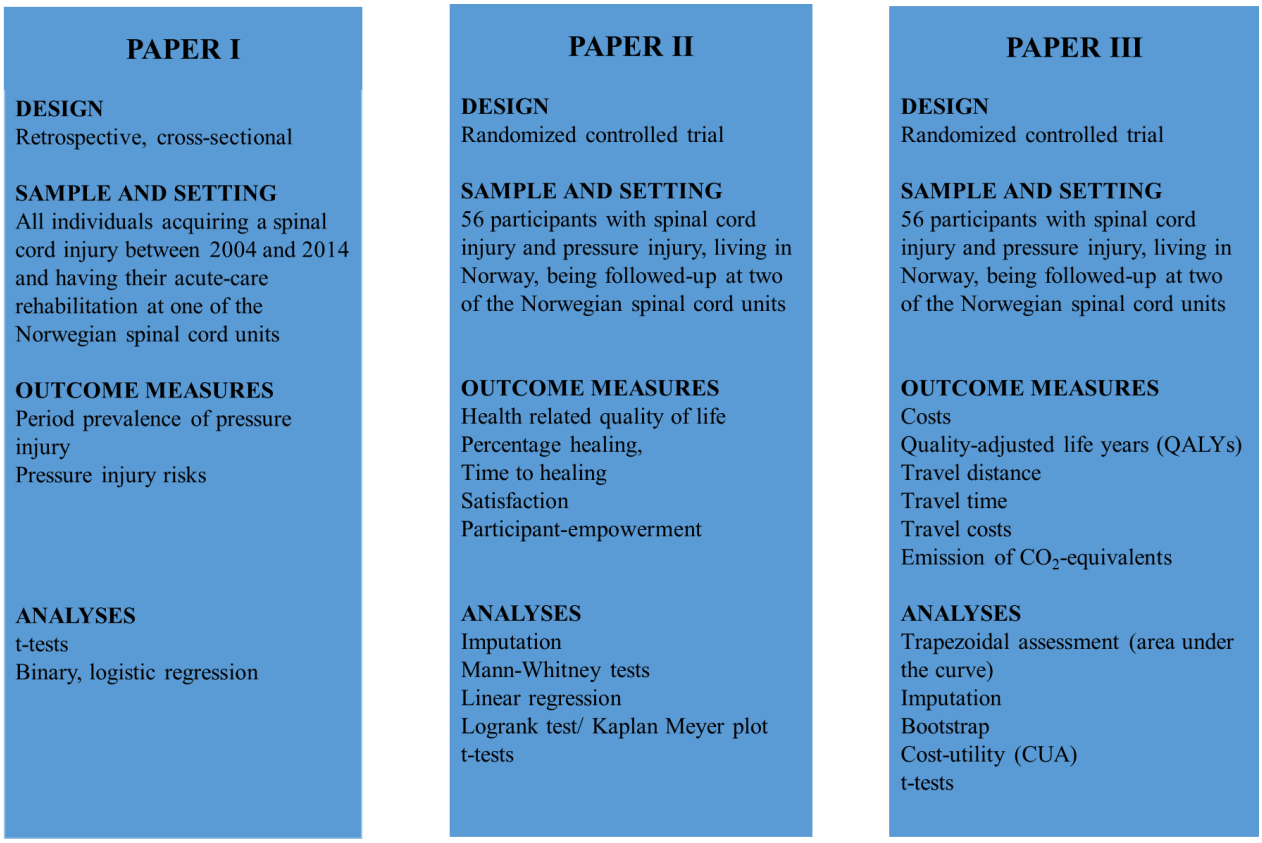


Figure 8. Overview of the design, settings, samples, outcome measures and the main analyses in the cross-sectional study (paper I) and the randomized controlled trial (paper II and III).

In paper I, a national cross-sectional study was conducted to identify the number of individuals with SCI and PIs, as well as to identify characteristics associated with the development of PI in individuals hospitalized with acute SCI in the Norwegian population. The time period examined was from 1 January 2004 to 1 January 2014. The acute rehabilitation period is defined as the continuous period from admittance to the SCU to final discharge from the SCU.

Paper II was an RCT. One group received regular care and additional follow-up by videoconference (Videoconference group, VCG), the other group received regular care only (Regular care group, RCG). The applicability of telemedicine for treatment of PI was explored in terms of HRQoL, healing, time to healing, as well as participant empowerment safety and satisfaction with the follow-up.

Paper III was a cost-utility analysis (CUA) alongside the RCT, involving the same population in the same two groups. Paper III explored current outpatient follow-up versus outpatient follow-up using a videoconference intervention in addition to current follow-up. The outcome was quality-adjusted life years (QALYs), derived from the EQ-5D-5L questionnaire, expressed as an incremental cost effectiveness ratio (ICER). Comparison of transportation-related costs and greenhouse gas emission in the two groups were secondary outcomes.

The RCT part of the study conforms to the Consolidated Standards of Reporting Trials (CONSORT) guidelines with extensions for randomized pilot and feasibility trials [94] (Paper II, Supplementary material 1). The timeline for study enrolment, intervention, and assessment in the RCT is described in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [95] (Paper II, Supplementary material 2). The Template for Intervention Description and Replication (TIDieR) [96] checklist and guide were used to record and describe the intervention in the RCT (Paper II, Supplementary material 3). The CUA is reported in compliance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines [97].

4.2. Study population

4.2.1. Participants and recruitment

The flowchart of the recruitment process in study 1 and 2 is shown in Figure 7.
A strategy for identifying potential participants from the EMRs was developed by a controller at Sunnaas Rehabilitation Hospital together with the author. In the cross-sectional study (paper I), 84 relevant diagnoses from the EMRs (Appendix 1) were scrutinized for SCI. Individuals with acquired TSCI or NTSCI, diagnosed according to The World Health

Organization (WHO) International Classification of Diseases and Health-Related Problems, 10th edition [24] between 1 January 2004 and 1 January 2014, were included. Each EMR was then reviewed to get the information required for the study. The research team and participants in a previous feasibility study [91] devised a form to map the required information, including demographic and etiological variables, PI occurrence during acute rehabilitation, as well as factors known to increase the risk of PI in the population [22, 51, 98].

Further, a PI-related questionnaire was developed to collect PI-related data after discharge from acute rehabilitation [59]. All eligible participants identified in the cross-sectional study (paper I) received the questionnaire, asking about PI after discharge, as well as ongoing PI at the time of answering the questionnaire. Those who answered yes to ongoing PI were invited to participate in the RCT, together with eligible persons referred to the SCUs due to PI issues.

4.2.2. Inclusion and exclusion criteria

Participants in the cross-sectional study (paper I) and the RCT (papers II and III) were selected based on the eligibility criteria shown in Table 2.

Table 2. Eligibility criteria for the cross-sectional study and the randomized controlled trial

Study		**Inclusion criteria**	**Exclusion criteria**
Paper I	National, cross-sectional	All individuals with acquired traumatic or non-traumatic spinal cord injury SCI.	Paresis or paralysis related to injury or illness in the spinal cord, not defined as acquired SCI, e.g. myelomeningocele (spina bifida), multiple sclerosis, amyotrophic lateral sclerosis or Guillain-Barré syndrome
		SCI incurred between 1 January 2004 and 1 January 2014	Unknown date of injury
		Acute rehabilitation at one of the three Norwegian spinal cord	

Study		Inclusion criteria	Exclusion criteria
		units and medical record available	
	Questionnaire	Age >18 years (adults)	Children and adolescents
		Willing and able to give their consent	Cognitive problems affecting the opportunity or ability to understand the consequences of giving consent
		Known/permanent Norwegian address	Unknown residential location
Pressure injury (PI)-related referrals to the SCUs: papers II and III	Randomized controlled trial	Acquired traumatic or non-traumatic SCI	Paralysis related to injury or illness in the spinal cord, not defined as acquired SCI, e.g. myelomeningocele, multiple sclerosis, amyotrophic lateral sclerosis or Guillain-Barré syndrome
		Ongoing PI	Ongoing wound, not categorized as PI, e.g. burns, incontinence-associated dermatitis, wound associated with diabetes mellitus or circulatory deficits-
		Age >18 years (adults)	Children and adolescents
		Known/permanent Norwegian address	Unknown residential location, or Norwegian inhabitant moved abroad
		Consent to participate	Cognitive problems affecting the opportunity or ability to understand the consequences of giving their consent to participate or to being exposed via a screen

4.2.3. Sample size

No sample size calculation was conducted for the cross-sectional study (paper I)
In the RCT (papers II and III), a sample size calculation was performed based on HRQoL (as measured by SF-36). The hypothesis was that HRQoL would increase in the intervention group compared with the regular care group. Little is known about HRQoL in this population in Norway, making a standard sample size calculation difficult. Thus, we decided to base the sample size calculation on Cohen's standardized differences [99], avoiding the need for any assumption about, e.g. the variation (SD) in the data. We assumed a standardized difference of at least 0.8, which is typically considered a large effect. With 80% power and a 5% significance level, 25 participants would be needed in each of the two groups, hence 28 were included in each group to take account of some dropouts.

4.2.4. Randomization and allocation

The participants in the RCT were randomized to a regular care group (RCG) or a group offering regular care and additional videoconference (videoconference group, VCG), using a random-number generator in SPSS statistical software. We performed blocked randomization, with block size of six, stratified by hospital. A statistician created the randomization list in advance of the study. The randomization numbers were provided in sealed, opaque envelopes, so that those who enrolled the participants were not aware of the group. At the time of inclusion, at least two people from the project group or one person from the group and one mercantile employee at the outpatient clinic were present to validate the allocation procedure.

4.2.5. Blinding of participants, personnel and assessors

In the RCT (paper II and III), the intervention involved videoconference consultations with the participants in the VCG, hence it was difficult to blind the participants or the staff members who were performing the follow-up, due to the fact that the video consultation was based on communication via a screen. For the rest of the project group, the identity of the participants and allocation to the VCG and RCG were unknown. Only the anonymous identification number, not the identity of the participants, was known during the analysis part of the study. A health economist, who did not participate in the clinical part of the study, analysed the cost-utility data in paper III.

4.2.6. Dropouts and missing data

Participation was voluntary, and withdrawal was possible at any time. The participants were informed they would still be able to complete follow-up treatment for the PI via the specialized health care service at the SCU if they dropped out of the study. The participants were also informed that anyone who needed to be hospitalized during follow-up, e.g. if they needed PI treatment that could not be provided by the district nurses or if surgery was needed, would be removed from the study during the hospitalization period and included in the study again after discharge from the hospital. The project group implemented routines for registering the length of any hospitalization, as well as the cause of the hospitalization. Missing data were handled by multiple imputation [100] (paper II).

4.2.7. Adverse events

The project team implemented a routine to collect information on adverse events or other unintended effects of the trial interventions or procedures in the RCT. The routine was based on collection, assessment and reporting the events and effects to the hospital, the health care authorities and the ethical committee, in accordance with Norwegian legislation and the guidelines of the ethical committee [101-106]. As stated in the study protocol, possible events and effects related to the follow-up were reported in the trial outcomes. If the PI did not heal during the follow-up period, the participant was invited to further follow-up after the end of their trial participation [59].

4.3. Ethical considerations and approval

> *After all these videoconferences, I think my butt is more famous than the one of Kim Kardashian (quotation from one of the participants in the RCT).*

PIs often occurs near intimate body areas, which may be visible on the screen. This is an ethical issue that needs to be emphasized, especially if health care professionals are performing telemedicine to a patient in his or her home. The same rules for privacy apply to videoconference and telephone consultations as for on-site consultations [103]. Protection of the patient's dignity is important in settings where the health care professionals meet with patient via the screen [103].

A feasibility study focusing on the standards and rules set by the Norwegian data protection authority [91] was conducted before the current project. In the feasibility study, we established guidelines and checklists about ethical and privacy concerns, as well as organizational responsibility and responsibility regarding technical and practical issues,

including routines for protection of privacy and dignity for the participants [91, 107]. These guidelines and checklists were emphasized during the project. Due to the Norwegian legislation regarding research, only adults were invited to answer the questionnaire asking for ongoing PI, as well as to be included in the RCT [108-110]. The legal age in Norway is 18 years [109]. According to the legislation, adolescents between 12 and 18 years can be included in research [108], but one needs to be aware of their legal competence to consent, their prerequisites for consenting on their own behalf, as well as parents` understanding of adolescent`s and children`s participation in research [110]. The regional ethical committee`s (REK) guidelines corresponds with the governmental legislation [108, 110], and the legislation is in accordance with the declaration of Helsinki [105]. Thus, only adults of 18 years or older were invited to participate in the RCT.

In accordance with the act on ethics and integrity in research [102, 105], oral and written information was provided to everyone invited to take part in the study, and informed consent was obtained. All data were collected and stored in accordance with the Norwegian Data and Telecommunications Authority's requirements for safe information flow [101, 103]. Only the author had access to the final datasets, but all supervisors had the option to get access on request, and in accordance with the Norwegian privacy legislation [103]. The statistician participating in papers I and II and the health economist participating in paper III had access to the data, but in an anonymized form.

In the RCT, the telemedicine consultations were performed as synchronous live, videoconferencing or telephone consultations in real time. The video and sound were not recorded. Encrypted communication channels from the Norwegian Health Net were used to protect the privacy of the participants during the videoconference sessions [103].

All participants in the RCT were insured trough the Norwegian health system and the hospital insurance program for adverse effects/those who suffer harm from trial participation [106]. Established guidelines and checklists regarding ethical and privacy concerns, organizational responsibility and responsibility about technical and practical issues were followed [59, 91, 107].

The research project was carried out in accordance with ethical guidelines for health services in Norway [102], based on the Code of Ethics of the World Medical Association (Declaration of Helsinki) [105] for experiments involving humans. Ethical approval was obtained from the

Norwegian Regional Committee for Medical and Health Research (REK), 2014/684/REK-Nord (https//www.rekportalen.no).

The research project was registered in Clinical Trials.gov in 2016 (NCT02800915. The privacy rights of the participants were followed throughout the study [103].

4.4. Intervention in the randomized controlled trial

After written consent was obtained, the baseline data were collected. Then the participants were randomized to the VCG and the RCG, and informed about the group allocation. For both groups, the follow-up was conducted by a multidisciplinary wound care team at the outpatient clinic at each of the two SCUs. The team consisted of a medical doctor with several years of experience in the treatment of PIs in patients with an SCI, a certified wound care nurse, and an occupational therapist with specialized skills regarding pressure measurements and PI prevention. In addition, a plastic surgeon and an orthopaedist were available if needed. The local health care contacts consisted mostly of district nurses or district wound nurses, and relatives. However also occupational therapists, assistant nurses, physical therapists and general practitioners participated. For both groups, the local health care contacts were present together with the participant at the participant's home during the video consultation and the telephone consultation; however, they did not participate in the on-site consultations at the wound clinic. For both groups, the local health care contacts performed the wound treatment, at the participant`s home, supported by remote guidance from the multidisciplinary wound care team at the outpatient clinic. The participants in both groups were followed until the PI healed or for a maximum of 52 weeks. Figure 9 shows the organization of the follow-up in the two groups.

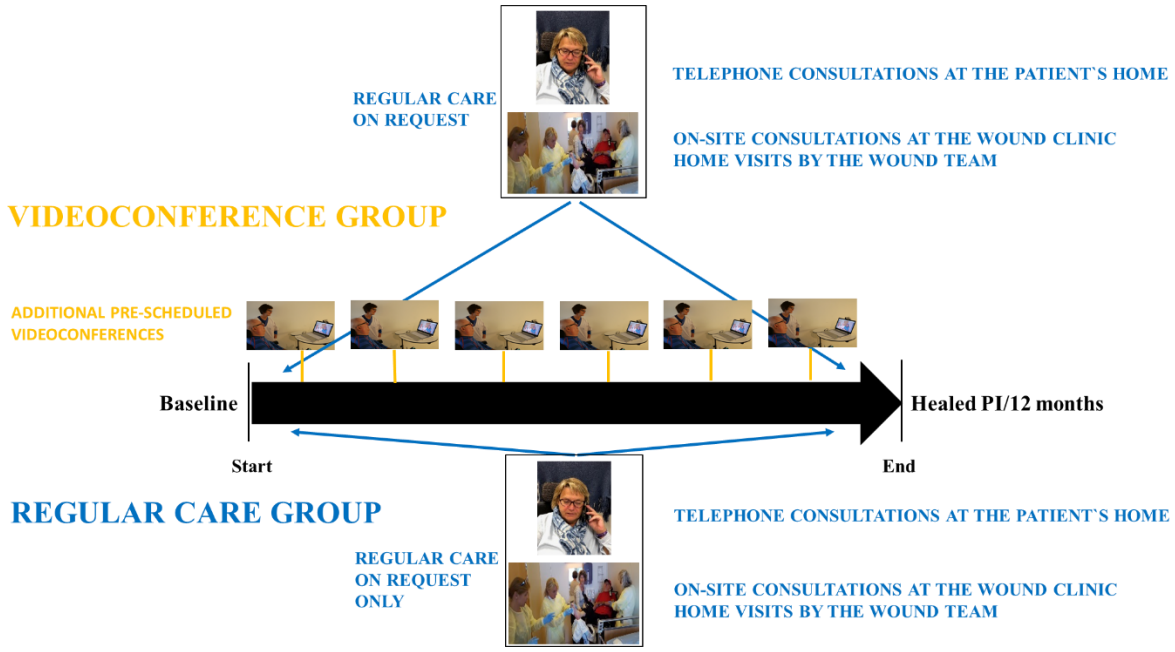


Figure 9. Organization of the follow-up in the two groups. The figure has been used previously in an article reporting on a randomized controlled trial [111]. Photos and copyright by the author, and with permission from the participants.

After the participant had accepted the invitation, the local health care contacts` management was informed and asked to allow the local health care contacts to participate. Table 3 shows the administration needed in the follow-up in both groups. Most of the logistics involved in the consultations was carried out by the wound care nurses at the wound clinics.

Table 3. Organization of the administration of the videoconferences in the project

Administration tasks	**Responsibility**
Participant information and consent	The wound care nurse and the author at Sunnaas Rehabilitation Hospital The wound care nurse and the physician at Haukeland University Hospital.
Information to the health care administration in the municipality and invitation to participate	The wound care nurse
Information to the local health care contacts and invitation to participate	The wound care nurse
Both groups	
Participate in requested telephone consultations	

Administration tasks	Responsibility
Participate in requested telephone consultations	The participants and the local health care contacts at the participants` home. The multidisciplinary wound care team at the outpatient clinic at the spinal cord units
The videoconference group	The participants and the multidisciplinary wound care team at the outpatient clinic at the spinal cord units
Install software on the participant's laptop	The wound care nurse
Coordinate video consultations with the participant and the local health care contacts	The wound care nurse
Manage the list of technical equipment that the participants had borrowed from the hospital	The wound care nurse
Order videoconference license from the Norwegian Health Network	The wound care nurse
Participate in predetermined video consultations	The participants, the local health care contacts at the participants` home. The multidisciplinary wound care team at the outpatient clinic at the spinal cord unit

4.4.1. The regular care group

The organization of the follow-up in the RCG was the same as the traditional follow-up at the SCUs' outpatient wound clinics (see Figure 9). The participants or their local health care contacts had to request a consultation at the outpatient wound clinic. No follow-up consultation was planned unless asked for by the participant or his or her local care providers. The participants in the RCG received evidence-based treatment and guidance. The local health care contacts participated in the telephone consultations at the participant's home and in consultations where the wound team visited the participant at home. The local health care contacts did not attend the on-site consultations at the outpatient wound clinic. The general practitioner received a medical report after each consultation. The local health care contacts received a medical report if requested by the participant.

4.4.2. The videoconference group (regular care and additional video conference)

For participants randomized to the VCG, arrangements for installation of software, together with training in the use of the software and equipment, were provided to the participants and local health care contacts by the wound care nurse at the outpatient

clinic. The participants in the VCG received evidence-based treatment and guidance via pre-scheduled videoconference consultations, as well as requested regular care, similar to the RCG (see Figure 9). This was done to secure availability to the health care service if the internet was disconnected, and to secure access to surgical treatment at the outpatient clinic, if needed. Thus, the additional, pre-scheduled videoconference consultation was the intervention in the study.

The local health care contacts participated in all videoconference consultations, telephone consultations and visits from the wound care team to the participant's home but did not attend on-site consultations at the outpatient wound clinic. The general practitioner received a medical report after each consultation. The local health care contacts received a medical report if requested by the participant.

The video consultations were performed synchronous live, in real-time, using a Cisco TelePresence System EX90 personal computer (PC) with a camera at the wound clinic. A laptop with a mobile web camera was used at the participant's home. All the participants had access to broadband or a mobile broadband connection ahead of the study, and the software used was free. The web cameras were borrowed from the hospital. Encrypted communication channels from the Norwegian Health Net were used to protect privacy of the participants [101, 103]. The videoconference connection was initiated from the wound clinic and had to be approved by the participant before log on. The technical setup was based on experience from a previous pilot study [91]. In accordance with this experience, as well as experience developed during everyday use of telemedicine at Sunnaas Rehabilitation Hospital [72, 107], guidelines regarding the performance were developed. These guidelines have been implemented into Sunnaas Rehabilitation Hospital's technical safety recommendations for all employees at the hospital [112]. Based on the experience and feedback from the participants in the pilot study [91], the frequency of the follow-up was set to every second to third week. Figure 10 shows the videoconference follow-up.

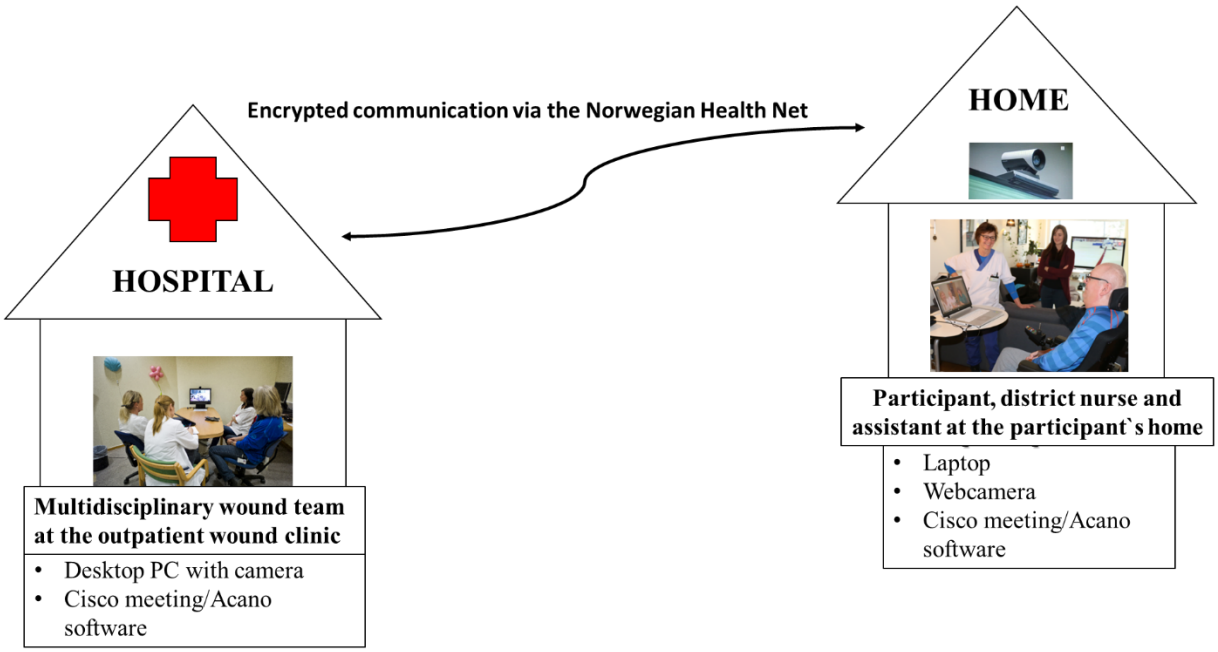


Figure 10. The videoconference consultation. The figure has been used previously in an article reporting on a randomized controlled trial [111]. Reproduced with permission from the participants.

4.5. Data collection

The collection of data in paper I was conducted at the three SCUs between 2015 and 2016. Data were extracted from the electronic medical records (EMRs).

In paper II, data regarding HRQoL and healing were collected at baseline and at the end of the study, which was either when the PI healed, or if not healed, after 52 weeks. The collection of data was performed at Haukeland University Hospital and Sunnaas Rehabilitation hospital between 2016 and 2019.

In paper III, the costs were collected at each consultation, and HRQoL data was collected at baseline and at end of the study. The collection of data was performed at Haukeland University Hospital and Sunnaas Rehabilitation hospital between 2016 and 2019.

4.5.1. Demographic and clinical variables

Demographic data for each of the participants in both studies were recorded, including age, gender, marital status, cause of the SCI, age at injury, time since injury, level and grade of the injury, any associated conditions, and any relevant comorbidity. Grouping by age and grading of the severity of the SCI were performed in accordance with the International Standards for Neurological Classification of SCI recommendations [33], including the clinical findings

standardized by the American Spinal Injury Association (ASIA) [34] Impairment Scale (AIS) [35]. PI history was collected and the PIs were categorized in accordance with the 2019 guidelines [113], prepared by the three collaborating PI organizations: the National Pressure Injury Advisory Panel, the European Pressure Ulcer Advisory Panel and the Pan Pacific Pressure Injury Alliance.

4.5.2. Outcome measures

Period prevalence of PI was the main outcome in paper I; HRQoL, healing and time to healing were reported and compared in paper II. In paper III, QALYs, derived from the EQ-5D-5L questionnaire [114] and costs collected at each consultation were reported and compared. The instruments and the outcome measures used in papers I, II and III are presented in Table 4.

Table 4. Instruments used and outcome measures in the cross-sectional study and the randomized controlled trial

Study	Paper	Instrument/ scale	Variables	Outcome measures
Cross-sectional	I	Electronic medical record mapping form[a]	Demographic variables (age, gender, marital status, education, work), comorbidity	Period prevalence of PI and PI risk associations during acute rehabilitation
			Spinal cord injury-related variables (age at injury, level and grade of injury, associated conditions)	
			PI history and categorization of any PI during acute rehabilitation	
		PI questionnaire	Occurrence of PI after discharge from acute care rehabilitation	Period prevalence of PI after discharge
			Ongoing PI at time of answering the questionnaire	Prevalence of ongoing PI
RCT	II	Multidisciplinary Wound Care Record Form[a]	Baseline variables	PI healing and time to healing
			Demographic variables (age, gender, marital status, education, work), comorbidity	
			Spinal cord injury-related variables (age at injury, level and	

Study	Paper	Instrument/ scale	Variables	Outcome measures
			grade of injury, associated conditions)	
			PI history and categorization of any previous PI, risk factors for the development of a PI	
			Home situation regarding assistive aids and assistance	
			Assessment of ongoing PI (volume)	
	II		Follow-up variables	PI healing and time to healing
			Volume of the PI from baseline to healing/end of follow-up	
			Changes in risk factors, assistive aids and assistance	
	II	Satisfaction scale[a]	End of follow-up	Follow-up satisfaction
			Satisfaction, interaction and patient-empowerment	
	II	SF-36	Baseline and end of follow-up	HRQoL
			HRQoL	
	II	ISCI-QoL-BDS	HRQoL	HRQoL
	II and III	EQ-5D-5L	HRQoL	HRQoL (II) and QALYs (III)
	III	Direct and indirect costs form[a]	Cost and transportation-related follow-up variables, including participating staff, time used, technical issues and cost of medication and dressings	Costs, transportation costs, transport-related emission of CO_2 equivalents

PI, pressure injury; SF-36, the 36 item short-form survey; HRQoL, health-related quality of life; ISCI-QoL-BDS, the International Spinal Cord Injury Quality of Life basic dataset; EQ-5D-5L, European Quality of Life 5 Dimensions 5 Level Version; QALYs, quality-adjusted life-years; CO2 equivalents, atmospheric pollutants or greenhouse gases, which include carbon dioxide, methane, nitrous oxide and fluorine gases (hydrofluorocarbons, perfluorocarbons and sulphur hexafluorides). To compare the gases' ability to heat the atmosphere, they are converted to carbon dioxide values, referred to as CO2 equivalents.
[a] Custom-made questionnaire and form devised by the research team.

4.5.3. Assessment instruments

In addition to the clinical and demographic variables, a selection of custom made assessment tools were used in the three papers which forms the basis of the present thesis.

Electronic medical record mapping form

The custom-made mapping form (Appendix 2) used in the cross-sectional study (paper I) was developed by the research team to extract the relevant clinical and demographic variables for analyses of the periodic prevalence and risk assessment (Table 4). The EMR was used as the source of the information. The mapping was performed by the author and conducted at each of the three SCUs.

Pressure injury questionnaire

A custom-made questionnaire (Appendix 3) was developed by the research team asking about previous and ongoing PIs after discharge from acute rehabilitation (Table 4). The questionnaire was sent to all eligible individuals identified in the cross-sectional study (paper I). All those who replied to the questionnaire and fulfilled the inclusion criteria for the RCT were invited to participate (Table 2). The author was responsible for the logistics regarding the sending the questionnaires and mapping the results.

Multidisciplinary wound care record form

A customized multidisciplinary wound care record form was developed by the research team, together with personnel at the outpatient wound clinics at Haukeland University Hospital and Sunnaas Rehabilitation Hospital (Appendix 4). This form was based on a mapping form in everyday use at the SCU at Sunnaas Rehabilitation Hospital, and with variables adjusted to fit the research project. The form consisted of a basic section, mapping the participants at baseline, before randomization, and a second section used for all further follow-ups in both groups. The baseline section mapped the demographic variables, comorbidities, SCI-related variables, PI-related variables, including potential risk factors for the development of a PI. The second section focused on the development of the PI and changes in any of the variables in the basic section (Appendix 4). For both groups, the condition of the PI was assessed using the TIMES form [115]. Further, variables regarding the location and volume (length × width × depth) of the PI, present treatment variables, marital status, occupational status, and housing conditions were mapped.

The wound team at the outpatient wound clinics at Haukeland University Hospital and Sunnaas Rehabilitation Hospital carried out the mapping jointly at each consultation in both groups.

Health-related quality of life questionnaires

HRQoL was assessed using the European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L) [114], the Short Form Health Survey (SF-36) [116] and the International Spinal Cord Injury Quality of Life basic dataset (ISCI-QoL-bds) [117].

The EQ-5D-5L is a standardized, generic self-assessment tool, defining health in terms of mobility, self-care, usual activities, pain/discomfort and anxiety [114].

SF-36 is a generic instrument, assessing general health perceptions, vitality, body pain and general mental health, as well as health-related limitations in activity, social activities and role activities, as well as limitations in social activities due to physical or emotional problems [116]. These two forms are standardized, non-disease-specific survey instruments for describing and evaluating HRQoL [118, 119].

The ISCI-QoL-bds [117] was also used. ISCI-QoL-bds is an SCI-specific instrument, assessing quality of life by rating satisfaction for three variables: general quality of life, physical health and psychological health [117]. The ISCI-QoL-bds is recommended for use in all studies involving people with SCI to facilitate universal comparisons of quality of life in this population [117]. The ISCI-QoL-bds questionnaire is similar to the version used by the Norwegian Spinal Cord Injury Registry (NorSCIR) [120].

All three questionnaires were recorded at baseline and at the end of the follow-up period, e.g. when the PI had healed or no later than 12 months after inclusion.

These three different assessment tools were complementary tools, and thus covered more aspects of quality of life than just one single assessment form. All three assessment forms were used in paper II, and EQ-5D-5L was used in paper III, based on current recommendations regarding cost-utility analysis [121].

Cost assessment form

A custom-made form was developed by the health economist based on the previous pilot study [91] to assess direct and indirect costs related to the follow-up (Appendix 5). The number of staff members participating at each consultation and their occupation were registered, together with the type and duration of the consultation. The stopwatch function on

the cell phone was used to calculate the time spent. Time delay due to technical issues was registered at each consultation, together with the cost of the dressings used. Transportation costs are a large proportion of the costs associated with outpatient follow-up in Norway [122], therefore assessment of the transportation was included in the cost form. Vehicles used for travel were mapped, together with exact addresses for the participants, the district nurses' offices and the outpatient wound clinics. The cost variables were registered by the wound nurse at Haukeland University Hospital and by the author at Sunnaas Rehabilitation Hospital.

Satisfaction and patient empowerment Form

A five-point Likert scale (1, not at all; 5, to a great extent/absolutely) (Appendix 6) was developed by the research team, together with members of the outpatient wound clinic at Haukeland University Hospital and Sunnaas Rehabilitation Hospital to assess the participants' satisfaction and experience of patient empowerment in the follow-up (Appendix). The scale was based on a scale developed by the Regional Health Care authorities (Helse Sør Øst) and is in daily use at the outpatient clinic at Sunnaas Rehabilitation Hospital [123].

4.6. Analyses

All statistical analyses were conducted using SPSS version 23 (paper I) and version 26 (papers II and III) statistical software packages. Microsoft Excel was used in the cost-utility analyses in paper III.

In all three papers, participant demographics and injury characteristics were analysed descriptively, with age, level of injury, severity of the SCI and PI categorization presented in accordance with international recommendations [33-35, 113]. Continuous variables are presented as mean values with standard deviation (SD), and categorical variables are presented as counts and percentages. The significance level was set at $P < 0.05$. Figure 8 and Table 5 show the analyses used in the three papers.

Table 5. Analyses used in the three papers

Study	Paper	Analyses	What	Software
Cross-sectional	I	Descriptive analyses	Demographics and injury characteristics	IBM SPSS Statistics, version 23
		Binary, logistic regression	Associations, Sensitivity analyses regarding any missing values	

Study	Paper	Analyses	What	Software
Randomized controlled trial	II	Descriptive analyses	Demographics and injury characteristics	IBM SPSS Statistics, version 26
		Multiple imputation	Missing data	
		Linear regression analysis with adjustment for baseline	Group comparison	
		Mann-Whitney test	Mean percentage reduction in PI size comparison	
		Log-rank test	Time to healing	
		Independent sample *t* tests	Comparison of participant satisfaction scores in the two groups	
Randomized controlled trial	III	Cost-utility analysis	Costs and Quality adjusted life-years (QALYs)	Microsoft Excel
		The trapezoid method	Calculation of the differences in QALYs between the two treatment groups	
		Bootstrapping	To illustrate the statistical uncertainty surrounding the incremental cost effectiveness ratio (ICER)	
		Mann-Whitney test	Comparison of the two groups	IBM SPSS Statistics, version 26
		Independent sample *t* tests	Comparison of the two groups	
		Linear imputation	Missing data	

4.6.1. Paper I

The term period prevalence was used to describe occurrence of PI during acute rehabilitation in the 10-year period from 2004 to 2014. To identify factors associated with the occurrence of PIs, potential risk factors were entered into a binary, logistic regression model. Crude and adjusted (for gender and age) odds ratios (ORs) were calculated along with 95% confidence intervals (CIs). Due to missing information in the EMR regarding PI, a logistic regression analysis, with missing PI values taken as "no PI", was performed as a sensitivity analysis.

4.6.2. Paper II

HRQoL and time to healing were used to compare the two groups in the RCT, together with analyses of participant satisfaction with the treatment. Analyses were performed according to the intention-to-treat principle. Three different HRQoL instruments were used, and the individual items in the forms were weighted in accordance with the recommended index version [114, 116, 117]. Based on instrument-specific guidelines, domain scores and total scores were calculated for each participant and for each form. Mean HRQoL scores with corresponding 95% CIs are presented for each of the two treatment groups at baseline and at the end of follow-up, and the groups are compared using linear regression analysis with adjustment for baseline. Missing data were handled by multiple imputation. Each missing value was replaced by $m = 20$ imputed values based on the predictive mean matching technique before analysis. The imputation models included age, gender and AIS grade in addition to the HRQoL scores. This analysis was repeated without imputation for missing values as well, for comparison. The mean percentage reduction in PI size was calculated with corresponding 95% CI for each of the two groups and compared using a Mann-Whitney test. Time to healing was analysed by the log-rank test and is presented as a Kaplan-Meier plot. Independent samples *t* tests were used to analyse the mean difference in participant satisfaction scores. Corresponding 95% CIs were calculated.

4.6.3. Paper III

The outcome measure in the cost-utility analysis was quality-adjusted life years (QALYs) derived from the generic questionnaire EQ-5D-5L [114]. The responses on each domain were converted to utility weights, by using a value set from a United Kingdom (UK) population, which is recommended to use in Norway [121, 124]. We calculated expected QALYs by multiplying utility weights (HRQoL) with the number of life years lived in that state (one year). The QALY results range from 0-1, where one is equal to perfect health, or the best imaginable health, while zero represents a health state equivalent to death.

The QALY combines the length of life and the quality of that life into a single index, which allows for comparisons of effectiveness between the treatment groups. The results are expressed as cost-per-QALY gained, reported as incremental cost-effectiveness ratio (ICER) [125], which is the difference in costs between the two groups, divided by the difference in effects (QALYs) as follows:

$$\text{ICER} = \frac{\text{cost of additional videoconference} - \text{cost of regular care}}{\text{effect of additional videoconference} - \text{effect of regular care}} = \frac{\Delta C}{\Delta E}$$

Imputation based on a linear imputation model [100] was conducted for missing data in the EQ-5D-5L score. The trapezoidal method (area under the curve) [126] was used to calculate the differences in QALYs between the two treatment groups, using utility scores from EQ-5D-5L at baseline and at end of follow-up. A sensitivity analysis (bootstrapping) with 1000 replications was performed [127] to illustrate the statistical uncertainty surrounding the ICER [125]. Travel costs and the environmental impact for the two groups were compared by independent samples *t* tests.

5. RESULTS

The main results from the three papers are presented in this chapter. The attached papers I, II and III provide in-depth information.

The baseline variables of the participants in the cross-sectional study and in the RCT are presented in Table 6.

Table 6. Baseline characteristics of the participants in the cross-sectional study and the randomized controlled trial

Variable	**Cross-sectional study**		**Randomized controlled trial**			
			VCG		**RCG**	
	No.	**%**	**No.**	**%**	**No.**	**%**
Total	1012	100	28	100	27	100
Gender						
Male	742	73	24	86	21	78
Female	270	27	4	14	6	22
Age at injury (years), mean (SD)	48	(19)	41	(14)	39	(13)
TSCI	639	63	22	79	24	89
NTSCI	372	37	6	21	3	11
Level of injury						
C1-C4	224	22	4	14	5	19
C5-C8	222	22	5	18	6	22
T1-S3	566	56	19	68	16	59
Cauda equine	86	8.5	0	0	0	0
AIS grade						
A	258	26	18	64	18	67
B	58	5.7	3	11	0	0
C	298	30	6	21	8	30
D	385	38	1	4	1	4
Unknown	12	1.2	0	0	0	0

VCG, videoconference group; RCG, regular care group; SD, standard deviation; TSCI, traumatic spinal cord injury; NTSCI, non-traumatic spinal cord injury; C, the cervical level of the spinal cord; T, the thoracic level of the spinal cord; S, the sacral level of the spinal cord; AIS grade, the completeness of the injury, e.g. the severity of paralysis in the affected part of the spinal cord.

The location of the PIs described in the cross-sectional study and in the RCT are presented in Figure 11.

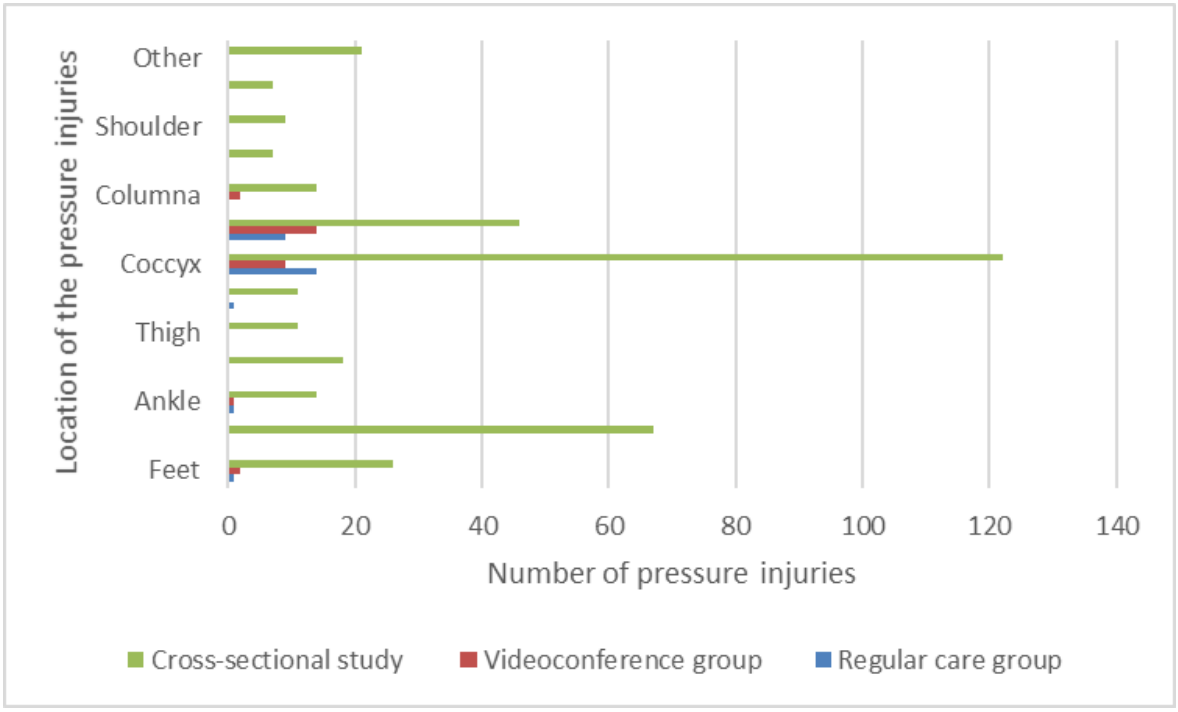


Figure 11. The location of the pressure injuries in the cross-sectional study and in each of the two groups in the randomized controlled trial.

5.1. Period prevalence of PIs and associated risks (paper I)

The EMR search revealed 1012 individuals to be investigated in the epidemiologic study; 891 (88%) had information regarding PI, and the period prevalence of PI in the population was 144/891 (16%, 95% CI, 0.14–0.19). The EMRs also had information about the number of PIs for 142 individuals; 61% had one PI (86/142 individuals) and 39% (56/142 individuals) had two or more. The total number of PIs recorded from the EMRs were 373, and 123 (33%) of the PIs described in the EMR were located at the coccyx (Figure 11).

Table 7 shows the PI risks related to the different variables investigated in the cross-sectional study. The results of the sensitivity analysis, where no PI mentioned = no PIs, are included for comparison.

Table 7. Pressure injury associations identified in the population in the cross-sectional study

	No. of PI/no. in subgroup	Adjusted (gender and age) values			Missing PI= 0 PI, Adjusted (gender and age) values		
		Odds ratio	95% confidence interval	*P* value	Odds ratio	95% confidence interval	*P* value
Gender							
Male	123/654	1.0			1.0		
Female	21/237	0.4	0.3 to 0.7	**0.001**	0.4	0.3 to 0.7	**<0.001**
Age at injury							
0–14 years	1/15.	0.3	0.04 to 2.2	0.22	0.3	0.04 to 2.4	0.26
15–29 years	39/188	1.0			1.0		
30–44 years	31/189	0.7	0.4 to 1.3	0.28	0.7	0.4 to 1.3	0.26
45–59 years	26/210	0.5	0.3 to 0.9	**0.03**	0.5	0.3 to 0.9	**0.017**
60–74 years	35/240	0.7	0.4 to 1.1	0.14	0.6	0.4 to 1.0	0.069
75+ years	12/49	1.4	0.7 to 2.9	0.40	1.1	0.5 to 2.3	0.74
Geographic location at time of injury							
Norway	130/847	1.0			1.0		
Abroad	14/44	2.4	1.3 to 4.8	**0.009**	2.1	1.1 to 4.0	**0.022**
AIS at admission[a]							
A	77/233	1.0			1.0		
B	14/51	0.8	0.4 to 1.6	0.54	0.8	0.4 to 1.6	0.53
C	33/263	0.3	0.2 to 0.5	**<0.001**	0.3	0.2 to 0.5	**<0.001**
D	18/331	0.1	0.1 to 0.2	**<0.001**	0.1	0.1 to 0.2	**<0.001**
Unknown	2/13						
Cauda Equine							
No	140/812	1.0			1.0		
Yes	4/79	0.3	0.1 to 0.7	**0.01**	0.3	0.1 to 0.8	**0.013**
SCI associated problems diagnosed before the PI							
Bladder dysfunction							
No	5/194	1.0			1.0		
Yes	136/676	9.2	3.7 to 23	**<0.001**	8.9	3.6 to 22	**<0.001**
Unknown	3/20						
Bowel dysfunction							
No	5/239	1.0			1.0		
Yes	136/623	13	5.3 to 33	**<0.001**	12	5.0 to 30	**<0.001**
Ventilator support							
No	128/848	1.0			1.0		
Yes	15/41	3.0	1.6 to 5.9	**0.001**	3.0	1.6 to 5.7	**<0.001**

Premorbid comorbidity							
Brain injury[b]							
No	106/746	1.0			1.0		
Yes	29/126	1.7	1.1 to 2.8	**0.021**	1.7	1.1 to 2.8	**0.026**
Unknown	9/19						
Diabetes mellitus							
No	111/774	1.0			1.0		
Type 1	7/12	7.9	2.4 to 26	**0.001**	7.4	2.4 to 23	**<0.001**
Type 2	12/56	1.6	0.8 to 3.2	0.19	1.5	0.7 to 2.9	0.269
Unknown	13/47						
Cardiovascular disease							
No	78/653	1.0			1.0		
Yes	51/192	3.6	2.3 to 5.9	**<0.001**	3.6	2.3 to 5.8	**<0.001**
Unknown	15/46						
Hypertension							
No	78/653	1.0			1.0		
Yes	52/193	3.7	2.3 to 5.9	**<0.001**	3.7	2.3 to 5.8	**<0.001**
Unknown	14/45						
Depression							
No	47/492	1.0			1.0		
Yes	67/251	3.8	2.5 to 5.8	**<0.001**	3.7	2.5 to 5.6	**<0.001**
Unknown	30/147						
Drug abuse (illegal and prescribed)							
No	26/216	1.0			1.0		
Yes	19/64	3.0	1.5 to 6.0	**0.002**	2.7	1.4 to 5.3	**0.004**
Unknown	99/610						

P values in bold type are significant.

PI, pressure injury.

[a]AIS American Spinal Injury Association Impairment Scale: A, motor/sensory complete; B, motor complete/sensory incomplete; C and D, motor/sensory incomplete; E, normal examination.

[b]Brain injury includes of all types of injury affecting brain function, including concussion.

According to the answers in the PI questionnaire in the cross-sectional study (Tables 4 and 5, Figure 7), 10% (*n* = 40/405) reported having a PI when responding to the PI-questionnaire. These 40 individuals were invited to participate in the RCT.

5.2. Applicability of additional telemedicine for assessing HRQoL and PI healing (paper II)

The flow-chart gives information about the participants in the RCT (Figure 7). Baseline characteristics of the participants are shown in Table 6.

No significant differences regarding HRQoL were found between the two groups (Table 8). Table 8 shows the analysis with imputed data for missing HRQoL values. For results based on complete data, see paper II.

Table 8. Differences in health-related quality of life between the videoconference group and the regular care group from baseline to the end of follow-up based on imputed data

Questionnaire		Group	Baseline		End of follow-up		Estimated mean difference	95% CI	*P* value
			Mean	95% CI	Mean	95% CI			
ISCI-QoL-BDS	Overall health	VCG	6.15	5.26 to 7.04	6.26	5.41 to 7.11	−0.93	−2.13 to 0.28	0.13
		RCG	5.60	4.52 to 6.69	5.07	3.93 to 6.21			
	Physical health	VCG	5.22	4.28 to 6.16	6.07	5.16 to 6.99	−0.99	−2.29 to 0.32	0.14
		RCG	5.05	4.10 to 6.00	5.03	3.90 to 6.15			
	Mental health	VCG	7.37	6.65 to 8.09	7.59	6.73 to 8.45	−1.09	−2.56 to 0.38	0.15
		RCG	5.95	4.78 to 7.13	5.79	4.38 to 7.20			
SF-36	Physical functioning	VCG	38.97	29.86 to 48.07	34.33	24.08 to 44.59	−5.37	−18.44 to 7.69	0.42
		RCG	32.04	22.71 to 41.37	26.51	16.67 to 36.35			
	Physical role	VCG	24.97	10.67 to 39.27	37.45	20.37 to 54.54	1.60	−22.66 to 25.87	0.90
		RCG	36.25	21.26 to 51.24	41.39	22.38 to 60.41			
	Pain	VCG	51.32	37.41 to 65.23	63.00	49.57 to 76.42	−6.45	−20.56 to 7.67	0.37
		RCG	48.45	37.66 to 59.25	54.88	43.40 to 66.37			
	General health perceptions	VCG	57.95	49.62 to 66.62	61.80	54.59 to 69.00	−6.92	−16.84 to 3.00	0.17
		RCG	50.52	41.20 to 59.84	52.24	43.62 to 60.86			
	Vitality	VCG	51.11	44.30 to 57.93	58.18	48.90 to 67.46	−5.72	−17.49 to 6.06	0.34

Questionnaire		Group	Baseline		End of follow-up		Estimated mean difference	95% CI	*P* value
			Mean	95% CI	Mean	95% CI			
		RCG	47.95	41.23 to 54.67	51.74	43.25 to 60.23			
	Social functioning	VCG	57.48	46.57 to 68.39	68.54	55.28 to 81.80	−9.90	−29.90 to 10.10	0.33
		RCG	70.19	58.94 to 81.45	63.34	46.58 to 80.11			
	Emotional problems	VCG	52.90	36.34 to 69.46	70.56	53.35 to 87.76	−16.77	−39.73 to 6.19	0.15
		RCG	65.38	48.57 to 82.20	57.56	39.78 to 75.34			
	Mental health	VCG	70.73	64.57 to 76.88	76.64	67.36 to 85.93	−4.03	−14.80 to 6.75	0.46
		RCG	70.35	63.11to 77.58	72.41	64.26 to 80.56			
EQ-5D	EQ-5 dimensions	VCG	0.09	0.01 to 0.16	0.06	−0.02 to 0.13	−0.05	−0.16 to 0.06	0.39
		RCG	0.09	0.03 to 0.15	0.04	−0.06 to 0.13			
	EQ-VAS	VCG	57.19	47.73 to 66.64	62.34	54.47 to 70.21	−4.89	−15.24 to 5.46	0.35
		RCG	57.19	48.54 to 65.85	57.45	49.21 to 65.69			

Estimated mean difference is the mean value at the end of the study minus the baseline mean value. All domains in the different health-related quality of life questionnaires are presented in the table. CI, confidence interval; ISCI-QoL-BDS, International Spinal Cord Injury Quality of Life basic dataset; VCG, group with regular care and additional videoconference consultations; RCG, regular care group; SF-36, the Short Form (36) Health Survey; EQ-5D= European Quality of Life 5 Dimensions.

Healing was achieved in 67% of the total population (37/56), of which 64% (18/28) in the VCG and 70% (19/27) in the RCG. Mean reduction in ulcer volume was 79% in the VCG vs 85% in the RCG. No significant difference was found regarding percentage healing (*P* = 0.32). The median time to heling in the VCG was 275 days (95 % CI= 111 to 43) vs 192 days (95 % CI= 114 to 270) in the RCG. No significant difference was found regarding time to healing (*P* = 0.56). Figure 12 shows the Kaplan-Mayer plot with a log-rank test regarding time to healing in the two groups.

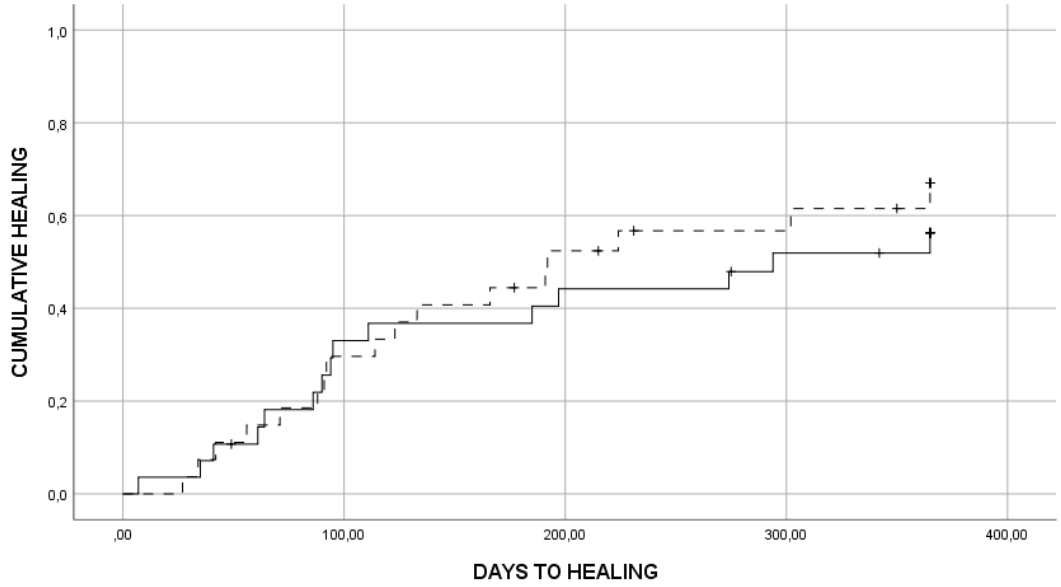


Figure 12. The Kaplan-Meier plot with a log-rank test shows time to healing in the two groups. The videoconference group is shown as a solid line; the regular care group is shown as a dashed line.

There was no significant difference in satisfaction or experienced patient empowerment in the two groups (*P* values ranged from 0.63 to 0.99) or among the local health care contacts cooperating with the outpatient wound clinics in the two groups (*P* values ranged from 0.30 to 1.0).

5.3. Applicability of telemedicine in relation to cost-utility and the environmental impact (paper III)

Table 9 gives information about the transportation-related characteristics regarding the participants and the health care contacts in the RCT.

Table 9. Transportation-related characteristics regarding the participants and the health care contacts in the randomized controlled trial

	Videoconference group		**Regular care group**	
	Mean	(SD)	Mean	(SD)
Roundtrip travel distance (Km)				
Patients	235	(176)	387	(464)
Local care workers	6.7	(7.0)	9.4	(12)
Wound Team	235	(176)	387	(464)
Roundtrip travel time (minutes)				
Patients	131	(102)	156	(124)
Local care workers	12	(11)	16	(15)
Wound Team	131	(102)	156	(124)
Roundtrip travel costs (Euro)				
Patients	20	(19)	42	(78)
District nursesLocal care workers	0.63	(1.8)	1.1	(1.9)
Wound Team	20	(19)	42	(78)
Roundtrip greenhouse gas emission (tons)				
Patients	0.04	(0.03)	0.06	(0.07)
Local care workers	0.0005	(0.001)	0.001	(0.002)
Wound Team	0.04	(0.03)	0.06	(0.07)

Transportation is described as one roundtrip. Km= kilometer, Min= minutes. Travel distance, travel time and travel costs for the participants and the wound team are equal regarding one roundtrip. SD= standard deviation.

The VCG had 158 more consultations compared to the RCG during the study period (464 vs 306). The RCG had more requested home visits from the ambulatory wound team (20 vs 6), and needed more telephone guidance from the wound team, compared to the VCG (58 vs 12). The VCG had more delays due to technical difficulties compared to the RCG (94 vs 13). The number of health care contacts (personnel) in the municipality health care service, including relatives, was higher in the VCG vs in the RCG (see paper III for details).

The outcome in the cost-utility analysis was quality-adjusted life years (QALYs), derived from the EQ-5D-5L questionnaire. The mean QALYs for the participants in the VCG was 0.45 (95% CI= 0.38 to 0.52) and 0.35 (95% CI=0.27 to 0.44) for the participants in the RCG. The mean total costs per patient was € 8819 in the VCG and € 3607 in the RCG, with a mean incremental effect of 0,1 QALYs. Table 10 shows the HRQoL (with and without imputation) and the mean cost (direct and indirect costs) per patient in the two groups.

Table 10. HRQoL (EQ-5D-5L with and without imputation) and the mean total cost (direct and indirect) per patient in each treatment group

	Videoconference group (n = 27)		**Regular care group** (n = 26)	
	Mean (SD)	**95% CI**	**Mean (SD)**	**95% CI**
Completed EQ-5D-5L without imputation				
HRQoL at Baseline (n= 27 and 26)	0.44 (0.19)	0.36 to 0.52	0.35 (0.24)	0.25 to 0.45
HRQoL at 12 months (n= 26 and 24)	0.46 (0.21)	0.38 to 0.54	0.37 (0.25)	0.27 to 0.47
Completed EQ-5D-5L with imputation				
HRQoL at Baseline (n= 27 and 26)	0.44 (0.19)	0.36 to 0.52	0.35 (0.24)	0.25 to 0.45
HRQoL at 12 months (n= 27 and 26)	0.46 (0.20)	0.38 to 0.54	0.35 (0.25)	0.25 to 0.45
QALYs from baseline to 12 months	0.45 (0.18)	(0.38 to 0.52)	0.35 (0.22)	(0.26 to 0.44)
Cost per patient				
Direct costs (n=27 and 26)	8687 (5088)	(6768 to 10606)	3509 (2131)	(2690 to 4328)
Indirect costs (n=27 and 26)	133 (118)	(88 to 178)	98 (179)	(29 to 167)
Total costs per patient (€)	8819 (5184)	(6865 to 10775)	3607 (2191)	(2765 to 4449)

The responses on each domain in the EQ-5D-5L questionnaire are converted to utility weights (between 0-1). To calculate the QALYs, the average utility weights (HRQoL) are multiplied by the time (from baseline to end of study) lived in that health state. Mean direct cost is costs related to consultations, personnel, and dressings. Mean indirect costs are costs related to transportation costs.

The differences in mean total costs and mean QALYs between the two treatment groups are summarized as an ICER, reported as cost per unit of QALY. The ICER was estimated to be € 52 120 per QALY gained (see Table 11).

Table 11. The incremental cost-effectiveness ratio (ICER)

	Mean costs	Incremental costs	Mean effect (QALYs)	Incremental effect (QALYs)	ICER (Cost/Effect)
Regular care (RCG)	€ 3 607		0,35		
Videoconference (VCG)	€ 8 819	€ 5 212	0,45	0,1	€ 52 120

ICER = difference in costs per patient divided with differences in effect (QALYs) per patient. QALYs: completed EQ-5D-5L with imputation.

We used the non-parametric bootstrapping method to investigate the uncertainty over mean differences. Uncertainty in the incremental cost and effects are illustrated as scatterplot on a cost-effectiveness plane (CE), with the incremental costs on the y-axis and the incremental effects on the x-axis (see Figure 13).

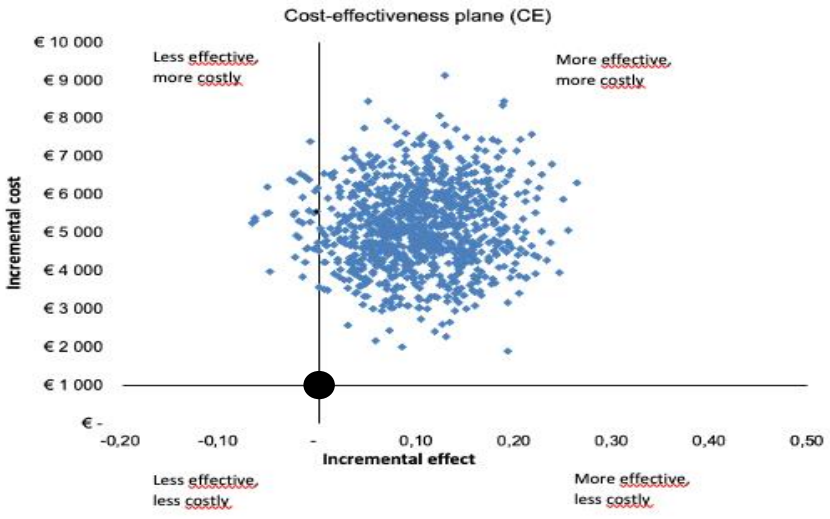


Figure 13. The incremental cost-effectiveness plane (CE-plane). The RCG is at the origin (black dot). The scatter (VCG) is in the north-east quadrant of the figure, in which the VCG generate more QALYs, but are more costly.

The transportation and environmental analyses showed no significant differences between the two groups, however a modelled analysis indicated that increased use of telemedicine solutions will benefit the environment (See Paper III for detailed information).

6. GENERAL DISCUSSION

The discussion is based on the results presented in Chapter 5 and the overall aim of the project. The discussion is divided into two main sections. The results of the three publications are discussed in the first section, and methodological considerations, including strengths and limitations, are discussed in the last.

6.1. The main results

The present study was based on a wish to get answers to some important questions related to SCI, PI occurrence and PI follow-up in Norway, raised in the SCUs.

To the best of our knowledge, this thesis provides new knowledge about the occurrence of PI during acute rehabilitation after acquiring an SCI in the Norwegian population (paper I). Further, the thesis provides new knowledge regarding the applicability and cost-utility of video conference in tandem with regular care compared to traditional outpatient follow-up for people with an SCI who need long-term PI follow-up. The applicability of the treatment is presented in paper II. The cost-utility of the treatment and the environmental impact are presented in paper III. The results of paper I, II and III are discussed in this chapter.

The study sample seems to be representative regarding the TSCI to NTSCI ratio and gender [26, 39, 40]. However, the mean age at the time of injury in the cross-sectional study is somewhat lower than previously described for the Norwegian population of people with SCI [6, 36-40]. The mean age of those participating in the RCT is even lower, although the mean age is similar in the two groups.

6.1.1. Pressure injury prevalence and risk associations

> … but we don't have any PIs in our ward (quotation from a staff member at one of the SCUs when the project was initiated).

The aim of paper I was to estimate the PI prevalence and identify potential risk factors for PI in the Norwegian population of people with an SCI during acute rehabilitation.

The period prevalence of PI during acute care rehabilitation after the SCI was found to be 16%, which is lower than described in the literature in people with SCI [6, 51, 53, 98, 128]. However, as discussed by Vanderwee et al. [58], it is difficult to compare prevalence proportions between different studies, as the results may be influenced by variation in the way each study was conducted. The authors point out that common problems in studies focusing

on PI prevalence are different patient groups, different PI definitions and different methods for data collection. This makes comparison difficult.

We identified risk locations and risk factors in accordance with previous research [6, 22, 51, 53, 58, 98, 128]. The review of the EMRs in the cross sectional study showed that many of the people examined had more than one PI, and that the coccyx was the location most at risk. This is in accordance with previous literature in this particular group [6, 7]. The risk associations identified in paper I are similar to several of the intrinsic and extrinsic risk factors described in Figure 5, and correspond with the risk factors mentioned in the literature [2, 20, 42, 53].

The occurrence of PI during acute rehabilitation is a reflection of the extent of the effectiveness of the SCU to protect the patients from PI during hospitalization. Registration of PIs provides the opportunity to monitor the extent of the occurrence of PIs. Regular mapping of the occurrence is a good way to increase awareness of the problem, and the need to initiate action plans to prevent the occurrence. Previous research on the prevalence of PIs at the Norwegian SCUs has not been undertaken in a national setting, and thus knowledge is limited [19, 46]. Further, the NorSCIR has not included information about PIs in the registry [130], and therefore it is difficult to monitor trends in development and to take action to improve the quality of care. Therefore, registration of PI occurrence is advisable in the future development of the NorSCIR [130]. The response to the initial question in this thesis is that development of PIs is a problem in the SCUs during acute rehabilitation, and the multidisciplinary team should pay more attention to the problem from admission. However, because a PI may take some time to be visually identifiable [51, 131], the staff at the acute care departments need to increase their knowledge about PI risk factors and PI prevention in this group [51, 128]. Even the ambulance staff who transport someone with a suspected SCI to the acute care hospital should increase their knowledge about PI prevention, at least if the transportation takes a long time [131-133]. A PI during acute rehabilitation has the potential to extend the duration of hospital rehabilitation, and the PI could delay and complicate the planned rehabilitation for the patient [21, 23, 46, 51]. Wang et al. describe a longer length of stay (16.5 days vs. 15.5 days, $P < 0.0001$) and less likelihood of being discharged to the community (OR, 0.75; 95% CI, 0.62 to 0.84) for those who have a PI, compared with those who do not, during acute rehabilitation [134]. Moreover, research has shown that the presence of a PI has an adverse impact on HRQoL and self-esteem in individuals with an SCI [21, 65, 111]. The occurrence of a PI during the acute rehabilitation period may have an adverse impact on life during a

period that is important for the person in terms of achieving the highest possible activity and participation, given the severity of the spinal injury [3, 18, 21, 46, 52, 65].

The results in paper I have contributed to increased knowledge about the occurrence of PI during acute rehabilitation, and PI risk factors to be aware of in the performance of the acute rehabilitation after a SCI in Norway.

6.1.2. Telemedicine and treatment outcome: applicability and advantages

> Do you people know how depressing it is to stay bedridden 24:7 at the hospital, when my family and friends are at home? You increase my burden of disease by keeping me here at the ward. I hate it (quotation from the patient who made us start thinking about alternative solutions for PI follow-up).

The main aim of paper II was to investigate the effect of additional videoconference in terms of HRQoL. Secondary outcomes were PI healing, satisfaction, safety and patient-empowerment. The VCG and RCG were balanced with regard to gender, age, PI occurrence, and PI location (Table 6, Figure 11).

Both groups had the possibility to request regular care, e.g. on-site consultations as well as telephone conferences. Thus, the additional videoconference in the VCG was the only difference between the two groups.

When the RCT was planned, a non-inferiority design was considered, with focus on PI healing. However, to reach sufficient power, the number of participants needed was too high, and a superiority design with focus on HRQoL was chosen instead. Hence, we do not have sufficient power to provide conclusive evidence regarding the comparison of PI healing or any of the other secondary outcomes.

In paper II we say "*videoconference consultations (e.g. VCG) seem to be an acceptable solution concerning treatment and follow-up. Our study shows feasibility and efficacy in the examined population*", and we conclude that "*Videoconference in a patient's home ensures safe and efficient quality of care without any reduction in HRQoL, PI healing, or satisfaction as compared to conventional outpatient care at the hospital*".
Although we had no significant findings regarding HRQoL, it seems relevant to mention that the estimated mean difference, although rather small, was in favour of the VCG for 12 out of 13 HRQoL scores (Table 8).

Furthermore, no significant difference was found regarding PI healing between the two groups, nor with regard to time to healing, as shown in Figure 12. The two curves follow each

other very closely, at least for the first 200 days, indicating that the additional videoconference service was as efficient as the conventional follow-up. However, we do not have sufficient power to formally claim non-inferiority.

As reported in previous studies, and confirmed in paper II, PIs seem to have an impact on HRQoL in the SCI population [21, 65, 111]. The participants in the RCT were asked to report the impact of the PI on their HRQoL at baseline and at the end of follow-up (paper II, including supplementary material 1). When comparing the results directly with the HRQoL-results at discharge, reported in the NorSCIR [130], we found that those with SCI and PI rated their overall health and their physical health lower than the general Norwegian population of people with a recent SCI. This may indicate that having a PI has a negative impact on HRQoL. However this comparison is based on comparing mean values only. No formal statistical test is carried out. Lala et al. performed a study where they compared the impact of PI on individuals living with an SCI [21]. They found that the number of PIs had a greater impact on HRQoL than having a PI.

In the present RCT, we did not ask about the impact of the PI on activity and participation. However, the HRQoL forms used in paper II included information about physical functioning, general health perceptions and social functioning, as shown in Table 8. The study population in the RCT scored poorer at baseline and at the end of follow-up, compared with the results found in a study looking at QoL and self-esteem in persons with paraplegia and PI [65]. The scores in the RCT were also substantially poorer than the scores from a general population survey performed in Norway [132].

Thus, if focusing on physical and social functioning and physical role, these are negatively affected by having a PI in people with an SCI, possibly because of the loss of control over bodily functions and loss of control over the ability to perform self-care [65]. In a study investigating participation and HRQoL in people living with SCI in Norway, the overall health, physical health and mental health scores were higher than the mean values in the VCG and RCG in our study [111, 135]. This indicates that PIs have a negative impact on HRQoL in the study population.

> I am so grateful for the possibility to collaborate and cooperate in this PI follow-up. Now the follow-up is much more coordinated and predictable, and I feel I have learned a lot (quotation from one of the district nurses participating in the RCT).

Telemedicine services, such as videoconferencing, is assumed to be a tool for cooperation in the rehabilitation process, according to previous findings [41, 72, 91]. The presence of a PI is found to increase the discomfort among people with SCI because of the PI itself and its treatment [3, 6, 18, 21, 46, 52, 65]. This indicates a need to improve the treatment options, and telemedicine in the long-term follow-up of PIs could be a promising intervention regarding knowledge transfer and interaction between the specialized health care providers, the patients and the local care workers.

Studies have shown that the quality of the treatment is important, and so is the time the person has to wait to get the treatment. However, the logistics and coordination of the service are also reported to be essential, as well as the possibility to participate and co-determine the treatment and follow-up [69-71]. In PI follow-up, it is paramount to make the patients understand why they have developed the PI and what needs to be done to treat the condition. Thus, an imperative role for the multidisciplinary wound team is to discuss possible triggers with the patient. If the patient understands their health condition, and the effect of the PI triggers on the body, they will feel able to participate in the decision-making regarding the treatment to a greater extent [69-72, 107]. In the present RCT, the PI treatment and guidance were similar in the RCG and the VCG, and the participants in both groups reported a safe, satisfactory and useful follow-up experience. The participants in both groups rated high on patient-empowerment and participation in the consultations, however no significant differences were found (see paper II).

Based on the results from the RCT, we cannot conclude that regular care with additional telemedicine is better than regular care with regard to any of our outcomes. Neither can we formally conclude about non-inferiority, due to the sample size. However, informally, all results indicate that additional telemedicine does not affect the outcome, by comparison of descriptive measures. A larger study with a non-inferiority design is warranted to formally investigate this.

In the present RCT, the cooperation between the participant, the district nurses and the multidisciplinary team was important, and coordinated, mutual person-adjusted goals were worked out in the follow-up consultations in both groups [28, 59, 111]. The participating district nurses in both groups seemed to be satisfied with the cooperation with the multidisciplinary wound team. The estimated mean differences in the satisfaction form in the two groups were minor, and no significant differences were found. The number of

respondents in the two groups were small, and the results must therefore be interpreted with caution. The RCT did not answer our questions regarding whether regular care with additional telemedicine is more effective than regular care, and the results should therefore be interpreted with caution. To capture potential differences in satisfaction, a larger study is warranted.

6.1.3. Telemedicine and cost-utility

In the cost-utility analysis (paper III), the result showed that the VCG costs € 5212 more for an additional 0.1 QALYs, giving an ICER of € 52 120 per QALY gained in a one year follow-up (Table 11) [136].

Several studies have investigated the cost of PIs, both in the general population and in the population of people with SCI [36, 61, 63, 64, 66, 137-139].

When a new treatment is added to the current, it is obvious that the cost will increase. As health care professionals, we are obligated to help and treat the patients [140, 141], but we also have a responsibility to allocate the health care resources in the best possible way. As mentioned, the occurrence of severe PIs often leads to long periods of hospitalization, and frequent outpatient follow-up visits to monitor the treatment [5, 6, 46, 137]. Stoupe et al found that the inpatient costs at a SCU were more than ten times higher for people with PI compared with the expenses for those without PI [137].

> In our feasibility study, we found that outpatient videoconferences constitute 15% of the costs compared with on-site consultations, and 3.2% of the costs compared with hospitalization (quotation by the author at a meeting with authorities at the Norwegian Health and Care Department, 2014).

Other studies have also found personnel costs to be an important part of the total expenses; however, these studies were about hospitalization, not outpatient follow-up [138, 139]. In the current RCT, the patients received outpatient follow-up only. No hospitalization was needed. Thus, there is no direct available comparison with inpatient costs of treating PIs at the Norwegian SCUs, even though the findings in our previous feasibility study indicate that the expenses for outpatient videoconference consultations were lower than those for on-site consultations at the outpatient clinic and for inpatient stays [91].

The CUA in paper III [136] found that the direct costs constituted most of the total costs in the VCG (98%) vs RCG (97%), and the personnel costs constituted 23% of the direct costs in the VCG vs 27% in the RCG (Chapter 5). The fact that the cost per consultation was set equal regarding videoconferences, telephone consultations and on-site consultations, makes the

number of consultations in the two groups the issue of importance regarding differences in the total costs for each group. Thus, the main difference in costs between the two groups was the number of pre-planned video consultations in the VCG. The design of the RCT [59] was based on clinical experience and feedback from the feasibility study [91]. Consequently, the frequency of consultations in the VCG was set to every second to third week. Retrospectively, the number of video consultations, and related costs, could probably have been reduced, without influencing the outcome of HRQoL and PI healing (Table 7, Figure 14). The number of participating health care professionals from the municipalities was higher in the VCG compared to the RCG, and a higher number of educated wound care district nurses participated in the VCG compared to the RCG, thus increasing the personnel costs in the VCG (Table 10, paper III) [136]. The increased number of personnel can be explained with a need for more personnel at the VCG consultations to learn to use the digital solution. However, more personnel participating, increased the possibility to transfer knowledge regarding SCI and PI treatment to more health care professionals.

Differences in transportation costs in the RCT, arise by chance, because the participants were included from all over the country. Thus, one participant living far from the SCU, will affect the results to a rather large extent. However, due to the high number of consultations in the VCG, the local health care workers will constitute increased costs related to visiting the patient. Based on the results from HRQoL and healing in the two groups, a reduced number of home visits is recommended. Reduced consultations will reduce the total costs of providing additional videoconference in the investigated population.

Previous research regarding costs in the population of people with SCI and PI is inconsistent, and makes it difficult to compare with our study [22, 68, 80-84, 142-145].

The purpose of a health economic evaluation is to provide better information in decision making that contribute to the most efficient use of the health sector's resources, in line with national guidelines for prioritization. There are various methods within economic evaluation, such as cost-effectiveness analysis (cost per QALY analysis). Cost per QALY analysis is the recommended analysis as decision support for prioritizing methods in Norway [146].

In Norway, the decisions are based on three priority criteria: effect, resource use and severity. The cost-effectiveness ratio (ICER), i.e. cost per QALY, must be assessed against the severity of the disease or condition [146].

There will always be an investment costs when starting new interventions, i.e. implementing a new technology. It is shown that the largest item of expenditure of implementing a digital remote follow-up is related to the personnel costs. Thus, it is important to choose a way of organization or pathway that does not consume more resources than necessary in the follow-up [147].

The current CUA presented the cost per QALY gained when regular care with additional videoconference was compared to regular care. Whether regular care with additional videoconference is cost-effective, depends on what the society is willing to pay per QALY gained. There is no consensus on the exact willingness-to-pay per QALY in Norway [148], and therefore we have no basis to conclude whether the intervention is cost-effective or not.

6.1.4. Telemedicine and environmental outcome

> Nature and the environment must be taken seriously on an individual, national and international level. All human activity that is harming the environment also harms ourselves. The health of the planet determines our health. The climate crisis threatens global public health in countless ways. The planet and out health need us to facilitate a health care system where the follow-up service to the individual can be maintained in a safe and sustainable way for the patient, as well as for the environment (quotation from Are Brean, Editor-in-Chief, *Journal of the Norwegian Medical Association*, 25 May 2020).

Geographic location can be a barrier to receiving rehabilitation services, because long-distance travel can cause suffering for people with SCI and PIs [2, 5, 15]. Expenses associated with transportation are high in terms of time and money, and as long as fossil fuels are used, the expenses are also high in terms of the carbon footprint [149].

In Norway, transportation is without problems most of the times, but climate change has interfered with the seasons, and the weather has become worse [150]. In some cases, the weather conditions have resulted in on-site consultations being cancelled for patients with SCI and PI. Further, pandemics, such as Covid-19, reduced activity in outpatient clinics [151--153], making it necessary for health care professionals to think creatively about future follow-up possibilities, rather than having ambulatory on-site consultations as the only option.

In the RCT (paper III), we assessed travel distance, travel time, travel costs and emission of greenhouse gases connected to transport related to PI treatment. No significant differences were found between the two groups. However, a modelled scenario with only videoconferences in the VCG and only ambulatory on-site consultation at the wound clinic in the RCG, showed significant results in favour of the VCG. The model was created using the

same number of consultations as provided in each of the two groups in the RCT, thus the results would have been even more in favour of the VCG if the consultations had been more in line with the original design of the study [59].

People with an SCI are particularly vulnerable to climate changes, due to limited mobility, the need for assistive devices, in-person assistance and reduced access to emergency services. In some countries, the vulnerability is even worse due to lack of financial resources. In addition, people with an SCI living in rural areas are affected by climate changes, making it difficult to travel for the necessary follow-up. [16, 27, 88]. Even though the present RCT did not find any significant differences between the two groups regarding transportation costs and greenhouse gas emission, a hybrid solution of follow-up, using regular care and additional telemedicine solutions, would give health care professionals the opportunity to offer satisfying health care options, no matter the geographical location of the patient [72, 83, 85, 91, 122, 147, 154].

6.2. Telemedicine and the ICF framework

In the present study, telemedicine was implemented within the ICF framework [24]. Because the participants, local health care contacts and the multidisciplinary wound care team cooperated in the follow-up, it was possible to take advantage of active involvement and feedback from the participants and the local care workers in the consultations [41, 72, 111, 136].

> This is a simple, good and safe way to cooperate. I feel you are together with me in my bedroom (quotation from a participant in the VCG).

Videoconferencing gave the multidisciplinary wound care team the opportunity to perform visual examinations via the screen.

With telephone consultations, the multidisciplinary wound care team had to rely on the description of the examination given by the district nurses. In addition, the wound care team missed out on non-verbal language, such as gestures and facial expressions that may add extra value to a conversation. For the multidisciplinary team, this was a problem in particular regarding the body function and structure domain and the environmental domain where visual examination of the PI and skin condition, sitting position, as well as technical and practical issues regarding the assistive aids, was needed.

The main goal for the patient is to achieve the best possible function and coping abilities, independence and participation in family and social life and in society. A PI may isolate the patient due to treatment recommendations, and this may be perceived as an additional burden on the patient [65].

The previous Norwegian Minister of Health and Care summarized the concept of good health in the Annual Speech of the Health and Care Service:

> Good health is not necessarily absence of disease. It is great to be completely free of illness, or to have an injury treated, whenever possible. However, it is also great to master life well, and feel that you have good health, even when you have a diagnosis, have to live with associated conditions after an injury, or experience weakness due to old age, as well as to the use of medications. Therefore, I believe that the definition of good health is similar to being able to master (quotation Bent Høie) [79].

To support patients in achieving the best possible function and coping ability, the health care service should involve them at an early stage in the treatment and follow-up, and such patient empowerment needs to be included in all the domains of the ICF framework [24, 78].

Previous research has shown that including the person in all aspects of the treatment and follow-up increases satisfaction with the treatment, as well as the results of the treatment [155]. This is also emphasized in *Tele-oncology*; where the authors recommend to "adopt a patient-centred focus, rather than merely present solutions that will soon become outdated" in telemedicine follow-up, because this can improve treatment and HRQoL [156, pp. 23-37]. However, to increase patient empowerment, the persons needs to be active in handling their condition, and this requires transfer of knowledge about the condition and treatment options from the health care professionals to the patient [69-71]. Both the participants and the district nurses in both groups reported an increased level of knowledge (Chapter 5). Even so, more research is needed focusing on patient-empowerment and knowledge transfer, to establish sufficient knowledge.

6.3. Methodological considerations

In this section, methodological considerations that must be taken into account when interpreting the results of the study are presented.

6.3.1. Study design

This study was conducted in Norway, and some of the information provided in the thesis is therefore specific to the Norwegian health care system.

In the epidemiologic study (paper I), we registered all patients who were admitted to one of the three SCUs in Norway between 2004 and 2014. However, due to less well-defined transfer protocols for people with NTSCI, compared with the protocols for newly acquired TSCI [26], we may have missed some cases of NTSCI. We were aware of this issue when the study was designed, but it would not have been possible to examine the EMRs of all hospitalized patients at all Norwegian hospitals in the time period. Hence, it was not an option to search for potential participants outside the three SCUs. In addition, we should have divided the time between acquiring the SCI and discharge from acute care rehabilitation into two separate periods (one period from the SCI to acute care discharge and one period from admission to discharge from acute care rehabilitation) to better record the time of onset of any comorbidity and associated SCI-related conditions in relation to the development of a PI. Unfortunately, this was not possible based on the information available in the EMRs.

A protocol was devised regarding the implementation and conduct of the follow-up in the RCT [59]. This protocol was in accordance with the telemedicine guidelines implemented at Sunnaas Rehabilitation Hospital [112]. In the RCT, one group was allocated to pre-planned videoconference follow-up and the other to on-site consultations at the outpatient wound clinic. The design of the study was based on the experience from a previous pilot study [91]. The feedback received in the pilot study did not give the research group any reason to believe there would be a problem with this design. However, in practice, what happened was that both groups wanted remote follow-up. The RCG preferred telephone consultations instead of on-site consultations, and the participants informed us they did not want to travel to the outpatient clinic if they could get safe and knowledge-based treatment at home. In both groups, telephone consultation was an option, and the participants in the RCG chose this way of cooperation. The pre-planned regularity of the video consultations in the VCG, compared with consultations according to perceived needs in the RCG, most likely increased the number

of consultations in the VCG. This increased the costs, travel time, kilometres driven and emission of atmospheric pollutants for the district nurses.

In the RCG, travelling was reduced because telephone consultations were preferred instead of on-site consultations. Retrospectively, the research group discussed if the participants and district nurses in both groups should have been asked to request assistance when needed, instead of scheduling the number of consultations in the VCG. This would probably have affected the results, at least in paper III. However, we did a modelled analysis to correct for these unexpected choices in the RCG. The analysis showed significant differences in favour of the VCG in relation to travel distance, travel time, travel costs and emission of environmental pollutants (paper III).

In the RCT, the power calculation is based on the HRQoL assessment, thus the study has low power regarding the other outcomes investigated in paper II. Retrospectively, it is clear that our assumptions regarding potential differences in HRQoL in the two groups were too optimistic.

A non-inferiority design would have been better to establish knowledge regarding if the additional videoconference follow-up was no worse than the traditional offer. However, this was not possible to perform due to the large number of participants needed.

6.3.2. Questionnaire data

Custom-made rather than validated forms were used to map data in all three papers (Appendices 2-6). The reliability of the forms was not assessed. This is a limitation in papers I, II and III. However the variables we wanted to investigate using those forms (paper I and II) were similar to variables used in previous studies in population of people with SCI [32, 34, 48].

In the RCT, validated questionnaires were used to map HRQoL [114, 116-119], and the recommended EQ-5D-5L questionnaire was used in the cost-utility analysis [121]. Hence, the results from those questionnaires should be reliable. However, because both groups in the RCT more or less ended up having remote follow-up at home, instead of one group having follow-up by videoconference and the other by on-site consultations, it was not to be expected that one group would achieve higher HRQoL than the other (paper II) and thus, no difference in the cost-utility analysis was expected (paper III).

6.3.3. Bias and confounding

Inaccuracy in the retrospective data in the EMR is a potential source of bias in the cross-sectional study. There was a lack of information about PIs in 12% of the EMRs investigated. This could reduce the validity of the results, and also statistical power. However, we performed a sensitivity analysis to investigate the impact of the missing data, without finding any significant change in the results (Table 7). In addition, more or less systematic lack of information in the EMRs, such as missing data regarding smoking and snuff and about the use and abuse of alcohol or narcotics, may have reduced the quality of the results. Hence, the results should be interpreted with some caution [157].

A high number of potential risk factors were investigated in the cross-sectional study, thus it was not feasible to develop causal models and adjust for all confounding factors. Therefore, the associations that we identified should be interpreted as indications. Further, a high number of statistical significance tests were performed, increasing the risk of type I errors [158], however, most of our significant findings seem clear and robust.

The satisfaction form (Appendix 6) in the RCT was completed at the end of follow-up, thus many of the PIs had healed, or at least had healed to some extent, compared with start of the follow-up (paper II). This may have influenced the answers in both groups in a more positive way than if the healing had not taken place. In addition, the author phoned the participants to get the answers for the satisfaction form. This may have biased the results. However, the same procedure was used in both groups, thus compensating for any differences at group level.

The author participated as a physician in the multidisciplinary wound team at one of the outpatient clinics and performed the assessment and mapping of the wounds. However, all assessments were made together with the wound care nurse, or the district nurse, to reduce the possibility of bias in the assessments. The wound care nurse and the district nurse did not participate in the analysis of the results. For some of the participants, there were problems with continuity among the district nurses, which meant that different nurses were included in the wound treatment, with the possibility that the treatment did not follow the recommended guidelines. This may have influenced the internal validity of the trial.

6.3.4. Random error

Random errors may have occurred when assessing the volume (length × width × depth) of the PIs. The measurements may have been performed differently even though the wound care team guided the district nurses in the assessment. However, volume assessment in wounds is difficult. It is impossible to get an accurate assessment due to the shape of the wound, and the optimal assessment tool is still to be developed. In addition, random errors may have affected the accuracy of the answers in the HRQoL forms.

6.3.5. External validity

The final consideration regarding the methodology is whether the samples in the epidemiologic study and in the RCT are representative of people with SCI and PI. In the cross-sectional study, all patients admitted to one of the three SCUs were included, thus making the findings on PIs robust and representative, even though some individuals with NTSCIs were probably not included. Regarding the PI risk associations, lack of information in the EMRs and small samples for some of the risk associations may have affected the generalizability of the results, and the results should therefore be interpreted with caution.

In the RCT, the low number of participants in the two groups makes the results difficult to generalize to the overall population, even though the number was not limited by strict inclusion and exclusion criteria.

6.3.6. Adverse events

Two participants in the RCT died during the follow-up, one because of pulmonary illness and the other due to cardiovascular complications. One participant died before the start of the follow-up due to cardiovascular complications. No deaths were reported to be related to the PIs. All participants in the RCT had the possibility to continue the PI follow-up, even though they choose to drop out of the trial [59].

7. CONCLUSIONS AND CLINICAL IMPLICATIONS

> This follow-up service must be expanded also to other conditions (quotation from an employee at a hospital not participating in the RCT).

In paper I the aims were to explore the period prevalence and potential risk factors for PI in individuals during the acute rehabilitation after a spinal cord injury. The identified period prevalence in the population was 16%, and risk factors affecting the odds of having a PI were the completeness of the SCI, being injured abroad, bowel and bladder dysfunction, diabetes mellitus type 1, depression, concomitant traumatic brain injury, need for ventilator support and drug abuse. These factors should be in focus regarding prevention of PI during acute care rehabilitation, as well as after discharge.

In paper II the aims were to study the effect of videoconference in addition to regular care, compared to regular care in the treatment of PI. No significant differences were found regarding HRQoL, healing, satisfaction, safety and patient empowerment in the follow-up, and more research is needed to be able to conclude whether or not additional videoconference follow-up is to be recommended.

In paper III the aim was to evaluate the cost-utility of videoconference in addition to regular care, compared to regular care alone. Comparison of the transport related costs and environmental impact of the treatment were secondary outcomes. The results show that the VCG costs € 5212 more for an additional 0.1 QALYs, giving an ICER of € 52 120 per QALY gained. No significant differences were found regarding transportation costs and greenhouse gas emission.

The results presented in the thesis is a contribution for future priority-setting decisions regarding telemedicine used in the long-term follow-up of persons with complex long-term needs.

8. FUTURE RESEARCH

The PI risk factors identified in the cross-sectional study should be further investigated to clarify casual relationships.

All participants with a known address received a questionnaire asking about the occurrence of PIs after discharge from the acute care rehabilitation. In the questionnaire, we asked about the participants' home situation their opinion regarding the reason for the PI. The results from these questionnaires are yet to be analysed, and this work will be part of future research in the context of the present study.

A selected number of participants, both patients and district nurses, in both groups in the RCT were interviewed after the end of the study. In the interview, the participants were asked about their knowledge and reflections on the follow-up. Transcription and analysis of these interviews have yet to be performed and will contribute to a better understanding of the experience in a coordinated, multidisciplinary PI follow-up.

A larger study with higher power related to the most important outcome variables should be performed. To achieve the needed number of participants, the study should be an international multi-centre study. Sub-studies should focus on differences between countries with regard to access and costs related to software, technical equipment and staff for outpatient telemedicine services compared with regular care.

Participants and their district nurses in both groups in the RCT scored high on interaction and satisfaction, with no significant differences regarding the follow-up in the two groups. A larger study with a non-inferiority design is warranted to gain more knowledge.

Based on the number of non-healing PIs in our study, a longer follow-up period may be an interesting topic for future research. The issue of non-healing PIs should also be further explored, no matter the mode of follow-up intervention. In the RCT, the general practitioners were not included. They were invited to participate, but did not respond to the invitation. In future studies, participation from the general practitioners would be welcomed.

9. CONCLUDING REMARKS

This study was conducted before the Covid-19 pandemic. As a result of the telemedicine guidelines implemented at Sunnaas Rehabilitation Hospital, no PI follow-ups had to be cancelled or postponed due to the strict infection regulations at the outpatient clinic. All the follow-ups were conducted as telemedicine consultations, either as videoconference consultations or as telephone consultations, in line with the patients' preferred follow-up, as demonstrated in this study. Further, the more I worked with the topic, the more I understood the importance of including climate sustainability in health care offerings. Climate change is a threat to all life, but poor people, indigenous people, people living in rural areas, the elderly and disabled are already affected by catastrophic events related to war, hurricanes, fires and flooding around the world. The Hippocratic oath [141] requires physicians to swear by numerous healing gods and dictates the duties and responsibilities of the physician when treating patients [141]. In my view, this responsibility also involves taking care of planet Earth. We need to take action and be proactive in performing green health care services. Telemedicine is a starter [154].

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APPENDICES

Appendix 1. SCI-related diagnosis used in study 1. Based on the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)-WHO Version for; 2016

ICD-10 Chapter	Disease chapter	Text	Spesific chapter and text
II Neoplasms	C70	Malignant neoplasm of meninges	C70.1Spinal meninges C70.9 Meninges unspecified
	C72	Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system	C72.0 Spinal cord C72.1 Cauda equina C72.8 Overlapping lesion of brain and other parts of central nervous system C72.9 Central nervous system, unspecified
	C79	Secondary malignant neoplasm of other and unspecified sites	C79.4 Secondary malignant neoplasm of other and unspecified parts of nervous system
VI Diseases of the nervous system	G04	Encephalitis, myelitis and encephalomyelitis	G04.1Tropical spastic paraplegia G04.2 Bacterial meningoencephalitis and meningomyelitis, not elsewhere classified G04.8 Other encephalitis, myelitis and encephalomyelitis, G04.9 Encephalitis, myelitis and encephalomyelitis, unspecified
	G82	Paraplegia and tetraplegia	G82.0 Flaccid paraplegia G82.1Spastic paraplegia G82.2 Paraplegia, unspecified, G82.3 Flaccid tetraplegia G82.4 Spastic tetraplegia G82.5 Tetraplegia, unspecified,

	G83	Other paralytic syndromes	G83.0 Diplegia of upper limbs, G83.1 Monoplegia of lower limb, G83.2 Monoplegia of upper limb, G83.3 Monoplegia, unspecified G83.4 Cauda equina syndrome, Incl.
	G95	Other diseases of spinal cord	G95.0 Syringomyelia and syringobulbia G95.1Vascular myelopathies G95.2 Cord compression, unspecified G95.8 Other specified diseases of spinal cord G95.9 Disease of spinal cord, unspecified
	G99	Other disorders of nervous system in diseases classified elsewhere	G99.2*Myelopathy in diseases classified elsewhere G99.8*Other specified disorders of nervous system in diseases classified elsewhere
XIII Diseases of the musculoskeletal system and connective tissue	M46	Other inflammatory spondylopathies	M46.0 Spinal enthesopathy M46.1 Sacroiliitis, not elsewhere classified M46.2 Osteomyelitis of vertebra M46.3 Infection of intervertebral disc (pyogenic) M46.4 Discitis, unspecified M46.5 Other infective spondylopathies M46.8 Other specified inflammatory spondylopathies M46.9 Inflammatory spondylopathy, unspecified
	M47	Spondylosis spondylopathies	M47.0†Anterior spinal and vertebral artery compression

			syndromes M47.1 Other spondylosis with myelopathy M47.2 Other spondylosis with radiculopathy M47.8 Other spondylosis M47.9 Spondylosis, unspecified
	M48	Other spondylopathies	M48.0 Spinal stenosis M48.2 Kissing spine M48.3Traumatic spondylopathy M48.4 Fatigue fracture of vertebra M48.5 Collapsed vertebra, not elsewhere classified M48.8 Other specified spondylopathies M48.9 Spondylopathy, unspecified
	M49	Spondylopathies in diseases classified elsewhere	M49.0*Tuberculosis of spine M49.1*Brucella spondylitis M49.2*Enterobacterial spondylitis M49.3*Spondylopathy in other infectious and parasitic diseases classified elsewhere M49.4*Neuropathic spondylopathy, Incl.: Neuropathic spondylopathy in: syringomyelia and syringobulbia, tabes dorsalis M49.5*Collapsed vertebra in diseases classified elsewhere M49.8*Spondylopathy in other diseases classified elsewhere

	M50	Cervical disc disorders	M50.0†Cervical disc disorder with myelopathy
	M51	Other intervertebral disc disorders	M51.0†Lumbar and other intervertebral disc disorders with myelopathy
XIX Injury, poisoning and certain other consequences of external causes	S12	Fracture of neck	S12.0 Fracture of first cervical vertebra S12.1 Fracture of second cervical vertebra S12.2 Fracture of other specified cervical vertebra S12.7 Multiple fractures of cervical spine S12.8 Fracture of other parts of neck S12.9 Fracture of neck, part unspecified
	S13	Dislocation, sprain and strain of joints and ligaments at neck level	S13.0 Traumatic rupture of cervical intervertebral disc S13.1 Dislocation of cervical vertebra S13.2 Dislocation of other and unspecified parts of neck S13.3 Multiple dislocations of neck S13.4 Sprain and strain of cervical spine S13.6 Sprain and strain of joints and ligaments of other and unspecified parts of neck
	S14	Injury of nerves and spinal cord at neck level	S14.0 Concussion and oedema of cervical spinal cord S14.1 Other and unspecified injuries of cervical spinal cord S14.2 Injury of nerve root of cervical spine S14.3 Injury of brachial plexus

			S14.4 Injury of peripheral nerves of neck S14.6 Injury of other and unspecified nerves of neck
	S15	Injury of blood vessels at neck level	S15.7 Injury of multiple blood vessels at neck level S15.8 Injury of other blood vessels at neck level S15.9 Injury of unspecified blood vessel at neck level
	S22	Fracture of rib(s), sternum and thoracic spine	S22.0 Fracture of thoracic vertebra S22.1 Multiple fractures of thoracic spine S22.8 Fracture of other parts of bony thorax S22.9 Fracture of bony thorax, part unspecified
	S23	Dislocation, sprain and strain of joints and ligaments of thorax	S23.0 Traumatic rupture of thoracic intervertebral disc S23.1 Dislocation of thoracic vertebra S23.2 Dislocation of other and unspecified parts of thorax S23.3 Sprain and strain of thoracic spine S23.5 Sprain and strain of other and unspecified parts of thorax
	S24	Injury of nerves and spinal cord at thorax level	S24.0 Concussion and edema of thoracic spinal cord S24.1 Other and unspecified injuries of thoracic spinal cord
	S25	Injury of blood vessels of thorax	S25.8 Injury of other blood vessels of thorax S25.7 Injury of multiple S25.9 Injury of unspecified blood vessel of thorax

	S29	Other and unspecified injuries of thorax	S29.0 Injury of muscle and tendon at thorax level S29.7 Multiple injuries of thorax S29.8 Other specified injuries of thorax S29.9 Unspecified injury of thorax
	S32	Fracture of lumbar vertebra and pelvis	S32.0 Fracture of lumbar vertebra S32.7 Multiple fractures of lumbar spine and pelvis S32.8 Fracture of other and unspecified parts of lumbar spine and pelvis
	S33	Dislocation, sprain and strain of joints and ligaments of lumbar vertebra and pelvis	S33.0 Traumatic rupture of lumbar intervertebral disc S33.1 Dislocation of lumbar vertebra S33.3 Dislocation of other and unspecified parts of lumbar spine and pelvis S33.5 Sprain and strain of lumbar spine S33.7 Sprain and strain of other and unspecified parts of lumbar spine and pelvis
	S34	Injury to nerves and spinal cord at abdominal level, lower back and pelvis	S34.0 Concussion and edema of lumbar spinal cord S34.1 Other injury of lumbar spinal cord S34.3 Injury of cauda equina
	S35	Injury of blood vessels at abdominal level, lower back and pelvis	S35.0 Injury of abdominal aorta S35.7 Injury of multiple blood vessels at abdomen, lower back and pelvis level

			S35.9 Injury of unspecified blood vessel at abdomen, lower back and pelvis level
	T09	Other injuries of vertebra and trunk, not specified	T09.3 Injury on the spinal cord not specified part
	T91	Sequelae after injury of neck and trunk	T91.3 Sequelae after spinal cord injury T91.1 Sequelae after fracture of spine T91.2 Sequelae after other fracture of thorax and pelvis T91.3 Sequelae after injury of spinal cord T91.8 Sequelae after other specified injuries of neck and trunk

Appendix 2.

The electronic medical record mapping form

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

HELSE BERGEN
Haukeland Universitetssjukehus

AVDELING FOR RYGGMARGSSKADER

en ny vidsyn Sunnaas sykehus HF

Landsforeningen for Ryggmargsskadde
Tilsluttet Norges Handikapforbund (NHF)

Ryggmargsskade og trykksår

Løpenr:

Kartleggingsskjema 1 Journal

Dato

Epidemiologiske data:

(Sett kryss eller tall i riktig rubrikk der dette er mulig)

Kjønn (M/ K) **Fødselsdato** **Dato for skade**

Innlagt akuttavdeling **Utskrevet fra akuttavdeling**

Innlagt primærrehabilitering **Endelig utskrevet fra primærrehab.**

Avbrudd i/ utskrivelse fra primæroppholdet (fravær > 7 dager, ikke permisjoner) **Nei** **Ja** **Antall ganger**

Årsak: Planlagt innleggelse annen avdeling **Uplanlagt innleggelse annen avdeling**

Tidspunkt (fra- til) **Totalt antall dager avbrudd**

Totalt antall dager innlagt primærrehabilitering

Diagnosekode (r) relatert til trykksår (registrert ved primærrehabiliteringsopphold)

Familie/ sosialt ved skadetidspunkt: *(Sett x)*

Enslig/ bor alene		**Skoleelev**				**Vet ikke**		
Bor med andre		**Student**				**Vet ikke**		
Samboer		**Høyeste fullførte utdanning**				**Grunnskole**		
Gift/ Partner						**Videregående skole**		
						Høyskole/ universitet		
Skilt						**Ukjent**		
Enke/ -mann		Yrkesaktiv		**Ja**		**Full tid**		
						Deltid		
Foreldre i live		Vet ikke		**Nei**		**Sykemeldt**		
Søsken (antall)		Vet ikke		**Vet ikke**		**Arbeidsavklarings penger**		
Barn (antall)		Vet ikke				**Uføretrygdet**		
Sivilstatus ukjent						**Pensjonist**		
						Vet ikke		

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

HELSE BERGEN
Haukeland Universitetssjukehus

AVDELING FOR RYGGMARGSSKADER

Sunnaas sykehus HF

Landsforeningen for Ryggmargsskadde
Tilsluttet Norges Handikapforbund (NHF)

Ryggmargsskade og trykksår

Løpenr:

Skadeårsak

	Traumatisk ☐	**Ulykkestype** ☐ **Trafikkulykke** **Bil** ☐ **Traktor** ☐ **MC** ☐ **4-hjuling** ☐ **Sykkel** ☐ **16 Fører** ☐ **Passasjer** ☐ **Fotgjenger** ☐ **Fall** ☐ **Fritid** ☐ **Arbeid** ☐ **Annet** ☐ **Hvis annet, angi hva:**
	Ikke- traumatisk ☐	**Årsak:** **Blodpropp(Ischemi)** ☐ **Blødning** ☐ **Malformasjon** ☐ **Tumor/ svulst, godartet** ☐ **Tumor/ svulst, ondartet** ☐ **Infeksjon** ☐ **Bakterie** ☐ **Virus** ☐ **Andre ikke- traumatiske årsaker** ☐
	Uspesifisert/ ukjent årsak ☐	**Annet** ☐ **Angi hva** ☐ **Operasjon** **Nei** ☐ **Ja** ☐ **I tilfelle hvilket sykehus** ☐

Skadeomfang ved innleggelse spinalenhet

Skadenivå	**C_1-C_4** ☐ **AIS A** ☐ **B** ☐ **C** ☐ **C_5-C_8** ☐ **AIS A** ☐ **B** ☐ **C** ☐ **T_1-S_5** ☐ **AIS A** ☐ **B** ☐ **C** ☐ **AIS D** ☐ **Respiratortrengende** ☐ **Cauda equine** ☐ **Ikke oppgitt** ☐	
Skade av naturlige funksjoner ved første gangs innleggelse spinalenhet	**Blære** **Nei** ☐ **Ja** ☐ **Lekkasje** **Nei** ☐ **Ja** ☐ **Tarm** **Nei** ☐ **Ja** ☐ **Lekkasje** **Nei** ☐ **Ja** ☐	**Bruk av** **RIK** ☐ **Permanent kateter** ☐ **Bleie** ☐ **Ukjent** ☐ **Analpropp** ☐ **Ukjent** ☐

Ryggmargsskade og trykksår

Løpenr:

Andre relevante sykdommer/ tilstander registrert v/ primæroppholdet

Bruddskader Nei ☐ Ja ☐

Hodeskade Nei ☐ Ja ☐

Diabetes Nei ☐ Ja ☐ Type 1 ☐ Type 2 ☐

Kostregulert ☐ Tabletter ☐ Insulin ☐

ADHD/ ADD Nei ☐ Ja ☐
Høyt blodtrykk Nei ☐ Ja ☐
Hjerte/kar sykdom/ Nei ☐ Ja ☐

Evt. hvilken _____

Blodpropp, nå/ tidligere Nei ☐ Ja ☐
Evt. hvor Ben (DVT) ☐ Lunger (Emboli) ☐ Hjerteinfarkt ☐ Hjerneslag ☐

Depresjon/ Nedtrykthet Nei ☐ Ja ☐

Spasmer Nei ☐ Ja ☐

Smerter Nei ☐ Ja ☐

Allergi/ Eksem/ Hudsykdom Nei ☐ Ja ☐
Høysnue ☐ Eksem ☐ Medikamentallergi ☐

Evt. spesifiser hva slags _____

Nytelsesmiddel

Røyk	Ukjent ☐	Nei ☐	Ja ☐	Antall sigaretter pr dag	☐
Snus	Ukjent ☐	Nei ☐	Ja ☐	Antall priser pr dag	☐
Alkohol	Ukjent ☐	Nei ☐	Ja ☐	Antall enheter pr uke	☐
Narkotiske stoffer	Ukjent ☐	Nei ☐	Ja ☐	Antall ganger pr måned	☐
Anabole steroider	Ukjent ☐	Nei ☐	Ja ☐	Antall ganger pr måned	☐

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

AVDELING FOR RYGGMARGSSKADER

Sunnaas sykehus HF

HELSE BERGEN
Haukeland Universitetssjukehus

Landsforeningen for Ryggmargsskadde
LARS
Tilsluttet Norges Handikapforbund (NHF)

Ryggmargsskade og trykksår

Løpenr:

Trykksår registrert i journal (v/primæropphold):

Registrert:	Trykksår under primærrehabiliteringsoppholdet Vet ikke ☐ Nei ☐ Ja ☐ 1 sår ☐ Flere sår ☐
Lokalisasjon	**Høyre kroppsside** ☐ Fot/ Tær ☐ Hæl ☐ Ankel ☐ Kne ☐ Hofte ☐ Sitteknute ☐ Ryggrad ☐ Albue ☐ Skulder ☐ Bakhode ☐ Øre ☐ Annet ☐ Evt. hvor_____ Haleben/ Sacrum ☐ **Venstre kroppsside** ☐ Fot/ Tær ☐ Hæl ☐ Ankel ☐ Kne ☐ Hofte ☐ Sitteknute ☐ Ryggrad ☐ Albue ☐ Skulder ☐ Bakhode ☐ Øre ☐ Annet ☐ Evt. hvor_____
	Såroperasjoner Nei ☐ Ja ☐
	Hvilket sykehus

Skadeomfang ved utreise fra primæropphold:

Skadenivå	**C_1-C_4** ☐ **AIS A** ☐ **B** ☐ **C** ☐ **C_5-C_8** ☐ **AIS A** ☐ **B** ☐ **C** ☐ **T_1-S_5** ☐ **AIS A** ☐ **B** ☐ **C** ☐ **AIS D** ☐ **Respiratortrengende** ☐ **Cauda equina** ☐
Skade av naturlige funksjoner (blære/ tarm)	**Blære Nei** ☐ **Ja** ☐ **Bruk av RIK** ☐ **Permanent kateter** ☐ **Lekkasje Nei** ☐ **Ja** ☐ **Bleie** ☐ **Analpropp** ☐ **Tarm Nei** ☐ **Ja** ☐ **Lekkasje Nei** ☐ **Ja** ☐
Fuksjonsnivå *(Flere kryss mulig)*	Gående Nei ☐ Ja ☐ Rullestolbruker Nei ☐ Ja ☐ Krykker Nei ☐ Ja ☐ Manuell rullestol ☐ Elektrisk rullestol ☐ Både manuell og elektrisk rullestol ☐
Utskrevet til	Hjem ☐ Annet sykehus ☐ Sykehjem ☐ Omsorgsbolig ☐ Bofellesskap ☐ Kriminalomsorg ☐ Hotell/ Motell ☐ Bostedsløs ☐ Annet/ uspesifisert ☐ Ukjent ☐

Appendix 3.

The pressure injury questionnaire

Løpenr:

Kartleggingsskjema 2 Pasient

Dato:

Har du pågående trykksår nå: ***Nei*** ☐ *Dersom **Nei**, skal kun **del 1 «Bakgrunnsinformasjon»** **side 1 og 2** fylles ut*

Ja ☐ *Dersom **Ja**, skal også **del 2; «Trykksåroppfølging»**, **side 3 og 4** fylles ut*

Del 1; Bakgrunnsinformasjon (*Denne delen skal besvares av alle, også dere som IKKE har/ har hatt trykksår*)

Sett kryss eller tall i rubrikkene der det passer. Du kan gjerne sette flere kryss dersom flere alternativer stemmer

Tidligere trykksår:	**Nei** ☐ **Ja** ☐ **Evt. årstall du hadde trykksår:**									
Dersom ja, hvor på kroppen hadde du disse sårene *Sett riktig tall i rubrikkene 1= Høyre side 2= Venstre side 3= Begge sider*	Fot/tær	☐	**Hæl**	☐	**Ankel**	☐	**Legg**	☐	**Kne**	☐
	Lår	☐	Hofte	☐	Sitteknute	☐	Haleben	☐	Ryggrad	☐
	Skulder	☐	Albue	☐	Bakhode	☐	Øre	☐	Annet	☐
	Evt. hvor:									
Årsak:	Feil sittestilling	☐	Ikke endret sittestilling	☐						
	Feil ved pute	☐	Feil ved madrass	☐						
	Ikke snudd i seng	☐	Trykk/ støt ved forflytning	☐						
	Trykk fra sko	☐	Trykk fra klær, knapper el	☐						
	Fuktighet/ svette	☐	Urin- eller avføringslekkasje	☐						
	Annet ☐ Evt. hva _____									
Hvor lenge hadde du sår	_____ **uker,** eller _____ **måneder**									
Hvem stelte såret/ sårene	Selv ☐ Ektefelle/partner ☐ Barn ☐ Foreldre ☐ Assistent ☐ Hjemmesykepleien ☐ Andre ☐									
Tidligere såroperasjoner	Nei ☐ Ja ☐ Evt. årstall _____ Hvilket sykehus ble du evt. operert på: _____									
Hvor på kroppen ble du evt. operert *Sett riktig tall i rubrikkene 1= Høyre side 2= Venstre side 3= Begge sider*										
	Fot/ tær	☐	Hæl	☐	Ankel	☐	Legg	☐		
	Kne	☐	Lår	☐	Hofte	☐	Sitteknute	☐		
	Haleben	☐	Ryggrad	☐	Skulder	☐	Albue	☐		
	Bakhode	☐	Øre	☐	Annet, evt. hvor	☐				

Landsforeningen for Ryggmargsskadde
Tilsluttet Norges Handikapforbund (NHF)

Løpenr:

Kartlegging Risikofaktorer nå: *Sett kryss eller tall i rubrikkene*

Hvor ofte skifter du sittestilling	Antall ganger Pr. time ☐ Pr. dag ☐ Vet ikke ☐
Hudfølelse	Nei ☐ Ja ☐
Hvor ofte gjennomføres hudinspeksjon	Daglig ☐ Ukentlig ☐ Månedlig ☐ Sjeldnere enn x 1/ mnd. ☐ Aldri ☐
Fuktighet **Inkontinens/ lekkasje**	Svetting ☐ Urin ☐ Avføring ☐ Begge ☐
Ernæringsstatus	Høyde ☐ cm Vekt ☐ kg
Diabetes	Nei ☐ Ja ☐ Type 1 ☐ Type 2 ☐ Kostregulert ☐ Tabletter ☐ Insulin ☐
Høyt blodtrykk **Hjerte/kar sykdom/**	Nei ☐ Ja ☐ Nei ☐ Ja ☐ **Evt. hvilken** _____
Blodpropp, nå/ tidligere **Evt. hvor**	Nei ☐ Ja ☐ Ben (DVT) ☐ Lunger (Emboli) ☐ Hjerteinfarkt ☐ Hjerneslag ☐ Ryggmargen ☐ Andre organ ☐
Depresjon/ Nedtrykthet nå	Nei ☐ Ja ☐
Spasmer nå	Nei ☐ Ja ☐
Smerter nå	Nei ☐ Ja ☐
Allergi/ hudsykdom nå **Evt. hva slags allergi/ hudsykdom:**	Nei ☐ Ja ☐ Høysnue ☐ Eksem ☐ Medikamentallergi ☐ Hudsykdom Nei ☐ Ja ☐ _____

Nytelsesmiddel		Nei	Ja		
	Røyk			Antall sigaretter pr dag	
	Snus			Antall priser pr dag	
	Alkohol			Antall enheter pr uke	
	Narkotiske stoffer			Antall ganger pr måned	
	Anabole steroider			Antall ganger pr måned	

Daglige legemidler	Nei ☐ Ja ☐
Navn på evt. legemidler	**1.** _____ **2.** _____ **3.** _____ **4.** _____ **5.** _____ **6.** _____ **7.** _____

Landsforeningen for Ryggmargsskadde
Tilsluttet Norges Handikapforbund (NHF)

Løpenr:

Del 2: Trykksår nå *(Denne delen skal besvares dersom du har trykksår nå)*

Aktuelle trykksår: *Sett kryss i rubrikkene Flere kryss er mulig.*

Årsak:	Feil sittestilling		Ikke endret sittestilling	
	Feil ved pute		Feil ved madrass	
	Ikke snudd i seng		Trykk/ støt ved forflytning	
	Trykk fra sko		Trykk fra klær, knapper el	
	Fuktighet/ svette		Urin- eller avføringslekkasje	
	Annet		Beskriv:	
Når oppstod såret/ sårene	Måned:		År:	
Hvor på kroppen er såret/ sårene *Sett riktig tall i rubrikkene* *1= Høyre side* *2= Venstre side* *3= Begge sider*	Fot/ Tær ☐ Hæl ☐ Ankel ☐ Kne ☐ Legg ☐ Lår ☐ Hofte ☐ Sitteknute ☐ Haleben ☐ Ryggrad ☐ Albue ☐ Skulder ☐ Bakhode ☐ Øre ☐ Annet ☐ Beskriv_____			
Hvem har hatt hovedansvaret for stell av såret/ sårene	Selv ☐ Ektefelle/partner ☐ Barn ☐ Foreldre ☐ Assistent ☐ Hjemmesykepleien ☐ Andre ☐			
Hvor ofte gjennomføres hudinspeksjon	Daglig ☐ Ukentlig ☐ Månedlig ☐ Sjeldnere enn x 1/ mnd. ☐ Aldri ☐			
Hvem utfører hudinspeksjonen	Selv ☐ Ektefelle/partner ☐ Barn ☐ Foreldre ☐ Assistent ☐ Hjemmesykepleien ☐ Andre ☐			
Andre typer sår nå *(f.eks leggsår, eksemsår, diabetessår)*	Nei ☐ Ja ☐ Antall ☐			
Dersom ja, hvor på kroppen har du disse sårene *Sett riktig tall i rubrikkene* *1= Høyre side* *2= Venstre side* *3= Begge sider*	Fot/ Tær ☐ Hæl ☐ Ankel ☐ Kne ☐ Legg ☐ Lår ☐ Hofte ☐ Sitteknute ☐ Haleben ☐ Ryggrad ☐ Albue ☐ Skulder ☐ Bakhode ☐ Øre ☐ ☐ Annet Beskriv_____			

Landsforeningen for Ryggmargsskadde

Løpenr:	

Hjelpemidler nå: *Sett kryss*

	Ja	Nei	Har ikke		Ja	Nei	Har ikke
Spesialmadrass da du fikk sår				**Pute i manuell stol,** nyere enn 2 år da du fikk sår			
Spesialseng da du fikk sår				**Elektrisk stol,** nyere enn 2 år da du fikk sår			
Manuell stol, nyere enn 2 år da du fikk sår				**Pute i elektrisk stol,** nyere enn 2 år da du fikk sår			

Fysisk aktivitet nå: *Sett kryss eller tall i rubrikkene*

Trener du	**Nei**		**Ja**		**Hvor mange ganger pr uke**	
Oppfølging av fysioterapeut	**Nei**		**Ja**		**Hvor mange ganger pr uke**	

Hjemmesituasjon og medisinsk oppfølging nå: *Sett kryss eller tall i rubrikkene*

Tilpasset bolig	**Nei**		**Ja**	
Hjemmesykepleie	**Nei**		**Ja**	**Antall ganger pr dag**
				Antall ganger pr uke
				Etter behov
Assistenter	**Nei**		**Ja**	**Antall timer pr dag**
				Antall timer pr uke
Oppfølging via fastlege	**Nei**		**Ja**	**Oftere enn hver måned**
				Hver måned
				Hver 1-3. måned
				Hvert halvår
				Hvert år
				Sjeldnere enn hvert år
Oppfølging av ergoterapeut	**Nei**		**Ja**	
Oppfølging fra spinalenhet	**Nei**		**Ja**	**Mer enn 1gang pr år**
				Årlig
				Hvert annet år
				Hvert 3.- 5. år
				Sjeldnere enn hvert 5. år
Individuell plan	**Nei**		**Ja**	**Vet ikke**

Hele svarskjemaet (alle sidene), samt underskrevet samtykkeskjema legges i vedlagte, frankerte svarkonvolutt og sendes til påført adresse.

Takk for hjelpen ☺

Appendix 4.

The multidisciplinary wound record form

Delstudie 2 Løpenr. ☐

Sunnaas sykehus HF

TVERRFAGLIG SÅRJOURNAL

Opprettet dato ☐

Behandlingsansvarlig:

Lege:	
Sykepleier:	
Ergoterapeut:	
Fysioterapeut:	

Aktuelle trykksår:

Første gang registrert	☐ Måned ☐ År
Første kontakt med primærhelsetjenesten	☐ Måned ☐ År
Første kontakt spesialisthelsetjenesten	☐ Måned ☐ År
Første kontakt med spinalenhet	☐ Måned ☐ År

Tidligere sår: Nei ☐ Ja ☐ Årstall: _____

Årsak:	
Varighet:	
Lokalisasjon:	Høyre side: ☐ Fot / tær ☐ Hæl ☐ Ankel ☐ Kne ☐ Hofte ☐ Sitteknute ☐ Haleben ☐ Ryggrad ☐ Albue ☐ Skulder ☐ Øre ☐ Bakhode ☐ Venstre side: ☐ Fot / tær ☐ Hæl ☐ Ankel ☐ Kne ☐ Hofte ☐ Sitteknute ☐ Haleben ☐ Ryggrad ☐ Albue ☐ Skulder ☐ Øre ☐ Bakhode ☐
Kategori:	☐

Delstudie 2 Løpenr. ☐

Tidligere såroperasjoner	Nei ☐ Ja ☐ Evt. årstall ☐ Sykehus ☐

Kartlegging risikofaktore ved første konsultasjon:

Stillingsendring Hyppighet stillingsendring	Nei ☐ Ja ☐ ➢ X 4 pr time ☐ X4 pr time ☐ x1-3 pr time ☐ sjeldnere enn x 1 pr time ☐ Aldri ☐
Hudfølelse:	Nei ☐ Ja ☐ Delvis ☐
Skjærekrefter/forflytning:	Nei ☐ Ja ☐ Kommentar:
Fuktighet/inkontinens:	Nei ☐ Ja ☐ Kommentar:
Smerter	Nei ☐ Ja ☐ Kommentar:
Spasmer	Nei ☐ Ja ☐ Kommentar:
Ernæringsstatus nå: Kost-/ og næringstilskudd (sett antall tabletter/ kapsler/ ml om ja)	Høyde ☐ cm Vekt ☐ Kg BMI ☐ Tran ☐ Omega 3 ☐ C-vit ☐ Sink ☐ Proteiner/ næringsdrikk ☐ Annet:
Aktivitet:	
Regelmessig hudinspeksjon: (> 2 ganger pr uke) Hvem utfører inspeksjonen:	Nei ☐ Ja ☐ Selv ☐ Ektefelle/ Partner/ Barn ☐ Assistent ☐ Hjemmesykepleier ☐ Andre ☐
Stemningsleie:	Fornøyd ☐ Nøytral ☐ Nedtrykt ☐
Diabetes, Siste målte morgenblodsukker	Type ☐ Kostregulert ☐ Tabletter ☐ Insulin ☐ ☐ Mmol/l

Delstudie 2 Løpenr. ☐

Hjerte/kar sykdom: (nå eller hatt tidligere)	Nei ☐ Ja ☐ Angina ☐ Høyt BT ☐ «Røykeben» ☐ Blodpropp ☐
Røyker/snuser:	Nei ☐ Ja ☐
Allergier	Nei ☐ Ja ☐ Hvilke_____
Medikamenter nå (navn og evt. dose)	1. 2. 3. 4. 5.

Hjelpemidler:		**Type/ alder**
Madrass:		
Seng:Bredde\regulerbar		
Manuell stol	Nei ☐ Ja ☐	
Pute i manuell stol	Nei ☐ Ja ☐	
Elektrisk stol	☐ ☐	
Pute i elektrisk stol	Nei ☐ Ja ☐	
Pute i bil	Nei ☐ Ja ☐	
Ekstra puter\trekk	Nei ☐ Ja ☐	
Ståstol	Nei ☐ Ja ☐	
Forflytningshjelpemidler	Nei ☐ Ja ☐	
Seil/ brett/ banan	Nei ☐ Ja ☐	
Toalett\dusjstol Avlastende sete?	Nei ☐ Ja ☐ Nei ☐ Ja ☐	**Type/ alder**
Magetralle	Nei ☐ Ja ☐	
Reise\fritid, (hvilke tekniske hjelpemidler)	Elektrisk stol ☐ Manuell stol ☐ Pute i bil ☐ Pute i fly ☐	
Trykkmåling/ sitteklinikk	Nei ☐ Ja ☐	**Når**

Fysioterapi:

Aktivitet og trening	Trener Nei ☐		Ja ☐	

Delstudie 2 Løpenr.

Hjemmesituasjon:

Tilpasset bolig	
Sosialt	
Jobb	
Hjemmesykepleie, hyppighet,område	
Assistenter	Antall timer/ dag Antall timer/ uke
Opplæringsbehov	Pasient : Ja Nei Pårørende : Ja Nei Hjelpere/personell : Ja Nei
Ergoterapeut	Ja Nei

Delstudie 2 Løpenr. ☐

Konsultasjon, dato _____

(denne delen skal opprettes ny og fylles ut for hver konsultasjon)

Tilstede lokalt, antall	Pasient ☐ Ektefelle/ Partner ☐ Barn ☐ Assistent ☐ Hjemmespl. ☐
Tilstede Spesialisthelsetjenesten	Lege ☐ Sårspl. ☐ Spl. ☐ Ergo. ☐ Fysio. ☐ Plastisk kirurg ☐ Ortoped ☐ ITK- tekniker ☐
Type konsultasjon VK= Videokonferanse MJ= MinJournal Tlf= Telefon	Oppmøte ☐ Tlf./ MJ ☐ VK/ MJ ☐
Varighet	☐ Minutter
Reiseavstand t/r (for den som har kjørt til konsultasjonen)	Pasient ☐ Km ☐ Minutter CO_{2-} utslipp ☐ Kg Hjemmespl. ☐ Km ☐ Minutter CO_{2-} utslipp ☐ Kg

Sårets utseende (cm)	Lengde: ☐ Bredde: ☐ Dybde: ☐ cm
	Fistel: Nei ☐ Ja ☐ Lengde: ☐ cm
Sårstell, hyppighet	X 2 pr dag ☐ Daglig ☐ Hver 2. dag ☐
	X2 pr uke ☐ Ukentlig ☐ < x 1 pr uke ☐
Nåværende sårstell	Lunkent springvann ☐ NaCl ☐ Polyhexamid ☐
Renses med:	Klorhexidin ☐ Hydrogenperoxyd ☐ Grønnsåpe ☐
Varighet	Vasker over ☐ < 5 min. ☐ 5-10 min. ☐
	10-15 min. ☐ 15-20 min. ☐ > 20 min. ☐
Bandasje	Hydrofiber ☐ Alginat ☐ Sølv ☐
	Honning ☐ Skumbandasje ☐
	Hydrokolloid bandasje ☐ Ingen bandasje ☐
Has i/ på såret	Hydrogel ☐ Sølvnitrat ☐ Cortison ☐
	Acetatbuffer ☐ Kaliumpermanganat ☐
	5% NaCl ☐ Jod ☐ Intet ☐

Delstudie 2 Løpenr. ☐

TIME gradering:
(Tissue Infection Moisture Edge)

Sekresjon:
Lett = inntil 1/3
Moderat= Inntil 2/3
Mye= Hele bandasjen

Sårbunn

Frisk :	Nei	☐	Ja	☐
Fibrin:	Nei	☐	Ja	☐
Biofilm:	Nei	☐	Ja	☐
Nekrose	Nei	☐	Ja	☐

Infeksjon

Inflammasjon	Nei	☐	Ja	☐
Infeksjon:	Nei	☐	Ja	☐

Bakterietype(r): ☐

Sekresjon

Ingen	Lett	☐	Moderat	☐	Mye	☐
Utseende	Tynt	☐	Tykt	☐		
Farge	Blank	☐	Blodig	☐	Grønn	☐
	Gullig/ brunlig			☐		

Sårkanter	Tørr	☐	Oppbløt	☐	Opphøyde	☐
Området rundt	(hud)	☐	Rolig	☐	Rødt	☐
					Dermatitt	☐
					Infeksjon	☐
					Eksem	☐

Kategori: ☐

Oppdatering Risikofaktorer:

Stillingsendring/hyppighet:	Forandring fra første konsultasjon Nei ☐ Ja ☐
Hudfølelse:	Forandring fra første konsultasjon Nei ☐ Ja ☐
Skjærekrefter/forflytning:	Forandring fra første konsultasjon Nei ☐ Ja ☐
Fuktighet/inkontinens:	Forandring fra første konsultasjon Nei ☐ Ja ☐
Ernæringsstatus nå:	Vekt ☐ kg BMI ☐
Kost-/ og næringstilskudd (sett dose om ja)	Tran ☐ Omega 3 ☐ C-vit ☐ Sink ☐ Proteiner/ næringsdrikk ☐ Annet:
Aktivitet:	
Regelmessig hudinspeksjon (> 2 ganger pr uke) Hvem utfører inspeksjonen	Nei ☐ Ja ☐ Selv ☐ Ektefelle/ Partner/ Barn ☐ Assistent ☐ Hjemmesykepleier ☐ Andre ☐

Delstudie 2 Løpenr. ☐

Forandring fra første konsultasjon	Nei ☐ Ja ☐
Stemningsleie: Forandring fra første konsultasjon	Fornøyd ☐ Nøytral ☐ Nedtryk ☐ Nei ☐ Ja ☐
Diabetes, Forandring fra første konsultasjon Siste morgenblodsukker	Type ☐ Kostregulert ☐ Tabletter ☐ Insulin ☐ Nei ☐ Ja ☐ ☐ Mmol/l
Hjerte/kar sykdom: Forandring fra første konsultasjon	Nei ☐ Ja ☐ Angina ☐ Høyt BT ☐ «Røykeben» ☐ Blodpropp ☐ Nei ☐ Ja ☐
Røyk/snus: Forandring fra første konsultasjon	Nei ☐ Ja ☐ Nei ☐ Ja ☐
Allergier Forandring fra første konsultasjon	Nei ☐ Ja ☐ Nei ☐ Ja ☐
Smerter Forandring fra første konsultasjon	Nei ☐ Ja ☐ Nei ☐ Ja ☐
Spasmer Forandring fra første konsultasjon	Nei ☐ Ja ☐ Nei ☐ Ja ☐
Medikamenter nå Forandring fra første konsultasjon j	Nei ☐ Ja ☐

Delstudie 2 Løpenr. ☐

Hjelpemidler:

	Forandring fra første konsultasjon	Type	Mottatt
Madrass:	Nei ☐ Ja ☐		
Seng:Bredde\regulerbar	Nei ☐ Ja ☐		
Manuell stol type	Nei ☐ Ja ☐		
Pute i manuell stol	Nei ☐ Ja ☐		
Elektrisk stol type	Nei ☐ Ja ☐		
Pute i elektrisk stol	Nei ☐ Ja ☐		
Gjort trykkmåling	Nei ☐ Ja ☐	Dato	
Pute i bil	Nei ☐ Ja ☐		
Ekstra puter\trekk	Nei ☐ Ja ☐		
Ståstol	Nei ☐ Ja ☐		
Forflytningshjelpemidler	Nei ☐ Ja ☐		
Heis/ Seil/ brett/ banan	Nei ☐ Ja ☐		
Toalett\dusjstol type\avlastende sete?	Nei ☐ Ja ☐ Nei ☐ Ja ☐		
Magetralle	Nei ☐ Ja ☐		
Reise\fritid,	Nei ☐ Ja ☐	Elektrisk stol ☐ Manuell stol ☐ Pute i bil ☐ Pute i fly ☐	

Fysioterapi:

Aktivitet og trening	Forandring fra første konsultasjon Nei ☐ Ja ☐

Hjemmesituasjon:

Tilpasset bolig	Forandring fra første konsultasjon Nei ☐ Ja ☐
Sosialt	Forandring fra første konsultasjon Nei ☐ Ja ☐
Jobb	Forandring fra første konsultasjon Nei ☐ Ja ☐
Hjemmesykepleie	Antall timer pr dag ☐ Pr uke ☐ Forandring fra første konsultasjon Nei ☐ Ja ☐
Assistenter	Antall timer pr dag ☐ Pr uke ☐ Forandring fra første konsultasjon Nei ☐ Ja ☐
Opplæringsbehov:	Forandring fra første konsultasjon Nei ☐ Ja ☐
Ergoterapeut	Forandring fra første konsultasjon Nei ☐ Ja ☐
Anbefalt videre sårstell: **Sårstell, hyppighet**	X 2 pr dag ☐ Daglig ☐ Hver 2. dag ☐ X2 pr uke ☐ Ukentlig ☐ < x 1 pr uke ☐

Delstudie 2 Løpenr. ☐

Renses med:	Lunkent springvann ☐ NaCl ☐ Polyhexamid ☐
Varighet	Vasker over ☐ < 5 min. ☐ 5-10 min. ☐ 10-15 min. ☐ 15-20 min. ☐ > 20 min ☐
Bandasje	Hydrofiber ☐ Alginat ☐ Sølv ☐ Honning ☐ Skumbandasje ☐ Tørr bandasje ☐ Hydrokolloid bandasje ☐ Ingen ☐
Has i/ på såret	Hydrogel ☐ Sølvnitrat ☐ Cortison ☐ Jod ☐ Acetatbuffer ☐ Kaliumpermanganat ☐ 5% NaCl ☐ Intet ☐
Bakterieprøve	Ja ☐ Nei ☐
Neste kontakt	☐ Dager ☐ Uker

Skjemautfyller ☐

Hjemmespl. = H.
Hjemmespl. med sårutdanning = HS.
Ektefelle/ partner = E/P
Barn = B
Assistent = A
Fastlege= FL
Sårspl. spesialisthelsetjenesten = SSS
Lege spesialisthelsetjenesten = LS

Appendix 5. The cost assessment form

PASIENT ID	

Konsultasjon dato

TYPE KONSULTASJON	
Hvem reiste til konsultasjonen	
Reiste fra (hvilken adresse til hvilken adresse) Km t/r	
Hvilket transportmiddel ble brukt (ambulanse, taxi, egen bil, fly, ferge, trikk, bane, buss, tog) Beskriv drivstoff	
Reisetid i minutter	
Reisekostnader (NOK) inkl. ferge, bom mv	
Var det noen forsinkelser ved reisen (minutter)	
Er timer blitt avlyst pga forsinkelser med transport før denne konsultasjonen?	
Pasienten	
Har pasienten med følge	
Hvis reisefølge, hvor mange er med?	
Var reisefølget der hele dagen/ konsultasjonen?	
Tapt arbeidstid for reisefølge (Ja/Nei)	
Konsultasjon	
Antall ansatte fra sykehuset tilstede under konsultasjonen?	
Hvilken ansatte tilstede? (sykepleier, lege ergoterapeut etc..)	
Tidsbruk ved konsultasjon	
Lege	
Sårsykepleier	
Ergoterapeut	
Hjemmetjenesten	
Andre (beskriv)	
Sårutstyr	
Materialer brukt (bandasje etc…) Kostnaden dekkes av Sykehus (S), Kommunen (K)	
Bistand	
Tekniker (JA/NEI)	
Andre (beskriv)	
Tidsbruk bistand totalt?	
Sårutstyr	
Materialer brukt (bandasjer etc…) NOK	
Teleutstyr	
Lap-top, egen/ lånt (E/ L)	
Telefon, egen/ hjemmetjenesten (E/H)	
Teknisk svikt av utstyr (JA/NEI)	
Tidsbruk svikt (min)	
Behov for support av tekniker (JA/NEI)	
Bistand ved oppkobling av egen laptop (JA/NEI)	
Bistand ved oppkobling av pasientens laptop (JA/NEI)	
Annen bistand. Beskriv	

Appendix 6.

The satisfaction form

Landsforeningen for Ryggmargsskadde
Tilsluttet Norges Handikapforbund (NHF)

Avdeling for Ryggmargsskader

løpenr.

Sunnaas sykehus HF

ST. OLAVS HOSPITAL
UNIVERSITETSSYKEHUSET I TRONDHEIM

HELSE BERGEN
Haukeland Universitetssjukehus

Tilbakemelding etter oppfølging i sårstudie

Vi vil gjerne vite om du er tilfreds med oppfølgingen fra sårteamet. Målet vårt er å gjøre tilbudet vårt enda bedre, og med størst mulig grad av brukermedvirkning. Derfor er dine meninger og tilbakemeldinger viktige, og vi håper at du vil svare på spørsmålene ved å sette kryss i de rubrikkene som passer best for deg.
Det tar ikke lang tid. Har du utfyllende kommentarer, kan du skrive disse på slutten av undersøkelsen.
Dersom du har problemer med å svare selv, kan du be en annen om å hjelpe deg.
Besvarelsen din er anonym.

Hvem er du	Kjønn	Alder
☐ Bruker/ pasient ☐ Pårørende ☐ Assistent ☐ Hjemmesykepleier ☐ Fastlege	☐ Kvinne ☐ Mann	☐ 16 – 18 år ☐ 19 – 29 år ☐ 30 – 39 år ☐ 40 – 49 år ☐ 50 – 59 år ☐ 60 – 69 år ☐ 70 – 79 år ☐ 80 år eller mer

Oppfølging via:

☐ Kontrollgruppe, med mulighet for telefonkontakt med sårteamet eller oppmøtepoliklinikk på sykehuset.

☐ Videokonferanse hjemmefra, med mulighet for telefonkontakt med sårteamet eller oppmøtepoliklinikk på sykehuset.

1. Fikk du tilstrekkelig informasjon om behandlingstilbudet før oppfølgingen startet?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

2. Opplevde du at det tok lang tid før behandlingen startet?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

3. Har det vært greit å få telefonkontakt med sårteamet ila oppfølgingen?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

4. Ble du mottatt på en god måte av sårteamet da såroppfølgingen startet?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

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Tilsluttet Norges Handikapforbund (NHF)

Avdeling for Ryggmargsskader

løpenr.

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5. Opplevde du at fagpersonene i sårteamet var forberedt til de polikliniske konsultasjonene?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

6. Opplevde du at sårteamet var opptatt av deg og din situasjon?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

7. Opplevde du at sårteamet planla en god oppfølging sammen med deg?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

8. Opplevde du at sårteamet gjennomførte en god oppfølging sammen med deg?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

9. Opplevde du at fagpersonene i sårteamet kommuniserte med deg på en måte som du forstod?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

10. Opplevde du at det ble brukt nok tid til å samtale og samhandle i sårkonsultasjonene?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

11. Opplevde du at det ble gjort et tilstrekkelig antall vurderinger av såret fra sårteamets side?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

12. Opplevde du at du fikk tilstrekkelig informasjon om såret og sårbehandlingen?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

13. Opplevde du at sårteamet var interessert i din vurdering av såret?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

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Tilsluttet Norges Handikapforbund (NHF)

Avdeling for Ryggmargsskader

løpenr.

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14. Opplevde du å få delta i avgjørelser som var viktige i sårbehandlingen?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

15. Opplevde du at sårbehandlingen som ble anbefalt var kunnskapsbasert og riktig?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

16. Har du følt deg trygg under oppfølgingen?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

17. Opplevde du å øke sårkunnskapen din gjennom samarbeidet med sårteamet?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

18. Opplevde du at sårteamet forberedte deg på tiden etter at oppfølgingen fra sårteamet ble avsluttet?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

19. Alt i alt, hvor fornøyd er du med tilbudet fra sårteamet ved spinalenheten?

Ikke fornøyd i det hele tatt	I liten grad fornøyd	I noen grad fornøyd	I stor grad fornøyd	I svært stor grad fornøyd	Ikke aktuelt

20. Alt i alt, hvor stort utbytte hadde du av tilbudet ved sårpoliklinikken?

Ikke utbytte i det hele tatt	I liten grad utbytte	I noen grad utbytte	I stor grad utbytte	I svært stor grad utbytte	Ikke aktuelt

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Dersom oppfølgingen skjedde via videokonferanse::

21. Var opplæringen i bruk av utstyret og programvaren i forkant av oppfølgingen tilfredsstillende?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

22. Opplevde du at utstyret fungerte tilfredsstillende i oppfølgingsperioden?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

23. Opplevde du at det var trygt å bruke videokonferanse i såroppfølgingen?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt

Kommentarer og forbedringsforslag:(Bruk evt. baksiden av arket til å kommentere)

_____

_____

_____

_____

Send svaret i vedlagte svarkonvolutt, eller på mail til ingebjorg.irgens@sunnaas.no

Tusen takk for at du tok deg tid til å svare ☺

PAPER I-III

I

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ISCoS The International Spinal Cord Society

ARTICLE

Spinal cord injury and development of pressure injury during acute rehabilitation in Norway: a national retrospective cross-sectional study

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Abstract

Study design A national, retrospective, cross-sectional study.

Objectives To analyze the prevalence of pressure injury (PI), and characteristics associated with PI development in the hospitalized population of persons with a newly acquired spinal cord injury (SCI) between 2004 and 2014.

Setting All three specialized Spinal Cord Units in Norway.

Methods Demographic data related to prevalence and potential risk factors were retrieved from the electronic medical record (EMR). Statistical analyses were performed, using IBM SPSS Statistics, version 23.

Results We identified 1012 individuals with a new SCI. Mean age at injury was 48 years (SD 19). The period prevalence of PI was 16% (95% CI = 0.14–0.19), and identified PI associations were complete SCI (OR = 0.1), being injured abroad (OR = 2.4), bowel (OR = 13), and bladder (OR = 9.2) dysfunction; comorbidities like diabetes mellitus 1 (OR = 7.9), diagnosed depression (OR = 3.8), ventilator support (OR = 3.0), drug abuse (OR = 3.0), and concurrent traumatic brain injury (OR = 1.7). Individuals in the age group of 15–29 years had higher odds of PI compared with middle-aged individuals (45–59 years).

Conclusion PI is a serious complication after SCI. The association between depression or comorbidity and PI occurrence should be investigated more thoroughly. We recommend implementation of a simple follow-up program regarding observation and prevention of PI. Increased awareness of factors that could contribute to PI will help to focus on better prevention and early recognition of PI. This will contribute to more optimal rehabilitation.

Introduction

Pressure injury (PI) is defined as localized damage to the skin and the underlying soft tissue, usually over a bony prominence, or related to medical or other devices. It can present as a red spot on intact skin or as an open ulcer and can be painful. It occurs as the result of intense or prolonged pressure, or pressure in combination with shear [1]. A

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systematic review published in 2013 concluded that overall there is no single factor, which can explain the risk of PI, but rather a complex interplay of factors that increase the probability of the development [2]. Impaired motor and sensory function, altered perfusion and circulation, moisture, and incontinence were found to be factors that significantly increased the risk of PI [2].

Due to paralysis, sensory loss, and prolonged exposure to moisture, individuals with spinal cord injury (SCI) are at particular risk for PI [2–5].

The occurrence of PIs during hospitalization of persons with SCI has shown to vary between 6 and 52% [6, 7], and comorbidities can affect the development of severe PI [6].

Persons with SCI are a heterogeneous group, and therefore risk factors may vary in specific subgroups [2, 8, 9]. Verschueren found that both complete injury and tetraplegia were significant risk factors for PI during the acute rehabilitation period [7], while Grigorian et al. found that a higher SCI level was associated with increased risk for PI as compared with the lower level [10]. The actual number of individuals with SCI and PIs in Norway is unknown; moreover, we do not know if the risk factors for PIs in the Norwegian population correspond to risk factors reported in other studies [2–5]. Therefore, a research program (NORSCIPI) at all three spinal cord units in Norway (NSCUs) was conducted to identify characteristics associated with PI development in the hospitalized population of persons with acute SCI [11]. The first study of this research program aims to investigate the prevalence of PI in the population, and further to investigate potential risk factors and associations for PI in these individuals from admission to and discharge from the NSCU [11].

Methods

Setting and population

All individuals acquiring either a traumatic SCI (TSCI) or nontraumatic SCI (NTSCI) during 2004–2014 and admitted to one of the three specialized NSCUs for acute rehabilitation after the injury, were included in the study. The acute rehabilitation period is defined as the continuous time period from admittance to the NSCU and to final discharge from the hospital. The electronic medical record (EMR), at each of the three NSCUs, was used to identify individuals and retrieve data. The system of care for persons with SCI in Norway has been described in a recent publication [12]. Because of the strict legislation regarding privacy, and the data collecting permission from the Ethical Committee [13–16], available information from the acute care hospitals is dependent on the information given in the transfer letters from the acute care hospitals to the NSCUs. These transfer letters do not include any information regarding the time from injury to the arrival at the acute care hospitals, neither any information regarding immobilization during transfer, mode of transport, or use of pressure-relieving devices or interventions.

Study design

We conducted a national, retrospective, cross-sectional study, with the aim to estimate the period prevalence of PI, and investigate potential risk factors for PI during the period between admission to and discharge from the acute rehabilitation. Available information from the EMR at the NSCUs was evaluated to retrieve potential risk factors.

Study variables

Study variables were recorded as “yes” if present, “no” if not present, and “unknown” if the information was missing. The term “PI” was used to describe pressure ulcers/wounds, according to the newest recommendations [1].

The International Standards for Neurological Classification of SCI (ISNCSCI) was used, including the clinical findings standardized by the American Spinal Injury Association Impairment Scale (AIS) [17]. Relevant information recorded from the EMR at the NSCUs were gender (male/female), date of birth, date of injury, marital status (single and living alone, single but living with parents/children, cohabitant, partner/married, divorced, widow/widower, and unknown), level of education (primary school, high school, college/university, and unknown) occupational status (full time, part time, social welfare benefits, retired, and unknown), etiology of the injury (traumatic and nontraumatic), neurological level of the injury (cervical, thoracic–sacral, and cauda equina), and any associated injury (brain injury and multitrauma). A complete examination of the skin was recorded within the first few weeks after the admission to the NSCU. Occurrence of PI, as well as use of alcohol and tobacco, and all abuse of drugs and SCI-associated problems, such as incontinence and ventilator dependence, in conjunction with premorbid comorbidities, such as hypertension, cardiac disease, diabetes mellitus (DM), clinically diagnosed depression, allergy, and skin disease, were recorded from information in the EMR. In addition, attention deficit/hyperactivity disorder (ADHD/ADD), which was previously not evaluated as a potential risk factor for PIs, was recorded if diagnosed before admittance to the NSCUs, and recorded in the EMR. The EMR

documentation used in this study does not specify any diagnostic tools regarding depression or ADHD/ADD; the variables recorded were "yes," "no," or "missing," depending on the information given in the EMR.

Data collection

A selection of 84 EMR diagnoses was scrutinized for SCI, and only individuals with acquired traumatic or non-traumatic SCI between January 1st 2004 and January 1st 2014 were included. Based on data obtained from the EMR, neurological level of injury and the AIS were examined and recorded during the first 3 weeks after admission to the NSCUs [12]. In some cases, the degree of impairment was not registered, but the EMR described the sensory and motor grade and level, as well as the sphincter tonus. In these cases, the impairment was graded by the first author (II) in accordance with the ISNCSCI [17–19].

Ethics

The Norwegian Data and Telecommunications Authority's requirements for safe information flow were followed [14]. The study was approved by the National Regional Ethical Committee (2014/684/REK-Nord) [15, 16].

Statistical analyses

Potential risk factors diagnosed before the occurrence of the PI were included in the analyses. Continuous variables are presented as mean with standard deviation (SD). Categorical variables are presented as counts and percentages.

The categorization of age into age groups is performed, according to the newest recommendations [17, 18].

Participants' demographics and injury characteristics are analyzed descriptively. The term "period prevalence" refers to the 10-year period between 2004 and 2014. To identify factors associated with PI occurrence, potential risk factors were entered into a binary, logistic regression model. Crude and adjusted (for gender and age) odds ratios (ORs) were calculated along with 95% confidence intervals (CIs). p values less than 0.05 were considered significant. The common confounding variables age and gender were adjusted for in the analyses. The adjusted results will be reported and discussed in the paper. As a sensitivity analysis, we also performed logistic regressions where missing values on the PI variable were taken as "no PI." Our reasoning was that if there was no PI during acute rehabilitation, PI would not be mentioned in the EMR.

IBM SPSS Statistics, version 23, was used for all statistical analyses.

Table 1 Demographics.

	N	Percentage
Total	1012	100
Gender		
Male	742	73
Female	270	27
Mean age		
At injury	48, 26 years (min. 0.47–max. 88.48), SD 19.18	
At admission acute rehabilitation	48, 46 years (min. 0.97–max. 88.50), SD 19.16	
Age grouping at admission to the NSCU		
0–14	14	1.4
15–29	201	20
30–44	208	21
45–59	239	24
60–74	273	27
75+	64	6.4
Geographical site of injury		
Norway	959	95
Outside Norway	53	5.2
Drugs/alcohol use at the time of injury		
Yes	110	11
No	715	71
Unknown	182	18
TSCI	639	63
NTSCI	372	37
Level of injury at admission		
C1–C4	224	22
C5–C8	222	22
T1–S3	566	56
Cauda equina	86	8.5
AIS at admission		
A	258	26
B	58	5.7
C	298	30
D	385	38
Unknown	12	1.2
Pressure injury		
No	747/891	84
Yes	144/891	16

SD standard deviation, *min.* minimum, *max.* maximum.

Results

Description of the population

After reviewing data from 1488 EMRs at the three NSCUs, 1012 individuals, 742 men (73%), and 270 women (27%) were included in the study. Demographics are presented in Table 1.

Period prevalence and location of the pressure injuries

We had information about PI in 891 of the individuals, and the period prevalence of PI in the studied population was

144/891 (16%, 95% CI = 0.14–0.19). We found that 61% of the population with a known number of PIs had a single PI (86/142 individuals), while 39% (56/142 individuals) had two or more.

The total number of PIs recorded from the EMR were 373. Most of the PIs were located at the coccyx (33%) (Fig. 1).

Factors associated with pressure injury development, classified by categories

A detailed overview of factors associated with PI in our population is provided in Table 2.

Gender

Men had an overall period prevalence of PIs of 19% (95% CI = 0.16–0.22), compared to 9.0% (95% CI = 0.05–0.13) among women.

Age

The mean age at injury was 48 years, SD 19 (minimum 0.47 years–maximum 88 years). The age group of 45–59 years had significantly decreased odds of PI (OR = 0.5, 95% CI = 0.3–0.9) compared with the reference group (15–29 years).

Marital status, education, and occupational activity

We did not find any significant variation in the occurrence of PI concerning marital status, level of education, or occupational activity at the time of injury.

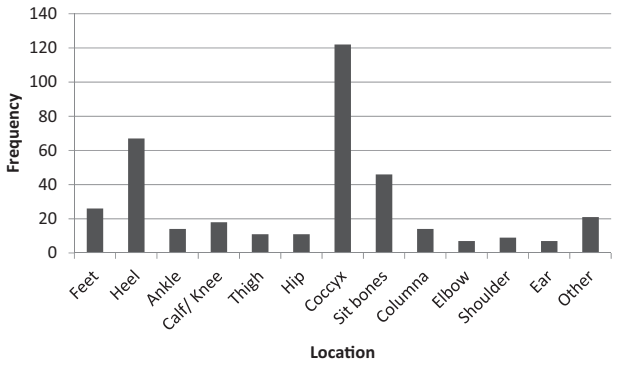

Fig. 1 Location and frequency of the PIs in the studied population. Most of the PIS were located at the seat ($n = 168$, hereof the coccyx $n = 122$ and the sit bones $n = 46$), and heels ($n = 67$). The feet ($n = 26$), ankle ($n = 14$), calf/ knee ($n = 18$), thigh ($n = 11$), hip ($n = 11$), column ($n = 14$), elbow ($n = 7$), shoulder ($n = 9$), ear ($n = 7$). The group other ($n = 21$) consists of PI at the chest/ abdomen ($n = 3$), face/ nose ($n = 2$), occipital ($n = 2$), neck ($n = 2$), penis ($n = 4$) and unknown location ($n = 8$).

Cause and severity of the spinal cord injury at admission

The occurrence of PI was higher among those who were injured outside Norway.

There was no significant difference in the occurrence of PI, based on having a traumatic or nontraumatic injury, or based upon the neurological level.

Individuals with AIS D had a 90% decreased odds of PI, compared to individuals with AIS A (OR = 0.1, 95% CI = 0.1–0.2, $p < 0.001$). The decrease in odds of PI for individuals with AIS C was 70%, compared to individuals with AIS A (OR = 0.3, 95% CI = 0.2–0.5, $p < 0.001$). A test for trend in the AIS categories showed a significantly decreasing trend ($p < 0.001$) (Fig. 2).

Spinal cord injury sequelae

A significantly higher occurrence of PIs was observed among individuals with bladder and bowel dysfunction related to the SCI, compared to no dysfunction. A corresponding pattern was found regarding the need for ventilator support before or at admission to the NSCUs. The occurrence of multitrauma together with the SCI did not associate with the occurrence of PI; however, having a concomitant traumatic brain injury did.

Comorbidity, acquired prior to the spinal cord injury

For patients diagnosed with diabetes mellitus type 1 (DM1) ahead of the SCI, there was approximately an eight-time increased odds of PI, compared with individuals with no DM1 diagnosis (OR = 7.9, 95% CI = 2.4–26, $p = 0.001$); however, we did not find any increased PI occurrence for DM2. Other comorbidities, such as hypertension (OR = 3.7, 95% CI = 2.3–5.9, $p < 0.001$) and cardiovascular disease (OR = 3.6, 95% CI = 2.3–5.9, $p < 0.001$) also significantly increased the odds of PI.

Clinically diagnosed depression was present in 285 (28%) of the total population during the acute rehabilitation, and there was a higher PI occurrence in those with depression, than in those without. ADHD/ADD diagnosed before the SCI did not show any association with PI occurrence.

Stimulants

Abuse of illegal or prescribed drugs before the SCI and registered in the EMR seemed to be associated with an increased occurrence of PI (OR = 3.0, 95% CI = 1.5–6.9, $p = 0.002$), while being under the influence of alcohol or drugs at the time of the injury (20% of the population) did

Table 2 Pressure injury associations.

	n PI/n subgroup	PI percentage	Crude values			Adjusted (gender and age) values		
			OR	95% CI	*p* value	OR	95% CI	*p* value
Gender								
Male	123/654	19	1.0			1.0		
Female	21/237	9.0	0.4	0.3–0.7	0.001	0.4	0.3–0.7	**0.001**
Age at injury								
0–14	1/15	6.7	0.3	0.04–2.1	0.22	0.3	0.04–2.2	0.22
15–29	39/188	21	1.0			1.0		
30–44	31/189	16	0.8	0.4–1.3	0.23	0.7	0.4–1.3	0.28
45–59	26/210	12	0.5	0.3–0.9	0.03	0.5	0.3–0.9	**0.03**
60–74	35/240	15	0.7	0.4–1.1	0.10	0.7	0.4–1.1	0.14
75+	12/49	25	1.2	0.6–2.6	0.62	1.4	0.7–2.9	0.40
Geographical location at the time of injury								
Norway	130/847	15	1.0			1.0		
Abroad	14/44	32	2.6	1.3–5.0	0.005	2.4	1.3–4.8	**0.009**
Marital status at injury								
Single, living alone	37/193	19	1.0			1.0		
Single, not living alone[a]	27/136	20	1.0	0.6–1.8	0.9	1.1	0.6–1.9	0.76
Cohabitant	23/135	17	0.9	0.5–1.5	0.62	0.9	0.5–1.6	0.69
Married/partner	48/372	13	0.6	0.4–1.0	0.049	0.61	0.4–1.0	0.068
Divorced	4/19	21	1.1	0.4–3.6	0.84	1.2	0.4–3.8	0.78
Widow/widower	2/12	17	0.8	0.2–4.0	0.83	1.1	0.2–5.5	0.94
Unknown	3/24	13						
Educational level at injury								
Not finished primary school	6/26	233	1.7	0.6–4.6	0.30	1.8	0.6–5.2	0.31
Primary school	36/242	15	1.0	0.6–1.7	0.97	1.0	0.6–1.7	0.96
High school	33/234	14	0.9	0.5–1.6	0.77	0.9	0.5–1.6	0.76
College/university	29/193	15	1.0			1.0		
Unknown	40/194	21						
Occupational activity at injury								
Full-time work	49/329	15	1.0			1.0		
Part-time work	4/62	6.5	0.4	0.1–1.1	0.084	0.5	0.2–1.3	0.14
No work[b]	70/409	17	1.2	0.8–1.8	0.42	1.3	0.8–1.9	0.26
Unknown	21/90	23						
Cause of injury								
Traumatic	96/567	17	1.0			1.0		
Nontraumatic	48/324	15	0.9	0.6–1.2	0.41	1.0	0.7–1.5	0.95
Neurological level of injury at admission								
C1–C4	25/191	13	0.8	0.5–1.3	0.39	0.8	0.5–1.3	0.32
C5–C8	40/197	20	1.4	0.9–2.1	0.15	1.4	0.9–2.1	0.15
T1–S3	79/503	16	1.0			1.0		
Tetraplegia	65/386	17	1.1	0.8–1.5	0.67	1.1	0.7–1.5	0.74
Paraplegia	78/501	16	1.0			1.0		
AIS at admission[c]								
AIS A	77/233	33	1.0			1.0		
AIS B	14/51	28	0.8	0.4–1.5	0.44	0.8	0.4–1.6	0.54
AIS C	33/263	13	0.3	0.2–0.5	<0.001	0.3	0.2–0.5	**<0.001**
AIS D	18/331	5.4	0.1	0.1–0.2	<0.001	0.1	0.1–0.2	**<0.001**
Unknown	2/13	15						
Cauda equina								
No	140/812	17	1.0			1.0		
Yes	4/79	5.1	0.3	0.1–0.7	0.01	0.3	0.1–0.7	**0.01**
SCI-associated problems diagnosed before the PI occurence								
Bladder dysfunction								
No	5/194	2.6	1.0			1.0		

Table 2 (continued)

	n PI/n subgroup	PI percentage	Crude values			Adjusted (gender and age) values		
			OR	95% CI	*p* value	OR	95% CI	*p* value
Yes	136/676	20	9.5	3.8–24	<0.001	9.2	3.7–23	**<0.001**
Unknown	3/20	15						
Bowel dysfunction								
No	5/239	2.1	1.0			1.0		
Yes	136/623	22	13	5.0–33	<0.001	13	5.3–33	**<0.001**
Ventilator support								
No	128/848	15	1.0			1.0		
Yes	15/41	37	3.2	1.7–6.3	<0.001	3.0	1.6–5.9	**0.001**
Premorbid comorbidity								
Multitrauma								
No	85/611	14	1.0			1.0		
Yes	50/259	19	1.5	1.0–2.2	0.045	1.4	0.9–2.1	0.14
Unknown	9/21	43						
Brain injury[d]								
No	106/746	14	1.0			1.0		
Yes	29/126	23	1.8	1.1–2.9	0.01	1.7	1.1–2.8	**0.021**
Unknown	9/19	47						
Diabetes mellitus								
No	111/774	14	1.0			1.0		
Diabetes mellitus 1	7/12	58	8.4	2.6–27	<0.001	7.9	2.4–26	**0.001**
Diabetes mellitus 2	12/56	21	1.6	0.8–3.2	0.15	1.6	0.8–3.2	0.19
Unknown	13/47	28						
ADHD/ADD								
No	129/848	15	1.0			1.0		
Yes	4/13	31	2.5	0.8–8.2	0.14	2.7	0.8–9.1	0.11
Unknown	11/30	37						
Cardiovascular disease								
No	78/653	12	1.0			1.0		
Yes	51/192	27	2.7	1.8–4.0	<0.001	3.6	2.3–5.9	**<0.001**
Unknown	15/46	33						
Hypertension								
No	78/653	12	1.0			1.0		
Yes	52/193	27	2.7	1.8–4.0	<0.001	3.7	2.3–5.9	**<0.001**
Unknown	14/45	31						
Depression								
No	47/492	9.6	1.0			1.0		
Yes	67/251	27	3.4	2.3–5.2	<0.001	3.8	2.5–5.8	**<0.001**
Unknown	30/147	20						
Allergy/eczema[e]								
No	94/613	15	1.0			1.0		
Allergy	30/188	16	1.0	0.7–1.6	0.84	1.2	0.8–1.9	0.44
Exema	20/90	22	1.6	0.9–2.7	0.1	1.5	0.9–2.7	0.13
Stimulants								
Alcohol/drug use at the time of injury								
No	91/632	14	1.0			1.0		
Yes	19/97	20	1.4	0.8–2.5	0.19	1.3	0.8–2.3	0.33
Unknown	33/159	21						
Regular use								
Tobacco								
No	47/356	13	1.0			1.0		
Yes	35/197	18	1.4	0.9–2.3	0.15	1.4	0.8–2.2	0.22
Unknown	62/338	18						
Snuff								
No	29/229	13	1.0			1.0		

Table 2 (continued)

	n PI/n subgroup	PI percentage	Crude values			Adjusted (gender and age) values		
			OR	95% CI	*p* value	OR	95% CI	*p* value
Yes	8/32	25	2.3	0.9–5.6	0.07	2.2	0.9–5.6	0.09
Unknown	107/630	17						
Alcohol								
No	13/141	9.2	1.0			1.0		
Yes	60/365	16	1.9	1.0–3.7	0.041	1.8	0.9–3.4	0.07
Unknown	71/385	18						
Drug abuse (illegal and prescribed)								
No	26/216	12	1.0			1.0		
Yes	19/64	30	3.1	1.6–6.1	0.001	3.0	1.5–6.0	**0.002**
Unknown	99/610	16						

The values in bold show variables with significant associations with PI.

OR odds ratio, *CI* confidence interval.

[a]The "Single, not living alone" subgroup consists of persons living with their parents and kids, in a collective, etc.

[b]The "No work" group consists of people on sick leave, retirement, disability benefits, unemployment benefits, and other social welfare benefits.

[c]AIS American Spinal Injury Association Impairment Scale, AIS A motor/sensory complete, AIS B motor complete/sensory incomplete, AIS C and D motor/sensory incomplete, AIS E normal examination.

[d]Brain injury consists of all kinds of injury affecting the brain function, including concussion.

[e]The "Allergy/skin disease" group consists of all kinds of allergy, eczema, and skin diseases.

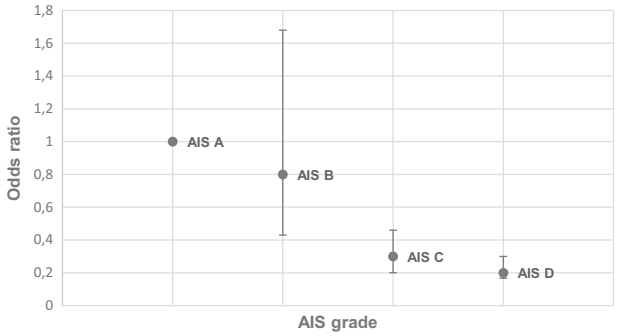

Fig. 2 The trend between the AIS grade and the PI risk in the studied population. The figure shows estimated odds ratios with corresponding 95% CI for AIS grades B, C and D compared to the reference grade AIS A.

not. Regular use of tobacco and alcohol did not show any significant increase in the risk of PI.

Discussion

NORSCIPI is the first national study of PI in the SCI population in Norway. Our study population was representative and comparable with previous studies in Norway [20, 21]. An important finding in our study was the association between psychological impairments and the risk of PI, which is in accordance with previous studies [2, 22].

It should be noted that no standardized instrument to assess depression was applied in this study, since we build on information retrieved from the EMR. There is some ambiguity in the recorded depression diagnoses; however, we refer to it as depression, based on clinical evaluation.

We found that the level of injury was insignificant regarding the risk of having a PI, while individuals with AIS A and B were more at risk of having a PI, compared with AIS C and D. Previous findings are inconsistent when it comes to the association between the degree of impairment, evaluated by the AIS grade and PI [23–26]. However, our results are in accordance with previous studies, where the completeness of the injury determines the risk of having a PI [2, 7, 23, 24]. In our study, the occurrence of PI was 16%, which is lower than previous studies [6, 27, 28], and lower than the occurrence of PI in the general inpatient population in both Norway and other comparable countries [6–9, 27–30]. Mawson et al. postulated that the most likely time for the development of PI is the immediate postinjury period of spinal shock, and that some of the PIs appearing during acute care may be the visible result of ischemic injuries occurring prior to acute admission [26]. Unfortunately, we could not obtain documentation on how patients were immobilized during transfer to the acute care hospitals or the NSCUs, the mode of transport, transfer surfaces used, or whether pressure-relieving devices or interventions were utilized during transportation and hospitalization [28]. In our study, 5% of the population were injured abroad, and the occurrence of PI among them was significantly higher, compared with those injured in Norway. We believe that delay in admittance to the NSCUs might explain the findings of the increased occurrence of PI in those injured abroad. Because of strict Norwegian guidelines, regarding the prevention of multiresistant bacteria, patients injured

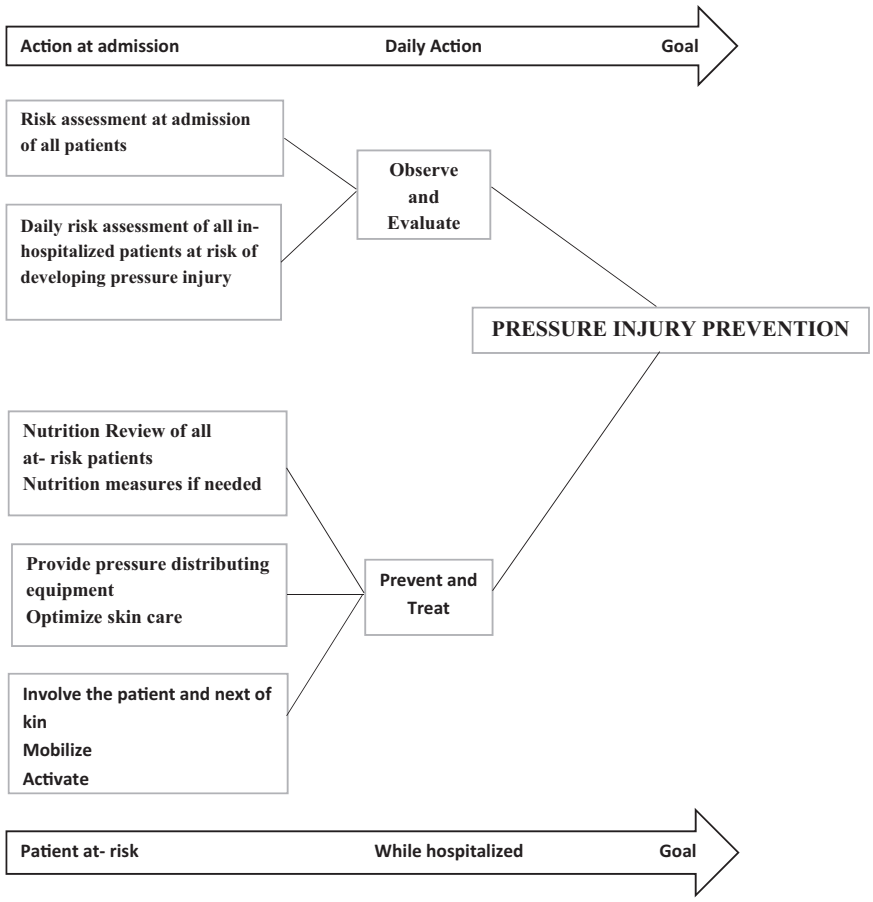

Fig. 3 Suggested action plan for prevention of PI. This should start with a risk assessment of each patient at admission to the spinal cord unit, followed by daily observation and re- evaluation of the risk. The patients, together with their families should be included in all parts of the prevention and treatment at all stages of the rehabilitation stay. Nutrition review and nutrition measures should be provided to all hospitalized at- risk patients, together with pressure distributing equipment and optimal skin care.

abroad are isolated at home or at the local hospital, and not admitted to the NSCUs until their infection status is clarified [31]. PI-preventing routines for the transportation, in-hospital preventing care at both the acute care wards, and the NSCUs are important issues in the future PI-preventing recommendations. Knowledge about PI prevention should be a part of the education and training for all staff members, as well as newly injured individuals, and their relatives [32]. The Norwegian "In safe hands" program (https://www.pasientsikkerhetsprogrammet.no/om-oss/innsatsomr%C3%A5der/_attachment/3304?_download=false&_ts=14e26104012) could be implemented as a simple way to identify patients at risk of developing PI, by asking three questions for risk assessment immediately after admittance to hospital:

(1) Does the patient have PI now?
(2) Does the patient need assistance in position changing?
(3) Is the patient at risk of developing PI during the hospitalization?

If the answer to any of these questions is "yes," an action plan should be initiated, with the aim to prevent the occurrence of any PI, or to treat an already-existing PI. The flowchart in Fig. 3. provides a visual overview of the action plan and recommended measures to achieve the "No PI" goal (Fig. 3). Checklists should be used to record this information in the EMR.

In NORSCIPI, the occurrence of PI was more than double among men, compared with women. The association between gender and PI has been studied with mixed results in previous studies [24, 26, 33]. We speculate that individuals with risk-taking behavior may continue this behavior into rehabilitation, and if there is more risk-taking behavior in the male population in our study, they may be more vulnerable to PI? This question requires further investigation. Another possibility is the difference in fat distribution in women versus men, as women often have increased adipose tissue at the buttocks and thighs, two areas that are especially vulnerable to PI [34]. Even if the cause for the gender difference is not sufficiently explored, it highlights the need for repeated information about prevention actions in vulnerable individuals, and that staff planning the rehabilitation are assessing each patient's risk for PI individually.

It is known that aging causes reduction of the micro-vascularization and of the proliferative activity of the dermis, as well as changes in the elasticity of the skin,

enhancing the effect of local pressure and stretch on the skin, and thus increasing the risk of PI [28]. Nevertheless, previous studies show contradictory results concerning the association between age and PI [23, 24, 26]. In the present study, the age group of 45–59 years actually had a 50% reduced odds of PI compared with the reference group (15–29 years). An analysis regarding differences in the age groups identified a higher occurrence of depression and AIS grades A–B in the age group of 15–29 years, and we believe that these were the reasons for the increased PI odds. These findings reinforce the need to focus on particularly at-risk individuals, or subgroups, during rehabilitation.

We did not find any association between the occurrence of PI and level of education or occupational activity. The social welfare system in Norway gives everyone the same opportunity for health care, regardless of education, occupation, or income [35], and this may influence the results in our study, compared with other reports [2, 23, 24].

Our findings reiterate that risk factors, such as incontinence, lack of sensation, ventilation support, hypertension and cardiovascular disease increase the odds of PI [2, 3, 5, 28, 36, 37].

Patients with DM1 showed a higher occurrence of PI, with an OR close to 8. Although we cannot claim a causal association, PI-preventing actions regarding persons with DM1 who are acquiring a SCI, should be in focus at all terms of postinjury care and follow-up. In contrast to previous research [2, 27, 28], we did not find an association for PI and DM2. There is limited information about the differences in the risk of PI in DM1 compared with DM2, and neuropathic abnormalities, together with poor circulation and immune function changes, each contributing to vulnerable alteration in the tissue among individuals with DM1 and DM2 [38]. One study found that independent risk factors include renal insufficiency [39]. About 30% of individuals with DM1 (juvenile onset), and 10–40% of those with DM2 (adult onset), eventually will suffer from kidney failure [40]. We speculate that renal insufficiency contributed to the differences in the association between DM and PI in our population; however, the population with DM1 in NORSCIPI only consisted of 13 individuals, with a mean age of 42 years, while there were 68 individuals with a mean age of 62 years with DM2. Thus, with this small population, further research is warranted.

Surprisingly, we did not find any association between the use of tobacco or alcohol and PI, while abuse of drugs seems to be associated with PI development. Thus, our findings do not support findings in previous studies related to the use of tobacco or alcohol [41]; however, uncertainty in the number of reported users in the investigated population may partially explain our results.

Study limitations

There are a number of limitations in our study related to the clinical care of patients with SCI in Norway. Individuals with SCI not admitted to one of the NSCUs post injury due to the limited need for third-line rehabilitation, or comorbidity are not included in the study. Clinical transfer protocols for individuals with newly acquired TSCI as compared with NTSCI are well known in Norway [12], but acute rehabilitation after NTSCI is less well defined. Thus, our NTSCI sample does not include all affected individuals, in contrast to our TSCI sample. Finally, we would optimally have divided the time between injury through acute rehabilitation into two separate periods: accident to acute rehabilitation transfer, and the acute rehabilitation period. Unfortunately, this was not possible to do, given the available information in the EMRs, and this is a limitation in our study.

Because of variable reporting in the EMR, there was missing information about PI in 121 of the individuals. This may reduce the statistical power of the results [42]; however, clinical experience indicates that if there is no information about PIs in the EMR, there is generally not a PI problem. Moreover, performing a logistic regression, by setting the missing PI to "No PI," did not change the (significance of the) results.

Information about drug abuse at the time of the injury is retrieved from available information in the transfer letter from the acute care hospital. Any missing information in this document will also be missing in the study. The lack of recorded information in the EMR regarding those who use tobacco, alcohol, and/or illegal drugs, and those who do not, results in missing data, and is another limitation of our study.

We have investigated a high number of potential risk factors. Thus, it was infeasible to develop causal models for all of them, and to adjust for all confounding factors. Hence, the identified associations should be taken as indications, worthy of further investigations to clarify casual relationships. We have also performed a high number of statistical significance tests, increasing the risk of type I errors [43]; however, most of our significant findings seem clear and robust; thus, we feel quite confident about our conclusions.

Conclusion

NORSCIPI has a unique design, because variables are recorded over a 10-year period, and data are retrieved from the EMR. The results are unique because they represent the national status of PI in the entire SCI population of Norway. We identified several factors, including DM1 and depression that may be worthy of further research to clarify their

role in the causal path to PI. We give recommendations for a simple program on observation and prevention of PIs for health care providers, patients, and next of kin. An increased understanding of factors that associate with PI will allow providers to focus on patients at particular risk. Checklists on factors associated with the occurrence of PI, as well as checklists and better focus on PI prevention should be a part of the acute care SCI rehabilitation. For better outcomes, further research should focus on PI prevention routines and actions during the acute post-injury rehabilitation.

Data availability

The data set is stored in a locked and fireproof research cabinet at the research department, Sunnaas Rehabilitation Hospital, Norway, and can be made available on request, according to the Norwegian Data and Telecommunications Authority's requirements for safe information flow [14].

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Author contributions II is a medical doctor (MD) at Sunnaas Rehabilitation Hospital, and a PhD fellow at the University of Oslo. She is the main investigator of the study, and the only investigator with access to the complete data set collected in the study. She is also the main contributor in the writing of the paper. TR is the main supervisor. TR and II were responsible for the design of the study. JKS is the research director at Sunnaas Rehabilitation Hospital, and the project manager. JMH and RJ are co-supervisors in the project. MA is a collaborator in the project. MT is a statistician, guiding in the statistical design of the study and analyses of the results. JKS, TR, JMH, RJ, MA, and MT all contributed to the draft of this paper. All authors read and approved the final paper before submission.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The research project was carried out in accordance with current ethical guidelines and privacy rights for health services in Norway [14], based on the Code of Ethics of the World Medical Association (Declaration of Helsinki) [44] for experiments involving humans. The research project was approved by the Norwegian Regional Ethical Committee (REC) on January 9th 2015 (2014/684 REK-Nord) [15], and registered in Clinical Trials.gov in May 2016 (NCT02800915).

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II

Original Paper

Videoconferencing in Pressure Injury: Randomized Controlled Telemedicine Trial in Patients With Spinal Cord Injury

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Abstract

Background: Geographical, financial and travel-related barriers may impact access to necessary health care for people in need of long-term follow-up.

Objective: The goal of the research was to perform a nonblinded, randomized, controlled trial on health-related quality of life (HRQoL), healing, interaction, and satisfaction of patients with spinal cord injury (SCI) and PI receiving multidisciplinary videoconference consultations from a wound clinic to the participant's home versus regular outpatient care. The multidisciplinary team consisted of a medical doctor, a wound nurse, and an occupational therapist. In both groups, district nurses attended the consultations at the participant's home.

Methods: A total of 56 participants, 28 in each group, were randomized to a videoconference group (VCG) or a regular care group (RCG). Validated questionnaires were used to measure and compare the follow-up effect on HRQoL. Percentage reduction of wound volume was measured at end of the follow-up. A Likert scale was used to measure the satisfaction of the patients and district nurses regarding the interaction between different modalities of care in the 2 groups.

Results: The HRQoL did not show significant differences between the 2 groups (P values ranging from .09 to .88) or the rate of PI healing, experienced interaction, and satisfaction in the groups. A total of 67% (37/55) of all PIs healed, 64% (18/28) in the VCG and 70% (19/27) in the RCG. Mean reduction in ulcer volume was 79% in the VCG and 85% in the RCG (P=.32). A Kaplan-Meier plot with a logrank test regarding time to healing did not show any significant difference between the 2 groups.

Conclusions: Videoconference-based care seems to be a safe and efficient way to manage PIs in terms of HRQoL, healing, interaction, and satisfaction compared to conventional care for people with SCI. This should be considered when planning for future care. SCI has a huge impact on the individual, the family, and the health care system. There is an urgent need to improve systems of care so that individuals who live far from specialists and require long-term follow-up for conditions such as PI can get optimal treatment.

Trial Registration: ClinicalTrials.gov NCT02800915; https://clinicaltrials.gov/ct2/show/NCT02800915 and Current Research Information System in Norway (CRISTIN) 545284; https://app.cristin.no/projects/show.jsf?id=545284

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KEYWORDS

telemedicine; telecommunication; videoconference; outpatient follow-up; spinal cord injury; pressure injury; healing; participant satisfaction; participant interaction; health-related quality of life

Introduction

Background

For people living in rural or medically underserved areas, treatment access may be limited or even nonexistent [1]. Financial situation, travel and treatment costs, ability to take paid time off from work to visit a clinic or hospital, health insurance issues, pandemics, climate change, and unpredictable weather conditions may all impact access to necessary health care [1,2]. Transportation to hospitals and outpatient clinics may be a barrier because of length and duration of the transportation, discomfort, stress, and risks related to the transport [3]. People with spinal cord injury (SCI) are at particular risk of developing pressure injury (PI) due to paralysis, reduced skin sensitivity, and skin exposure to moisture for extended periods of time [4]. They are often hospitalized for long periods of time and need frequent outpatient care for treatment and to monitor the treatment [5]. However, long transport can cause new wounds to develop [6]. This may cause people not to attend to needed appointments [7]. Telecommunication could help to overcome such limitations [2,8]. Telecommunication between hospital and home is a potential way to offer effective health services, regardless of the geographical location of the patient and health care professional [9,10]. Telecommunication in health care covers a broad range of digital remote care services, all with the aim to provide investigation, monitoring, and management of patients and education for patients and staff using technology, allowing access to expert advice and patient information, no matter where the patient or relevant information is located [11]. Different solutions are in use, depending on the health service offered, technology needed, and performance of the service. There are real-time services like videoconferencing, videophone solutions and phone calls, store-and-forward services like text messages and electronic data collection and transmission, and web-based interactive platforms [7,12]. Services can be used to deliver education, consultation, therapy, social support, data collection and monitoring, and clinical care delivery [7,12]. Real-time video consultations allow health care professionals to perform remote visits to the patients' homes with the possibility to communicate and interact directly with each other [10,11]. Moreover, local care providers, like district nurses, can be included in the consultation. Thus, this system of care delivery increases the possibility of interaction between members at different health care levels and the patient.

Prior Work

Today there are telecommunication services available for many different health care issues. Teleradiology, telepathology, teledermatology, and telepsychiatry are popular and established areas all with the purpose of transmitting images, test results and medical information, as well as performing evaluations and consultations. The transmitting is via digitalized solutions, video and telephony [7,12-18]. Some services, like cardiology, electrocardiography, ultrasonography and mammography, are available at several hospitals and in different countries, while some services, like emergency medicine, immunology, hematology and speech therapy, are only performed in individual countries or individuals hospitals [7,16,18,19]. As in rehabilitation, research into long-term follow-up has shown mixed evidence of feasibility and efficacy regarding use of telecommunication solutions [15-18,20,21].

The Sunnaas model of telerehabilitation [22] has been used to provide videoconferencing as part of inpatient and outpatient rehabilitation services at a Norwegian rehabilitation hospital. A feasibility study evaluated videoconference as a possible alternative method for outpatient follow-up for patients with SCI and PI [4].

Goal of the Study

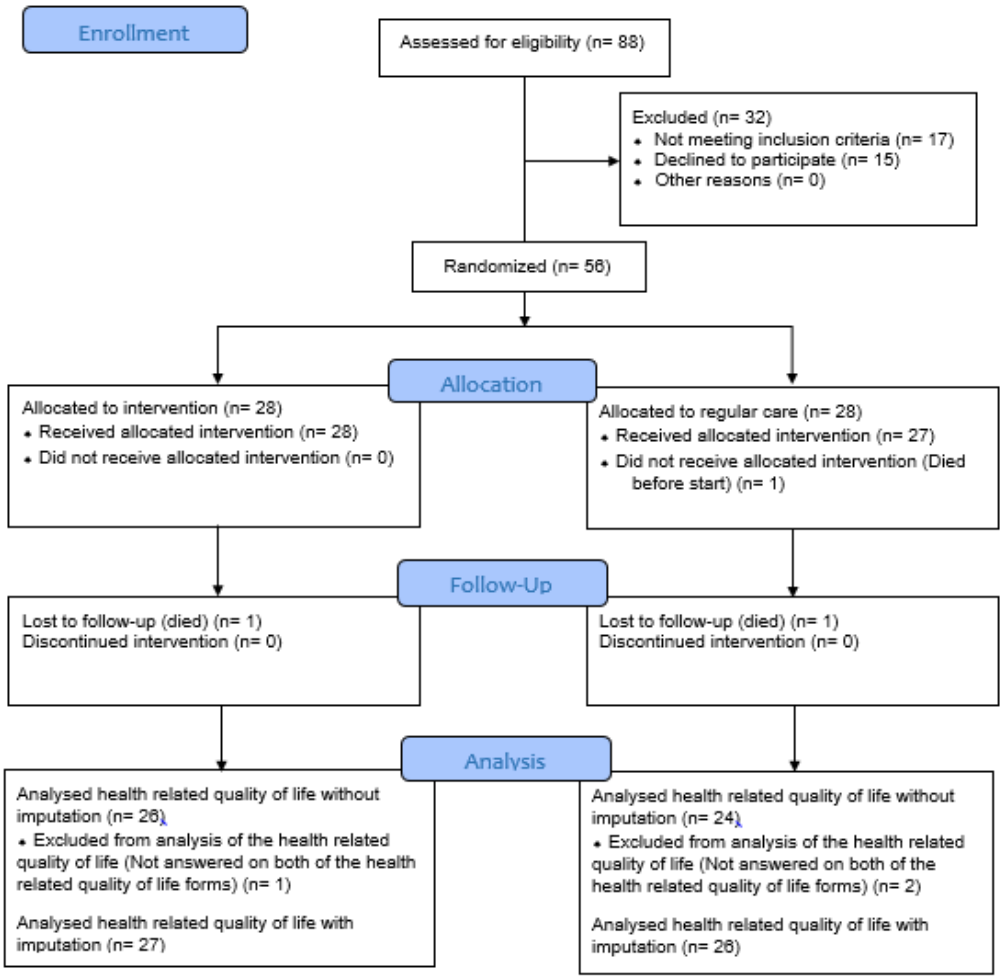
The primary aim of this study was to investigate if videoconference consultations could increase health-related quality of life (HRQoL) in people with SCI and PI. Secondarily, we wanted to determine whether PI healing, perceived interaction, and satisfaction could be considered as good and efficient as conventional follow-up [11].

Methods

Recruitment

People with SCI and ongoing PI were invited to participate in a nonblinded, national, randomized controlled study at 2 spinal cord units in Norway, located at Haukeland University Hospital in western Norway and Sunnaas Rehabilitation Hospital in southeastern Norway. Participants were invited based on response to a questionnaire [11] and from referrals to the outpatient wound clinic at the units. Inclusion criteria were traumatic or nontraumatic SCI, ongoing PI, aged over 18 years, and consent to participate. Individuals were included regardless of concomitant medical concerns. Exclusion criteria were not living in Norway and unable to give their consent due to cognitive impairments. Eligible participants were provided with written and oral information and signed a written consent before inclusion. The study took place between March 6, 2016, and October 19, 2019. The study flowchart is shown in Figure 1.

Figure 1. CONSORT 2010 (Consolidated Standards of Reporting Trials 2010) flow diagram of the trial.

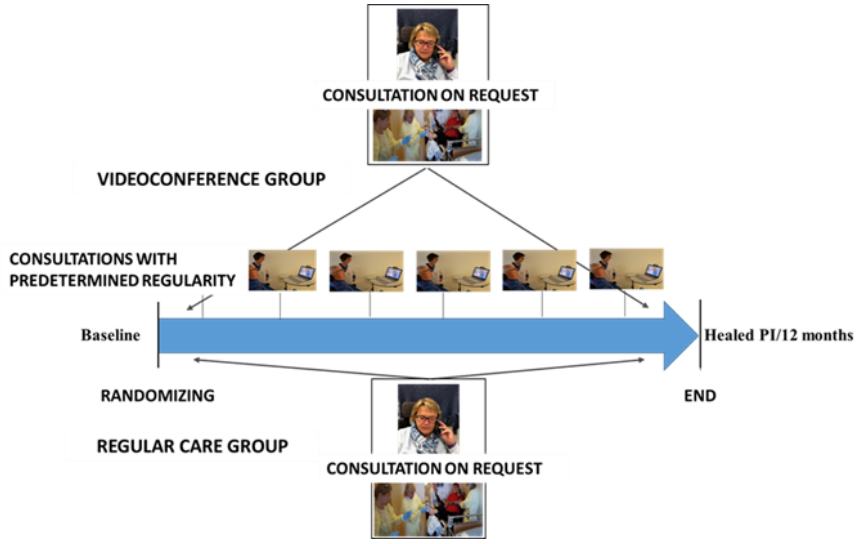


Study Design

Once the written consent was given, baseline data were collected and participants were randomized to a videoconference group (VCG) and a regular care group (RCG) by use of the random number generator in the statistical software SPSS (version 25, IBM Corp). The group allocations were then told to the participants. For both groups, a multidisciplinary wound team conducted the follow-up from the outpatient clinic. The team consisted of a medical doctor with several years of experience in PI treatment, a certified wound care nurse, and an occupational therapist with specialized skills regarding pressure measurements and PI follow-up. For both groups, district nurses were present with the participant at the participant's home during the consultations. The district nurses performed the wound treatment supported by remote guidance from the multidisciplinary wound team at the outpatient clinic. The participants in the RCG received treatment and guidance based on existing routines (ie, by telephone or outpatient consultations at the hospital, if requested). The participants in the VCG were offered treatment and guidance via predetermined videoconference consultations and regular care similar to the RCG. Both groups were followed until healing of the PI or for a maximum of 52 weeks. Figure 2 shows the organization of the follow-up in the 2 groups.

The timeline for study enrollment, intervention, and assessment is described in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [23]. The Template for Intervention Description and Replication (TIDieR) [24] checklist and guide were used to record and describe the intervention. The study conforms to the Consolidated Standards of Reporting Trials (CONSORT) guidelines extension for randomized pilot and feasibility trials [25].

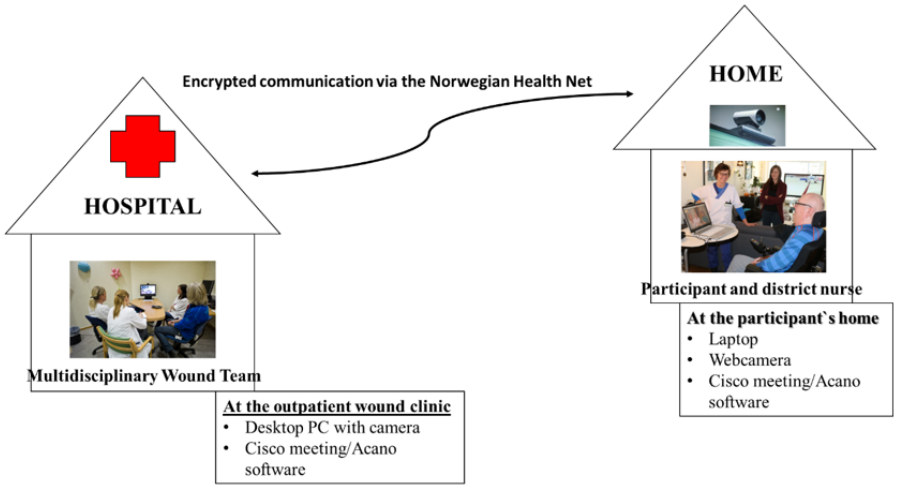
Figure 2. Organization of follow-up for the videoconference and regular care groups.



Technical Logistics

In both groups, the district nurses used their work phone or the participant's cell phones for telephone consultations. For participants in the VCG, arrangements for installation of encrypted software and rehearsal in the use of the program and equipment were addressed immediately after randomization. All participants in the VCG had available broadband or mobile broadband connection. Most of them used their private laptops in the consultations or they borrowed laptops from the hospital's storage. All of them borrowed mobile webcams from the hospital's storage. The consultations were performed as synchronous live, videoconferencing in real time, using a Cisco TelePresence System EX90 PC with camera at the wound clinic and a laptop with a mobile webcam at the participant's location. Encrypted communication channels via the Norwegian Health Net were used to protect privacy of the participants [26]. The wound care nurse at the outpatient wound clinic tested the equipment with the participant and the district nurses before start of the follow-up. Each participant was given a unique subscription number. The wound care nurse at the outpatient wound clinic addressed the participant at each session, and the participant had to accept the call before the consultation could start. Figure 3 shows the organization of the videoconference consultations.

Figure 3. Organization of the videoconference consultations.



Information and Guidance

For both groups, the participants gave their consent to send medical records to the general practitioner and their district nurses after each consultation, no matter the kind of consultation. For both groups, all treatment and guiding were conducted in accordance with evidence-based wound therapy guidelines [27] and individualized in accordance with each participant's needs. The district nurses in both groups were guided in treatment principles according to their knowledge needs. Clinical guidelines, online education programs, and e-learning programs were accessible for the district nurses in both groups.

Study Variables

Demographic information included gender, date of birth, age at SCI, time since SCI, etiology (traumatic, nontraumatic), level and grade of the SCI, and SCI associated problems. SCI was described according to the International Standards for Neurological Classification of SCI recommendations including clinical findings standardized by the American Spinal Injury

Association (ASIA) Impairment Scale (AIS) [28]. Any use of alcohol or tobacco or abuse of drugs was recorded. In addition, information regarding any previous PIs and PI recurrence was recorded, together with the number of present PIs, as well as the category and volume of the present PIs. All PIs were categorized and numbered according to the joint 2019 guideline prepared by the 3 collaborating PI organizations: National Pressure Injury Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance [27]. According to this guideline, the categorization of PIs varies with size and severity of the tissue affected, ranging from reddening of the skin (category 1) to damage to muscle and underlying bone (category 4). In category 1 and 2, the injury is partially going through the skin, while in category 3 and 4, there is a full thickness skin wound. In a suspected deep tissue injury, the depth and severity of the wound is unknown. In an unstageable PI, the wound cannot be categorized due to sloughing/scarring [27]. The PI categorization and volume, (length × width × depth) was measured at baseline by the medical doctor and wound care nurse and at the end of the follow-up by either the medical doctor and wound care nurse at the outpatient wound clinic or by the district nurses guided by the wound team. A ruler adapted for PI measurement was used. The district nurses gained access to the rulers via the multidisciplinary wound team. Difference in volume was calculated as percentage change. Time to healing was measured as days from baseline to healing. Changes in HRQoL in the 2 groups were compared using the Norwegian versions of the 36-item Short Form Health Survey (SF-36) [29] and the Five-Dimension European Quality of Life (EQ-5D) scale [30]. In case of lack of an available Norwegian index version of the EQ-5D scale, the validated UK index is recommended to be used in analyses regarding Norwegian subpopulations [30]. We also used the International Spinal Cord Injury Quality of Life Basic Data Set (ISCI-QoL-BDS) questionnaire [31] to measure the HRQoL among the participants. The form used is similar to the version used by the Norwegian Spinal Cord Injury Registry [32].

The participants reported subjective ratings regarding satisfaction, safety, and level of interaction during the follow-up using a Likert scale with 1 being completely dissatisfied and 5 being totally satisfied. Moreover, as an ad hoc analysis, we wanted to gain knowledge about the district nurses' experience, and thus we invited them to report their ratings as well.

Ethics

The research project was carried out in accordance with ethical guidelines and privacy rights for health services in Norway [26] based on the code of ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Established routines to secure confidentiality and ethical guidelines for conducting consultations involving examinations related to intimate body areas, which may be visible on the screen, were established before the study was initiated [22]. Knowledge and expertise achieved through a previous feasibility study [4] was applied in this study. Communication occurred through the Norwegian Health Network's encrypted video channels. The study was performed in compliance with Norwegian data security and privacy standards [26]. The study was approved by the regional committees for medical and health research (2014/684/REK-Nord) [33] and registered with ClinicalTrials.gov (NCT02800915). All participants were insured through the Norwegian health care system and the hospitals' insurance programs for adverse effects.

Statistical Analyses

Demographic variables were descriptively analyzed. Continuous variables are presented as mean with standard deviation whereas categorical variables are presented as counts and percentages. For the HRQoL scores, missing data were handled by multiple imputation. Each missing data point was replaced by m=20 imputed values based on the predictive mean matching technique before analysis. The imputation models include age, gender, AIS grade, and HRQoL scores.

Mean HRQoL scores with corresponding 95% confidence interval are presented for each of the 2 treatment groups at baseline and end of follow-up, and the groups were compared using linear regression analysis with adjustment for baseline. This analysis was repeated without imputation for missing values as well, for comparison. The mean percentage reduction in PI size was calculated with corresponding 95% confidence interval for each of the 2 groups and compared using a Mann-Whitney test. Time to healing was analyzed by the logrank test and is presented by a Kaplan-Meier plot.

$P<.05$ is considered significant. Independent *t* tests were used to analyze the mean difference in participant satisfaction scores. Corresponding 95% confidence intervals were calculated. All statistical analyses were performed using SPSS statistical software.

Sample Size

We based our sample size calculation on investigation of HRQoL and the group comparison at the end of follow-up. Our hypothesis was that HRQoL would increase in the VCG as compared to the RCG, and the sample size calculation was based on an expectation of a standardized difference of at least 0.8 (typically considered a large effect). With 80% power, we would need 25 patients in each of the 2 groups.

Results

Demographics

A total of 56 participants were included, with 28 in each group. One participant in the RCG died of acute illness prior to start of the follow-up, and the participant's data were excluded from the analyses. Furthermore, 2 participants, 1 in each group, did not complete any of the HRQoL questionnaires and were removed from the analysis of the primary outcome. Two participants, 1 in each group, died during the follow-up. They are included in the analysis of wound healing as not healed PIs. All deceased participants were male and causes of death were reported to be cardiovascular disease (2) and pneumonia (1). Of the 55 participants included in the analysis, the majority were male, 86% (24/28) in the VCG and 78% (21/27) in the RCG. The mean age was 58 years in both groups. Baseline data of the included participants are shown in Table 1.

Table 1. Baseline data of the participants in the 2 groups.

Characteristics	Videoconference group (n=28)	Regular care group (n=27)
Gender, n (%)		
Male	24 (86)	21 (78)
Female	4 (14)	6 (22)
Age (years), mean (SD)	57.50 (14.2)	57.96 (12.81)
Age group (years), n (%)		
15-29	0 (0)	1 (4)
30-44	6 (21)	3 (11)
45-59	8 (29)	12 (44)
60-74	12 (43)	9 (33)
75+	2 (7)	2 (7)
Years since SCI[a], mean (SD)	16.30 (12.7)	18.90 (15.0)
Etiology of injury, n (%)		
TSCI[b]	22 (79)	24 (89)
NTSCI[c]	6 (21)	3 (11)
Level of injury[d], n (%)		
C1-C4	4 (14)	5 (19)
C5-C8	5 (18)	6 (22)
T1-S3	19 (68)	16 (59)
AIS grade[e], n (%)		
A	18 (64)	18 (67)
B	3 (11)	0 (0)
C	6 (21)	8 (30)
D	1 (4)	1 (4)
SCI-associated problems, n (%)		
Incontinence	25 (89)	23 (85)
Pain (all types)	8 (29)	9 (33)
Spasticity	9 (32)	8 (30)
PI[f] category, mean (SD)	2.90 (0.86)	2.82 (0.98)
Other PIs/PI recurrence, n (%)		
No	3 (11)	7 (26)
Yes, other PI	11 (39)	9 (33)
Yes, recurrence	13 (46)	10 (37)
Yes, both	1 (4)	1 (4)
Comorbidity, n (%)		
DM1[g]	1 (4)	1 (4)
DM2[h]	6 (21)	2 (7)
Hypertension	10 (36)	4 (15)
CV disease[i]	4 (14)	7 (26)
TE disease[j]	6 (21)	6 (22)
Depression/low mood	2 (7)	3 (11)

Characteristics	Videoconference group (n=28)	Regular care group (n=27)
Regular use/abuse, n (%)		
None	9 (32)	9 (33)
Tobacco	14 (50)	15 (56)
Alcohol	13 (46)	11 (41)
Illegal drugs	0 (0)	1 (4)

[a]SCI: spinal cord injury.

[b]TSCI: traumatic spinal cord injury.

[c]NTSCI: nontraumatic spinal cord injury.

[d]Level of injury: location of the injury in the spinal cord (C: cervical, T: thoracic, and S: sacrum).

[e]AIS grade: completeness/severity of the injury.

[f]PI: pressure injury.

[g]DM1: diabetes mellitus type 1.

[h]DM2: diabetes mellitus type 2.

[i]CV disease: cardiovascular disease.

[j]TE disease: thromboembolic disease.

Pressure Injuries at Baseline

In the VCG, 32% (9/28) of the PIs were category 2, 50% (14/28) category 3, 11% (3/28) category 4, and 7% (2/28) could not be categorized at the time of inclusion. The distribution in the RCG was 52% (14/27) were category 2, 22% (6/27) category 3, 19% (5/27) category 4, and 7% (2/27) were unstageable.

Most of the PIs were located at the ischial tuberosities: 50% (14/28) in the VCG and 33% (9/27) in the RCG. At the sacrum-gluteal cleft, PIs occurred in 32% (9/28) of the participants in the VCG and 48% (13/27) in the RCG.

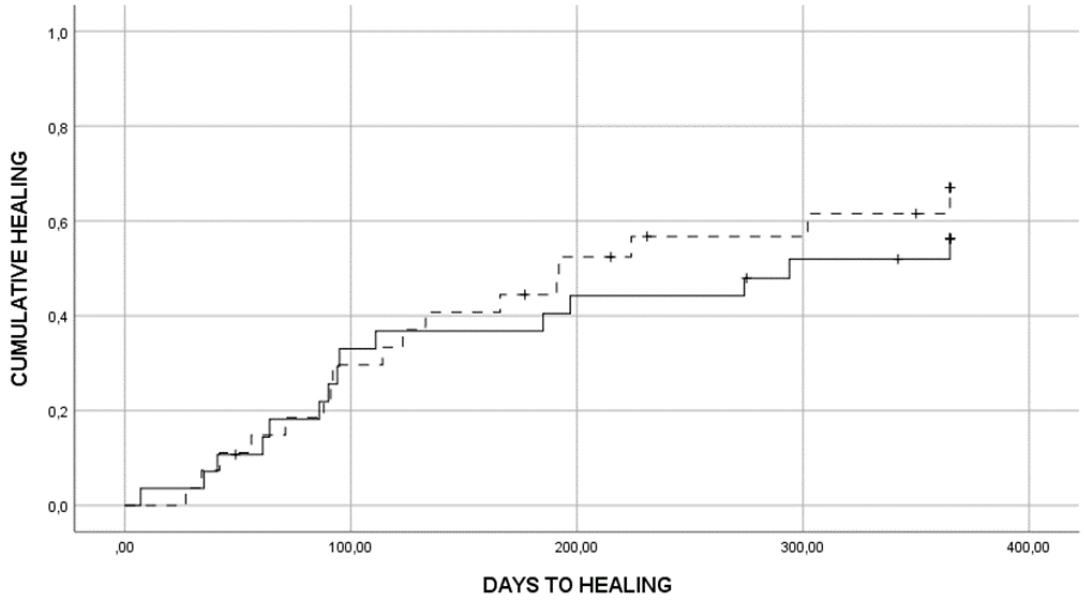
Health-Related Quality of Life

The SF-36 scale, the UK version of the EQ-5D scale, and the ISCI-QoL-BDS basic data set were used to measure and compare changes in HRQoL. Performing a linear regression analysis, comparing the 2 groups with adjustment for baseline, did not yield any significant differences regarding HRQoL, as shown in Multimedia Appendix 1 (imputed data). Multimedia Appendix 2 shows the complete data.

Healing

A total of 67% (37/55) of all PIs healed completely during follow-up: 64% (18/28) in the VCG versus 70% (19/27) in the RCG. Mean reduction in ulcer volume in the VCG was 79% versus 85% in the RCG. No significant difference in the 2 groups were found (P=.32). The median time to healing in the VCG was 275 days (95% CI 111.18-438.83) versus 192 days (95% CI 113.71-270.29) in the RCG. A Kaplan-Meier plot (Figure 4) with a logrank test regarding time to healing did not show any significant difference between the 2 groups (P=.56). Figure 4 displays time to healing in both groups.

Figure 4. Kaplan-Meier plot showing time to healing in the two groups (videoconference: solid line; regular care group: dotted line).



Interaction, Satisfaction, and Safety

A total of 85% (47/55) of the included participants responded to the feedback form, 86% (24/28) in the VCG and 85% (23/27) in the RCG. No significant differences were found in interaction, satisfaction or safety, and the estimated mean differences were minor. Table 2 shows the mean difference between the RCG and VCG, with corresponding confidence intervals and P values. The district nurses were also asked to report their experienced interaction, satisfaction, and safety with the follow-up. A total of 45% (24/55) of the nurses responded, 52% (14/28) in the VCG and 38% (10/27) in the RCG. No significant differences were found in the 2 groups.

Table 2. Comparison of interaction, satisfaction, and safety experienced by participants and district nurses as reported at follow-up.

	Mean difference[a]	95% CI	P value[b]
Participants			
Planning	–0.08	–0.78 to 0.62	0.82
Implementation	–0.04	–0.73 to 0.81	0.91
Interaction	0.14	–0.59 to 0.87	0.70
Participation	–0.13	–0.67 to 0.94	0.74
Safety	–0.01	–0.77 to 0.76	0.99
Usefulness	–0.19	0.97 to 0.60	0.63
Overall satisfaction	0.11	0.66 to 0.88	0.78
District nurses			
Planning	0.21	–0.41 to 0.82	0.49
Implementation	0.04	–0.55 to 0.63	0.88
Interaction	0.33	–0.32 to 0.99	0.30
Participation	0.00	–0.60 to 0.60	1.00
Safety	0.16	0.41 to 0.74	0.56
Usefulness	–0.15	0.87 to 0.56	0.65
Overall satisfaction	–0.16	–0.68 to 0.36	0.52

[a]Mean difference: difference in mean values (regular care group minus videoconference group).

[b]Based on an independent *t* test.

Discussion

Principal Findings

SCI has a huge impact on the individual, the family, and the health care system. Regular contact with specialized health care is required for the condition itself as well as the frequent related complications such as PI. Thus, there is an urgent need to secure availability of high-quality services for patients who live far from specialists and require long-term follow-up [5,34]. Individuals with SCI and PI require frequent outpatient care to monitor their wounds [34]. Long travel distances to receive treatment, resulting in time-consuming transport, can attribute to greater morbidity [6]. To our knowledge, this is the first randomized controlled study using videoconferencing to provide long-term treatment to persons with PI. The results from our study indicate that regular home-based videoconferences are as safe for patients and their district nurses as conventional care with in-person attendance.

According to our study, the HRQoL was not dependent of the type of health service offered. We still find it relevant to mention that the estimated mean difference was in favor of the VCG for 12 out of 13 HRQoL scores. There were no substantial differences between the analyses based on the imputed data (Multimedia Appendix 1) and the complete case analysis (Multimedia Appendix 2).

In this study, the 2 groups were evenly distributed by gender, age, PI occurrence, and PI location. There were no significant differences regarding healing between the 2 groups. Looking at the Kaplan-Meier plot (Figure 4), the 2 curves follow each other very closely, at least for the first 200 days, indicating that the videoconference service was as efficient as the conventional follow-up. All participants and their district nurses were given similar guidance regarding nutrition, skin care, PI prevention, position change, and pressure relieving mattresses and cushions, and an individual treatment plan was established for each participant in both groups [27].

We also investigated the association between potential risk factors and time to healing as a post hoc analysis. Interestingly, overall comorbidities did not show any association regarding time to heal. Due to low number of concomitant diseases among the participants in our study (Table 1), further substudies could not be performed.

Participants in both groups and their district nurses reported acceptable levels of experienced interaction and satisfaction, with no significant differences regarding the follow-up. This indicates videoconference consultations offer satisfactory remote

interaction with the district nurses as compared to regular follow-up. However, we believe a larger study with a noninferiority design would be warranted to establish this.

There is a lack of studies regarding PI and long-term follow-up in the literature. Based on the number of nonhealing PIs in our study, a longer follow-up period may be an interesting topic for future research. We also think that the issue of nonhealing PI should be further explored, no matter the mode of follow-up intervention.

Telemedicine has been widely adapted in many fields of medicine, especially in recent years. We believe that this should also be the case for rehabilitation and that individualized follow-up where a hybrid solution of video communication and conventional consultations is used, may be a promising path for the future.

Limitations

When the present study was designed, we based our sample size calculation on an investigation of HRQoL. However, we do not have sufficient statistical power to provide conclusive evidence regarding the rest of the comparisons we performed in this study.

Comparison With Prior Work

This study is the first randomized, controlled, multidisciplinary long-term study using videoconference as mode of administration of treatment to provide care to persons with SCI and PI [15]. Videoconference consultations seem to be an acceptable solution concerning treatment and follow-up. Our study shows feasibility and efficacy in the examined population. However, the heterogeneity regarding participants, modalities, and the level of mixed evidence in previous research makes it difficult to compare with prior work [15,35]. This is also in line with previous research [13,15,17,20,21,36].

Conclusion

Videoconference in a patient's home ensures safe and efficient quality of care without any reduction in HRQoL, PI healing, or satisfaction as compared to conventional outpatient care at the hospital. Long-term videoconference at home under these circumstances ensures interaction with patients and district nurses and assures they receive relevant information on-site. Further research should assess and compare the value of videoconference for routine long-term care, such as managing spasticity, urinary tract and bowel needs, and chronic pain.

Data Archiving

The dataset is stored in a locked and fireproof research cabinet at the research department, Sunnaas Rehabilitation Hospital, Norway, and can be made available on request according to the Norwegian Data and Telecommunications Authority's requirements for safe information flow [26].

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Authors' Contributions

II and TR designed the protocol of the study. JMH, RJ, MT, and JKS coauthored the protocol, in particular regarding the methodology and design of the custom-made forms and scales. II collected and entered the data. II and MT performed data analysis. II was the main author of the article, and JMH, RJ, MA, JKS, MT, and TR coauthored the manuscript and supervised during the writing. The main author and all coauthors critically read and approved the final manuscript before submission and publishing.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Differences in health-related quality of life between the two groups from baseline to end of follow-up, based on imputed data.
[DOCX File , 19 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Differences in health-related quality of life between the two groups from baseline to end of follow-up, based on actual data.
[DOCX File , 21 KB-Multimedia Appendix 2]

Multimedia Appendix 3

CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 96 KB-Multimedia Appendix 3]

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Abbreviations

AIS: American Spinal Injury Association (ASIA) Impairment Scale
ASIA: American Spinal Injury Association
CONSORT: Consolidated Standards of Reporting Trials
EQ-5D: Five Dimensions European Quality of Life scale
HRQoL: health-related quality of life
ISCI-QoL-BDS: International Spinal Cord Injury Quality of Life Basic Data Set
PI: pressure injury
RCG: regular care group
SCI: spinal cord injury
SF-36: 36-item Short Form Health Survey
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
TIDieR: Template for Intervention Description and Replication
VCG: videoconference group

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Additional file 1. CONSORT 2010 checklist

CONSORT 2010 checklist of information to include when reporting a pilot or feasibilitytrial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1, Abstract
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1 Results and conclusion NA
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3
	2b	Specific objectives or research questions for pilot trial	3- 4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4-7, 10-11
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	9-10 Fig. 1
	4b	Settings and locations where the data were collected	7- 8, 11
	4c	How participants were identified and consented	7- 10 Fig 1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10, 14 TiDier checklist
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-14
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	14-15
Sample size	7a	Rationale for numbers in the pilot trial	16-17
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			

Sequence generation	8a	Method used to generate the random allocation sequence	10-11
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	10-11
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	11
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-10, 21
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	17
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	NA
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Table 1
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Fig. 2, Table 1
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	NA
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	NA
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	19

Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	NA
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	19
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	2 NCT02800915
Protocol	24	Where the pilot trial protocol can be accessed, if available	Clinical Trials.gov
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21
	26	Ethical approval or approval by research review committee, confirmed with reference number	6, 22

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org

Supplementary materials 2. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Address on page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1,2,20, 21
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	ClinicalTrials.gov NCT02800915
2b		All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	Last updated Oct. 9th 2017
Funding	4	Sources and types of financial, material, and other support	21
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	21
5b		Name and contact information for the trial sponsor	21
5c		Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	No involvement
5d		Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	21
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2- 4
6b		Explanation for choice of comparators	3-4
Objectives	7	Specific objectives or hypotheses	3-4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4-7, 10-11 Fig. 1, Fig. 2, Table 2
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5, 7- 8, 13
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-10, 14
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10, 14
11b		Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
11c		Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
11d		Relevant concomitant care and interventions that are permitted or prohibited during the trial	13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-13 Fig 2, Table 1

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	20 Fig 2, Table 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16-17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10 Fig 1
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	10-11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10- 11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7-10, 21
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
17b		If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7, 9-10, 14-15, 21 Available on request
18b		Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8, 17
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
20b		Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
20c		Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	21-22
21b		Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	22
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-14

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	21-22 Fig 2, Table 1
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2, 6
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	New application to the Ethics committee
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9-10
26b		Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9-10 Concent form available on request
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	8, 13-14 All participants are covered by the hospital's research insurance and by the Norwegian health insurance program
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20.
31b		Authorship eligibility guidelines and any intended use of professional writers	In line with the Vancouver guidelines and the Helsinki declaration
31c		Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Available on request
Appendices :			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available on request
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

Supplementary material 3

Table
The intervention illustrated by main features from the Template for intervention Description and Replication (TIDieR) Checklist and Guide

Brief name: Outpatient treatment of pressure ulcer from home by TeleSCI	
Why: To improve the outpatient follow up in patients with spinal cord injury and pressure ulcer	
What: Outpatient pressure ulcer follow- up from the participant`s home, using videoconferencing as a tool to cooperate, compared to usual care. The therapy will be tailored from the specialized health care system to the participant`s home in cooperation with the local home care nurses, with focus on wound healing, quality of life, cooperation, user participation and costs.	
Who provided: The wound team, consisting of a medical doctor, a wound nurse and an occupational therapist sited at Haukeland University Hospital and Sunnaas Rehabilitation Hospital. The local home care nurses will receive training in how to treat and prevent pressure ulcer among the group of persons with spinal cord injury by videoconference within the context of a clinical trial	
How: Using videoconference and remote control software to a laptop at the patient's location	
Where: From Haukeland University Hospital and Sunnaas Rehabilitation Hospital to the patient's home or institution, e.g., rehabilitation ward or nursing home	
When/How much: The experimental intervention consists of pressure ulcer treatment guidance every second or third week until the pressure ulcer has healed, or in maximum 52 weeks.	

III