Statistical Analysis Plan

A Pain and Coordination Plan (PAC plan) in Transition Between Hospital and Primary Care to Reduce Opioid Use in Patients After Accidental Injuries: A Randomized Controlled Trial

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Revision History

Version	Date	Section updated	Description of change
2.0	20 Mar 2026	7.3.1	Section 7.3.1 was updated to include “length of hospital stay” as a prespecified covariate, aligning with the description in Section 9.1 (Primary Efficacy Analysis). This change ensures consistency across the document and does not affect the planned statistical analysis.

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Contents

1. Trial identifications

TRIAL FULL TITLE	A Pain and Coordination Plan (PAC plan) in Transition Between Hospital and Primary Care to Reduce Opioid Use in Patients After Accidental Injuries: A Randomized Controlled Trial
SHORT TITLE	A Pain and Coordination Plan for Reduced Opioid Use After Accidental Injuries
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2. Abbreviations and definitions

AIS	Abbreviated Injury Scale
AO/OTA	Arbeitsgemeinschaft für Osteosynthesefragen (AO Foundation) / Orthopaedic Trauma Association (OTA)
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
GP	General Practitioner
ICD-10	International Classification of Diseases- tenth revision
ISS	Injury Severity Scale
NISS	New Injury Severity Scale
NTR	Norwegian Trauma Registry
OMEQ	Oral Morphine Equivalent
OUH	Oslo University Hospital
PAC plan	Pain and Coordination plan
PROMs	Patient Reported Outcome Measures

3. Introduction

3.1 Background

Pain is a common and expected consequence of physical injuries, with orthopedic injuries and trauma-related procedures often producing some of the most intense pain experiences (1). While opioids may be necessary for managing pain in the acute phase following these injuries, their use is associated with significant risks, including adverse side effects, as well as potential for misuse and the development of opioid use disorder (2). Despite these risks, many patients lack opioid management plans and adequate information regarding their expected recovery trajectory after surgery (3). Furthermore, general practitioners (GPs) often receive insufficient information about patients at discharge, complicating follow-up care (4;5). The opioid epidemic in the United States poses a serious public health crisis (6), underscoring the importance of learning from this experience and adapting safer pain management practices. In Norway, the use of strong opioids has increased in recent years (7).

This study aims to explore whether implementing a Pain and Coordination (PAC) plan for patients recovering from orthopedic injuries can reduce opioid use after accidental injuries, both in short-term and long-term perspectives. The purpose of this paper is to focus on short-term effects of the intervention.

3.2 Purpose of the analyses

The analyses will assess whether a Pain and Coordination (PAC) plan reduces opioid use after accidental injuries, compared with the control group. In addition, the analyses will assess whether there are differences between the groups in relevant PROMs.

3.3 Purpose of the statistical analysis plan (SAP)

This document outlines the statistical methods to be implemented during the analyses of data collected within the scope of our protocol titled “A Pain and Coordination Plan (PAC plan) in Transition Between Hospital and Primary Care to Reduce Opioid Use in Patients After Accidental Injuries: A Randomized Controlled Trial”.

The purpose of this SAP is to establish a structured framework that enables the study objectives outlined in the protocol to be addressed in a statistically sound manner, free from bias or analytical shortcomings, using methods defined prior to the database lock.

Specifically, this plan aims to:

- Prospectively define the types of analyses and data presentations that will form the foundation for study conclusions.
- Provide a detailed description of how the data will be managed and analyzed, in accordance with widely accepted biostatistical principles and standards. Any departures from these procedures must be justified with appropriate statistical reasoning and fully documented in the final study report.

The analyses described in this analysis plan are consistent with the analyses described in the study protocol. The order may be changed for clarity. If there are discrepancies between the protocol and SAP, the SAP will serve as the definitive analysis plan.

4. Study objectives and endpoints

4.1 Study objectives and hypotheses

4.1.1 Primary objective and hypothesis

The primary objective is to evaluate whether the intervention (PAC plan) leads to a reduction in opioid use compared with the control group, 6 weeks after hospital discharge.

The primary hypothesis is that the intervention group will have a lower Oral Morphine Equivalent (OMEQ) use at six weeks post-discharge than the control group.

4.1.2 Secondary objectives

The secondary objectives are to explore differences between groups at 6 weeks post-discharge in:

- Pain intensity
- Sleep quality
- Perceived injustice
- Optimism
- Physical activity
- Symptoms of depression
- Health-related quality of life

4.2 Endpoints

4.2.1 Primary endpoints

Patient-reported opioid consumption, measured in oral morphine equivalents (OMEQ), will be assessed at 6 weeks post-discharge. Participants will be asked to report all opioid medications taken in the prior 24 hours, including name, strength, route, and number of doses.

4.2.2 Secondary endpoints

Secondary endpoints include patient-reported outcomes collected at six weeks post-discharge:

- **Pain intensity** today measured using the Numeric Rating Scale (NRS).
- **Perceived insomnia severity** assessed using the Insomnia Severity Index (ISI) last 2 weeks.
- **Perceived injustice after injury** assessed using the Injustice Experience Questionnaire (IEQ).
- **Optimism** assessed using the Life Orientation Test- Revised (LOT-R).
- **Physical activity level** assessed using the HUNT1 (the Nord-Trøndelag health study) Physical Activity Questionnaire (HUNT1 PA-Q).
- **Depressions symptoms** assessed using the Patient Health Questionnaire-9 (PHQ-9).
- **Health-related quality of life** assessed using EQ-5D-5L.

In addition, we will report opioid use or no opioid use 6 weeks after discharge.

4.2.3 Exploratory endpoints

The following exploratory endpoints will be evaluated. All exploratory endpoints are hypothesis-generating and will be interpreted descriptively.

A. **Use of non-opioid analgesics (paracetamol, NSAIDs, and gabapentin/pregabalin)**. These endpoints were not prespecified as a primary or secondary endpoint in the study protocol or registered at ClinicalTrials.gov. However, evaluation of non-opioid analgesic use is considered clinically relevant in the context of a randomized controlled trial with opioid consumption as the primary outcome. Non-opioid analgesic use may reflect overall pain management strategies and may provide important contextual information for the

interpretation of opioid use and secondary patient-reported outcomes. Data on non-opioid analgesic use were prospectively collected through the 6-week questionnaire.

B. **Associations between opioid consumption (OMEQ) and other patient-reported outcomes** at 6 weeks (e.g., IEQ, ISI, PHQ-9).
C. **Associations between persistent opioid use at 6 weeks and baseline characteristics.**

5. Study methods

5.1 General study design and plan

This study is a prospective, pragmatic, parallel randomized controlled trial where participants were recruited from the Department of orthopedic surgery, Oslo University Hospital (OUH), Norway from 25 sept 2023 until 24 April 2025. The participating patients were randomized in a 1:1 ratio to either the intervention group (PAC plan) or the control group (postoperative standard care).

The intervention comprised three key elements:

- Pre-discharge: Patients received oral and written education on opioids and a tapering plan
- Follow-up appointment: The study team scheduled an appointment for patients with their regular GP to address injury-related issues, particularly focusing on discontinuing opioid use. The appointment was intended to take place within 2 weeks and no later than 4 weeks post-discharge.
- Ongoing support: From the time of discharge until 1 year after the injury, GPs have the option to consult with an orthopedic surgeon or anesthesiologist at the hospital for additional guidance.

5.2 Inclusion-exclusion criteria and general study population

The participants were recruited from both the day-care unit and the in-patient unit at the Department of orthopedic surgery, Oslo University Hospital, Norway.

<u>Inclusion criteria</u>

- Age 18 years or older
- Undergone acute orthopedic surgery following accidental injury
- Discharged with opioids

<u>Exclusion criteria</u>

- Unable to read or understand Norwegian
- Severe cognitive impairment/not able to consent
- Not discharged to home
- Undergoing active cancer treatment

Patients who underwent surgery distal to the wrist and foot carpals were not considered for inclusion, as they are typically discharged without the use of opioids. To distinguish between acute and non-acute surgeries, we utilized a four-week time frame as the cutoff.

5.3 Randomization and blinding

The participating patients were randomized in a 1:1 ratio to either the intervention group (PAC plan) or the control group (postoperative standard of care).

Randomization was performed manually by the principal supervisor (PS) using a permuted block method with varying block sizes of 4, 6, 8 and 10 (in random order), and opaque sequentially

numbered concealed envelopes were utilized to maintain allocation concealment. The PS did not take part in screening, recruitment or intervention. Two study nurses were responsible for selecting and opening the envelopes. To ensure that no GPs were included in both study arms, the GPs retain their initial allocation if they had additional patients in the study. In practice, this corresponds to cluster-randomization at the GP level.

Randomization occurred after obtaining informed consent from the patients.

The study was unblinded, as neither the patients nor the study team could administer the intervention without being aware of the allocation. However, outcome assessments will be controlled by a senior statistician who remains blinded to the group assignments.

5.4 Study variables

Data for this study are obtained from several sources.

A) Questionnaires

Variables originate from self-administered questionnaires completed by participants at two time points: **baseline** (during hospital admission) and **six weeks post-discharge**. These are study-specific questionnaires developed for the project.

The baseline questionnaire combines demographic and background information with a set of standardized and validated patient-reported outcome measures (PROMs). The six-week questionnaire includes questions on opioid use and repeats the same PROMs as those administered at baseline.

B) Electronic medical records

Additional inpatient and injury-related variables are extracted from electronic medical records.

C) Derived variables

Several variables are calculated or derived from the collected data and the authorized Excel lookup file.

5.4.1 Baseline variables collected from questionnaire

Brief summary: Key analysis variables include patient demographics and PROMs including the Numeric Rating Scale (NRS), EQ-5D-5L, Patient Health Questionnaire (PHQ-9), Injustice Experience Questionnaire (IEQ), Life Orientation Test Revised (LOT-R), Insomnia Severity Index (ISI), and HUNT1 (the Nord-Trøndelag health study) Physical Activity Questionnaire (HUNT1 PA-Q). The complete list of baseline variables, including variable names, labels, values and validation rules, is provided in Appendix 1, Section A.1. Appendix 1 is part of this SAP, version 2.0, dated 2026-03-20.

5.4.2 Baseline variables collected from electronic records

Brief summary: Key analysis variables include inpatient and injury-related variables such as length of hospital stay, amounts of opioids at discharge, number of injuries, and ASA classification. The complete list of baseline variables collected from electronic records, including variable names, labels, values and validation rules, is provided in Appendix 1, section A.2. Appendix 1 is part of this SAP, version 2.0, dated 2026-03-20.

5.4.3 6-week follow-up variables collected from questionnaire

Brief summary: Key analysis variables include patient reported opioid consumption in the prior 24 hours, including name, strength, route, and number of doses. In addition, the PROMs mentioned in section 5.4.1.

The complete list of all 6-week follow-up variables collected from questionnaire, including variable names, labels, values and validation rules, is provided in Appendix 1, section A.3. Appendix 1 is part of this SAP, version 2.0, dated 2026-03-20.

5.4.4 Calculated or derived variables

Age at inclusion

The variable is derived from the patient-reported questionnaire at baseline.
Variable name: alder
Label: Participant age at inclusion (years).
Value: Integer (years).
Derivation rule: Calculated as the difference between the year of the first questionnaire submission (baseline) and the birth year: year of inclusion [inkl_aar] – birth year [aar].

Municipality number

The variable is derived from the patient-reported questionnaire at baseline.
Variable name: bosted_SSB.
Label: SSB code/number.
Value: Integer, categorical.
Derivation rule: For participants residing in Oslo, the corresponding SSB (Statistics Norway) urban district code is used. If the urban district cannot be determined, the Oslo municipality code is used instead. For all other municipalities, the standard SSB municipality code is applied.

Geographical area classification

The variable is derived from the patient-reported questionnaire at baseline.
Variable name: bosted_kat.
Label: Oslo municipality classification.
Value: Integer, categorical.
Derivation rule: A five-category classification based on Oslo urban districts is used for participants residing in Oslo, where sufficient urban district information is available. Participants residing in municipalities outside Oslo are assigned a separate category. Participants who report Oslo as their place of residence but do not provide enough information to assign them to one of the five Oslo categories are assigned a separate "Oslo – unspecified" category.

Body Mass Index (BMI)

The variable is calculated from the patient-reported questionnaire at baseline. Height is converted from centimeters to meters by generating a new variable, “hoyde_m”, prior to bmi calculation.
Variable name: bmi.
Label: Calculated BMI, kg/m^2.
Value: Continuous numeric (decimal), unit = kg/m^2.
Calculation rule: Calculated as weight (kg) / height $(m)^2$ if both weight and height are present and valid; set to missing if either component is missing.

BMI will be used as a continuous variable. Categories will be applied only as needed
- <18.5: Underweight
- 18.5–24.9: Normal weight

• 25.0–29.9: Overweight
• ≥30.0: Obese

Abbreviated Injury Scale (AIS) codes
AIS codes are assigned to all injuries for each study patient by the study team using the AIS 2005 Update 2008 manual, based on available clinical information (including radiology and other relevant documentation).
Variable names: ais1, ais2, ais3, ais4, ais5, and ais6.
Labels: AIS code, injury 1–6.
Value: Free text entry, 7-digit AIS code including the severity digit after the decimal point (e.g., 854471.2).
Derivation rule: The AIS code for each injury the patient has is entered, for up to 6 injuries. If a patient has more than 6 injuries, any injury that was surgically treated is always included. The remaining injuries are selected based on the highest AIS severity values, with a maximum of six injuries recorded per patient.

Maximum Abbreviated Injury Score (AIS)
The variable is derived from the AIS codes.
Variable name: aismaks.
Labels: Highest Abbreviated Injury Scale (AIS) severity code.
Value: Integer; allowed range 1–6.
Derivation rule: The highest AIS severity code (post-dot severity digit) across all recorded injuries for the patient.

Injury Severity Score (ISS) and New Injury Severity Score (NISS)
ISS and NISS are calculated by the study team from Abbreviated Injury Scale (AIS) codes (AIS 2005 Update 2008) using standard scoring methods. ISS and NISS represent the overall severity of a patient's injuries.

Variable name: iss.
Label: Injury Severity Score (ISS).
Value: Integer; allowed range 1–75.
Derivation rule: Calculated as the sum of the squares of the highest AIS severity codes in the three most severely injured body regions: ISS = $(AIS_1)^2 + (AIS_2)^2 + (AIS_3)^2$.

Variable name: niss.
Label: New Injury Severity Score (NISS).
Value: Integer; allowed range 1–75.
Derivation rule: Calculated as the sum of the squares of the three highest AIS severity codes, regardless of body region: NISS = $(AIS_1)^2 + (AIS_2)^2 + (AIS_3)^2$.

NISS and ISS will be analyzed as continuous variables; categories will be applied only as needed:
• 1–8: Minor injury
• 9–15: Moderate injury
• 16–24: Severe injury
• ≥25: Critical injury

Type of injury
The variable is derived from electronic medical records.
Variable name: sos_class_mostcomplex_num.
Label: Injury classification.
Value: 0=other injuries, 1=simple fracture, 2=complex fracture.

Derivation rule: Injuries are classified into three groups—simple fractures, complex fractures, and other injuries. See Section 7.3.1 for further description and rationale.

OMEQ at discharge
The variable is calculated from electronic medical records.
Variable name: omeq_ut.
Label: Total oral morphine equivalent dose at discharge (mg).
Value: Numeric (decimal), unit = mg oral morphine equivalent; store to one decimal place.
Calculation rule: Total oral morphine equivalent (OMEQ) dose prescribed at hospital discharge, representing the patient's total opioid load standardized to oral morphine. Calculated by converting all opioid medications prescribed at discharge to oral morphine using the pre-specified conversion factors provided in Appendix 1, section A.4 (Opioid conversion table). The sum of all converted doses yields the total OMEQ.

OMEQ at 6 weeks
The variable is calculated from the self-reported 6-week follow-up questionnaire.
Variable name: omeq_6.
Label: Total oral morphine equivalent dose at 6 weeks (mg).
Value: Numeric (decimal), unit = mg oral morphine equivalent; store to one decimal place.
Calculation rule: Total OMEQ dose based on self-reported opioid use during the 24-hour period prior to the 6-week follow-up questionnaire. Each reported opioid medication (including formulation, strength, dose, and frequency) will be converted to oral morphine equivalents using the pre-specified conversion factors provided in Appendix 1, section A.4 (Opioid conversion table). The total daily OMEQ will be computed as the sum of all converted doses: OMEQ_6w = Σ (reported daily dose × conversion factor). If the participant reports no opioid use, the value will be set to 0 mg.

Opioids at six weeks
The variable is derived from the self-reported 6-week follow-up questionnaire.
Variable name: opioid_6.
Label: Opioid use at six-week follow-up (yes/no).
Value: Binary, 0 = No, 1 = Yes.
Derivation rule: 1 = Yes (participant reports using opioids at six weeks) and
0 = No (participant reports not using opioids at six weeks).

Non-opioid analgesics at six weeks
The variable is derived from the self-reported 6-week follow-up questionnaire.
Variable name: non_opioid_6.
Label: Use of non-opioid analgesics at six-week follow-up.
Value: Binary, 0 = No, 1 = Yes.
Derivation rule: 0 = No (participant reports not using non-opioid analgesics at six weeks) and
1= Yes (participant reports using non-opioid analgesics at six weeks)

All analgesics
The variable is derived from the self-reported 6-week follow-up questionnaire.
Variable name: analgetika_total_6.
Label: Use of any analgesics (opioid or non-opioid) at six weeks.
Value: Binary, 0 = No, 1 = Yes.
Derivation rule: 0 = No (participant reports not using analgesics at six weeks) and
1= Yes (participant reports using analgesics at six weeks).

Injustice Experience Questionnaire (IEQ) score

The variable is calculated from the self-reported questionnaires administered at baseline and at 6-week follow-up, representing two separate measurement time points.

Variable name: ieq_calc/ieq_calc_6.

Label: Calculated IEQ score at baseline/6 weeks.

Value: Integer (0–48).

Calculation rule: The total score of the IEQ ranges from 0 to 48. The IEQ score is calculated according to the user manual and if needed categorized as low (<19), medium (19-29) and high (30+) levels of perceived injustice.

Life Orientation Test Revised (LOT-R) score

The variable is calculated from the self-reported questionnaires administered at baseline and at 6-week follow-up, representing two separate measurement time points.

Variable name: lot_calc/lot_calc_6.

Label: Calculated LOT-R score at baseline/6 weeks**.**

Value: Integer (0–24).

Calculation rule: The total score of the LOT-R ranges from 0 to 24 and is calculated according to the user manual and reported as continuous values.

Patient Health Questionnaire-9 (PHQ-9) score

The variable is calculated from the self-reported questionnaires administered at baseline and at 6-week follow-up, representing two separate measurement time points.

Variable name: phq_calc/phq_calc_6.

Label: Calculated PHQ-9 score at baseline/6 weeks.

Value: Integer (0–27).

Calculation rule: The total score of the PHQ-9 ranges from 0-27 and is calculated according to the user manual. The score can be used either as a continuous variable or categorized to indicate the severity of depressive symptoms: none (0-4), mild (5-9), moderate (10-14), moderately severe (15-19), and severe (20-27).

HUNT (the Nord-Trøndelag health study) Physical Activity Questionnaire (HUNT1 PA-Q) index

The variable is calculated from the self-reported questionnaires administered at baseline and at 6-week follow-up, representing two separate measurement time points.

Variable name: hunt_calc/ hunt_calc_6.

Label: Calculated HUNT1 PA-Q index at baseline/6 weeks.

Value: Decimal (0–12); allow up to 2 decimal places.

Calculation rule: HUNT1 PA-Q measures physical exercise as the product of average weekly frequency (0.0-5.0 points), duration (0.10-1.00 points) and intensity (1-2.4 points), giving an index ranging from 0.00 to 12.00. The score can be used either as a continuous variable or categorized to indicate levels of physical activity according to predefined cut-offs (8).

EQ 5D-5L index

The variable is calculated from the self-reported questionnaires administered at baseline and at 6-week follow-up, representing two separate measurement time points.

Variable name: eq_calc/ eq_calc_6.

Label: Calculated EQ-5D-5L index at baseline/6 weeks.

Value: Decimal (−0.453 to 1.000), allow up to 3 decimal places.

Calculation rule: EQ-5D-5L utilities are derived from the five domain responses using the Norwegian EQ-5D-5L value set (9).

Insomnia Severity Index (ISI) score
The variable is calculated from the self-reported questionnaires administered at baseline and at 6-week follow-up, representing two separate measurement time points.
Variable name: isi_calc/ isi_calc_6.
Label: Calculated ISI score at baseline/6 weeks.
Value: Integer (0–28).
Calculation rule: The total score is the sum of each individual item and can range from 0 to 28.

General practitioner (GP) ID
The variable is derived from the authorized Excel lookup file.
Variable name: gpID.
Label: Cluster identifier for participant GP at baseline.
Value: Integer (cluster ID), unique numeric identifier for each GP/cluster.
Derivation rule: If the variable StudieID (study ID) begins with "A", gp_id is set to the integer value given by the numeric part of StudieID (i.e., remove the leading "A" and convert the following characters to an integer). Example: StudieID = "A12" → gp_id = 12. If the variable StudieID begins with "B", the corresponding GP identifier is looked up in the authorized Excel lookup file stored on the secured OUH server.

Group allocation
The variable is derived from the authorized Excel lookup file.
Variable name: allocation.
Label: Allocation arm.
Value: Binary (0,1).
Derivation rule: The group allocation variable will be derived from the authorized Excel lookup file. Treatment groups will be represented by numeric codes. The correspondence between numeric codes and treatment arms will be documented separately and will not be specified in the SAP in order to preserve blinding of the senior statistician.

6. Sample size
The sample size is based on the following: The annual number of orthopedic trauma patients meeting our inclusion criteria is approximately 1000 at the Department of Orthopedic Surgery, OUS. The power calculation is based on preliminary data from the registry linkage between the Trauma Registry at OUS and the Norwegian Prescription Database, as well as relevant literature (10). We consider a 33 % difference between the groups to be clinically relevant. Given a p-value of 0.05 and a power of 80 %, the required sample size is 116 in each group (232 total).

7. General considerations
7.1 Timing of analyses
The primary analysis will be initiated once data collection from the 6-week follow-up questionnaire has been completed and all available data have been entered, verified, and cleaned. The database will be locked after this process.

Analyses will not be postponed awaiting late or missing questionnaire responses. Participants who do not return the 6-week questionnaire or provide incomplete information will be included in analyses according to the pre-specified missing-data handling procedures.

No interim analyses are planned. All primary and secondary analyses will be conducted after the 6-week data lock. The statistical analyses will not commence until the final version of this Statistical Analysis Plan has been approved and uploaded to ClinicalTrials.gov.

7.2 Analysis population

7.2.1 Randomized (Intention-to-Treat) population

The Randomized Population (also referred to as the Intention-to-Treat [ITT] population) includes all participants who were randomized to a study group, regardless of adherence to the intervention or availability of outcome data.

Participants will be analyzed according to the group to which they were originally randomized.

This population constitutes the entire study population, which is the population of main interest.

7.2.2 Complete case ITT population

The Complete Case ITT Population will include all participants from the ITT population with available data for the outcome of interest at the six-week follow-up. The number of participants included in complete case analyses may vary depending on the specific outcome being analyzed, as some participants may have submitted the six-week questionnaire but provided incomplete responses for individual outcome measures.

7.2.3 Per Protocol (PP) population

The Per Protocol Population will include participants from the ITT population who had no major protocol deviations, including but not limited to incorrect group assignment or substantial non-adherence to the allocated intervention.

Analyses using the PP population will be conducted as sensitivity analyses.

7.2.4 Complete Case Per Protocol Population

The Complete Case Per Protocol Population will be derived from the Per Protocol Population by excluding participants with missing data for the outcome of interest at the six-week follow-up.

As for the Complete Case ITT population, the number of participants included in complete case PP analyses may vary depending on the specific outcome analyzed, as some participants may have incomplete responses despite submission of the follow-up questionnaire.

Analyses using the complete PP population will be conducted as sensitivity analyses.

7.3. Covariates and subgroups

7.3.1 Covariates

The following covariates are expected to potentially influence the primary and secondary endpoints and will be considered in statistical analyses as appropriate:

- Regular opioid use during the 12 months prior to injury (yes/no)
- Type of injury (complex fractures/simple fractures/other injuries) *
- Injury severity measured using the New Injury Severity Scale (NISS; 1–8/>8)

- Hospital length of stay (continuous covariate)
- Age (continuous covariate)
- Gender (male/female)
- Pain intensity measured using the Numeric Rating Scale (continuous covariate 0–10)
- Socioeconomic status using highest completed education (13 years or less/13–16 years/17 years or more)
- OMEQ at discharge (continuous covariate)
- Self-reported current or previous anxiety or depression (yes/no)
- Alcohol consumption (never to monthly or less/ 2–4 times a month/ 2–3 times a week, 4 or more times a week)
- Other substance use (never/currently/previously)

* *Rationale for injury type categorization: Injuries will be classified into three groups — simple fractures, complex fractures and other injuries. This is a study-specific operational grouping that reflects severity levels described in the literature and is further informed by clinical judgment, with the aim of capturing clinically meaningful differences in expected pain trajectories. Classification will be based primarily on AIS pre-dot codes. When AIS codes do not provide sufficient detail to distinguish between complex and simple fractures, the AO/OTA classification will be used. Simple fractures: Extra-articular end-segment fractures, shaft fractures, pelvic/acetabular/spine fractures AO/OTA type A, ankle fractures AO/OTA type A, and proximal end-segment fractures of the femur and humerus AO/OTA type A. Complex fractures: Intra-articular end-segment fractures, both complete and partial. In addition, proximal end-segment fractures of the humerus and femur AO/OTA type B and C, ankle fractures AO/OTA type B and C, Lisfranc injuries, and pelvic/acetabular/spine fractures AO/OTA type B or C. Other injuries: Soft tissue injuries involving muscles, tendons, ligaments or menisci.*

Covariate adjustment will be performed by including relevant covariates directly in the regression models.

If sample sizes are small in any category, related categories may be combined; the exact mapping and any collapsing rules will be reported.

7.3.2 Subgroups analyses

Exploratory subgroup analyses will be conducted to examine whether the effect of the intervention differs across clinically relevant subgroups, including:

- Regular opioid use during the 12 months prior to the injury: yes/no
- Age: categorized as 18–34/35–64/ ≥ 65*
- Gender: male/female
- Type of injury: categorized based on type of injury (see section 7.3.1) and subgroups according to AIS body regions (small groups will be collapsed)
- Hospital length of stay: day surgery with no overnight admission vs. at least one overnight hospital admission
- First patient per GP
- OMEQ at discharge: ≤ 200 vs. > 200**
- Socioeconomic status
    - Highest completed education (13 years or less/13–16 years/17 years or more)
    - Annual salary (< 300 000, 300 000–500 000, 500 000–750 000, > 750 000 NOK)
- Smoking habits: smoker vs. non-smoker

- Alcohol consumption: never to monthly or less/ 2–4 times a month/ 2–3 times a week, 4 or more times a week
- PHQ-9 depression scores: categorized as none (0–4), mild (5–9), moderate (10–14), moderately severe (15–19), and severe (20–27)

*Rationale for age categorization: The prespecified age bands (18–34, 35–64, ≥65) were chosen to be consistent with the Norwegian Trauma Registry (NTR) grouping and to capture meaningful differences across younger, middle-aged and older adults in trauma care and opioid use. Using the same categories as the NTR enhances comparability with national registry analyses.
**Rationale for OMEQ cut-point: The dichotomous discharge OMEQ variable (≤ 200 vs > 200) is pre-specified based on the clinical observation that most participants are discharged with roughly 150 OMEQ. A 200 OMEQ threshold is therefore chosen as a pragmatic, rounded, and clinically interpretable boundary between typical and higher discharge opioid quantities.

If sample sizes are small in any category, related categories may be combined; the exact mapping and any collapsing rules will be reported.

Subgroup analyses will focus on interaction effects between the intervention and subgroup variables in relation to the primary and secondary endpoints.

All subgroup analyses will be considered exploratory; results will be interpreted cautiously, with no formal adjustment for multiple testing.

7.4 Missing data

Missing data are coded as ”.” and the number of missing values will be reported by variable and group. Missingness may occur if participants do not return the questionnaire or omit relevant questions. The questionnaire is designed with validation rules aimed at reducing the likelihood of missing values. In addition, missing values may also arise from variables collected from electronic records.

7.5 Multiple testing

This study has a single predefined primary endpoint—opioid use (OMEQ) at six weeks post-discharge—and therefore no formal adjustment for multiple testing will be applied to the primary analysis.
Analyses of secondary and exploratory outcomes are considered hypothesis-generating. P-values from these analyses will be interpreted descriptively, and results will be presented together with effect sizes and 95% confidence intervals. No formal correction (e.g. Bonferroni) will be applied unless clearly indicated in exploratory analyses involving a large number of related variables.

8. Summary of study data

Descriptive statistics will be used to summarize all study data prior to formal analysis. Summary tables will typically include one column for each randomization group (intervention and control) and an overall total column. Variables will be ordered by type (demographics, inpatient and injury related).

Continuous variables (e.g., age, BMI, ISS, NISS, OMEQ) will be summarized using means, standard deviations, medians, interquartile ranges, minima, and maxima as appropriate, depending on data distribution. Categorical variables (e.g., sex, education level, ASA classification, type of injury, transfer status) will be summarized using counts and percentages.

8.1 Subject disposition

The number of patients screened, randomized, allocated to each group, completing follow-up, and included in each analysis population will be summarized in a CONSORT flow diagram.

8.2 Protocol deviations

Major protocol deviations (e.g., randomization errors, loss to follow-up before 6 weeks) will be listed and summarized.

8.3 Demographic and baseline variables

Demographic and baseline variables (age, sex, BMI, ISS, NISS, injury type, education level, etc.) will be summarized by group at baseline.

9. Efficacy analysis

All efficacy analyses will compare the intervention group (PAC plan) with the control group (standard care). Analyses will primarily be conducted on the Full Analysis Population (ITT principle). Continuous variables will be summarized using means, standard deviations, medians, and interquartile ranges, and categorical variables will be summarized as frequencies and percentages.

Between-group differences will be assessed using appropriate parametric or non-parametric statistical tests, depending on data distribution. The two-sided significance level will be set at 0.05. Confidence intervals will be reported for all main estimates.

9.1 Primary efficacy analysis

The primary endpoint is self-reported oral morphine equivalents (OMEQ) at six weeks after discharge.

Objective: To test whether the intervention reduces opioid use (OMEQ) compared with standard care at six weeks post-discharge.

Statistical Hypotheses:

- Null hypothesis (H_0): Mean OMEQ use at six weeks after discharge is the same in the intervention and control group ($\mu_{int}=\mu_{ctrl}$).
- Alternative hypothesis (H_1): Mean OMEQ use at six weeks after discharge differ between groups ($\mu_{int}\neq\mu_{ctrl}$).

Although the a priori expectation is that the intervention will reduce mean OMEQ use, all hypothesis tests will be two-sided and performed at the 5% significance level.

Statistical Methods:

The primary analysis will compare mean OMEQ at six weeks between groups using a linear mixed model with a random effect for cluster (prescribing medical doctor) and adjustment for prespecified baseline covariates. The prespecified covariates for the primary adjusted model are regular opioid use during the 12 months prior to injury, baseline OMEQ at discharge, current or previous anxiety or depression, type of injury and length of hospital stay (see section 7.3.1).

To accommodate what is expected to be a small number of missing values, the analysis will be performed as an ITT analysis of the complete case population, which, in the case of missing data, still will identify the average treatment effect in the entire study population under the assumption of

missing at random (i.e. when baseline covariate sufficiently predict missingness and outcome). Sensitivity analyses, such as simple best- or worst-case imputations or multiple imputations, will be performed to further assess the possible impact of missing values.

To assess sensitivity for model choice, we will also fit a mixed model without baseline adjustment, and covariate adjusted and unadjusted linear regressions (the latter corresponding to a regular two-sample t-test) with confidence intervals calculated using clustered bootstrap (resampling on clusters/prescribing medical doctors). For further sensitivity analyses, we will also present results from additional adjusted models that adjust for more of the variables available in the full set of candidate covariates listed in Section 7.3.1.

Results will be presented with 95% confidence intervals and corresponding p-values. If the distribution of OMEQ is right skew, tests will also be performed on transformed values of OMEQ and/or using regression models that better accommodate right skewed data. Analyses with opioid use after six weeks transformed to a binary outcome (use/no use) will also be explored.

9.2 Secondary efficacy analyses

Secondary endpoints are listed in section 4.2.2.

Statistical Methods:

Between-group comparisons at 6 weeks will be performed as for the primary endpoint, adopted to the analysis of binary endpoints where necessary.

All p-values will be two-sided and interpreted descriptively, without adjustment for multiple testing (see Section 7.5).

9.3 Exploratory efficacy analyses

Differences between groups in use of paracetamol, NSAIDs and gabapentin/pregabalin at 6 weeks after discharge will be analyzed separately (each drug class as a distinct binary outcome: yes/no). For each drug class we will report counts and proportions by randomized group (n/N and %).

Exploratory analyses will also be performed to examine associations between opioid use (OMEQ) and other patient-reported outcomes (e.g., IEQ, ISI, PHQ-9) and to explore potential predictors of persistent opioid use at six weeks.

These analyses may include linear or logistic regression models, depending on the outcome type. Covariates such as age, sex, injury severity (ISS/NISS), and baseline opioid use may be included.

All exploratory analyses will be considered hypothesis-generating, and results will be interpreted cautiously. No correction for multiple comparisons will be applied.

10. Safety analysis

This study does not involve administration of investigational drugs or medical devices. Therefore, a formal safety analysis is not applicable. Any unexpected adverse events or complications potentially related to study procedures will be summarized descriptively for all participants who received the intervention or control. No statistical testing will be performed.

11. Reporting conventions

All tables and figures will be presented in accordance with standard conventions for descriptive and inferential statistics. Continuous variables will be summarized using mean ± standard deviation (SD), median and interquartile range (IQR), minimum and maximum, as appropriate. Percentages will be rounded to one decimal place. Missing values will be indicated as "n missing" and excluded from percentage calculations unless otherwise stated. All OMEQ values will be presented in milligrams (mg).

For statistical comparisons, p-values will be two-sided with a significance level of 0.05, and 95% confidence intervals will be reported where appropriate. Tables will display the intervention group first, followed by the control group, and a column for all participants. Abbreviations used in tables and figures will be defined in footnotes.

P-values ≥0.001 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001".

12. Technical details

All questionnaires were administered online via the University of Oslo´s Nettskjema, with data stored directly in Services for Sensitive Data (TSD). Data from the medical records were extracted into excel files, which were saved on a secure server at Oslo University Hospital in a designated drive, accessible only to parts of the research team after a formal application procedure.

Analysis will be conducted using STATA version 18 (StataCorp, Texas, USA) by the principal investigator Gunhild Nytrøen and main supervisor Trygve Skonnord. The senior statistician Jon Michael Gran will independently reproduce the analysis. The co-supervisors and co-authors will review the results and log-files.

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14. Appendix

Section A1

Baseline variables collected from questionnaire

Variable name	Label	Value	Validation rule
StudieID	Study-ID:		Free text**
aar	What year were you born?	1-88 (1923-2010)	Singel choice
kjonn	Please state your gender	1. Woman 2. Man 3. Self-defined	Singel choice. If answer 3, optional to further describe
egendef	If self-defined, please describe here:		Optional to further describe in free text**
bosted	Which district/municipality do you live in? If unsure, please give your postal code		Free text answer**
sivilstand	Civil status	1. Unmarried 2. Cohabiting 3. Married 4. Divorced/separated 5. Widow /widower	Single choice
utdanning	What education have you completed? Please state only your highest completed level of education	1. Primary/secondary school (13 years or less) 2. University college or university (13-16 years) 3. University college or university (17 years or more)	Single choice
yrke	What is your occupation?		Free text answer**

lonn	Please indicate your annual salary in Norwegian kroner	1. <300 000 2. 300 000-500 000 3. 500 000-750 000 4. >750 000	Single choice
syssel	What was your main activity BEFORE the injury occurred? Select the options that best describe the situation	1. Employed 2. School pupil/student 3. Unpaid work (e.g., (household work) 4. Unemployed 5. Disability pension /retired 6. Sick leave	Multiple choice
sykdommer	Have you, or have you ever had, any of the following illnesses? (select the applicable answers) Please select all that apply	1. High blood pressure 2. Angina, heart attack, other heart disease 3. Asthma, bronchitis, COPD, other lung disease 4. Allergy, hay fever, eczema 5. Arthritis / rheumatism 6. Cerebral haemorrhage / stroke 7. Cancer 8. Neurological disease (disease of the brain or nervous tissue) 9. Diabetes 10.Thyroid / metabolic disorder 11. Chronic fatigue syndrome / ME 12. Widespread muscle pain / fibromyalgia 13. Anxiety and/or depression 14. Previous surgery in the same area that you have now been operated on	Multiple choice
Annen_syk	Any other illness, if applicable (briefly describe)		Free text answer**
Hoyde	What is your height in centimetres? Please answer with numbers		Free text answer**
vekt	What is your weight in kilograms? Please answer with numbers		Free text answer**
alk_ofte	How often do you have a drink containing alcohol?	1. Never 2. Monthly or less* 3. 2-4 times a month*	Single choice

		4. 2-3 times a week* 5. 4 or more times a week*	
alk_enh	*How many alcohol units do you have on a typical day when drinking? Examples of alcohol units • 1 alcopop or cider (33 cl) • 1 bottle of beer (33 cl) • 1 glass of wine (12 cl) • 1 glass of fortified wine (8 cl) • 1 spirit drink, e.g. cognac, whisky, vodka (4 cl)	1. 1-2 2. 3-4 3. 5-6 4. 7 -9 5. 10 or more	Single choice. Displayed if option 2, 3, 4 or 5 in variable alk_ofte
alk_seks	*How often do you have six or more drinks?	1. Never 2. Rarely 3. A few times a month 4. A few times a week 5. Almost daily	Single choice. Displayed if option 2, 3, 4 or 5 in variable alk_ofte
alk_bek	Has a relative, friend, or doctor been concerned about your drinking or suggested you cut down?	2. No 0. Yes, but not in the past year 1. Yes, during the past year	Single choice
rus	Do you use, or have you used, illegal drugs/other drugs besides alcohol (e.g., cannabis, amphetamine, heroin, GHB or similar)?	2. No 1. Yes, currently 0. Yes, previously	Single choice
rus_lege	Do you use, or have you used, prescription medicines to get high? For example: sedatives, sleeping pills, painkillers, ADHD medication, etc.	2. No 1. Yes, currently 0. Yes, previously	Single choice
royk	Do you smoke daily?	1. Yes 2. No	Single choice
Life Orientation Test Revised (LOT-R)			
Life Orientation Test Revised (LOT-R)	**Questions about how you currently experience yourself** Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. Answer according to your own feelings, rather than how you think "most people" would answer.		

lot_usikre	In uncertain times, I usually expect the best.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_slappe	It's easy for me to relax.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_galt	If something can go wrong for me it will.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_optimist	I'm always optimistic about my future.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_trives	I enjoy my friends a lot.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_viktig	It's important for me to keep busy.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_forvente	I hardly ever expect things to go my way.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_opprort	I don't get upset too easily.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_regner	I rarely count on good things happening to me.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_flere	Overall, I expect more good things to happen to me than bad	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
Numeric Rating Scale (NRS)			

nrs	**Pain intensity** On a scale from zero to ten, where 0 = “no pain” and 10 = “worst imaginable pain”: How intense is your pain today?	0-10	Single choice either by entering a numeric value from **0 to 10** (inclusive) or by moving the cursor along a scale ranging from 0 to 10.
Questions about pain-relief medication			
smertest_for	Have you used pain-relief medication regularly in the last year BEFORE the injury?	1. Yes* 2. No	Single choice
opioider_for	*Select if the pain-relieving medications you used regularly in the last year BEFORE the injury match any of the options below	6. Tramadol (Nobligan, Tramagetic) 7. Paralgin forte, Pinex forte, Altermol 8. Oxycodone (Oxycontin, Oxynorm, Reltebon, Targiniq, Targin, Tanonalla) 9. Morphine (Dolcontin) 10. Tapentadol (Palexia) 11. Ketomebidone (Ketorax) 12. Pain patches (Norspan, Fentanyl, Durogesic)	Multiple choice. Displayed if answer 1 in smetest_for
opioider_dager	How many days during the year BEFORE the injury did you use the pain medication mentioned above?	0-365	Single choice either by entering a numeric value from **0 to 365** (inclusive) or by moving the cursor along a scale ranging from 0 to 365. Displayed if selected one of the options in opioider_for
HUNT1 Physical Activity Questionnaire (HUNT1 PA-Q)			
HUNT1 PA-Q	**Questions about exercise** By exercise we mean, for example, going for walks, skiing, swimming or training/sport		

	Answer for the period BEFORE the injury.		
hunt_ofte	How frequently do you exercise? (Give an average)	0. Never 1. Less than once a week* 9. Once a week* 2. 2-3 times per week* 3. Almost every day*	Single choice.
hunt_hard	*If you do such exercise as frequently as once or more times a week: How hard do you push yourself? (Give an average)	1. I take it easy without breaking into a sweat or losing my breath 2. I push myself so hard that I lose my breath and break into a sweat 3. I push myself to near exhaustion	Single choice. Displayed if answer 9, 2 or 3 in hunt_ofte
hunt_lenge	*How long does each session last? (Give an average)	1. Less than 15 minutes 2. 16-30 minutes 3. 30 minutes to 1 hour 4. More than 1 hour	Single choice. Displayed if answer 1, 9, 2 or 3 to hunt_ofte
Patient Health Questionnaire (PHQ-9)			
Patient Health Questionnaire (PHQ-9)	**Problems in the past 2 weeks** Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems? Select one option		
phq_interesse	Little interest or pleasure in doing things	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_nedfor	Feeling down, depressed, or hopeless	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_sovne	Trouble falling or staying asleep, or sleeping too much	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_trett	Feeling tired or having little energy	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_appetitt	Poor appetite or overeating	0. Not at all 1. Several days	Single choice

		2. More than half the days 3. Nearly every day	
phq_misf	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_kons	Trouble concentrating on things, such as reading the newspaper or watching television	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_beveg	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_tanker	Thoughts that you would be better off dead or of hurting yourself in some way	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_vanskelig	If you checked off <u>any</u> problems, how <u>difficult</u> have these problems made it for you to do your work, take care of things at home, or get along with other people?	0. Not difficult at all 1. Somewhat difficult 2. Very difficult 3. Extremely difficult	Single choice
Insomnia Severity Index (ISI)			
Insomnia severity index (ISI)	**Insomnia Severity Index (ISI)** LAST 2 WEEKS Full questionnaire text is copyrighted by Morin, C.M. (1993, 1996, 2000, 2006), distributed/licensed by Mapi Research Trust and is not reproduced here		
isi_sovne	1. Sleep onset difficulty	0. 0 - None 1. 1 - Mild 2. 2 - Moderate 3. 3 - Severe 4. 4 - Very Severe	Single choice
isi_vaknenatt	2. Sleep maintenance difficulty	0. 0 - None 1. 1 - Mild 2. 2 - Moderate 3. 3 - Severe 4. 4 - Very Severe	Single choice

isi_vaknetidlig	3. Early morning waking	0. 0 - None 1. 1 - Mild 2. 2 - Moderate 3. 3 - Severe 4. 4 - Very Severe	Single choice
isi_tilfreds	4. Sleep satisfaction	0. 0 – Very Satisfied 1. 1 - Satisfied 2. 2 - Neutral 3. 3 - Dissatisfied 4. 4 - Very Dissatisfied	Single choice
isi_redusere	5. Daytime impairment from sleep	0. 0 - Not at all Interfering 1. 1 - A Little Interfering 2. 2 - Somewhat Interfering 3. 3 - Much Interfering 4. 4 - Very much Interfering	Single choice
isi_merkbare	6. Noticeability of sleep problem	0. 0 - Not at all Noticeable 1. 1 - A Little Noticeable 2. 2 - Somewhat Noticeable 3. 3 - Much Noticeable 4. 4 - Very much Noticeable	Single choice
isi_bekymre	7. Sleep worry	0. 0 - Not at all 1. 1 - A Little 2. 2 - Somewhat 3. 3 - Much 4. 4 - Very much	Single choice
EQ-5D-5L			
EQ-5D-5L	**Questionnaire about health** Full questionnaire text is copyrighted by EuroQol Research Foundation and is not reproduced here. EQ-5D™ is a trademark of the EuroQol Research Foundation		
eq5d_gange	MOBILITY	1–5 (no problems → unable)	Single choice
eq5d_stell	SELF-CARE	1–5 (no problems → unable)	Single choice
eq5d_gjore	USUAL ACTIVITIES	1–5 (no problems → unable)	Single choice

eq5d_smerte	PAIN / DISCOMFORT	1–5 (no pain/discomfort → extreme)	Single choice
eq5d_angst	ANXIETY / DEPRESSION	1–5 (no anxiety/depression → extreme)	Single choice
eq5d_vas	VAS Self-rated health today	1-100	Single choice either by entering a numeric value from **0 to 100** (inclusive) or by moving the cursor along a scale ranging from 0 to 100
Injustice Experience Questionnaire (IEQ)			
Injustice Experience Questionnaire (IEQ)	**Thoughts and feelings about your injury** Statements describing different thoughts and feelings that might be experienced when thinking about the injury. Full questionnaire text is copyrighted by Michael JL Sullivan 2002, distributed/licensed by Mapi Research Trust and is not reproduced here.		
ieq_ieq_folk	1. Statement 1	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ ieq_livet	2. Statement 2	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ ieq_lider	3. Statement 3	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree	Single choice

		4. 4 - All the time	
ieq_ ieq_ingen	4. Statement 4	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ieq_vilbare	5. Statement 5	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ ieq_foler	6. Statement 6	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ ieq_urett	7. Statement 7	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ieq_bekymret	8. Statement 8	0. 0 - Aldri 1. 1-Sjelden 2. 2 - Noen ganger 3. 3 - Ofte 4. 4 - Hele tiden	Single choice
ieq_ieq_ingenting	9. Statement 9	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ ieq_fratatt	10. Statement 10	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_ ieq_frykt	11. Statement 11	0. 0 - Aldri	Single choice

		1. 1-Sjelden 2. 2 - Noen ganger 3. 3 - Ofte 4. 4 - Hele tiden	
ieq_ ieq_ikketro	12. Statement 12	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice

*The answers marked with * are activated answers. When * appears after the answer-category, it means that this answer activates a new question. Activated questions are marked with a * before the question.*

** Free text answers will be coded by the researcher

Section A2

Baseline variables collected from electronic records

Variable name	**Label**	**Value**	**Validation rule**
asa	Enter the patient's ASA value	1-5	Free text answer in numbers between 1 and 5
antskader	Enter the number of injuries the patient has	1-9	Free text answer in numbers between 1 and 9
overint	Was the patient transferred internally at OUH?	1. Yes 2. No	Single choice
liggetid	What was the patient's length of stay in the hospital? Length of stay = number of days. The first calendar day is counted as one day. An admission from the 12th to the 13th counts as 2 days. A same-day admission (day surgery) counts as 1 day. Includes time spent at another hospital. Does not include any leave of absence.	1-14	Free text answer in numbers between 1 and 14
overfra	Was the patient transferred from another (external) hospital?	1. Yes* 2. No	Single choice

opannet	* Was the patient operated on at a hospital other than OUH?	1. Yes* 2. No	Single choice
opannetsyke	* If the patient was operated on at a different hospital, what was the hospital name?		Free text answer**
ullaker	Is the patient an Ullevål or Aker patient? Answer based on where the patient underwent surgery; if the patient had surgery at another hospital, select the hospital from which the patient was discharged.	2. Aker hospital 1. Ullevål hospital	Single choice
traumeteam	Was the trauma team activated for this patient?	1. Yes 2. No	Single choice
skadelok	Injury type by region — select the region the patient was operated on.	1. Scapula 2. Clavicle 3. Humerus 4. Radius/ulna 5. Femur 6. Patella 7. Tibia/fibula 8. Foot (Lis franc) 9. Spine 10. Pelvis 11. Luxations 12. Soft tissue injuries (tendons, ligaments, muscles)	Multiple choice
opioider_dogn	Describe the opioids (name, strength and number of tablets) the patient received in the last 24 hours before discharge (07:00–07:00)		Free text answer**
opioider_ut	Select the opioid(s) prescribed at discharge.	6. Tramadol (Nobligan, Tramagetic) 7. Codein (Paralgin forte, Pinex forte, Altermol, Kodein) 8. Oxycodone (Oxycodon, Oxynorm, Reltebon, Targiniq, Targin, Tanonalla) 9. Morphine (Dolcontin) 10. Tapentadol (Palexia)	Multiple choice

		11. Ketomebidone (Ketorax) 12. Pain patch (Norspan, Fentanyl, Durogesic)	
Opioider_ut_navn	Describe the name, strength and number of tablets the patient was discharged with		Free text answer**
ICD-10 code(s)			
ICD-10 code(s)	Enter ICD-10 diagnosis code(s) here		
icd10_1	ICD-10 code 1		Free text answer**
icd10_2	ICD-10 code 2		Free text answer**
icd10_3	ICD-10 code 3		Free text answer**
icd10_4	ICD-10 code 4		Free text answer**
icd10_5	ICD-10 code 5		Free text answer**
icd10_6	ICD-10 code 6		Free text answer**
Procedure code/operation code			
Procedure/operation code	Enter the procedure/operation code(s)		
prosedyre_1	Procedure/operation code 1		Free text answer**
prosedyre_2	Procedure/operation code 2		Free text answer**
prosedyre_3	Procedure/operation code 3		Free text answer**
prosedyre_4	Procedure/operation code 4		Free text answer**
prosedyre_5	Procedure/operation code 5		Free text answer**
prosedyre_6	Procedure/operation code 6		Free text answer**

*The answers marked with * are activated answers. When * appears after the answer-category, it means that this answer activates a new question. Activated questions are marked with a * before the question.*

** Free text answers will be coded by the researcher

Section A3

6-week follow-up variables collected from questionnaire

Variable name	Label	Value	Validation rule

StudieID	Study-ID:		Free text**
aar_6	What year were you born?	1-88 (1923-2010)	Singel choice
kjonn_6	Please state your gender	1. Woman 2. Man 3. Self-defined*	Singel choice. If answer 3, optional to further describe
egendef_6	* If self-defined, please describe here:		Optional to further describe in free text
Life Orientation Test Revised (LOT-R)			
Life Orientation Test Revised (LOT-R)	**Questions about how you currently experience yourself** Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. Answer according to your own feelings, rather than how you think "most people" would answer.		
lot_6_lot_usikre_6	In uncertain times, I usually expect the best.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_slappe_6	It's easy for me to relax.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_galt_6	If something can go wrong for me it will.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_optimist_6	I'm always optimistic about my future.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_trives_6	I enjoy my friends a lot.	5. Strongly agree	Single choice

		6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	
lot_6_lot_viktig_6	It's important for me to keep busy.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_forvente_6	I hardly ever expect things to go my way.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_opprort_6	I don't get upset too easily.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_regner_6	I rarely count on good things happening to me.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
lot_6_lot_flere_6	Overall, I expect more good things to happen to me than bad.	5. Strongly agree 6. Agree 7. Neutral 8. Disagree 9. Strongly disagree	Single choice
Numeric rating scale (NRS)			
nrs_6	**Pain intensity** On a scale from zero to ten, where 0 = "no pain" and 10 = "worst imaginable pain": How intense is your pain today?	0-11	Single choice either by entering a numeric value from **0 to 10** (inclusive) or by moving the cursor along a scale ranging from 0 to 10.
Questions about pain-relief medication			
smertest_siste_6	Which painkillers have you used in the **last 24 hours**, and how much of each?	1. Paracetamol (Paracet, Panodil, Pinex)	Multiple choice

	Please select the medications here, and use the field below to describe the strength and the number of tablets you have taken in the past 24 hours	2. Ibuprofen (Brufen, Ibumetin, Ibux) 3. Diclofenac (Voltaren, Voltarol, Cataflam, Arthrotec) 4. Naproxen (Naprosyn, Napren-E, Vimovo) 5. Gabapentin, Pregabalin (Neurontin, Lyrica) 6. Tramadol (Nobligan, Tramagetic) 7. Paralgin forte, Pinex forte, Altermol 8. Oxycodone (Oxycontin, Oxynorm, Reltebon, Targiniq, Targin, Tanonalla) 9. Morphine (Dolcontin) 10. Tapentadol (Palexia) 11. Ketomebidone (Ketorax) 12. Pain patch (Norspan, Fentanyl, Durogesic) 13. Other 14. Does not use any painkillers	
smertest_navn_6	Please describe the name, strength and number of tablets you have taken in the last 24 hours For example: Nobligan 50 mg 3 tablets, Ibux 600 mg 4 tablets and Norspan patch 10 micrograms/hour		Free text answer**
smertest_samsvar_6	Does the use of painkillers in the last 24 hours (as stated above) correspond to what you have used on	1. Yes 2. No*	Single choice

	average per day during the past week?		
smertest_ikkesamsvar_6	*If no, what do you think you have used on average per day during the past week?		Free text answer**. Displayed if answer 2 in smertest_samsvar_6
HUNT1 Physical Activity Questionnaire (HUNT1 PA-Q)			
HUNT1 PA-Q	**Questions about exercise** By exercise we mean, for example, going for walks, skiing, swimming or training/sport		
hunt_ofte_6	How frequently do you exercise? (Give an average)	0. Never 1. Less than once a week* 9. Once a week* 2. 2-3 times per week* 3. Almost every day*	Single choice.
hunt_hard_6	*If you do such exercise as frequently as once or more times a week: How hard do you push yourself? (Give an average)	1. I take it easy without breaking into a sweat or losing my breath 2. I push myself so hard that I lose my breath and break into a sweat 3. I push myself to near exhaustion	Single choice. Displayed if answer 9, 2 or 3 in hunt_ofte_6
hunt_lenge_6	*How long does each session last? (Give an average)	1. Less than 15 minutes 2. 16-30 minutes 3. 30 minutes to 1 hour 4. More than 1 hour	Single choice. Displayed if answer 1, 9, 2 or 3 to hunt_ofte_6
Patient Health Questionnaire (PHQ-9)			
Patient Health Questionnaire (PHQ-9)	**Problems in the past 2 weeks** Over the last 2 weeks, how often have you been bothered by any of the following problems? Select one option		

phq_6_phq_interesse_6	Little interest or pleasure in doing things	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_nedfor_6	Feeling down, depressed, or hopeless	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_sovne_6	Trouble falling or staying asleep, or sleeping too much	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_trett_6	Feeling tired or having little energy	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_appetitt_6	Poor appetite or overeating	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_misf_6	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_kons_6	Trouble concentrating on things, such as reading the newspaper or watching television	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_beveg_6	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_6_phq_tanker_6	Thoughts that you would be better off dead or of hurting yourself in some way	0. Not at all 1. Several days 2. More than half the days 3. Nearly every day	Single choice
phq_vanskelig_6	If you checked off <u>any</u> problems, how <u>difficult</u>	0. Not difficult at all	Single choice

	have these problems made it for you to do your work, take care of things at home, or get along with other people?	1. Somewhat difficult 2. Very difficult 3. Extremely difficult	
Insomnia severity index (ISI)			
Insomnia severity index (ISI)	**Insomnia Severity Index (ISI)** LAST 2 WEEKS Full questionnaire text is copyrighted by Morin, C.M. (1993, 1996, 2000, 2006), distributed/licensed by Mapi Research Trust and is not reproduced here		
isi_sovne_6	1. Sleep onset difficulty	0. 0 - None 1. 1 - Mild 2. 2 - Moderate 3. 3 - Severe 4. 4 - Very Severe	Single choice
isi_vaknenatt_6	2. Sleep maintenance difficulty	0. 0 - None 1. 1 - Mild 2. 2 - Moderate 3. 3 - Severe 4. 4 - Very Severe	Single choice
isi_vaknetidlig_6	3. Early morning waking	0. 0 - None 1. 1 - Mild 2. 2 - Moderate 3. 3 - Severe 4. 4 - Very Severe	Single choice
isi_tilfreds_6	4. Sleep satisfaction	0. 0 - Very Satisfied 1. 1 - Satisfied 2. 2 - Neutral 3. 3 - Dissatisfied 4. 4 - Very Dissatisfied	Single choice
isi_redusere_6	5. Daytime impairment from sleep	0. 0 - Not at all Interfering 1. 1 - A Little Interfering 2. 2 - Somewhat Interfering	Single choice

		3. 3 - Much Interfering 4. 4 - Very much Interfering	
isi_merkbare_6	6. Noticeability of sleep problem	0. 0 - Not at all Noticeable 1. 1 - A Little Noticeable 2. 2 - Somewhat Noticeable 3. 3 - Much Noticeable 4. 4 - Very much Noticeable	Single choice
isi_bekymre_6	7. Sleep worry	0. 0 - Not at all 1. 1 - A Little 2. 2 - Somewhat 3. 3 - Much 4. 4 - Very much	Single choice
EQ-5D-5L			
EQ-5D-5L	**Questionnaire about health** Full questionnaire text is copyrighted by EuroQol Research Foundation and is not reproduced here. EQ-5D™ is a trademark of the EuroQol Research Foundation		
eq5d_gange_6	MOBILITY	1–5 (no problems → unable)	Single choice
eq5d_stell_6	SELF-CARE	1–5 (no problems → unable)	Single choice
eq5d_gjore_6	USUAL ACTIVITIES	1–5 (no problems → unable)	Single choice
eq5d_smerte_6	PAIN / DISCOMFORT	1–5 (no pain/discomfort → extreme)	Single choice
eq5d_angst_6	ANXIETY / DEPRESSION	1–5 (no anxiety/depression → extreme)	Single choice

eq5d_vas_6	VAS Self-rated health today	1-100	Single choice either by entering a numeric value from **0 to 100** (inclusive) or by moving the cursor along a scale ranging from 0 to 100
Injustice Experience Questionnaire (IEQ)			
Injustice Experience Questionnaire (IEQ)	**Thoughts and feelings about your injury** Statements describing different thoughts and feelings that might be experienced when thinking about the injury. Full questionnaire text is copyrighted by Michael JL Sullivan 2002, distributed/licensed by Mapi Research Trust and is not reproduced here.		
ieq_6_ieq_folk_6	1. Statement 1	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq _livet_6	2. Statement 2	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_lider_6	3. Statement 3	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree	Single choice

		4. 4 - All the time	
ieq_6_ieq_ingen_6	4. Statement 4	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice.
Ieq_6_ieq_vilbare_6	5. Statement 5	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_foler_6	6. Statement 6	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_urett_6	7. Statement 7	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_bekymret_6	8. Statement 8	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_ingenting_6	9. Statement 9	0. 0 - Not at all	Single choice

		1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	
ieq_6_ieq_fratatt_6	10. Statement 10	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_frykt_6	11. Statement 11	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
ieq_6_ieq_ikketro_6	12. Statement 12	0. 0 - Not at all 1. 1 - To a slight degree 2. 2 - To a moderate degree 3. 3 - To a great degree 4. 4 - All the time	Single choice
Questions about follow-up			
kontroll	Have you had a follow-up appointment with your GP after the injury?	1. Yes* 2. No*	Single choice
bestilt	*Was this an appointment that was booked during the hospital stay?	1. Yes 2. No* 3. Don't remember*	Single choice. Displayed if answer 1 in kontroll
hvorfor	*Why was this appointment scheduled? Describe		Free text answer**. Displayed if answer 2 or 3 in bestilt

egentlig	*Was a GP appointment actually scheduled during your hospital stay?	1. Yes* 2. No 3. Don't remember	Single choice. Displayed if answer 2 in kontroll
hvorforikke	* Describe why the appointment was not carried out		Free text answer**. Displayed if answer 1 in egentlig
hvorforbestilt	*Why was this appointment scheduled? Describe		Free text answer**. Displayed if answer 1 in egentlig

*The answers marked with * are activated answers. When * appears after the answer-category, it means that this answer activates a new question. Activated questions are marked with a * before the question.*

** Free text answers will be coded by the researcher

Section A4

Oral Morphine Equivalents (OMEQ) conversion chart (adapted from the Norwegian Health Economics Administration) (11)

Opioid	Conversion Factor
Codein oral/rectal	0,10
Tramadol oral	0,15
Tapentadol oral	0,20
Morphine oral	1,00
Oxycodone oral	1,50
Ketobemidone oral	1,00
Hydromorphone oral	5,00
Pethidine rectal	0,10
Fentanyl	
Transdermal	100,00
Sublingual/intranasal	250,00
Buprenorphine	
Transdermal	92,5
Sublingual	48