

The importance of soft tissue massage for patients admitted to intensive care

Submission date 06/09/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/10/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

More people than ever are surviving critical illness and receiving treatment in intensive care units (ICUs). While modern technology has improved survival, many patients in the ICU experience anxiety, fear, stress, loneliness, pain, and a loss of control during their stay. The ICU environment can be overwhelming, with constant monitoring, noise, medical equipment, and frequent care activities.

Human touch is a fundamental need and an important part of nursing care. Soft tissue massage is a simple, non-invasive intervention that may help patients feel more relaxed and supported. Previous studies in different patient groups have shown that soft tissue massage may reduce anxiety, pain, and discomfort, improve sleep and well-being, and promote relaxation. However, there is limited research on the effects of soft tissue massage among patients admitted to the ICU.

The aim of this study is to investigate the significance and effects of soft tissue massage for patients admitted to an intensive care unit. The study will examine whether soft tissue massage can reduce anxiety, improve physiological measurements such as heart rate, blood pressure, respiratory rate and blood glucose levels, and reduce the use of anti-anxiety medication.

Who can participate?

Adults aged 18 years or older who are receiving treatment in an intensive care unit can participate. Participants must have been admitted to the ICU for more than four hours and be awake enough to communicate with healthcare staff.

What does the study involve?

Participants will be assigned to either an intervention group or a control group.

Patients in the intervention group will receive soft tissue massage performed by trained healthcare staff in addition to rest period ("hands-off time"), which is part of routine care at intensive care units (ICUs).

Information will be collected on anxiety levels, vital signs such as heart rate, blood pressure, respiratory rate, and blood glucose levels. The use of anti-anxiety medication will also be recorded. Measurements will be compared between the groups to determine whether soft tissue massage has beneficial effects for ICU patients.

Participation in the study will not affect the patient's access to regular medical treatment or nursing care.

What are the possible benefits and risks of participating?

Participants may experience increased relaxation, reduced anxiety, improved comfort, and a greater sense of well-being. Soft tissue massage may also contribute to improvements in physiological measurements and reduce the need for anti-anxiety medication.

Soft tissue massage is generally considered a safe intervention and serious adverse effects are not expected. However, some patients may find touch uncomfortable or unpleasant. Participants may stop the massage at any time without providing a reason and without affecting their ongoing care.

Where is the study run from?

The study is conducted in three general intensive care units at participating hospitals in Sweden.

When is the study starting and how long is it expected to run for?

January 2020 to June 2026.

Who is funding the study?

University of Borås, Sweden.

Who is the main contact?

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Study information

Scientific Title

The effect of soft tissue massage on patients admitted to intensive care: A randomized controlled trial

Study objectives

The objective of this study is to evaluate the effects of soft tissue massage, compared with rest, on anxiety, physiological parameters, arterial blood glucose levels, and the use of anxiolytic medication among adult patients receiving care in an intensive care unit (ICU).

The hypotheses are that the intervention involving soft tissue massage:

Primary Hypothesis

Adult ICU patients receiving soft tissue massage will demonstrate lower anxiety levels, as measured by the State-Trait Anxiety Inventory (STAI), compared with patients receiving a period of rest.

Secondary Hypotheses

Compared with patients receiving a period of rest, patients receiving soft tissue massage will:

1. Exhibit lower blood pressure, heart rate, and respiratory rate
2. Demonstrate arterial blood glucose levels closer to the normal physiological range
3. Reduces the use of anxiolytic (anti-anxiety) medications

Ethics approval required

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Ethics approval(s)

1. Approved 05/11/2019, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46104750800; registrator@etikprovning.se), ref: 2019-05369
2. Approved 09/10/2020, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46104750800; registrator@etikprovning.se), ref: 2020-04609
3. Approved 08/05/2023, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46104750800; registrator@etikprovning.se), ref: 2023-02341-02
4. Approved 20/02/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46104750800; registrator@etikprovning.se), ref: 2025-00167-02

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Dose comparison

Assignment

Parallel

Purpose

Supportive care

Study type(s)**Health condition(s) or problem(s) studied**

Critically ill patients admitted to a general intensive care unit (ICU).

Interventions

Intervention group: Soft tissue massage of the hands, feet, and lower legs provided by a registered nurse or nursing assistant trained in soft tissue massage therapy.

Control group: Rest period ("hands-off time"), which is part of routine care at intensive care units (ICUs).

Participants will be recruited from three general intensive care units (ICUs) at three hospitals in Sweden. Participants are randomly allocated to the intervention or control group using block randomization.

A sample size calculation was performed based on the primary outcome, anxiety ($SD = 5$), using a significance level of 0.05. The calculation indicated that a total sample of 84 patients was required, 42 patients in the intervention group and 42 patients in the control group.

Research nurses enrol patients after they have been admitted to the ICU for at least four hours.

Intervention group (soft tissue massage)

Frequency: Three treatment sessions.

Timing: For example, morning, evening, and the following morning.

Duration: Approximately 30 minutes of massage followed by 15 minutes of rest (45 minutes total per session).

Mode of delivery: Manual soft tissue massage of the hands, feet, and lower legs using an unscented vegetable oil.

Setting: A quiet environment with dimmed lighting; no nursing procedures or additional physical contact are permitted during the intervention.

Control group (rest)

Frequency: Three sessions.

Timing: For example, morning, evening, and the following morning.

Duration: 45 minutes of uninterrupted rest per session.

Mode of delivery: Rest in the ICU room without physical contact or nursing procedures.
Setting: Dimmed lighting and minimized disturbances, equivalent to the intervention group.

Intervention Type

Other

Primary outcome(s)

1. Anxiety measured using the Trait Anxiety subscale of the State-Trait Anxiety Inventory (STAI-T) at inclusion in the study
2. Participant's current level of anxiety measured using the State Anxiety subscale of the State-Trait Anxiety Inventory (STAI-S) at 1 hour before the intervention (rest or massage) and again 1 hour after the intervention

Key secondary outcome(s)

1. Blood pressure measured using an invasive arterial catheter (arterial line) at 30 minutes before the intervention, 15 minutes after the start of the intervention, and 30 minutes after completion of the intervention (rest or massage)
2. Heart rate measured using electrocardiography (ECG) at 30 minutes before the intervention, 15 minutes after the start of the intervention, and 30 minutes after completion of the intervention (rest or massage)
3. Respiratory rate (breaths/minute) measured using electrocardiography (ECG) at 30 minutes before the intervention, 15 minutes into the intervention, and 30 minutes after the intervention (rest or massage)
4. Arterial blood glucose level measured using standard methods in blood samples taken via an arterial catheter at 30 minutes before and after the intervention (rest or massage)
5. Anxiolytic medication consumption, assessed as total dose administered during the ICU stay measured using data collected from patient medical records on the consumption of anxiolytic medication, in millilitres (mL), at the end of the study

Completion date

30/06/2026

Eligibility

Key inclusion criteria

1. Patients aged 18 years or older
2. Patients cared for in either single-bed rooms or multi-bed rooms to ensure variation in the study setting
3. Patients who have been admitted to the intensive care unit (ICU) for more than 4 hours
4. Assessment of the patient's level of consciousness:
 - 4.1. Reaction Level Scale (RLS 85) - Patients should have an RLS score between 1 (alert, oriented, and readily responsive) and 2 (drowsy or slightly confused, but responsive to verbal and tactile stimulation)
 - 4.2. Or Richmond Agitation-Sedation Scale (RASS). Patients should have a RASS score between -1 (drowsy, responsive to verbal stimulation) and +1 (restless).

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

53

Key exclusion criteria

1. Patients with acute neurological disease and/or traumatic brain injury, as these conditions may alter the perception of touch and pain. Patients with secondary neurological disease or traumatic brain injury may be included if the primary reason for ICU admission is another condition. In such cases, the patient's neurological status, including the degree of aphasia and cognitive impairment, must have been assessed.
2. Patients with a previously diagnosed psychotic disorder, as gentle massage may be perceived as intrusive or distressing
3. Fever
4. Body temperature $>38.5^{\circ}\text{C}$, measured axillary or tympanically. Previous studies have shown that receiving soft tissue massage during high fever may be painful
5. End-of-life care
6. Patients receiving end-of-life care, as they are unlikely to be able to complete the study
7. Delirium
8. Patients exhibiting symptoms of delirium, as gentle massage may be perceived as intrusive or distressing

Date of first enrolment

01/01/2020

Date of final enrolment

31/12/2020

Locations**Countries of recruitment**

Sweden

Sponsor information

Organisation

University of Borås

ROR

<https://ror.org/01fdxwh83>

Funder(s)**Funder type****Funder Name**

Ekhagastiftelsen

Alternative Name(s)

Ekhaga foundation, Ekhagastiftelsen Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Region Kronoberg

Alternative Name(s)**Funding Body Type**

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available