

Increasing Physical Activity among Medical Inpatients by Digital Nudging of Patients and Staff (the IPAMINA trial): A Stepped Wedge Cluster Randomised Multicentre Study Protocol

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Study protocol

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Title {1a}

Increasing Physical Activity among Medical Inpatients by Digital Nudging of Patients and Staff (the IPAMINA trial): A Stepped Wedge Cluster Randomised Multicentre Study Protocol

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Abstract

Background: Low physical activity levels and sedentary behaviour during hospitalisation increase risk of functional decline, and adverse outcomes for medical inpatients. Increasing inpatients' physical activity and reducing sedentary behaviour can be challenging in a busy hospital setting. Digital nudging and feedback using real-time data from wearable accelerometers may help promote in-hospital activity and improve recovery for patients.

Aim: To determine whether a digital nudging intervention, targeting patients and staff, increases daily average physical activity (minutes/day) among adult medical inpatients compared with usual care. Secondly, an embedded qualitative study aims to explore the healthcare staff's experience with the intervention and explore their perspectives on its usability in and impact on practice.

Methods: This trial will be a stepped wedge cluster randomised multicentre trial, in which medical inpatients from four hospital clusters, across the Kingdom of Denmark, sequentially will receive a digital nudging intervention. All participants' activity levels (control and intervention group) will be measured with wearable

accelerometers. The intervention involves real-time activity feedback to patients and staff regarding patients' physical activity levels during hospitalisation.

In the qualitative study, healthcare staff from all four sites will attend focus group interviews.

The primary outcome is daily average minutes of physical activity. Secondary outcomes include daily minutes of sedentary behaviour, readmission, and length of stay. Target sample size is 400 patients, powered to detect a between-group difference of ≥ 38 minutes activity/day.

Data will be collected at enrolment (<48 hours of admission to ward), during hospitalisation, at discharge, and 90 days post-discharge.

Discussion: By testing a digital intervention on a multicentre scale, this trial seeks to change the paradigm of inactivity during hospitalisation, making physical activity and reduction of sedentary behaviour integral to hospital care. We aim to address multiple factors, that are known to impact inpatient mobilisation, by implementing a relatively simple digital intervention aimed at both patients and staff.

The findings will inform best practices for patientcare and culture regarding inpatient physical activity in medical wards.

Trial registration: Clinicaltrials.gov: NCT06983977. Prospectively registered May 14th, 2025. Date of first recruitment: May 19th, 2025. Ethics approvals have been obtained in all three countries.

Keywords

Digital health, physical activity, medical inpatients

Structured summary {1b}

Item	Description
Primary Registry and Trial Identifying Number {4}	Clinicaltrials.gov: NCT06983977. https://clinicaltrials.gov/study/NCT06983977?term=NCT06983977&rank=1#study-overview Prospectively registered May 14 th , 2025. Date of first recruitment: May 19 th , 2025
Secondary Identifying Numbers	Ethics committee approvals Denmark: VMK-2403916 Greenland: 2024-9829 The Faroe Islands: Exempt Institutional Review Board (IRB) determination, no reference number (confirmation mail, date May 30 th , 2024).
Source(s) of Monetary or Material Support	Department of physio- and occupational therapy, University Hospital Bispebjerg and Frederiksberg The Association of Danish Physiotherapists (R71-A1701-B398) Research Council Faroe Islands (0369) Greenland Research Council (68b7b) Internal Research Fund of the Hospital Service, Faroe Islands (7061) Health Innovation Fund, North Denmark Region (2025-0012)

Primary Sponsor and contact information {3b}	Department of physio- and occupational therapy, University Hospital Bispebjerg and Frederiksberg Bispebjerg Bakke 23, DK-2400 Copenhagen, Denmark Naja.Lotte.Mark.Henriksen@regionh.dk
Role of sponsor and funder {3c}	Sponsor will provide facilities for conducting and managing the trial and Open access funding. The sponsor will have no role in the design, conduct, analysis or interpretation of the data, the writing of the report or decisions regarding submission for publication. All decisions regarding the trial conduct, protocol amendments, statistical analyses and publication rest solely with the principal investigator and the research team.
Contact for Public Queries	Christian Have Dall, principal investigator Department of physio- and occupational therapy, University Hospital Bispebjerg Frederiksberg Bispebjerg Bakke 23, DK-2400 Copenhagen, Denmark christian.have.dall@regionh.dk
Contact for Scientific Queries	Christian Have Dall, principal investigator Department of physio- and occupational therapy, University Hospital Bispebjerg Frederiksberg Bispebjerg Bakke 23, DK-2400 Copenhagen, Denmark christian.have.dall@regionh.dk
Public Title	The IPAMINA trial
Scientific title	Increasing Physical Activity among Medical Inpatients by Digital Nudging (the IPAMINA trial): A Stepped Wedge Cluster Randomised Multicentre Study Protocol
Countries of Recruitment	Denmark, Greenland, The Faroe Islands
Health Condition(s) or Problem(s) Studied	Medical inpatients' physical activity and sedentary behaviour during hospitalisation
Intervention(s)	Intervention: Measurement of patients' physical activity and digital nudging intervention targeting patients and healthcare staff Control condition: Usual care and measurement of physical activity
Key Inclusion and Exclusion Criteria	Participants must be admitted to participating hospital ward and have signed informed consent. Participants will be excluded if they have an expected hospitalisation of less than 24 hours, if there are contraindications for mobilisation or ethical concerns regarding participation.
Study Type	This will be a cluster randomised, stepped wedge trial evaluating the effect of a

	digital intervention on medical inpatients' physical activity. All clusters will start in the control condition. At fixed time intervals ("steps"), clusters will crossover from control to intervention according to a randomly assigned sequence. By the end of the study, all clusters will have received the intervention. Each cluster contributes data to both the control and intervention periods. Clusters are randomly allocated to one of the four crossover positions in a 1:1:1:1 ratio. Blinding of participants and clinical staff will not be possible given the nature of the staged rollout. Outcome assessors and data analysts will remain blinded until analyses are complete. The study uses a superiority framework, testing whether the intervention yields better outcomes than standard practice during the control periods. We will also embed a qualitative study to explore the healthcare staff's experience with the intervention and their perspectives on how and why the digital intervention was (or was not) used, and how it impacted practice. Healthcare staff across sites will attend focus group interviews by the end of the trial.
Date of First Enrolment (planned)	First enrolment was May 19 th , 2025.
Sample Size	400
Primary outcome(s)	Daily average time of physical activity (minutes/day)
Key Secondary outcome(s)	Daily average time of sedentary behaviour (minutes/day), length of stay (days), readmission within 90 days of discharge (yes/no), death within 90 days of discharge (yes/no), in-hospital falls (yes/no) and discharge destination (own home, nursing home, rehabilitation, other)
Ethics Review	Denmark: Medical Research Ethics Committee; ref.nr. VMK-2403916 Greenland: The Greenland Research Ethics Committee; ref.nr. 2024-9829 The Faroe Islands: The Faroese Health Research Ethics Committee; Exempt Institutional Review Board (IRB) determination, no reference number (confirmation mail, date May 30th, 2024).
Individual Trial Participant Data sharing statement	Individual participant data will not be shared due to confidentiality considerations and data protection regulations (GDPR). De-identified dataset can be made available upon reasonable request.

Protocol version {2}

Protocol version 1.1, version date May 14th, 2025.

Introduction

Background and rationale {9a}

Prolonged low physical activity (PA) levels and sedentary behaviour (SB) during hospitalisation are associated with significant loss of muscle mass, muscle strength and independence in daily function (1-3). This decline increases the risk of further complications, such as readmission, institutionalisation, and mortality, leading to high socioeconomic costs, and prolonged rehabilitation needs for surviving patients (4, 5). Hospital culture traditionally accepts long periods of SB (6) and increasing PA among inpatients is a complex task that requires multidisciplinary focus and effort in a busy hospital setting (7, 8). Attempts to enhance PA levels has shown limited results, often due to the high staff effort required, resulting in restricted implementation in routine care (9).

A systematic review (10) confirmed the benefits and safety of PA interventions to reduce functional decline and adverse events associated with acute hospitalisation in older adults. The minimal effective dose of PA during hospitalisation was estimated to be ~40 min/day of light effort or 25 min/day of moderate effort activities with superior effects of ambulation over other active intervention modalities (10).

International recommendations for PA for older adults while hospitalised with acute medical illness (11) recommend that the patients should be as active as their abilities and health status allow and long periods of uninterrupted SB should be minimised. Self-monitoring and feedback are recommended as well as the importance of the roles and clear responsibilities of the staff in supporting and assisting the patients when needed, is highlighted (11).

In recent years, technology has developed rapidly, and digital health interventions yield enormous potential for improving health and healthcare (12). Valid wearable accelerometers (13, 14), with wireless (Bluetooth) connection to secure data servers, enable measuring of patient PA levels and provision of real time feedback to - and nudging of - patients and healthcare staff (15). This form of digital intervention has the potential to target several of the cardinal issues regarding sedentary behaviour during hospitalisation, such as lack of joint multidisciplinary focus, responsibility, and encouragement of patients to be active as well as it provides patients the possibility of self-monitoring.

Our group has previously shown in a pilot (N=57) (15) and a large randomised study (N=354) (16) that measuring medical inpatients' PA levels through wearable accelerometers and providing instant feedback, increases their PA levels, promoting recovery. Building on these studies, this trial tests the effect of digital nudging at scale, where the current intervention addresses both patients and healthcare staff with the aim of reaching most patients, including the frail and less resourceful, to support them in being more active and less sedentary during hospitalisation.

The intervention provides continuous and independent, real-time, round the clock feedback and nudging regarding patients' PA levels to:

- Inpatients and their visiting relatives, via gamification through a tablet by the patients' bedside
- The healthcare staff, via a digital overview of the inpatients' PA levels and degree of SB.

In this way, the intervention aims to encourage patients to increase their PA levels during hospitalisation, while simultaneously strengthening the staff's multidisciplinary focus on and responsibility for supporting inpatients in becoming more active.

Primary aim: To determine whether a digital nudging intervention targeting patients and staff increases daily

average physical activity (minutes/day) among adult medical inpatients compared with usual care.

Secondary aim: To explore the healthcare staff's experience with the intervention and their perspectives on how and why the digital intervention was (or was not) used, and how it impacted practice.

Explanation for the choice of comparator {9b}

The comparator for this trial is usual care, representing the standard clinical practices in routine management of medical inpatients. Usual care reflects the real-world clinical practice and provides a meaningful benchmark against which the effectiveness of the intervention can be evaluated. This comparator also ensures that all participants receive an ethically acceptable level of care throughout the study.

Objectives {10}

The primary objective is to assess the effectiveness of the digital intervention that aims to increase daily PA among medical inpatients compared to standard care, as measured by daily average minutes of PA.

The secondary objectives are to assess effects on the patients' SB, length of stay, in-hospital falls, discharge destination, readmission and mortality within 90 days of discharge.

In the embedded qualitative study, the objective is to explore the healthcare staff's experience with the intervention and their perspectives on how and why the digital intervention was (or was not) used, and how it impacted practice.

Primary hypothesis: We hypothesise that patients hospitalised in the intervention period, where patients and staff receive the digital intervention, will be more physically active compared to control (usual care).

Methods: Patient and public involvement, and trial design

Patient and public involvement {11}

Participating patients were interviewed as part of the pilot study (15, 17) and a healthcare staff advisory group reviewed the study design and the first ideas for the digital staff overview during the protocol development. Patients' input resulted in adjustment and optimisation of the digital patient feedback and participant material. The healthcare staff's input was used to adjust and refine the digital staff overview.

Trial design {12}

This trial will be a cluster randomised, stepped wedge trial (18, 19) with an embedded qualitative study.

The stepped-wedge design has been chosen due to the following key considerations:

- 1) The design is well-suited for a real-world clinical setting where the aim is to implement an intervention to be evaluated as part of routine practice, it enables a better allocation of resources over time as the intervention is introduced in phases, allowing for potential adjustments based on initial feedback.
- 2) The trial will employ cross-sectional sampling which is particularly appropriate in settings with high turnover, such as clinical environments, because it reduces participant burden, simplifies logistics, and

ensures that each measurement reflects the population currently present in the cluster when the intervention is introduced.

3) The gradual implementation of the intervention at the different sites is essential for the feasibility of this study.

4) The design is statistically efficient when there is an assumption of substantial between-cluster variability because each cluster acts as its own control at different time points which can enhance the precision of the estimated intervention effect.

5) Ethical considerations in regard to all sites receiving the intervention at some point which also heightens the potential for further insights through the qualitative study.

All clusters will start in the control condition. At fixed time intervals (“steps”), clusters will crossover from control to intervention according to a randomly assigned sequence. By the end of the study, all clusters will have received the intervention (Fig. 1). Each cluster contributes data to both the control and intervention periods. Clusters are randomly allocated to one of the four crossover positions in a 1:1:1:1 ratio.

Cluster	Period 1	Period 2	Period 3	Period 4	Period 5
1	Control	Intervention	Intervention	Intervention	Intervention
2	Control	Control	Intervention	Intervention	Intervention
3	Control	Control	Control	Intervention	Intervention
4	Control	Control	Control	Control	Intervention

Figure 1. Stepped-wedge design matrix. Each period is 8 weeks.

The study applies a superiority framework, testing whether the intervention yields better outcomes than standard practice during the control periods.

In the qualitative study, data will be gathered through focus group interviews (20) with the healthcare staff at all four sites to get a deeper understanding of and explore the healthcare professionals’ perspectives on how the digital intervention was used, and how it impacted practice.

Methods: Participants, interventions and outcomes

Trial setting {13}

The trial will be conducted across four hospital sites within The Kingdom of Denmark. All participating sites provide acute inpatient medical care and represent a mix of specialized and general medical wards.

The four sites are described below.

University Hospital Copenhagen, Bispebjerg, Denmark: A large urban tertiary hospital located in Copenhagen. The trial will be conducted in a pulmonary and infectious diseases ward, which admits adult patients with acute and chronic respiratory infections and complex infectious diseases.

University Hospital Aalborg, Hobro, Denmark: A regional hospital serving a mixed urban–rural population.

The participating ward is a mixed medical ward that admits adult patients with a broad spectrum of medical conditions.

Queen Ingrid's Hospital, Nuuk, Greenland: The largest medical facility in Greenland, providing secondary care to the national population. The participating ward is a mixed medical ward that admits adult patients with a broad spectrum of medical conditions.

The National Hospital of the Faroe Islands, Tórshavn, Faroe Islands: The primary secondary-care hospital for the Faroese population. The participating ward is a mixed medical ward that admits adult patients with a broad spectrum of medical conditions.

Across sites, the trial will recruit adult inpatients admitted for medical conditions. All locations have full access to electronic health records, standard diagnostic equipment, and the staffing necessary to ensure safe trial procedures.

Characteristics of the people who are needed for the trial

Characteristic	The people we would expect to see included
Age	All adults over the age of 18, meeting the inclusion criteria, can be included. We expect to see mostly older participants (> 60) given the nature of the trial being conducted in a medical hospital ward setting.
Sex	All sexes, meeting the inclusion criteria, can be included. Male and female will be reported, based on the participants' social security numbers.
Gender	Man and woman will be reported
Race, ethnicity and ancestry	Participants' race, ethnicity and ancestry will not be reported as this data will not be collected.
Socioeconomic status	Participants' socioeconomic status will not be collected nor reported
Geographic location	We will report in which country participants were recruited for the trial. The countries are Denmark, Greenland and The Faroe Islands. We expect that most participants will be from Denmark, as two of the four sites, one large, are in Denmark.
Other characteristics relevant to the trial	

Eligibility criteria for participants {14a}

A patient is eligible to participate in the study if he/she/they meet all criteria below:

1. Is admitted to one of the participating wards
2. Has understood and signed informed consent
3. Reads and understands Danish, Faroese, Greenlandic or English

A patient is not eligible to participate in the study if he/she/they meet any of the criteria below:

1. Has an expected hospitalisation less than 24 hours after potential recruitment
2. Is not able to give informed consent to participate in the study
3. Has allergy towards band aid
4. Not able to (shortly – 15 seconds) stand in an upright position even with maximal assistance
5. There are contraindications for the patient to mobilise or be physically active due to unstabilised acute medical conditions, including, but not limited to, acute aortic dissection, -myocardial infarction, -pulmonary embolism, -sepsis.
6. There are ethical concerns regarding the patients' participation in the study, including, but not limited to, the patient being:
 - In the terminal phase of life
 - In a crisis state regarding their disease/situation and deemed unfit for participation

To ensure medically responsible inclusion of patients, the project personnel will confer with the treatment responsible medical doctor, or their delegate, before including a potential participant for the trial.

Eligibility criteria for sites and those delivering interventions {14b}

Sites are eligible to participate if the majority of their admissions involve patients requiring medical (non-surgical) treatment. Sites where their primary admissions consist of patients requiring surgical, trauma, psychiatric, or neurological care, are not eligible.

Individuals responsible for recruiting patients and delivering the intervention (project personnel) will be physiotherapists employed at the respective trial sites. The logistical arrangements for project personnel's assignments in the trial and their specific assignments within the department, will be coordinated and agreed upon with site management.

Who will take informed consent? {32a}

Oral and written information will be provided to the eligible patient by project personnel within the first 48 hours of the patient's admission. Consent prior to participation in the trial will be given based on the written and oral information. Due to the nature of the study, conducted in an acute hospital setting, with high patient turnover, the typical 24-hour consideration time will not always be possible to provide. However, the patient will be provided with the time needed to read and understand the information given. If a participant decides to participate and sign the consent form, they can withdraw their consent at any time without any impact on any future investigations and/or treatments at any site or by any of the members of the research group or project personnel. Informed consent from an eligible participant is sought within the first 24 hours of the first contact by the designated project personnel at the respective site.

Additional consent provisions for collection and use of participant data and biological specimens {32b}

N/A as no ancillary study is planned.

Intervention and comparator

Intervention and comparator description {15a}

All participating patients (control and intervention period) will have their PA measured with a valid and reliable SENS Motion® activity monitor, a tri-axial accelerometer (sensor) (13, 14) embedded in a medical band aid (Fig. 2). The sensor will measure and record the participants' PA and is discretely worn on the lateral side of the thigh, approximately 10 cm above the lateral condyle of the femur. The sensor is waterproof and does not interfere with other activities related to the treatment or care of the patients. The adhesive used is tested for allergens and is standard in medical adhesives and can easily be changed and moved under supervision.

The sensor samples accelerations at 12.5 Hz continuously during hospitalisation and is connected via Bluetooth technology to a dedicated app that uploads data to a secure server. The sensor has on board memory capacity for approximately two weeks to prevent data loss due to occasional lack of connectivity. In the app, an inbuilt algorithm detects the orientation and movements of the sensor and classifies the recordings as lying/sitting, standing, or walking, as well as it records the number of steps taken by the patient.

Comparator (control period):

Participants will receive usual hospital care and be provided with a sensor placed on their thigh collecting data on their PA level during hospitalisation (Fig. 2), by the project personnel. A device with an application, that connects with the sensor (uploading data to server), will be placed out of sight from the participant with the screen turned off.

Intervention (intervention period):

The intervention targets 1) patients and 2) staff and is described in the following:

- 1) Besides receiving usual hospital care and being provided with a sensor placed on their thigh collecting data on PA level during hospitalisation, the participants in the intervention period will also be provided with a monitor placed at their bedside (Fig. 3B) by the project personnel. The monitor has an application installed that displays information about their PA level, in terms of time (hours and minutes) of PA (comprising measurement of standing and walking) and step count based on the participants' real-time PA measurement. The monitor also nudges the participant towards increasing their PA, using gamification that illustrates the participant getting further and further towards a goal based on their amount of PA, i.e., the more active the patients is, the closer to the goal they get. This feedback and nudging will be visible to the health personnel, the patients, and their relatives.
- 2) In the intervention period, the healthcare staff will have a digital display monitor (Fig. 3C) placed at

their offices at the respective site, providing continuous information about the patients' PA levels. The display monitor will highlight the most sedentary patients by classifying their mobilisation status as:

- Green: The patient has been active, i.e., has stood up and/or walked (with/without help) for ≥ 15 seconds in the last three hours.
- Yellow: The patient has **not** been active, i.e., has **not** stood up or walked (with/without help) for ≥ 15 seconds, in the last three to twelve hours.
- Red: The patient has **not** been active, i.e., has **not** stood up or walked (with/without help) for ≥ 15 seconds, in over twelve hours.

If a patient's mobilisation status is yellow or red, it will turn green as soon as the patient gets out of bed (stands upright and/or walks (with/without help) for ≥ 15 seconds).

The patients' mobilisation status will turn grey on the display monitor in the nighttime (from midnight to 6AM), indicating sleeping period.

The first three hours of the patient's participation in the intervention, before the algorithm classifies whether the patient's mobilisation status is 'green', 'yellow' or 'red', it will remain blue on the staff's display monitor.

The project leader (D.G.) will coordinate with the respective site management in order to place the staff monitor at an appropriate location at the wards as they stepwise are randomised and allocated to intervention period.



Figure 2. Control period (Image: Courtesy of SENS Innovation)

Patients will be provided with a sensor, placed on their thigh, measuring their physical activity during hospitalisation.



Figure 3. Intervention period (Image: Courtesy of SENS Innovation)

Patients will be provided with a sensor, placed on their thigh, measuring their physical activity during hospitalisation (Fig. 3A) and a monitor, placed on their bedside table, providing feedback, and nudging regarding physical activity, by means of gamification (Fig. 3B).

The staff will have a digital overview over the patients' physical activity levels at their offices (Fig. 3C). An algorithm highlights the most sedentary patients.

Qualitative study

A qualitative study with the aim of exploring the healthcare staff's experience with the intervention and their perspectives on how and why the digital intervention was (or was not) used, and how it impacted practice, is planned to be conducted at the end of the clinical trial.

The study will use a qualitative, multi-site design employing semi-structured focus group interviews with healthcare staff across the four hospital sites.

The approach will primarily be deductive as the data analysis and the analytical approach will be informed by two complementary theoretical lenses:

1. Normalisation Process Theory (NPT) as this approach provides a tool to examine the work that individuals and teams undertake to implement and embed a new practice (sense-making, engagement, enactment, appraisal) (21, 22).
2. Technological mediation (TM) as the approach explores how the digital intervention shapes perception, action, and relations in care practices (e.g., how activity becomes "visible," how responsibilities shift, and how interactions with patients are transformed) (23).

Together, these approaches will support analysis of both implementation dynamics (NPT) and practice/experience transformation (TM). Further, the analyses are open to other perspectives, thereby having an inductive approach as well.

Participants will be eligible if they are employed as healthcare staff at one of the four sites in the intervention period, have had experience with using the digital intervention in inpatient care in the intervention period, and are able to participate in a focus group conducted in Danish or Faroese. Participants must provide informed consent before participation.

Data will be collected through one semi-structured focus group interview at each of the four sites. Each focus group will include a sample of 5-8 participants (20). The focus group interviews will be audio recorded and

transcribed verbatim.

Analysis will be conducted using reflexive thematic analysis (24) to identify patterns of meaning across the dataset, while being sensitised by the study's theoretical lenses. NPT and TM will be used as interpretive frameworks, supporting explanation of *how* and *why* the intervention was (or was not) used, and *how* it shaped practice.

Findings will be reported in accordance with established qualitative reporting standards.

Criteria for discontinuing or modifying allocated intervention/comparator {15b}

Participants will generally continue in their assigned intervention or control group for the full duration of the trial. However, discontinuation or modification may occur under the following circumstances.

Participant request: Participants may withdraw from the digital intervention or comparator at any time without providing a reason and without consequences for their usual care.

Adverse events or safety concerns: If the participant reports adverse effects, significant discomfort, technical issues causing distress, or any safety concern judged by the research team to be related to the digital intervention, access may be paused or discontinued.

Clinical deterioration: If a participant's clinical condition substantially worsens such that continued participation is inappropriate or burdensome (as determined by the clinical team), the intervention may be modified or stopped.

Technical limitations: Persistent technical problems (e.g., device incompatibility, system failure) that prevent meaningful use of the intervention may lead to discontinuation or modification.

Non-adherence that compromises safety or data integrity: If the participant repeatedly misuses the intervention in a way that poses risk or undermines the trial's safety principles, the research team may discontinue access.

Investigator decision: The principal investigator may discontinue or modify the allocated intervention if required for participant safety, ethical reasons, or regulatory guidance.

In all cases, participants who discontinue the intervention will be encouraged to remain in the study for outcome assessments unless they request full withdrawal. All reasons for discontinuation or modification will be documented in the trial log.

Strategies to improve adherence to intervention/comparator {15c}

To improve adherence to the digital intervention and ensure consistent exposure across participants and health care staff, the following strategies will be implemented:

Participants will receive an introduction to the tablet-based system, after enrolment to the trial, including a brief demonstration of key functions. The interface is designed to be intuitive, with clear icons, and provide immediate feedback, nudging the participant to increase their PA levels. The project personnel will adapt their demonstration and take questions from the participants to make sure that the participant understands the feedback and nudging mechanisms.

To enhance the implementation and use of the intervention by the healthcare staff, we will employ the Normalisation Process Theory (21) as implementation framework, promoting sense-making, engagement,

enactment and appraisal among the staff.

The healthcare staff at each site will attend standardised information and training sessions on the intervention at the start of the intervention period to ensure sense-making as well as consistent understanding and implementation across locations.

To facilitate engagement, local champions within the existing staff structure will be identified and recruited to function as embedded facilitators who support the integration of the intervention into routine clinical workflows. Their responsibilities will include promoting awareness of the intervention, encouraging consistent use, providing informal troubleshooting, and identifying context-specific barriers that may influence implementation fidelity.

To enhance staff awareness, enactment and promote consistent focus on patient mobilisation, the trial incorporates a feedback mechanism summarising ward-level PA and SB patterns from the preceding week. Feedback is delivered using a traffic-light system (green, yellow, red), which provides an immediate, easily interpretable indication of performance relative to the previous week. This structured visualisation is intended to support desired behaviours, and prompt reflection and appraisal on potential facilitators and barriers to patient activity within routine care.

The project personnel will check up on the digital equipment (tablets, chargers, sensors, staff overview) on a daily basis and will make sure to replace defect equipment as soon as possible when a technical issue has been detected. The project leader (D.G.) and project personnel will have access to continuous technical support by SENS Innovation for rapid troubleshooting.

Concomitant care permitted or prohibited during the trial {15d}

For safety reasons, participants must not wear the sensor during MR scans. In these events, the sensor will be removed during the scan and replaced afterwards. This procedure will be logged with date and time for removal and replacement.

Ancillary and post-trial care {34}

N/A – there is no ancillary or post-trial care planned. No compensation to those who suffer harm from trial participation.

Outcomes {16}

Primary Outcome

The primary outcome will be daily average minutes of PA (standing and walking time combined) measured in minutes per day, using the SENS Motion® activity monitor (sensor).

- Measurement variable: Daily active time (minutes/day), defined as periods classified as *activity* (standing and walking time combined) by the monitor's activity algorithm.
- Analysis metric: Mean/median minutes of PA/day.
- Method of aggregation: Mean/median minutes of PA/day at cluster level and at group level (intervention vs. control)

- Time point(s): From enrolment until discharge, maximum measurement time is seven days (aligns with the general average length of stay in the participating wards and captures the full expected range of in-hospital activity patterns) (Table 1).

Secondary outcomes

Daily average minutes of SB (sitting/ lying time) measured in minutes per day, using the SENS Motion® activity monitor (sensor).

- Measurement variable: Daily sedentary time (minutes/day), defined as periods classified as *sedentary* (sitting and lying time combined) by the monitor's activity algorithm.
- Analysis metric: Mean/median minutes of SB/day.
- Method of aggregation: Mean/median minutes of SB/day at cluster level and at group level (intervention vs. control).
- Time point(s): From enrolment until discharge, maximum measurement time is seven days (Table 1).

Daily average number of steps per day, using the SENS Motion® activity monitor (sensor).

- Measurement variable: Daily step count, defined as periods classified as *stepping* by the monitor's activity algorithm.
- Analysis metric: Mean/median steps/day.
- Method of aggregation: Mean/median steps/day at cluster level and at group level (intervention vs. control)
- Time point(s): From enrolment until discharge, maximum measurement time is 7 days (Table 1).

Length of stay.

- Measurement variable: Days of hospitalisation
- Analysis metric: Mean/median days of hospitalisation, defined as day count from date of admission to hospital to date of discharge.
- Method of aggregation: Mean/median days of hospitalisation at cluster level and at group level (intervention vs. control)
- Time point(s): At discharge (Table 1).

Readmission within 90 days

- Measurement variable: Was the participant readmitted within 90 days of discharge
- Analysis metric: Dichotomous (yes/no). *Yes* and *no* are defined as whether or not readmission is registered in the patient record within 90 days of discharge.
- Method of aggregation: Proportion of participants who experienced at least one readmission during the measurement period at cluster level and at group level (intervention vs. control)
- Time point(s): 90 days follow-up (Table 1).

Discharge destination

- Measurement variable: Discharge destination

- Analysis metric: Categorical (own home, nursing home, rehabilitation facility, other). Categories are defined as destination registered in the patient record in the discharge summary.
- Method of aggregation: Proportion of participants discharged to each destination category at cluster level and at group level (intervention vs. control)
- Time point(s): At discharge (Table 1).

In hospital falls.

- Measurement variable: Did the participant fall during hospitalisation
- Analysis metric: Dichotomous (yes/no). *Yes* and *no* are defined as whether or not a fall is registered in the patient record during the measurement period.
- Method of aggregation: Proportion of participants who experienced at least one fall during the measurement period at cluster level and at group level (intervention vs. control)
- Time point(s): At discharge (Table 1).

Death within 90 days

- Measurement variable: Did the participant die within 90 days of discharge
- Analysis metric: Dichotomous (yes/no). *Yes* and *no* are defined as whether or not death is registered in the patient record within 90 days of discharge.
- Method of aggregation: Proportion of participants who died during the measurement period at cluster level and at group level (intervention vs. control)
- Time point(s): 90 days follow-up (Table 1).

Demographic and clinical descriptive outcomes

Participants' age (number), sex (male/female), height (cm), weight (kg), current smoking status (yes/no) will be obtained from the participants' patient records at enrolment (Table 1).

Participants' preadmission functional level, measured by New Mobility Score (NMS) (25, 26), will be collected by questionnaire at enrolment (Table 1).. The NMS scores three activities - indoor walking, outdoor walking, and walking while shopping - each from 0 (not able) to 3 (independent) points, resulting in a total score ranging from 0-9 points. A higher total score indicates higher preadmission functional level.

Current basic mobility level, measured by Cumulated Ambulation Score (CAS) (27), will be collected by clinical assessment at enrolment (Table 1). The CAS assesses a patient's basic mobility - getting in/out of bed, going from sitting to standing, and walking inside - each scored from 0 (not able) to 2 (independent) points, resulting in a total score ranging from 0-6 points. A higher total score indicates a higher basic mobility level.

Participants' primary and secondary diagnoses (as registered in participant's discharge summary in the patient record) will be obtained from participants' patient records at discharge.

Harms {17}

The following potential harms might be anticipated and will therefore be registered and reported

1. Falls during participation due to potential higher degree of PA
2. Skin irritation related to the adhesive used for attaching the sensor
3. Other unforeseen adverse events (e.g., discomfort, device-related issues)

Definition and assessment of harms: Expected harms include minor skin irritation associated with adhesive use and falls occurring during hospitalisation. Unexpected harms are defined as any adverse event not routinely associated with the intervention or monitoring procedures. All harms will be assessed systematically through daily monitoring conducted by project personnel throughout the participant's involvement in the study.

Monitoring procedures: Project personnel will perform daily check-ins to identify whether any harm has occurred (yes/no). If a harm is reported or observed, the event will be examined and documented in the study log. In the case of skin irritation, the affected area will be visually inspected, and the severity and extent will be recorded. For any harm requiring clinical attention, a physician will be consulted.

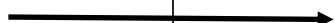
Classification and terminology: Harms will be grouped and categorised using a predefined set of categories (e.g., falls, skin-related events, other).

Reporting of harms: All harms identified during participation, both expected and unexpected, will be systematically recorded and included in trial documentation. The trial's final publications will report all recorded harms.

Participant timeline {18}

Table 1. Participant timeline

	TRIAL PERIOD				
	Enrolment		Project period		Follow-up
TIMEPOINT	<i>Admission to ward</i>	<i>Within 48 h of admission</i>	<i>Hospitalisation</i>	<i>Discharge</i>	<i>90 days post discharge</i>
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation to pre-specified current cluster status (control/intervention)		X			
INTERVENTION/ COMPARATOR:					
<i>Intervention period</i>		X if cluster is in			

		intervention period			
Control period		X if cluster is in control period			
ASSESSMENTS:					
Demographic and clinical data		X			
Preadmission functional level (New Mobility Score)		X			
Basic mobility score (Cumulated Ambulation Score)		X			
Daily PA time (sensor)			X 		
Daily SB time (sensor)			X 		
Daily step count (sensor)			X 		
Length of stay				X	
In-hospital falls				X	
Discharge destination				X	
Readmission within 90 days					X
Death within 90 days					X

Sample size {19}

With four clusters, an assumed standard deviation of 80, derived from the pilot study (15) and the previous randomized study (16), an average cluster size of 20 (a total number of 400 observations), a dropout rate of 10% (i.e., a total of 440 observations adjusting for drop-out), and an intra cluster correlation (ICC) of 0.1, the planned stepped-wedge trial will be adequately powered (80%) to detect a difference of more than 38 minutes in daily physical activity. A clinically meaningful difference based on recent and robust available knowledge in the field (10).

Recruitment {20}

Potential eligible participants will be identified during daily interdisciplinary conferences at the participating wards, where project personnel review printed patient lists used for treatment purposes. The project personnel will discuss possible candidates with the ward staff, and if a patient appears eligible according to the in- and exclusion criteria, they consult the responsible medical doctor (or delegate) to confirm the patient's suitability (emphasis on safety and ethical considerations) for the trial. Individuals who meet preliminary eligibility criteria will then be approached by the project personnel, who will provide verbal and written information about the study, including purpose, procedures, risks, and benefits.

To mitigate risk of selection bias, the project personnel will start at the same end of the ward every day and work their way from there, consecutively approaching preliminary eligible patients.

Assignment of interventions: randomisation

Sequence generation: who will generate the sequence {21a}

The random allocation sequence determining the order in which the clusters transition from control to intervention will be generated by an independent statistician using computer algorithm.

Sequence generation: type of randomisation {21b}

The randomisation will be simple/unrestricted. Clusters (hospital wards) will be the unit of randomisation, an independent statistician (not involved in recruitment) will randomly allocate clusters to one of four groups indicating the order of transition for each cluster.

Allocation concealment mechanism {22}

An independent statistician will generate the concealed randomisation schedule. The allocation sequence will be stored in a secure, restricted-access file and will not be accessible to investigators or project personnel until each cluster's transition point. Allocation will be revealed step-by-step through a centralised system (e-mail from independent statistician to project leader) following completion of each cluster period. Only then will the respective cluster be informed of their assigned crossover date.

Implementation {23}

Project personnel who will enrol and assign participants will not have access to the random allocation sequence. At each scheduled step of the stepped-wedge rollout, the cluster assigned to transition from control to intervention will be notified and begin implementation within 48 hours following the preceding data-collection period. Project personnel at all sites will receive training and operational guidelines to ensure readiness for implementing the intervention when it is their turn. Fidelity will be monitored using structured checklists, any deviation will be addressed promptly. Data collection will continue identically before and after crossover to maintain comparability across steps.

Assignment of interventions: blinding

Who will be blinded {24a}

Due to the nature of the intervention and study design, blinding of project personnel directly involved in recruitment and intervention delivery will not be feasible. Nor will it be possible to blind the participants. Outcome assessment of the primary outcome (daily minutes of PA) and two of the secondary outcomes (daily minutes of SB and daily step count) is objective (measured by accelerometer) and will thus not be affected by the issue of blinding. Outcome assessors for the remaining secondary outcomes (in-hospital falls, length of stay, discharge destination, readmission within 90 days, and death within 90 days) will not be blinded. This is not considered a major concern, as these outcomes are routinely documented in the patient records and therefore not easily influenced or altered by the assessors. Data analysts will be blinded to cluster allocation throughout the trial as the primary analyses will be conducted on datasets without allocation labels.

How will be blinding be achieved {24b}

Data analysts will be blinded to cluster allocation throughout the trial as the primary analyses will be conducted on datasets without allocation labels.

Procedure for unblinding if needed {24c}

Unblinding will not occur for operational convenience and will only be authorised by the principal investigator (PI) (C.D.) in situations where it cannot compromise study integrity. In the event of the necessity for unblinding, a designated member of the data management team, who is *not* involved in statistical analysis, will perform the unblinding.

Data collection and management

Plans for assessment and collection of outcomes {25a}

Outcome assessors will receive training before commencement of the trial and regular calibration meetings will be held across sites throughout the trial to ensure data quality.

All data (besides PA and SB, that will be uploaded to server) will be collected, either by assessment or from the patient records, and registered in designated data collection forms (Table 2).

PA and SB data will be obtained via the wearable tri-axial accelerometer and be continuously upload to a secure server. At the end of the trial, the accelerometer data will be exported from the server (CSV format) for analyses.

Table 2. Data collection form

Data collection form	
Patient information at enrolment	
Patient ID	
Sensor ID	
Ward name	
Verbal and written information provided	Yes/No
Informed consent obtained	Yes/No
Sensor placed on thigh	Yes/No
Tablet placed out of sight for data collection (control)	Yes/No
Tablet introduced to participant (intervention)	Yes/No
Patient ID registered in trial log	Yes/No
Age	Number
Sex	Male / Female
Height	Cm
Weight	Kg
Current smoker	Yes/No
New Mobility Score	Questionnaire, 0-9 points, higher score indicates higher preadmission functional level
Cumulated Ambulation Score (incl. walking aid)	Clinical test, 0-6 points, higher score indicates higher current basic mobility level
Date of admission to hospital	Day, month, year
Date of admission to ward	Day, month, year
Date and time of application of sensor	Day, month, year; hour, minutes
Isolated at ward (infection risk)	Yes/No
Patient information at discharge	
Patient is <i>discharged</i> in SENS Motion® app	Yes/No
The sensor, tablet, charger and tablet holder (only intervention) has been disinfected correctly	Yes/No
Date and time of removal of sensor	Day, month, year; hour, minutes
Date of discharge/transfer from ward	Day, month, year
Date of discharge from hospital	Day, month, year
Discharge destination	From participants patient record (own home, nursing home, rehabilitation facility, other)
Falls during hospitalisation	Yes/No
Primary diagnosis	From participant's discharge summary in patient record
Secondary diagnoses	From participant's discharge summary in patient record

Skin irritation	Yes/No, if yes: describe severity and action
Other harm	Yes/No, if yes: describe severity and action
Was a physician consulted regarding harm	Yes/no
Did the digital feedback and nudging make sense to the patient?	Yes/No/Neither/Not asked; Patient comment (if applicable)
Patient information at 90 days follow-up from discharge	
Readmitted within the last 90 days	
Died within the last 90 days	

Plans to promote participant retention and complete follow-up {25b}

Given that this trial will be conducted in a hospital setting with medical inpatients, where all primary data are collected during the inpatient stay and follow-up outcomes can be obtained directly from patient records, we anticipate high participant retention and a minimal risk of loss to follow-up.

For participants who discontinue or deviate from the intervention, the following outcome data will still be collected whenever feasible: Primary and secondary outcome measures, clinical outcome measures as well as safety outcomes.

Data management {26}

Approved data management agreements across all sites and with SENS Innovation are in place. All agreements are registered and uploaded at the Capital Region's official research registry (ref.nr. p-2023-15144).

Data will be entered into a designated Redcap trial database using standardised electronic case report forms. To minimise entry errors, the system will incorporate built-in validation rules. Data entry will be performed by trained study personnel at each site, and all entries will be date- and time-stamped to ensure traceability.

All collected variables will be coded according to a predefined data dictionary developed before trial initiation. Qualitative or free-text fields will be coded using structured categories as appropriate.

All electronic data will be stored on secure, encrypted servers compliant with institutional data-security policies. Access will be role-restricted based on the principle of least privilege, ensuring that personnel only access the data necessary for their trial duties.

Data will be backed up automatically at regular intervals using institutionally approved backup procedures.

All study data will be retained for the legally required 5 years. After this retention period, data will be securely destroyed unless ongoing storage is approved for secondary research.

Confidentiality {33}

Participant confidentiality will be safeguarded through the use of unique study identifiers in place of personal information. Only authorised members of the data-management and analysis teams will have access to re-identification keys, which will be stored in a password-protected and encrypted file separate from study data. Any transfer of data between sites or investigators will occur through secure, encrypted channels. Routine data-quality checks will be conducted throughout the trial, including assessments of completeness, internal consistency, and adherence to coding rules. Queries generated from these checks will be issued to site staff for clarification or correction. A final data-cleaning process will be completed prior to database lock and statistical analysis.

Statistical methods

Statistical methods for primary and secondary outcomes {27a}

Baseline characteristics will be summarized descriptively using counts and percentages for categorical variables and means with standard deviations or medians with ranges for continuous variables as appropriate. The extent of missing baseline data will be reported.

The primary outcome will be analysed using a linear mixed-effects model based on the Hussey–Hughes framework (28), with random intercepts for sites and participants, fixed effects for intervention status and time period, and a constraint ensuring no baseline differences between study conditions. All tests will be two-sided with statistical significance defined as $p \leq 0.05$. The secondary continuous outcomes, sedentary behaviour, and steps per day, will be analysed using linear mixed-effects models with the same random and fixed effects structure as the primary analysis. The secondary binary outcomes, in-hospital falls, 90-day readmission, and 90-day mortality, will be evaluated using mixed-effects logistic regression with random intercepts for sites and participants when repeated measurements are present, along with fixed time-period and intervention effects. Results for binary outcomes will be reported as odds ratios with 95% confidence intervals. The secondary count outcome, length of stay, will be analysed using mixed negative binomial regression models with a random intercept for sites and participants and fixed effects for time period and intervention. The secondary categorical outcome, discharge destination, will be compared using multinomial logit models with cluster-robust variance estimation. All secondary outcomes will be presented with point estimates and 95% confidence intervals. No adjustments for multiplicity are planned.

All statistical models will account for the stepped-wedge cluster randomized design by incorporating both cluster (site) and time-period effects. Participant flow through the trial will be summarized using a CONSORT diagram adapted for stepped-wedge trials (18). All analyses will be conducted by a study statistician using validated statistical software.

Who will be included in each analysis {27b}

All analyses will follow the intention-to-treat principle. Participants will be included in the analytical dataset if they remained in the study for at least 24 hours.

How missing data will be handled in the analysis {27c}

Missing data will be addressed using mixed complete-case models, which provide valid likelihood-based estimates under missing-at-random assumptions. The extent of missing data for each outcome will be reported.

Methods for additional analyses (e.g. subgroup analyses) {27d}

Prespecified subgroup analyses will explore whether intervention effects differ by age, sex, baseline functional status, or study site. These analyses will be implemented by adding interaction terms between intervention status and each subgroup variable to the mixed-effects models and will be interpreted as exploratory.

Interim analyses {28b}

No interim analyses are planned.

Protocol and statistical analysis plan {5}

The complete statistical analysis plan (SAP) will be uploaded as a separate document to the ClinicalTrials.gov record prior to data lock and start of any data analysis. Any subsequent amendments to the protocol or SAP will be documented, dated, and reported in the trial registry to ensure full transparency.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {3d}

The coordinating centre for this trial will be the PI (C.D.) and the project leader (D.G.), both employed at the Department of physio- and occupational therapy, University Hospital Bispebjerg and Frederiksberg. The coordinating centre will be responsible for the overall organisation and day-to-day conduct of the trial, including communication with participating wards, staff training, monitoring protocol adherence, and addressing operational issues. It will also oversee ethical and regulatory compliance, manage protocol amendments, and ensures that timelines and study milestones will be met. The coordinating centre will meet bi-weekly throughout the trial period.

The trial steering committee will be C.D. (PI), M.R. and M.P. The committee will provide strategic oversight and ensure that the study is conducted in accordance with the approved protocol, good clinical practice, and ethical guidelines. The steering committee will meet approximately every other month.

The data management team will be the PI (C.D.) and the project leader (D.G.), and they will be responsible for establishing and maintaining secure data systems, monitoring data completeness and accuracy, and conducting routine quality checks. The team will manage data queries, ensure adherence to data protection regulations, and prepare final datasets for analysis. The team will meet bi-weekly throughout the trial period.

Composition of the data monitoring committee, its role and reporting structure {28a}

There will not be appointed an independent data monitoring committee, as the intervention is a low-risk behavioural intervention with very limited safety concerns and short exposure.

Frequency and plans for auditing trial conduct {29}

The coordinating centre will perform **regular central monitoring** through weekly online meetings with the local project personnel across sites and through access to back-end version of the digital intervention.

Monitoring will include checks for missing data, range errors, protocol deviations, timeliness of reporting and quality check of devices/equipment.

Protocol amendments {31}

In the event of important protocol modifications, the coordinating centre and trial steering committee will follow a predefined amendment process to ensure regulatory compliance and transparency, including contacting the respective health research ethics committees, trial registries, and institutional- and regulatory bodies. Implementation of any substantial amendment will not occur until formal written approval has been obtained. All amendments will be logged and communicated as appropriate to relevant parties.

Dissemination policy {8}

Study findings will be published in peer-reviewed journals, presented at conferences, and shared with participating hospital staff and patients, regardless of the direction, magnitude, or statistical significance of the results.

This protocol adheres to the *Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)* checklist (29). The reporting of the findings will follow *Reporting of stepped wedge cluster randomised trials: extension of the CONSORT2010 statement* (19) (Appendix 1).

Discussion

We believe that this study protocol, describing a large multicentre trial, will represent a significant contribution to the field of hospital-based PA promotion and digital health implementation in a clinical setting. However, conducting a trial involving implementation of a digital intervention in a busy hospital ward environment, may introduce some practical and operational considerations. The study will to a high degree be dependent on close collaboration with clinical staff, whose competing clinical responsibilities may influence the consistency of intervention delivery and data collection. To address this, structured training, regular communication, and ongoing support will be integrated into the study procedures. The trial will also rely on routine clinical data registration, which may be affected by variations in documentation practices or temporary equipment failures. Mitigation strategies will include predefined data-quality checks and the use of multiple data sources when available.

Conducting the study within an acute care setting will also require careful planning to minimise disruption to

clinical workflows. Factors such as patient turnover, isolation precautions, and variable staffing levels may affect implementation across time periods. Furthermore, the stepped roll-out of the intervention may introduce logistical challenges related to timing and staff familiarity, which will be monitored by the coordinating team. Although these issues have been considered in the design and operational planning of the trial, unforeseen challenges may still arise during implementation. Any such issues will be documented, reviewed by the trial steering committee, and reported transparently in future publications.

In the embedded qualitative study, we will explore contextual, practical, and relational factors that shape the use and impact of the intervention in the clinical setting. We will examine both anticipated and unanticipated influences and challenges related to implementation and use among the staff. In this way the qualitative study can complement the knowledge that will derive from the clinical trial by shedding light on healthcare professionals' perspectives and generate insights and a deeper understanding of the results.

Trial status

Protocol version 1.1., version date May 14th, 2025.

The trial is ongoing, with participant recruitment not yet complete. Recruitment began May 19th, 2025, and will be complete by March 20th, 2026.

This protocol describes a prospective clinical study that has not completed recruitment and thus eligible for protocol publication in BMC journals. The study has received external funding and formal ethics approvals, meeting BMC's requirements for considering protocol manuscripts.

Abbreviations

PA: Physical activity

SB: Sedentary behaviour

NMS: New Mobility Score

CAS: Cumulated Ambulation Score

PI: Principal investigator

SAP: Statistical analysis plan

Declarations

Acknowledgements

We would like to thank all members of the research team and collaborating institutions for their valuable contributions to the development of this study protocol.

We acknowledge the support of the sponsor, which has made this work possible. Sponsor had no role in the design of the study, the writing of this manuscript or in the decision to submit the protocol for publication.

Authors' contributions {3a}

The study was conceived and designed by C.D. (PI) and D.G. (project leader), with substantial methodological and clinical input from M.R., M.P., S.S. and J.A.

D.G. led the development of the trial protocol, coordinated contributions from all authors, and oversaw revisions. N.B., the trial statistician, designed the statistical analysis plan and provided guidance on sample size calculations and analytical methods.

All authors reviewed, critically revised, and approved the final protocol manuscript.

Corresponding author: Durita Viderø Gunnarsson

Sources of funding and other support {7a}

Department of physio- and occupational therapy, University Hospital Bispebjerg Frederiksberg

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Research Council Faroe Islands (0369)

Greenland Research Council (68b7b)

Internal Research Fund of the Hospital Service Faroe Islands (7061)

Health Innovation Fund, North Denmark Region (2025-0012)

No funding body has had any role in the design of the study, nor will they have any role in analyses, interpretation of data or in writing of the manuscript.

Availability of data and materials {6}

Individual participant data will not be shared due to confidentiality considerations and data protection regulations (GDPR). De-identified dataset can be made available upon reasonable request.

The PI (C.D.) and project leader (D.G.) will have access to the final dataset.

Ethics approval and consent to participate {30}

Ethics approval has been obtained in all three relevant countries.

Denmark: Medical Research Ethics Committee; ref.nr. VMK-2403916

Greenland: The Greenland Research Ethics Committee; ref.nr. 2024-9829

The Faroe Islands: The Faroese Health Research Ethics Committee; Exempt Institutional Review Board (IRB) determination, no reference number (confirmation mail, date May 30th, 2024).

Consent for publication

Not applicable

Competing interests {7b}

The authors declare that they have no competing interests.

Authors' information (optional)

Appendices

Appendix 1: *Reporting of stepped wedge cluster randomised trials: extension of the CONSORT2010 statement*

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