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Telemedicine-supported hospital-at-home for acutely admitted patients at Nordsjaellands Hospital, Denmark: a study protocol for a randomised controlled trial

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ABSTRACT

Introduction The combination of a reduction in the Danish hospital bed count, the shortage of hospital staff and demographic changes challenges the Danish hospital capacity. This was further highlighted during the COVID-19 pandemic when hospitals worldwide were overwhelmed by infected patients requiring acute hospital care. To address these challenges, a hospital-at-home (HaH) programme offers an alternative to conventional in-hospital admission. Furthermore, HaH has the potential to improve patient outcomes, reduce costs and increase patient satisfaction. However, few studies have evaluated HaH in a Scandinavian setting, and this article describes the protocol for a randomised controlled trial (RCT) comparing an HaH model with continued conventional in-hospital admission. The main aim of the trial is to evaluate physical activity level and mental wellbeing in patients admitted at home compared with conventionally admitted patients.

Methods and analysis 110 clinically stable patients from two internal medical wards at Nordsjaellands Hospital in Denmark will be included and randomised in a ratio of 1:1 to either continued conventional in-hospital admission (control group) or virtual HaH model (intervention group). The control group will receive standard hospital treatment, and the intervention group will be transferred home for continued treatment (eg, intravenous antibiotics or oxygen treatment). The primary outcome measures are physical activity assessed using daily step count (during the first 24 hours after inclusion, as an intermediary indicator of the risk of adverse events) and treatment satisfaction (assessed using a patient satisfaction survey). Secondary outcome measures are adverse events of special interest, escalation of care, readmission rate postdischarge (30 days and 90 days), mortality (associated and 7 days, 30 days and 90 days postdischarge), process data (eg, the number of teleconsultations) and a health economic evaluation.

Ethics and dissemination The study was approved by the Danish Research Ethics Committees (no. 2303051) and the Danish Medicines Agency (CIV-23-03-042542) and will be monitored by the Copenhagen University Hospital Good Clinical Practice unit. Results will be published in peer-reviewed journals and presented at relevant national and international conferences. We also plan to communicate the results to relevant stakeholders in the Danish healthcare system.

Trial registration number NCT05920304.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The randomised controlled trial (RCT) has been preceded by usability and feasibility studies that have informed the design of the RCT including the selected endpoints.
⇒ By evaluating both patient-related outcomes, telemedicine and organisational outcomes and economic outcomes of our vHaH model, results of this RCT may aid stakeholders in decision-making, thereby impacting healthcare practices and resource utilisation.
⇒ Use of a validated motion sensor for reliable and unbiased monitoring of patients' physical activity levels.
⇒ Due to the nature of the study, where participants are randomly allocated to treatment at two different locations (home or hospital department), blinding of participants is not feasible.

INTRODUCTION

Over the past decades, the Danish healthcare system has centralised its medical and surgical specialties. This has led to the closure of smaller local hospitals and the construction of fewer but larger hospitals. As a result, the national hospital bed count for somatic care has decreased over the years from 16 241 beds in 2010 (2.93 beds per 1000 citizens) to 11 675 beds in 2021 (2.00 beds per 1000 citizens), representing a reduction of 31.7%.[1] Concurrently, the Danish healthcare system is facing challenges in recruitment and retention,

particularly with a shortage of nurses, compounded by demographic changes[2 3] that increase the demand for hospital care among the elderly. These factors are already straining hospital capacity, emphasising the necessity to prioritise hospital beds without compromising the general quality of care. Furthermore, seasonal epidemics such as influenza and respiratory syncytial virus (RSV) and indeed pandemics such as COVID-19 can lead to sudden surges in hospital admissions, potentially exceeding hospital capacity.[4]

By receiving hospital care at home, frail and elderly patients can benefit from hospital quality care and treatment without the risk of hospital-associated complications. This approach also tends to result in higher satisfaction for patients and their families.[5–9] Hospitalisations and sudden immobility due to acute illness are associated with a variety of clinical complications, such as an increased risk of nosocomial infections, thromboembolic events, delirium and functional decline due to inactivity.[10–15] These are conditions that affect a large proportion of patients worldwide and cause increased morbidity and mortality, as well as an increased duration of hospitalisation. Maintaining physical activity has the potential to improve appetite,[16 17] prevent muscle loss, hyperglycaemia and constipation, and thereby enhance overall patient outcomes.[18–20]

Various versions of hospital-at-home (HaH) models have been implemented as an emergency solution to a steep increase in the number of hospitalisations during the COVID-19 pandemic crisis. Conventionally, epidemic patients who require medical monitoring will be admitted to the hospital. Recently, patients hospitalised for COVID-19 requiring medical supervision for an extended period—sometimes weeks—have been admitted to their homes supported by telemedicine and/or a mobile hospital-based care team (MHCT). Various models of home-based admissions of pandemic patients have been implemented internationally with great results regarding safety and effectiveness.[21–24] These models are mostly based on the physical attendance of physicians in the patient's home and are in most situations implemented out of need. Home-based models provide promising results regarding costs, but results are based on low-quality evidence.[9] Health systems facing capacity constraints and rising costs need to allocate resources based on high-quality evidence.

Reducing hospital admissions and delivering treatment closer to or in the patients' homes is a key objective for various stakeholders in the Danish healthcare system, aimed at fostering a more cohesive and accessible healthcare experience.[25] However, Danish healthcare infrastructure and capacity will not allow for HaH models primarily depending on the physical attendance of physicians in the patient's home, nor will it be possible to manually monitor all patient-reported data. Therefore, we saw a need for a telemedicine-supported virtual HaH (vHaH) model with a smart algorithm alarming clinical staff and thereby aiding in the timely handling of patient data and clinical state. This also aligns with other models being evaluated in randomised controlled trials (RCTs), for example, Mayo Clinic's Advanced Care at Home programme.[26]

This controlled clinical trial will be part of a large project called *Influenzer*, which aims to develop, implement and evaluate a novel HaH model that will enable safe and satisfactory admission of hospitalised patients, including epidemic patients, in their homes. This study protocol is based on the results from two other small-scale studies embedded within the *Influenzer*. The development stages before the RCT included the development of the technology and standard operating procedures, an in-hospital usability test and a feasibility study.[27]

The *Influenzer* vHaH model is comprised of features of complex interventions as defined by Medical Research Council guidance, and the work has been guided by a framework for complex intervention development.[28] Therefore, relevant stakeholders were involved in the development of the telemedicine solution and the workflows around home hospitalisations. Also, key learning points from the feasibility study drove the decision on how to design the RCT and guided in the development of our programme theory (see figure 1*: Influenzer programme theory*). This was developed informed by the existing evidence, for example, the positive effects of physical activity[20] and the empirical data from the interviews with patients and primary informal caregivers who experienced the programme in the feasibility trial.[27] It is expected that patients admitted at home will have a higher physical activity level when compared with conventionally admitted patients, thereby leading to better clinical outcomes for the patients.

Objective

This article describes the protocol for an RCT that compares the *Influenzer* vHaH model to a conventional in-hospital admission. The aim is to investigate the effect on the primary endpoints (physical activity level and patient mental wellbeing, satisfaction and perceived safety) and the secondary endpoints (patient-related endpoints, process data and economic endpoints).

Hypotheses

We hypothesise that physical activity level, nutritional status and mental wellbeing will increase in patients hospitalised with acute illness or an acute exacerbation of chronic disease if they are randomised to a telemedicine-supported vHaH model (intervention group) compared with patients randomised to a conventional in-hospital trajectory (control group).

Also, we hypothesise that the intervention group will experience their treatment course to be at least as safe and satisfactory as the control group.

Finally, we hypothesise that the intervention will be a viable, cost-neutral alternative to the conventional in-hospital patient trajectory for the selected patient population.

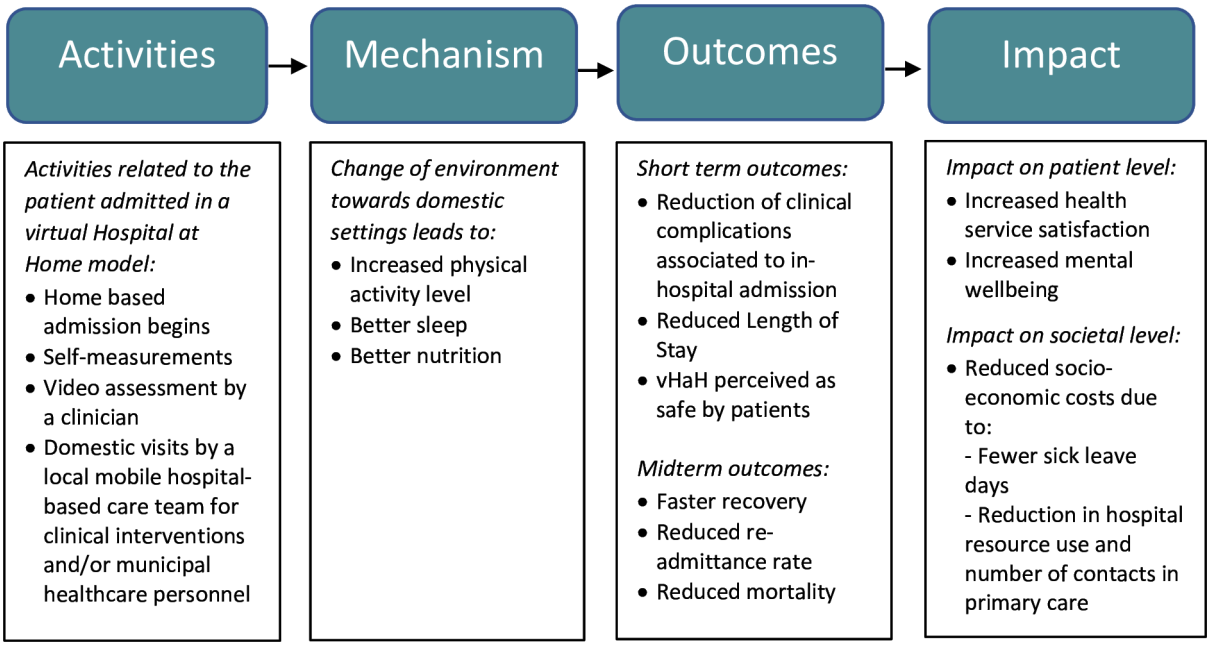

Figure 1 Influenzer programme theory. vHaH, virtual hospital-at-home.

METHODS AND ANALYSIS

The *Influenzer* RCT study flow is presented in figure 2: *Influenzer RCT study flow.*

Study design and setting

We will conduct an RCT in the period between 1 June 2023 and 1 June 2025, where enrolled participants will be randomised to either vHaH (intervention group) or conventional hospitalisation (control group) in a ratio of 1:1.

The study will be carried out at Nordsjaellands Hospital, Hilleroed, Denmark, in collaboration between four departments—the Department of Clinical Research (where the trial is coordinated and the research team is rooted), the Department of Pulmonary and Infectious Diseases (DPID) and the Department of Endocrinology and Nephrology (ENA) (from where the participants will be included) and the Department of Multimorbidity (where the local MHCT is rooted).

The protocol was developed per the Standard Protocol Items: Recommendations for Interventional Trials.[29] This is V.1.4 of the protocol, and it was registered at https://www.clinicaltrials.gov/ on 26 May 2023 (NCT05920304), before initiating the inclusion of participants. Any amendments to the protocol will be reported to the Danish Research Ethics Committees and the Danish Medicines Agency.

Apart from aiding in the development of the *Influenzer* programme theory through interviews from our feasibility study, patients and the public were not formally involved in the design and planning of the RCT.

Participants

The study aims to include 110 patients admitted to either DPID or ENA at Nordsjaellands Hospital. Inclusion criteria are as follows: age of 18 years or older; a patient admitted to DPID or ENA; residential address (either permanent or temporary, ie, a holiday home) within the catchment area of Nordsjaellands Hospital and a treatment regimen which can be handled within the vHaH model. Exclusion criteria are as follows: unstable clinical condition defined by a current Early Warning Score (EWS) >6 or single score=3 (see online supplemental table 1); permanent physical or cognitive impairment or observed non-compliance that might negatively affect the ability to perform required actions during the intervention, such as self-measurements, data transfer via the app and communication through telephone or video consultation; unproficiency in Danish and pregnancy.

Recruitment process and informed consent

Patients admitted to the DPID or ENA will be identified as potential study participants by their clinicians. The identified individuals will be provided with a short information pamphlet about vHaH and requested by clinicians for interest in being a part of the *Influenzer* project. If interest is expressed, the potential study participants will receive full oral and written information regarding the study provided by a member of the research team.

According to Danish legislation when testing new medical devices, women of childbearing age will be tested for possible pregnancy.

A medical doctor (MD) will assess the potential study participant's eligibility against all inclusion and exclusion criteria, and the information will be entered into the database (Research Electronic Data Capture (REDCap)). Also, consent to participate will be documented and registered by the study group in REDCap.

Because home-based admission is a complex intervention and logistics in some cases require several hours and even days of activities ahead of the early transfer,

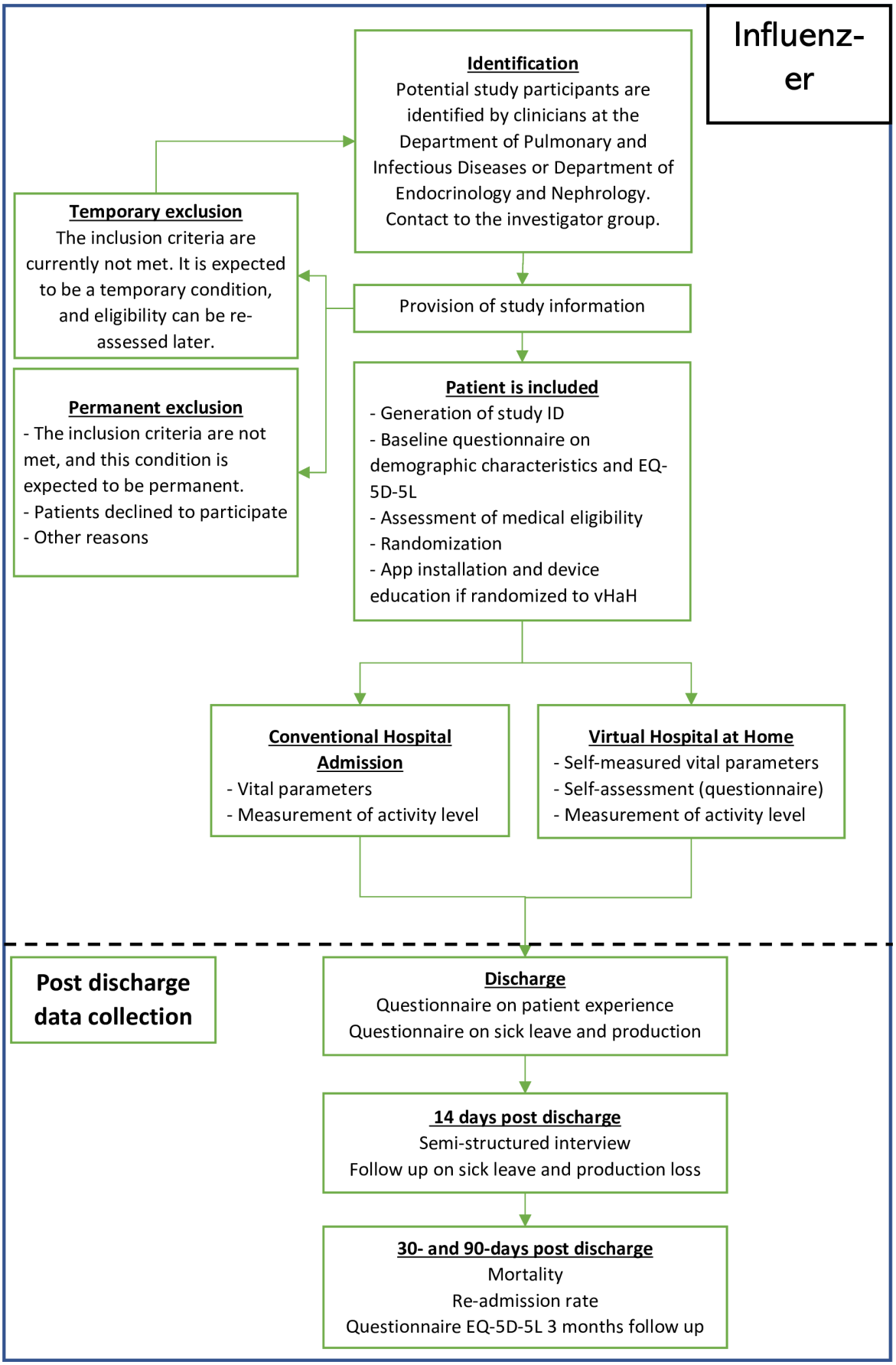

Figure 2 Influenzer RCT study flow. RCT, randomised controlled trial. EQ-5D-5L, The EuroQol-5 Dimension-5 Levels questionnaire.

participants who enrol in the intervention group will undergo a final clinical assessment by an MD (non-study) on the day of the transfer to home-based admission. If any condition that has an impact on the eligibility of the participant changes, the participant will stay at the hospital and be excluded from the intervention, but stay in the study, and will be a part of the intention-to-treat analysis. Furthermore, any reason for non-initiated intervention (defined as a participant who is randomised to the intervention group but never gets transferred from the hospital to his home) will be noted in REDCap.

Patients who do not wish to participate in the study will be asked for reasons for declining participation, to shed light on the underlying causes.

Randomisation and blinding

Study participants will be randomised to either vHaH or conventional hospitalisation in a ratio of 1:1. Randomisation will be stratified by the hospital department of admission. The randomisation process will be performed by a member of the research team using a computer-generated randomisation sequence in the randomisation module in REDCap. Due to the nature of the intervention, where patients are physically treated and monitored at a different location than the hospital, blinding of participants, informal caregivers and hospital staff will not be possible, which introduces a potential risk of detection and performance bias.[30 31] However, the SENS motion activity sensor and other similar activity trackers have previously been validated to be used for monitoring patients' activity levels.[32]

Treatment courses

All participants will wear an activity tracker on the thigh (SENS motion sensor), and they will be asked to answer questionnaires at baseline, on discharge and 3 months after discharge.

Conventional hospital admission (control group)

Participants in the control group will continue their hospital treatment unchanged, and they will be discharged when there is no further need for hospital admission.

Virtual hospital-at-home (vHaH; intervention group)

Participants in the intervention group will be provided with expanded information about the concept of vHaH before initiation of home-based admission. Information includes a description of the telemedicine monitoring and communication model, the technology used, all relevant workflows for both participants and healthcare staff, together with detailed safety instructions and an emergency plan. The participant will be provided with mobile equipment for domestic use, which includes a pulse oximeter (which also measures respiratory rate), an electronic blood pressure monitor and a thermometer. If relevant, participants can be further provided with other equipment such as a blood glucose metre or a weighing scale.

Any necessary domestic arrangements will be made before home-based admission begins, and participants will be offered transportation home. For those requiring supplemental oxygen therapy, the oxygen installation will be completed in their home prior to the home-based admission. Participants and their relatives will receive comprehensive instructions on the safe use of the domestic oxygen equipment.

When home-based admission begins, participants will be monitored and be able to get in touch with hospital staff 24/7. Patients are required to report health data at least two times per day according to EWS. They will receive daily ward rounds Monday through Friday and during the weekend if found necessary (same procedure as for conventionally admitted patients). Ward rounds will be virtual and will be supported by video if applicable. The hospital staff are not dedicated solely to the HaH patients; they work in a regular hospital ward and care for both HaH patients and conventionally admitted patients. Therefore, it is necessary for the information technology (IT) system to generate alarms so that staff can be guided in timely handling of patients.

The telemedicine component is developed by an external provider in collaboration with the researchers who founded the idea and concept of the home-hospital care model and the hospital staff. The IT solution is comprised of a dedicated app on the patient's smartphone or a tablet (designed for transferring vital parameters, self-reported symptoms and contact requests as well as having an overview of the planned activities) and a hospital-based monitoring programme for the hospital staff (designed for receiving patient data, generating alarms in case of, for example, out-of-range data, and planning activities for the patient).

Supporting the telemedicine concept, hospital-based or community-based healthcare personnel will perform clinical tasks including intravenous administration of medications, blood samples and on-site clinical assessment in the participant's home, when relevant.

Hospital staff can terminate home-based admission and transfer the participant back to the hospital if found necessary (ie, due to clinical deterioration or lack of compliance). The participant and their coliving informal caregiver can also terminate home-based admission if feeling insecure.

Participants will be discharged when they are assessed by an attending MD as of no further need of admission.

Outcome measures

The primary outcome measures will be physical activity level stratified by study inclusion day, for example, day 0=first 24 hours after study inclusion, day 1=24–48 hours after study inclusion, etc, and evaluation through questionnaires and semistructured

Box 1 Outcome measures

Primary outcomes:
- ⇒ Physical activity level. Day 1 and day 2 will be time windows of primary interest.
  - ⇒ Daily step count
  - ⇒ Time (minutes) in different activities (eg, rest time, standing time, walking time, running and high intensity movement time and cycling time)
- ⇒ Evaluation through questionnaires and semistructured interviews of:
  - ⇒ Patient mental wellbeing
  - ⇒ Patient satisfaction
  - ⇒ Patient-perceived safety
- ⇒ Patient-related endpoints
  - ⇒ Demographic characterisation of patients eligible for virtual hospital-at-home
  - ⇒ Biomarkers (measured in routine blood samples):
    - ⇒ Albumin level in plasma
    - ⇒ C reactive protein
    - ⇒ Leucocytes
  - ⇒ Weight in dialysis patients (measured routinely in relation to dialysis)
  - ⇒ Adverse events of special interest (AESI)
  - ⇒ Readmittance rate postdischarge (30 days and 90 days)
  - ⇒ Mortality (associated and 7 days, 30 days and 90 days)
- ⇒ Process data (only relevant for participants in the intervention group)
  - ⇒ Percentage of timely service delivery in response to red alarms as a sign of clinical deterioration (health workers demonstrate adequate ability in telemedicine service delivery).
  - ⇒ Percentage of scheduled video consultations which were delivered.
  - ⇒ Important device events
- ⇒ Economic endpoints (3 months follow-up):
  - ⇒ Intervention costs
  - ⇒ Number of in-hospital days
  - ⇒ Number of outpatient visits
  - ⇒ Costs of hospital resource use
  - ⇒ Number of contacts in primary care (general practitioner, physiotherapy, etc)
  - ⇒ Costs of primary care resource use
  - ⇒ Total costs of health care utilisation per patient
  - ⇒ Quality adjusted life years gained

interviews of patient mental wellbeing, patient satisfaction and patient-perceived safety.

Secondary outcome measures will include patient-related outcomes, process data and economic evaluations. Please see box 1 for a full list of outcomes.

Sample size

A previous study performed at the Department of Pulmonary and Infectious Diseases, Nordsjaellands Hospital, Denmark[20] has shown that patients admitted with pneumonia were predominantly sedentary with a median daily step count of 1356 steps per day (IQR 778–1965). The study also showed a reduction in length of stay and reduction in in-hospital and 30-day mortality for every 500-step increase in daily step count. As this is the same department with the same patient profile, we find a difference of 500 daily steps to be clinically relevant. Therefore, we want to test if patients admitted at home will have a daily step count of 500 steps or more above the conventionally admitted patients. With an α of 0.05, a power of 0.8 and a δ of 500, we will need to include 47 participants in the intervention arm and 47 participants in the control arm, when including in the ratio 1:1. To account for potential dropouts or other circumstances, we wish to include 55 participants in the intervention arm and 55 participants in the control arm.

Data

After randomisation and before the potential commencement of home-based admission, study participants will be equipped with an activity tracker (a SENS motion sensor) to measure daily step count and physical activity level during admission. Also, study participants will be asked to complete questionnaires according to the study flow diagram in figure 2. In case of missing completion of follow-up questionnaires (on discharge and 3 months postdischarge), the participant will receive a reminder—either electronically (via secure mail) or by phone.

Process data will be extracted from Modulus Care (MC) and the Electronic Patient Record (EPR).

Biomarkers (routine blood samples), weight in dialysis patients, adverse events of special interest, readmittance rate and mortality will be extracted from the EPR.

Data on resource use and costs will be collected from:
- Administrative systems: MC, EPR and The National Health Insurance Register
- Observations and time registrations of work processes
- Questionnaires: baseline, sick leave and productivity loss and EuroQoL EQ-5D-5L[33]

Data from MC and EPR will be collected by a research physician who is not involved in the intervention or the treatment of the patients. Data from The National Health Insurance Register will be collected by a health economist.

Data from the activity tracker will be stored in the SENS database, and other data will be collected and managed using REDCap electronic data capture tools hosted at the Capital Region of Denmark.[34 35] REDCap is a secure, web-based software platform designed to support data capture for research studies. All data will be handled and stored per the Danish Data Protection Agency requirements.

Statistical analyses

Statistical analyses will be performed by the research physician and the health economist with the assistance of an external biostatistician without any knowledge of the participants. Analyses will be performed using R (R Core Team, 2023).[36]

Demographic variables will be visualised using descriptive statistics using means and ranges for continuous variables and percentages for categorical variables.

The primary analysis of the primary endpoint will be a linear regression additively adjusted for age and gender as well as the stratification variable (department

of admission). We employ a significance level of 5% and report 95% CI for the adjusted mean difference.

Secondary outcomes will be analysed as the primary for continuous variables and using adjusted logistic regression for binary variables. In case of severe non-normality in the residuals of the linear regressions, a bootstrap procedure will be employed to ensure valid p values. Secondary outcomes will be assessed at a 5% level with no adjustment for multiple testing. A test hierarchy with mortality and readmission (in that order) will be employed. Accordingly, firm conclusions are possible on the primary endpoint and the two secondary endpoints in the test hierarchy. For other secondary endpoints, significant findings will be considered explorative.

The primary analyses will be in the intention-to-treat population. An explorative analysis excluding patients in the intervention group who never end up being home-admitted will be performed.

There are no subgroup analyses planned.

No interim analyses will be performed.

We expect that some patients will have incomplete information on the primary outcome. This can happen when the activity monitor is removed (or otherwise fails) before the first full 24 hours. To accommodate this, as well as respect natural variations in activity across the day and night, we will record step counts per completed 1-hour interval. If some of these are missing, we will do multiple imputation for missing 1-hour slots using activity measures and adjustment variables, as well as time of day as covariates. These 24 variables for each person will then be summed to provide a measure for the full 24 hours. For completely measured patients, the procedure will of course not change the value of the primary outcome variable. We will perform the full analysis, as described above, on each of five imputed datasets and will then combine using Rubin's rule as per standard multiple imputation technique.

Health economic evaluation will be based on the clinical study and use an estimation approach, rather than a hypothesis testing approach.

Mean resource use, costs, utility values and quality-adjusted life years (QALY) will be estimated for the intervention and control groups.

Resource use and costs will be reported by arithmetic mean per patient on average and by 95% CIs. Data on healthcare use might be skewed, so the difference between groups on total costs will be estimated accordingly. Coefficient of the group variable will be reported for crude and adjusted models.

QALYs will be derived from EQ-5D-5L values at baseline and 90 days after randomisation. Danish utility weights will be assigned to the EQ-5D-5L responses, to obtain utility scores. The area under the resulting utility curves will be used to calculate mean QALY in each group. For the estimation of mean QALYs in the *Influenzer* and control arm, a regression-based adjustment will be carried out.

The incremental cost-effectiveness ratio will be estimated based on incremental costs and QALYs. Overall uncertainty of the ICER will be evaluated through probabilistic sensitivity analysis with bootstrap resample and 95% CI.

Ethics and dissemination

The *Influenzer* study adheres to the principles of the Helsinki Declaration. The study was approved by the Danish Research Ethics Committees (no. 2303051) and the Danish Medicines Agency (CIV-23-03-042542) and will be monitored by the Copenhagen University Hospital Good Clinical Practice unit.

All participants will receive written and oral information about the trial aims and procedures by a member of the research group before informed consent (please see online supplemental material for information material and consent form). It will be clearly stated that participation is voluntary and that they can withdraw at any time. Withdrawal from the study will not affect any subsequent treatments. Participants will be covered by the standard patient compensational arrangements (Patienterstatningen), since all participants suffering an injury caused by a health science experiment in Denmark are covered by Patienterstatningen.

Information on (serious) adverse events and device events is documented consecutively and will be reported to relevant authorities.

Results will be published in peer-reviewed journals and presented at relevant national and international conferences, for instance, the World Hospital at Home Congress. We also plan to communicate the results to relevant stakeholders in the Danish healthcare system, and we are already in contact with central Danish health authorities (such as the Ministry of the Interior and Health, Danish Health Authority, Danish Patient Safety Authority, Danish Medical Agency and Danish Medical Association) who are following our study with interest.

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Contributors Each author has made substantial contributions to the conception and design of the trial, including the formulation of research questions and the provision of methodological expertise. TKF, as the originator of the idea of evidence-based HaH in a Danish setting, played a pivotal role in conceptualising and advocating for this innovative model. TKF and CDvS, serving as project managers, were instrumental in fostering collaborative efforts and ensuring the successful execution of the project. They also prepared the proposals for grant applications. MNL drafted the initial version of this study protocol and was responsible for

protocol development and approval processes with authorities. TKF, CDvS and TLN provided overarching guidance throughout the project. MKR led the economic analysis aspect of the design. All authors had a key role in revising the manuscript and have approved the final manuscript. TKF is the guarantor.

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Competing interests None declared.

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