Cost effective and Appropriate care by age and frailty adjusted Risk stratification of older patients in the Emergency medical Services

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Project title

Danish

Associationen mellem præhospital implementering af Clinical Frailty Scale (CFS) kombineret med en struktureret samtale og færdigbehandling på stedet samt omkostningseffektivitet – et implementerings- og kvalitetssikringsstudie (WHO-CARES II)

English

Associations of Prehospital Implementation of the Clinical Frailty Scale (CFS) Combined with a Structured Conversation with Non-Conveyance and Cost-Effectiveness – An Implementation and Quality Improvement Study (WHO-CARES II).

This study protocol has been translated from the original Danish study protocol using co-pilot.

Background

In Denmark, elderly patients constitute a significant proportion of prehospital contacts. A nationwide Danish registry-based study of ambulance contacts during the period 2018–2024 demonstrated that individuals aged 65 years or older accounted for more than half of all included ambulance contacts. Furthermore, this population exhibited an ambulance utilization incidence rate more than four times higher than that of individuals under the age of 65 (1).

A substantial proportion of patients assessed by the ambulance services and in emergency departments live with frailty. In a Danish multicenter study conducted across three emergency departments, more than 58% of patients aged 65 years or older were classified as frail (2). Similarly, a British study among patients assessed by ambulance services reported a mean age of 78 years, with 58.7% of the cohort presenting with frailty (3).

Among hospitalized elderly patients, frailty is associated with an increased risk of delirium, functional decline, and mortality, as well as a prolonged length of hospital stay (4, 5).

A systematic review examining the preferences and expectations of elderly patients regarding emergency department care showed that patients emphasized the importance of being involved in treatment decisions and having their individual needs and preferences taken into account (6). Additionally, an interview study among 22 elderly patients living with frailty indicated that participants generally preferred to remain in their own homes rather than being hospitalized; they placed significant value on feeling safe and receiving

adequate support at home (7). This underscores the need for person-centered acute care pathways for elderly patients living with frailty, where individual needs and preferences are integrated into clinical decision-making.
The Clinical Frailty Scale (CFS) is a validated clinical assessment tool used to identify and grade frailty in elderly patients (8, 9). Higher CFS scores are associated with increased mortality and functional decline (10, 11). The CFS is already utilized across various clinical settings, including emergency departments (10, 11). Furthermore, the CFS has previously been applied in prehospital practice (3), and a vignette-based study among ambulance personnel has demonstrated good inter-rater reliability during CFS assessments (12).

The CFS is scheduled to be implemented as part of the prehospital clinical assessment of elderly patients within the ambulance services in the Central Denmark Region (*Region Midtjylland*). The CFS can provide relevant information regarding the degree of frailty to inform clinical evaluation, while decisions regarding subsequent management should be based on a broader assessment of the patient's overall situation (10, 11, 13). Furthermore, the evidence supporting the application of frailty assessments in prehospital practice remains limited (14).
To structure this broader clinical evaluation, the Geriatric 5Ms framework can be utilized. This is a simple and structured framework that assists clinicians in maintaining focus on core domains of a holistic geriatric assessment, encompassing Mind, Mobility, Medications, Multi-complexity, and Matters Most (15, 16). The Danish version was recently adapted to the Danish healthcare system as an interprofessional and person-centered reference framework, focusing on applicability in clinical practice (16). Consequently, this framework can supplement data on the degree of frailty and contribute to a more holistic clinical assessment of elderly patients living with frailty (16).
However, there is still insufficient research on how combining frailty assessments with a structured, Geriatric 5Ms-based approach in the ambulance service impacts clinical decision-making and subsequent patient pathways (14, 17).
In addition, investigating how frailty screening can be combined with subsequent geriatric interventions has been highlighted as a key research priority within geriatric emergency medicine (17). Because the CFS is scheduled for a phased roll-out across the ambulance

services, this simultaneously provides an opportunity to evaluate the approach in prehospital practice before it is fully implemented region-wide.

Objectives

The objective of this project is to investigate whether the implementation of the Clinical Frailty Scale (CFS) combined with a structured conversation can support more person-centered and qualified decision-making regarding the management of elderly patients in prehospital care, including decisions regarding hospital admission or non-conveyance (treatment on scene).
Additionally, the project aims to investigate the associated clinical and healthcare economic consequences, including subsequent acute contacts, readmissions, mortality, length of hospital stay, and resource utilization.

Hypothesis

It is hypothesized that the implementation of a systematic prehospital assessment using the Clinical Frailty Scale (CFS) combined with a structured conversation based on the Geriatric 5Ms will increase the proportion of prehospital contacts that result in non-conveyance without transport to the hospital, compared to standard prehospital care.
Simultaneously, it is anticipated that the intervention will not lead to an increased incidence of subsequent acute hospital contacts, readmissions, or mortality.
Furthermore, it is expected that the intervention will be associated with a reduction in acute healthcare-related resource utilization and lower acute healthcare costs.

Study Design

The project will be conducted as a matched cluster-randomized parallel-group trial within the ambulance services of the Central Denmark Region, featuring delayed implementation in the control clusters after the completion of the study period.
The project is integrated with a regional administrative decision to implement the Clinical Frailty Scale (CFS) as part of the prehospital assessment of elderly patients. The intervention consists of the systematic application of the CFS combined with a structured geriatric conversation to support overall clinical decision-making.

Due to organizational and operational constraints, implementation cannot be carried out simultaneously across all ambulance units. This phased roll-out is therefore leveraged for a systematic evaluation: randomized intervention clusters will implement the CFS and the structured conversation during the study period, while matched control clusters continue standard prehospital care during the same calendar period. Following the completion of the study period, the intervention will be implemented in the control clusters in accordance with the regional implementation plan. Consequently, no permanent control group is established.

This design was selected to enable a comparison between ambulance clusters with and without the CFS implemented during the same calendar period. This reduces the risk of bias related to seasonal variation, shifts in the patient population and activity levels, as well as concurrent organizational changes within the healthcare system throughout the study period. Furthermore, the design allows for before-and-after analyses of patient pathways within the same cluster where relevant.

The project involves no experimental treatments, invasive procedures, or research-specific clinical examinations. The intervention consists of systematizing clinical assessments and communication, both of which fall within the scope of standard prehospital practice.

A questionnaire is included as part of the implementation and quality improvement component of the project. The questionnaire does not involve clinical intervention, alterations to treatment, additional diagnostics, or physical burden for the patients. Following a separate evaluation by the Regional Committee on Health Research Ethics, the questionnaire component is not inherently subject to notification requirements. The questionnaire component is therefore deemed not to alter the nature of the notified cluster trial as a low-risk study under Section 5a of the Committee Act (*Komitéloven*).

The CFS and the structured conversation are utilized as decision and communication support tools and do not alter the ambulance personnel's treatment responsibilities, triaging authority, available treatment options, or existing regional clinical guidelines. The option for non-conveyance already exists within current standard prehospital practice.

The methodological distinction between the intervention and control clusters is that the timing of implementation for the new clinical practice is determined by randomization, and that data for effectiveness and safety outcomes are subsequently retrieved from existing prehospital and hospital-based electronic health records and registry sources.

Cluster Definition and Randomization

Ambulance units constitute the primary cluster unit in this study. Clusters are defined based on the operational and organizational affiliation of the ambulance units. Ambulance units that share a physical station, personnel, shift structure, or daily operations are considered part of the same operational cluster.

Cluster formation was chosen to reduce the risk of contamination among ambulance personnel, as the intervention consists of the systematic application of the Clinical Frailty Scale (CFS) and a brief structured geriatric conversation as a supplement to the prehospital assessment. The intervention is assessed to have the potential to influence clinical decision-making and communication across personnel who work closely together within the same operational environment. Ambulance personnel within the same station frequently work across different ambulance units, share clinical experiences, and participate in joint organizational and professional workflows. Individual randomization was therefore deemed methodologically inappropriate due to the substantial risk of contamination between the intervention and control periods.

Prior to randomization, each ambulance cluster was characterized using historical, aggregated activity data from the prehospital dispatching system, LOGIS, for the period from June to November 2025. Data were compiled at the ambulance cluster level and included the total number of prehospital contacts, the distribution across urgency tiers A and B, the operational shift profile of the ambulance unit, and the proportion of contacts completed without hospital transport. The proportion of contacts completed without hospital transport was utilized as an indicator of the baseline level of non-conveyance (treatment on scene). These data were used solely for the characterization and matching of ambulance clusters and contained no personal data, electronic health record information, or personally identifiable data.

A predefined hierarchical matching strategy is applied, focusing on the comparability between clusters across variables with direct relevance to the primary analyses. The primary matching variable is the proportion of patients managed on scene at baseline, defined as the proportion of prehospital contacts completed without hospital transport relative to the total number of prehospital contacts.

Secondary matching variables include the proportion of patients managed on scene within predefined urgency tier categories as well as absolute activity volume. Urgency tiering is

stratified according to dispatch levels. Urgency tier A is defined as the highest urgency level involving ambulance dispatch with emergency lights and sirens, while urgency tier B is defined as the second-highest urgency level with a target response time within 30 minutes without emergency driving. Matching is performed based on both overall activity data and within the individual urgency tier categories.

To reduce the risk of contamination, ambulance units are grouped at the station level based on a shared physical base address. No station contributes ambulance units to both the intervention and control groups simultaneously. Where feasible, priority is given to assigning ambulance units from single-ambulance stations to the intervention group, whereas stations with multiple ambulance units primarily enter the control group. If multiple ambulance units from the same station are included in the intervention group, the entire station is treated as a single operational intervention cluster.

Only ambulance units with the same operational shift profile are matched with one another. Consequently, ambulances with a 24-hour shift profile (“DO”) are matched exclusively with other 24-hour shift ambulances, while day/intermediate shift profiles (“DA”) are matched with equivalent day/intermediate shift profiles.

Ambulance units simultaneously participating as intervention units in other ongoing interventional trials regarding non-conveyance and point-of-care testing (POCT) are excluded from participation to avoid overlap between interventions and potential confounding of the study data. The re-use of control ambulances from the POCT study is permitted.

Based on the total pre-intervention data from June to November 2025, the intervention group encompassed 6,980 prehospital contacts, and the control group encompassed 7,250 prehospital contacts. The proportion of patients managed on scene was comparable between the groups, at 22.3% in the intervention group and 21.9% in the control group, respectively. Minor residual differences between individual ambulance units are accepted, provided that the aggregated group-level data and the proportions of patients managed on scene remain comparable between the intervention and control groups.

Based on the baseline data, 15 matched cluster pairs are established, each consisting of one intervention ambulance and one control ambulance with comparable activity and dispatch profiles. The final matched cluster pairs define the cluster structure to be utilized

in all subsequent analyses. The complete overview of the matched ambulance clusters is provided in Appendix 5.

Following matching, the ambulance clusters are randomized 1:1 to either the intervention or control group via computer-generated randomization performed by an independent statistician with no involvement in clinical operations or data analysis. Intervention clusters will implement the systematic application of the Clinical Frailty Scale (CFS) and a brief structured geriatric conversation based on the Geriatric 5Ms as a supplement to the prehospital assessment, while control clusters continue standard prehospital care without the systematic use of the CFS.

Implementation is carried out sequentially due to organizational and operational constraints, meaning that the intervention is activated in a phased manner among the randomized intervention clusters. Control clusters continue standard care during the study period. Following the completion of the study period, the intervention will be implemented in the former control clusters as part of the regional roll-out.

The randomization sequence is stored centrally with the principal investigator until implementation. Blinding of ambulance personnel is not possible due to the nature of the intervention. Outcome data will subsequently be retrieved from existing electronic health records and registry data, and analyzed using pseudonymized datasets.

Study Population

Patient Population

Inclusion is assessed at the level of the individual prehospital contact. Consequently, the unit of analysis in this study is the individual ambulance contact and not the individual patient.

The study population encompasses patients aged 65 years or older who are assessed by the ambulance services following a 1-1-2 emergency call within the Central Denmark Region.

The age threshold of 65 years was selected as this is utilized both nationally and internationally to define elderly patients (18, 19). This age limit should not be interpreted as a biological boundary for frailty, nor does it imply that all patients aged 65 years or older live with frailty.

The CFS was originally developed as a clinical tool to grade the level of frailty in elderly individuals (8). The CFS has subsequently been evaluated prospectively among 2,191 emergency department patients aged 65 years or older. In this population, a higher CFS score was associated with shorter survival, even after adjusting for age, sex, and chief complaint (20).

Thus, documentation exists for the prognostic value of the CFS in an acute patient population that includes patients from the age of 65. In Denmark, the CFS has been introduced in emergency departments as part of the national DANFRAIL database, where—due to the clinical workload—it was decided to initially include patients aged 80 years or older. It is intended that DANFRAIL will eventually expand to include all elderly individuals over 65 years with frailty in the database (21).

However, the literature does not provide an unequivocal basis for establishing a higher age threshold at which the combined prehospital intervention using the CFS and the Geriatric 5Ms-based conversation yields the greatest clinical benefit. A higher age threshold would exclude patients in the 65–69 age group from systematic CFS assessment, including elderly patients with frailty and complex treatment or triaging needs. Inclusion from the age of 65 makes it possible to map the prevalence of frailty and the distribution of CFS scores among the included elderly patients assessed by the ambulance services in the Central Denmark Region. Concurrently, it enables the investigation of associations between age, degree of frailty, prehospital management, and subsequent patient pathways. The results can thereby contribute exploratory knowledge regarding the age groups for which the intervention may be particularly relevant, establishing a foundation for further research. On this basis, the inclusion criterion of 65 years or older is maintained.

Patient Inclusion Criteria

Patients are included in the study if:

- **The patient is 65 years or older** at the time of the prehospital contact.
- **The patient is assessed by the ambulance services** following a 1-1-2 emergency call within the Central Denmark Region.

Patient Exclusion Criteria

Patients are excluded if the prehospital contact involves:

- **Ongoing cardiac arrest** upon arrival of the ambulance personnel.
- **Any other time-critical or life-threatening condition** where required treatment or transport to the hospital must not be delayed.
- **Inter-hospital transport**.
- **Planned or scheduled patient transport**, including non-emergency supine patient transport/non-acute medical transport requested by a physician, general practice, hospital department, or other healthcare professional.
- **Inability to receive or comprehend trial information** and to make a decision regarding the research-related use of data.

Cluster and Personnel Criteria

Ambulance units constitute the primary unit for cluster formation and randomization. Included clusters encompass ambulance units operating within the Central Denmark Region and include *Præhospitalet, Region Midtjylland* (The Prehospital Emergency Medical Services, Central Denmark Region) and *Falck A/S, Region Midtjylland*. Ambulance units from Falck Samsø are excluded from participation, as a suitable matching cluster could not be identified for the randomization and matching process. Included personnel encompass ambulance staff with independent clinical treatment competencies employed within the ambulance services of the Central Denmark Region and affiliated with the included ambulance clusters.

Intervention

The intervention consists of a structured, frailty-based decision and communication support tool integrated into the existing prehospital assessment. The intervention does not alter available treatment options, referral pathways, escalation procedures, or formal criteria for hospital admission. All treatment and management decisions continue to be made within existing regional guidelines and under the standard clinical responsibility of the ambulance personnel.

Prior to initiating the two components of the intervention, and as part of standard prehospital care, the ambulance personnel perform a clinical assessment of the patient's condition. This includes an ABCDE review and an evaluation of whether a time-critical or life-threatening condition is present where required treatment or transport to the hospital must not be delayed.

If the initial clinical assessment indicates no immediate need for urgent treatment or transport to the hospital, ambulance personnel in the intervention clusters perform an initial assessment of the patient's frailty using the Clinical Frailty Scale (CFS). This is done to determine whether the patient is frail (defined as CFS ≥5) or non-frail (defined as CFS <5). This initial screening is supported by the project-specific training in the CFS provided to the ambulance personnel and a pocket card focusing on the distinction between CFS <5 and CFS ≥5. In case of doubt regarding the threshold between CFS <5 and CFS ≥5, the patient is classified as frail (CFS ≥5), in accordance with the recommendation to apply the higher CFS level when undecided between two categories (8). Patients with a known diagnosis of dementia are also classified as frail during the initial screening, in compliance with the CFS guidelines from the Danish Geriatric Society (*Dansk Selskab for Geriatri*) (22).

The initial assessment is only performed if it can be completed without delaying necessary treatment or transport. This applies to patients who otherwise meet the inclusion criteria. The initial CFS assessment is based on the patient’s baseline functional capacity prior to the current illness episode—typically corresponding to the patient’s functional status approximately two weeks before the acute prehospital contact—and not on the severity of the acute illness.

Patients classified as frail (CFS ≥5) during the initial CFS assessment subsequently receive the supplementary component of the intervention. This consists of a structured, holistic conversation based on a Danish-translated and prehospital-adapted version of the Geriatric 5Ms framework. The conversation serves as a systematic extension of the ambulance personnel’s standard history-taking and clinical information gathering. The conversation is conducted with the patient and, where relevant, involves relatives or care staff as part of the clinical assessment.

Patients classified as non-frail (CFS <5) during the initial CFS assessment do not receive the structured Geriatric 5Ms-based conversation; instead, they continue to be assessed and treated according to standard prehospital care. The threshold selecting patients with a CFS score of five or higher was chosen because this level is established in the literature as an indicator of clinical frailty (3, 22). This patient population frequently presents with complex treatment and referral needs and may therefore benefit particularly from a more

holistic approach. Following the completion of the patient contact, the precise CFS score (1–9) is determined and recorded in REDCap by the ambulance personnel.
The purpose of the structured conversation is to support the ambulance personnel's assessment and decision-making for patients with identified frailty and complex treatment or referral needs.
Information obtained from the initial CFS assessment and the structured conversation is utilized as decision support within the overall clinical evaluation, including during dialogue with the PEC physician (Prehospital Emergency Care physician / *AMK-læge*) and when evaluating the most appropriate management pathway within existing clinical treatment and referral frameworks. The intervention serves to support clinical reflection and structured communication; it is not utilized as a standalone triaging tool, scoring system, or algorithm for treatment decisions.
The application of the CFS and the structured conversation is part of the scheduled implementation of a more systematic frailty assessment for elderly patients in prehospital care. The intervention does not alter the ambulance personnel's treatment responsibilities, decision-making authority, or applicable clinical guidelines. Ambulance personnel continue to perform assessment and treatment according to standard care and may consult with the PEC physician as needed, in line with standard clinical practice.
Prior to implementation, ambulance personnel receive training on the application of the CFS and the Geriatric 5Ms. Additionally, local resource persons are designated to support the consistent application of the intervention.

Clinical Frailty Scale (CFS)

The Clinical Frailty Scale (CFS) is a clinical assessment scale based on overall functional capacity and the degree of frailty. The scale consists of nine categories ranging from 1 (very fit) to 9 (terminally ill) and is used to categorize patients based on their baseline functional level and overall degree of frailty.
The assessment is based on the patient's baseline function prior to the current illness episode, typically corresponding to the patient's functional status approximately two weeks before the acute prehospital contact. Thus, the CFS is utilized to assess the patient's baseline functional capacity and not to evaluate acute physiological illness severity. The

CFS is validated for use in patients aged 65 years or older and has previously been applied in both emergency departments and prehospital settings.
In the intervention clusters, the Danish version of the Clinical Frailty Scale, prepared and distributed by the Danish Geriatric Society, is used. The Danish version includes an official structured algorithm based directly on the original CFS category descriptions. The algorithm operationalizes the assessment through sequential questions corresponding to the individual CFS levels and is used as decision support to promote a more consistent assessment within the prehospital context. The CFS algorithm used is presented in Appendix 7.
As part of the project's implementation and quality improvement component, the precise CFS score is systematically recorded in REDCap following the completion of the patient contact to enable continuous monitoring of the implementation and subsequent analysis.
The CFS is applied without modifications to the official Danish version. Permission to use the Danish version was obtained from the Danish Geriatric Society (DSG) prior to the start of the study

The Structured Conversation – Geriatric 5Ms

The Geriatric 5Ms is a structured geriatric reference framework developed to support person-centered assessment, communication, and shared decision-making for elderly patients. The framework encompasses the domains of Mind, Mobility, Medications, Multi-complexity, and Matters Most.
In this project, a prehospital-adapted version is utilized, focusing on rapid holistic assessment, clinical reflection, and structured communication within the prehospital setting. This adaptation was carried out to ensure feasibility and utility in an acute prehospital context. The individual domains are operationalized as practically applicable questions, observations, and reflection points related to the patient's current situation, baseline functional capacity, social circumstances, and treatment preferences. The prehospital-adapted version is detailed in Appendix 6.
Matters Most is prioritized as a core domain in order to identify the patient's wishes, treatment goals, and preferences in the current situation. Where appropriate, relatives or caregivers may contribute to the conversation.

Mind encompasses the assessment of cognitive function, awareness, and any acute changes in mental status. **Mobility** includes baseline functional capacity, mobility, balance, gait function, and fall history. **Medications** covers medication utilization, recent medication changes, treatment adherence, and factors with potential relevance to the patient's current condition. **Multi-complexity** encompasses multimorbidity, social situation, care requirements, frequency of healthcare utilization, and other factors contributing to the patient's overall complexity.

The Geriatric 5Ms framework is applied to support structured holistic assessment, clinical reflection, and communication. The framework does not function as an algorithm, scoring system, or exclusion tool, and it does not introduce changes to the ambulance personnel's treatment competencies or applicable clinical guidelines.

The prehospital version was developed through Danish translation and contextual adaptation for prehospital use. The final version was subsequently qualified through feedback from ambulance personnel prior to its implementation in the study.

Training of Ambulance Personnel

Prior to the implementation of the intervention, ambulance personnel in the intervention clusters receive training on the application of the Clinical Frailty Scale (CFS) and the prehospital-adapted version of the Geriatric 5Ms. The objective of this training is to support correct and uniform application of the intervention components within the prehospital assessment of elderly patients.

The training is delivered via e-learning and consists of three short modules covering: CFS assessment, the Geriatric 5Ms as a structured approach to assessing elderly patients, and the application of the CFS and Geriatric 5Ms in prehospital clinical practice.

The anticipated total completion time is approximately 30–45 minutes. The content covers the assessment of the patient's baseline functional capacity, distinguishing between acute functional decline and baseline frailty, the application of the CFS (including the initial screening between CFS <5 and CFS ≥5), and the use of the Geriatric 5Ms as structured support for holistic assessment, communication, and clinical reflection.

The modules include short theoretical sections, case-based elements, reflection exercises, and integrated learning questions designed to reinforce comprehension and application of the CFS and Geriatric 5Ms in prehospital practice. The training is completed before the

intervention is activated within each individual intervention cluster. The CFS is presented as a clinical decision support tool and not as a standalone criterion for treatment limitation, hospital admission, non-conveyance, or other treatment and triaging decisions. It is emphasized that all decisions regarding treatment, referral, and subsequent patient management continue to be made within existing regional guidelines and under the standard clinical responsibility of the ambulance personnel.

Control

Control clusters continue standard prehospital care without the systematic application of the Clinical Frailty Scale (CFS) and without the use of the structured conversation based on the Geriatric 5Ms. Ambulance personnel in the control clusters do not receive training on the application of the CFS or the 5Ms during the study period.
Patients in the control clusters are assessed and treated according to applicable regional clinical guidelines and standard prehospital care. Ambulance personnel continue to perform standard clinical evaluations based on symptoms, vital signs, medical history, and overall clinical impression, and they may consult with the PEC (Prehospital Emergency Care) physician as needed as part of standard practice.
The option for non-conveyance (treatment on scene) without hospital admission already exists as part of current prehospital care and remains unaltered by the project. Consequently, the control group is not deprived of existing treatment options or clinical courses of action. No systematic recording of the CFS or structured geriatric conversations will be conducted in the control clusters during the study period.
Following the completion of the study period, the intervention will be implemented in the former control clusters as part of the regional roll-out of the CFS within the ambulance services.

Outcomes

Primary Outcome

The primary outcome is the proportion of prehospital contacts that are managed on scene (non-conveyance) without transport to the hospital.

Secondary Outcomes

Secondary outcomes encompass:

- **Unplanned hospital contact within 72 hours** following the prehospital contact among patients managed on scene.
- **Unplanned hospital admission within 72 hours** following the prehospital contact among patients managed on scene.
- **Repeated contact with the ambulance services within 72 hours** following the prehospital contact among patients managed on scene.
- **On-scene time** (time spent at the scene of the incident).
- **30-day all-cause mortality**.
- **Length of stay** during the index hospital admission.
- **Hospital-free days within 30 days** following the prehospital contact.
- **Intensive Care Unit (ICU) admission** during the index hospital admission.

Healthcare economic outcomes encompass resource utilization related to ambulance transport and hospital contacts within 7 days following the prehospital contact. This includes costs related to emergency department care, diagnostics, outpatient contacts, and hospital admissions, calculated utilizing relevant DRG (Diagnosis Related Groups) and DAGS (Danish Outpatient Grouping System / *Dansk Ambulant Grupperingssystem*) tariffs, as well as activity-based registry data.

Data Collection and Data Sources

Data are collected from existing prehospital and hospital-based electronic health records and registry databases, as well as from entries made by ambulance personnel in the intervention clusters. Electronic health record and registry data are retrieved for patients in both the intervention and control clusters, whereas project-specific recordings of the CFS and the Geriatric 5Ms are performed exclusively within the intervention clusters.

Prehospital data are retrieved from the electronic prehospital patient record (PPR / *PPJ*) and the dispatch and logistics system, LOGIS. From LOGIS, information is obtained regarding the urgency tier, the chief complaint based on the Danish Index criteria recorded during dispatch, and data on the prehospital disposition—including whether the patient was transported to a hospital or managed on scene and, in the event of transport, to which

hospital the patient was conveyed. Furthermore, information is retrieved regarding the ambulance dispatch and task timeline, including relevant timestamps for task assignment, arrival on scene, departure from scene, and completion of the assignment. Information concerning repeated contact with the ambulance services within 72 hours following the prehospital contact is also obtained.

Hospital data are retrieved from the electronic health record (EHR / *EPJ*) as well as relevant regional healthcare registries. This encompasses information regarding the patient's hospital course, including diagnostic data to describe the cause of admission and compile comorbidities, the CFS score recorded in the emergency department, hospital contacts and admissions within 72 hours following the prehospital contact, length of stay during the index admission, hospital-free days within 30 days, ICU admission during the index admission, and 30-day all-cause mortality.

The data sources are linked at the individual level via the civil registration number (CPR number) and the unique incident ID to identify the study population, prehospital management, hospital contacts, admissions, mortality, and other outcomes.

From the PPR (*PPJ*), data are retrieved regarding vital signs recorded during the prehospital contact, including heart rate, oxygen saturation, blood pressure, and respiratory rate, alongside necessary identification and linkage details, specifically the CPR number and incident ID. Information on age and sex is primarily retrieved from the PPR and supplemented with data from the EHR in cases of missing or ambiguous records. Since the documentation of vital signs can vary in prehospital practice, a new vital-sign-based proxy variable for acute illness severity is constructed based on how many of the four defined vital signs are documented at least once. This variable is categorized into three levels: no documented vital signs, partially documented vital signs (corresponding to one to three of the four defined vital signs), or a complete set of documented vital signs (corresponding to the recording of all four vital signs at least once). A higher number of documented vital signs is assumed to potentially reflect a higher severity of acute illness.

The CFS score and documentation verifying the execution of the Geriatric 5Ms-based conversation are recorded in REDCap as part of the project’s implementation and quality improvement framework to continuously monitor, support, and refine the implementation throughout the study period.

REDCap is thus utilized as a secure project and research database for the structured collection, quality assurance, and subsequent analysis of implementation, effectiveness, and safety data. REDCap registration is restricted to data necessary for documenting intervention delivery, monitoring implementation rates, and evaluating project outcomes; it does not involve additional clinical examinations or patient-facing research procedures. Healthcare economic data are retrieved from relevant registry and activity data and encompass resource utilization related to ambulance transport, emergency department care, diagnostics, outpatient contacts, and hospital admissions. Costs are calculated using relevant DRG and DAGS tariffs combined with activity-based registry data.

Statistical Analysis Plan

The project will be conducted as a pragmatic cluster trial using ambulance units as the unit of randomization and non-conveyance (treatment on scene) as the primary outcome. All analyses will be performed according to the intention-to-treat principle, whereby prehospital contacts are analyzed based on the cluster to which the ambulance unit was randomized.

The unit of analysis for the study is the individual prehospital contact. Since the same patient may account for multiple prehospital contacts during the study period, statistical adjustments will be made to account for the correlation between repeated contacts from the same patient.

Power Calculation

The power calculation is based on the primary outcome, defined as the proportion of prehospital contacts completed with non-conveyance on scene without transport to the hospital.

The calculations are based on a cluster-randomized design involving 30 ambulance units distributed 1:1 between the intervention and control groups. The expected baseline proportion of patients managed on scene is estimated at 15% based on pre-intervention data. Calculations have been performed for clinically relevant absolute increases in the proportion of patients managed on scene from 15% to 20% and 25%, respectively.

The power calculation utilizes a two-sided significance level of 5% and a statistical power of 80%. Dependence among observations within the same ambulance cluster is adjusted for by applying the design effect (DE):

\(DE=1+(m-1)\times ICC\)

where *m* denotes the average number of included prehospital contacts per ambulance unit, and *ICC* represents the intraclass correlation coefficient.

Because the outcome is expected to be primarily influenced by individual patient factors, and the prehospital patient population concurrently exhibits heterogeneity within the individual ambulance clusters, the intraclass correlation coefficient (ICC) is estimated to be low. Consequently, sensitivity calculations have been performed using ICC values of 0.001, 0.005, and 0.008.

The expected recruitment base is calculated from historical activity data from the 30 ambulance units participating in the trial. From June to November 2025, a total of 14,230 ambulance contacts with urgency tier A or B following a 1-1-2 emergency call were recorded among patients aged 65 years or older. Assuming a corresponding level of activity over the 12-month study period, this equates to a recruitment base of approximately 28,500 prehospital contacts among potentially eligible patients (14,230 × 2 ≈ 28,500).

Not all patients within this recruitment base are expected to be included. Some will meet an exclusion criterion, be unable to receive or comprehend the participant information, decline participation, or be unable to be included during the prehospital contact due to clinical or practical reasons. In calculating recruitment feasibility, it is conservatively assumed that 80% of potentially eligible patients will not be included, corresponding to an inclusion rate of 20%.

With a conservatively assumed inclusion rate of 20%, this corresponds to an estimated recruitment potential of approximately 5,700 patients over the 12-month study period (28,500 × 0.20 ≈ 5,700). The actual recruitment potential may turn out to be higher or lower depending on the activity level and the true inclusion rate. An ICC of 0.005 is considered the most plausible planning value for this study and is utilized as the primary ICC assumption.

For the smallest predefined clinically relevant difference—corresponding to an absolute increase in the proportion of patients managed on scene from 15% to 20% (5 percentage points)—a total of 2,610 included patients is required.

Sensitivity Analysis – Scenario A: Absolute increase in non-conveyance on scene from 15% to 20%

At 80% statistical power, the required average number of patients per ambulance unit (*m*) and the corresponding total number of patients (N = 30 × m) are:

- **ICC = 0,001:** 65 patients per ambulance unit → N ≈ 1,950 patients
- **ICC = 0,005:** 87 patients per ambulance unit → N ≈ 2,610 patients
- **ICC = 0,008:** 116 patients per ambulance unit → N ≈ 3,480 patients

Sensitivity Analysis – Scenario B: Absolute increase in non-conveyance on scene from 15% to 25%

At 80% statistical power, the required average number of patients per ambulance unit (*m*) and the corresponding total number of patients (N = 30 × m) are:

- **ICC = 0.001:** 17 patients per ambulance unit → N ≈ 510 patients
- **ICC = 0.005:** 19 patients per ambulance unit → N ≈ 570 patients
- **ICC = 0.008:** 20 patients per ambulance unit → N ≈ 600 patients

Based on the primary planning assumption of ICC = 0.005, a total of 2,610 included patients is required to detect the minimum predefined difference of 5 percentage points with 80% statistical power. Given the expected activity level and a conservatively assumed inclusion rate of 20%, it is deemed feasible to accrue the necessary number of patients within the 12-month study period.

At the highest evaluated ICC value of 0.008, the most demanding scenario requires 3,480 patients. This sensitivity calculation is used to illustrate the vulnerability of the power calculation to the assumption regarding the intraclass correlation coefficient (ICC). The calculations do not account for a potential gain in efficiency resulting from the planned matched-pair design and adjustment for matched cluster pairs in the primary analysis.

Based on the primary planning assumption, the study is expected to include a total of 2,610 patients during the study period. The maximum number of included patients is 3,480, corresponding to the highest evaluated ICC scenario (ICC = 0.008) in the power calculation. If, during the execution of the trial, a need arises to include more than the stated maximum of 3,480 patients, a protocol amendment will be applied for before additional patients are enrolled.

Primary Analysis

The primary outcome will be analyzed as the absolute difference in the proportion of prehospital contacts completed with non-conveyance on scene between the intervention and control groups.

Regression models adapted to the individual outcomes will be used, accounting for the dependence between observations within the same ambulance cluster. The matched cluster design will be handled by adjusting for the matched cluster pairs.

Both unadjusted and adjusted analyses will be performed. The prespecified covariates in the adjusted analyses include age, sex, urgency tier, comorbidity, chief complaint based on the Danish Index criteria recorded in the PPR (*PPJ*), and a vital-sign-based proxy for acute illness severity. Intervention effects will be reported as absolute differences with 95% confidence intervals.

Secondary Analyses

Binary secondary outcomes, including subsequent acute hospital contacts, readmissions, repeated ambulance contacts, ICU admissions, and 30-day mortality, will be analyzed using regression models following the same overarching principles as the primary analysis.

Continuous outcomes, including time spent on scene, length of stay, and hospital-free days within 30 days following the prehospital contact, will also be analyzed using regression models following the same overarching principles as the primary analysis.

Descriptive Analyses

Patient and cluster characteristics will be described descriptively for both the intervention and control groups. Continuous variables will be reported as mean with standard deviation or median with interquartile range, depending on the data distribution. Categorical

variables will be reported as frequencies and percentages. Hypothesis testing of baseline differences between the groups will not be performed.

Healthcare Economic Analyses

Healthcare economic analyses will be conducted from a healthcare system perspective and will encompass total acute healthcare expenditures within 7 days following the prehospital contact.

The analyses include costs related to ambulance transport, emergency department care, diagnostics, outpatient contacts, and hospital admissions based on DRG and DAGS tariffs as well as activity-based registry data.

Costs will be compared between the intervention and control groups as average cost differences per patient. Due to the expected skewed distribution of cost data, these will be analyzed using regression models following the same overarching principles as the primary analysis.

Sensitivity Analyses

Prespecified sensitivity analyses are planned to investigate potential contamination between the intervention and control clusters.

The development in the proportion of patients managed on scene will be analyzed over time at the cluster level before and after implementation. This will be done to investigate potential temporal contamination and shifts in non-conveyance practices between the intervention and control clusters throughout the study period.

Risks, Burden, and Safety

The project will be conducted as a pragmatic cluster trial. The intervention consists of a systematic assessment of frailty using the Clinical Frailty Scale (CFS) alongside a structured, person-centered conversation based on the Geriatric 5Ms framework for patients with a CFS score ≥5, serving as a support tool for clinical evaluation, reflection, and communication.

The intervention does not involve experimental treatment, invasive procedures, or changes in clinical responsibility, triaging authority, or available clinical treatment options. All treatment and management decisions continue to be made by the ambulance personnel

within existing regional guidelines and under standard clinical responsibility. The intervention functions as a decision and communication support tool and is not utilized as a standalone triaging tool or an algorithm for treatment decisions.
The option for non-conveyance (treatment on scene) without hospital admission already exists as part of current prehospital practice and remains unaltered by the project. Consequently, the control group is not deprived of existing treatment options or clinical courses of action.
The project is assessed not to entail any significant additional risk or burden for the patients beyond standard prehospital assessment and treatment, as the intervention primarily consists of systematizing and structuring existing clinical evaluations and communication. Prior research demonstrates that frailty assessment, including the use of the CFS, is feasible within a prehospital context, while the Geriatric 5Ms framework was developed as a structured clinical framework that can be adapted to specific clinical settings (3, 14, 16).
The CFS assessment and the Geriatric 5Ms-based conversation are integrated into the prehospital assessment and are performed when the patient's clinical condition permits. Necessary clinical assessment, treatment, and transport always take precedence. The CFS assessment and the Geriatric 5Ms-based conversation are therefore deferred or omitted if they cannot be performed without causing undue delay to these core actions.
The initial CFS assessment is performed following the primary clinical evaluation and is based on information regarding the patient's baseline functional capacity, including mobility, degree of independence, and the need for assistance with activities of daily living. The assessment does not require specialized equipment or specimen collection and is supported by a pocket card focusing on the distinction between CFS <5 and CFS ≥5.
Prior to the intervention, ambulance personnel complete a project-specific training program on the application of the CFS, including the evaluation of baseline functional capacity and the differentiation between CFS <5 and CFS ≥5. Previous prehospital research indicates that the CFS can be effectively utilized by ambulance personnel and underscores the importance of relevant training for prehospital application of the CFS (3, 12). During the prehospital contact, the initial screening between CFS <5 and CFS ≥5 is used to determine whether the Geriatric 5Ms-based conversation should be initiated. The precise CFS score

is recorded after the patient contact ensures that this part of the procedure does not delay necessary treatment or transport.
The ambulance personnel participating in the research project are trained and legally authorized healthcare professionals (23) who routinely assess and treat patients within existing regional guidelines in their daily clinical work, either independently or in collaboration with other healthcare professionals, and are accustomed to navigating both acute and non-acute situations.
As part of the standard clinical patient evaluation, including the primary ABCDE assessment, the ambulance personnel evaluate the patient's level of consciousness (24). Simultaneously, they routinely assess the patient's orientation, communication, and capacity to comprehend information and participate in decisions regarding examination and treatment. Furthermore, a subset of the ambulance personnel has already completed supplementary training in the assessment and management of subacute and complex patients, including elderly individuals. This training further strengthens their competencies in evaluating this patient population, including the patient's capacity to comprehend information and participate in decision-making.
Thus, the ambulance personnel’s assessment of a patient's capacity in relation to research participation builds upon clinical competencies that are already routinely applied during standard patient evaluations. In this project, these competencies are utilized to determine whether the patient can receive and comprehend the project information, including the option to decline, and can express a potential objection.
The project-specific training and the accompanying project instructions supplement these competencies and clarify the criteria for when a patient cannot be included in the research. In case of doubt, the ambulance personnel can consult with a PEC (Prehospital Emergency Care) physician, who will be briefed on the project's inclusion procedures prior to study initiation. If doubt persists after this consultation regarding the patient's capacity to understand the information or express a potential objection, the patient will not be included in the research data.
Implementation will occur in a phased manner due to organizational and operational constraints, as simultaneous implementation across all ambulance units is practically unfeasible. This introduces a temporary variation in clinical practice between ambulance clusters with and without systematic use of the CFS and Geriatric 5Ms during the study

period. Following the implementation period, all ambulance units will transition to the same standardized practice.

The project data are based on routinely recorded prehospital, hospital, and registry-based information, alongside prospective recording of the CFS score and the utilization of the Geriatric 5Ms in REDCap performed by the ambulance personnel in the intervention clusters.

Outcome data from prehospital records, hospital records, and healthcare registries will be linked retrospectively using civil registration numbers (CPR numbers). Data will be processed and analyzed in a pseudonymized format in compliance with the General Data Protection Regulation (GDPR) and applicable Danish data protection legislation.

Ethical Considerations and Application of Section 5a (Simplified Informed Consent)

The project will be conducted as a pragmatic cluster-randomized low-risk study, where the intervention is implemented at the ambulance cluster level as part of the prehospital assessment of elderly patients. The cluster design was selected because the intervention consists of systematic assessment and communication support within clinical practice, and because individual randomization was deemed methodologically inappropriate due to the risk of contamination among ambulance personnel within the same operational environment. Thus, the cluster design is justified by the nature and organization of the intervention and not by the age of the patients.

The intervention consists of the systematic assessment of frailty using the Clinical Frailty Scale (CFS) alongside a structured Geriatric 5Ms-based conversation for patients with a CFS score ≥5. The CFS and the Geriatric 5Ms are utilized as decision, reflection, and communication support tools within existing prehospital practice, and do not function as independent treatment interventions, standalone triaging tools, scoring systems, or algorithms for treatment decisions.

The project is assessed to fulfill the criteria for simplified informed consent under Section 5a of the Committee Act (*Komitéloven*), given that the intervention is carried out within existing prehospital clinical frameworks and does not involve experimental treatment, invasive procedures, or research-specific clinical examinations. The intervention does not

alter the ambulance personnel's treatment responsibilities, triaging authority, available treatment options, or applicable regional clinical guidelines. Both groups receive standard prehospital assessment and treatment, and the option for non-conveyance (treatment on scene) without hospital admission already exists as part of current prehospital practice.
A questionnaire is included as part of the project's implementation and quality improvement framework. The questionnaire does not involve clinical intervention, alterations to treatment, or additional diagnostic or therapeutic procedures. Following a separate evaluation by the Regional Committee on Health Research Ethics, the questionnaire component is not inherently subject to notification requirements. The questionnaire component is therefore deemed not to alter the nature of the project as a low-risk cluster trial under Section 5a.
The study population encompasses elderly patients assessed by the ambulance services in an acute situation. It has therefore been taken into consideration that acute illness, as well as cognitive, visual, auditory, or communication difficulties in some patients, may make it more difficult to receive and comprehend information and actively opt out. However, advanced age or frailty does not inherently imply that a patient lacks the capacity to make decisions regarding research participation. Consequently, the capacity to comprehend information and make a decision is assessed concretely for each individual patient and not based on age or frailty alone (25).
Patients are identified only following a 1-1-2 call and an initial clinical assessment, meaning the intervention is integrated into an acute prehospital assessment scenario. Obtaining conventional informed consent prior to research inclusion is deemed inappropriate in this situation, as a standard consent procedure could disrupt the clinical workflow and simultaneously lead to systematic selection bias, favoring patients who are less acutely affected and better able to complete the procedure. Elderly patients with frailty and complex needs, who constitute a central part of the study population, would thus run the risk of being underrepresented (25).
The simplified informed consent procedure makes it possible to provide the patient with brief and adapted information during the prehospital contact without a prolonged consent process, while simultaneously giving the patient the opportunity to opt out of having their data used for research purposes. A decision to opt out of the research utilization of data

results in no changes to the clinical assessment, treatment, or access to other healthcare and support services.

Concurrently, prior research supports that brief research-related information and assessment procedures among elderly patients in an acute clinical context can be carried out without perceived patient burden and without reported disruption to emergency care. In a prospective pilot study among patients aged 70 years or older with suspected infection or hip fracture, such a procedure was completed within 20 minutes without patients experiencing participation as burdensome, and without healthcare staff evaluating the procedure as disruptive to acute care (26). The study thus supports that a brief and adapted research-related information procedure can be successfully executed among selected elderly patients in an acute clinical situation.

To ensure that patients are not included in the research without a genuine opportunity to opt out, the written information is delivered in person and supplemented with brief verbal information. It is clearly stated in both the verbal explanation and the written information that the patient's data will be included in the research project unless the patient actively opts out, and that opting out has no consequences for the patient's treatment or other rights.

The patient can object directly to the ambulance personnel or subsequently contact the project coordinator using the contact details provided in the participant information. Patients who are unable to receive and comprehend the information, including the option to opt out, or who cannot articulate a potential objection, will not be included in the research data.

The specific procedure for participant information, registration of objections, and handling of subsequent data collection is described separately in the section "Participant Information and Opt-Out Procedure," while data protection is detailed in the section "Data Protection."

Participant Information and Opt-Out Procedure

Participant information is delivered in person by the ambulance personnel during the prehospital contact and is supplemented with brief verbal information. Along with the participant information, separate information regarding the processing of personal data is provided in accordance with the disclosure requirements of data protection regulations.

Upon delivery of the written participant information, the eligible patient is included in the research project, provided the patient does not object to participation. The patient may at any time actively request that data concerning them not be utilized in the research project. Two versions of the written participant information are utilized: one version for patients in the intervention clusters and one version for patients in the control clusters.

The delivery of participant information occurs as early as the patient's clinical condition and therapeutic needs permit, and it must not delay or compromise necessary prehospital assessment, treatment, or transport. Since the intervention is integrated into the acute prehospital assessment and implemented at the cluster level, the clinical application of the CFS and the structured Geriatric 5Ms-based conversation may, in certain situations, take place before written participant information can practically be delivered. In such cases, the participant information is delivered to the patient as soon as possible before the end of the patient contact, following the simplified informed consent procedure under Section 5a of the Committee Act (*Komitéloven*).

If personal delivery of participant information is not possible due to practical reasons within the specific situation and prior to the end of the patient contact, the patient is not included in the research project. Furthermore, all patients included in the research project will subsequently be sent the participant information via digital post (*Digital Post*). If the patient is not registered for digital post, or if digital transmission is unfeasible, efforts will be made to send the information via regular mail, provided this is practically possible. When participant information is sent subsequently, it is reiterated that the patient's data will be included in the research project unless the patient actively opts out, and instructions on how the patient can decline continued participation are provided.

The patient can actively decline the research-related utilization of their data either directly to the ambulance personnel in connection with the delivery of the information or subsequently by contacting the project coordinator using the contact details provided in the participant information. If the patient objects during the prehospital contact, the patient is not included in the research project, and no data concerning the patient will be collected or utilized for research purposes.

If, during the prehospital contact, the patient is unable to receive or comprehend the written participant information or to articulate an objection to their data being used for research purposes, the patient is not included in the research project.

The participant information describes the project's purpose and organization as a cluster trial, what data are collected, and from which data sources. The intervention version additionally describes the nature of the intervention, while the control version describes participation under standard prehospital assessment and treatment. The control version does not describe the specific content of the intervention, as the intervention is not applied within the control clusters during the study period. The distinction between the versions is justified by the requirement that participant information must reflect the prehospital practice within the respective cluster, and to limit the risk of expectation bias and contamination. Both versions describe the patient's right to decline the research-related use of their data without consequences for current or future treatment, rights, or access to healthcare services. Finally, both versions outline how an objection can be communicated, registered, and handled.

Objections against the research-related utilization of data are registered by the project coordinator in REDCap. When a patient objects to the research-related use of data, no further data extraction, registry linkage, or continued data collection regarding the patient will be conducted for the research project. The handling of data already collected prior to the objection will be managed in compliance with applicable data protection legislation and the current guidelines of the data-controlling institutions.

The project will be conducted in accordance with the Declaration of Helsinki, applicable Danish legislation, and the rules governing cluster trials with simplified informed consent under Section 5a of the Committee Act.

Patients Lacking Capacity (Incompetent Patients)

The research project does not include patients who lack decision-making capacity. Patients who, for any reason, are unable to receive or comprehend the written participant information and make a decision regarding the research-related use of their data will not be included in the research project. The description of how patients are assessed as lacking capacity is further elaborated in the section on ethical considerations and the application of simplified informed consent.

Data Protection

The project is planned and conducted within the Central Denmark Region in collaboration with Aarhus University (Department of Clinical Medicine) and the Center for Emergency Medicine Research (*Center for Akutforskning*) at Aarhus University Hospital. The Central Denmark Region and Aarhus University act as independent data controllers for the processing of personal data that each institution performs as part of the research project. The processing and storage of research data are conducted within approved and access-restricted research server environments at Aarhus University and the Central Denmark Region, in compliance with the General Data Protection Regulation (GDPR), the Danish Data Protection Act (*Databeskyttelsesloven*), and current guidelines for the processing of research data.

The project processes personal data and health data, including civil registration numbers (CPR numbers) as well as data from prehospital electronic patient records, dispatch records (LOGIS), hospital records, regional healthcare registries, and project entries in REDCap. REDCap is utilized as a secure, web-based research database hosted and administered by Aarhus University for the processing and storage of research data, including personally identifiable information.

Once final ethical approval for the project is obtained, data from the PPR (*PPJ*), EHR (*EPJ*), LOGIS, and other relevant patient systems will be disclosed to the research project pursuant to Section 46(1) of the Danish Health Act (*Sundhedsloven*). Health data and other special categories of personal data covered by Article 9(1) of the GDPR are processed for scientific research purposes pursuant to Section 10(1) of the Danish Data Protection Act. If data are retrieved through direct access to electronic health records or other electronic patient systems, this will only occur after obtaining the necessary authorization pursuant to Section 46(5) of the Danish Health Act, and will be carried out exclusively by individuals possessing the required access rights and authorization.

Directly identifying personal data, including the CPR number, are used solely for data linkage between data sources, registry follow-up, quality assurance of data linkages, and the management of the project's opt-out procedure. CPR numbers are utilized during the initial phase to link prehospital data, hospital data, and registry data. Following this, a pseudonymized analytical dataset featuring unique study IDs is established. Concurrently, a separate, access-restricted linkage file is created to link the CPR number with the project's study ID. This linkage file is stored separately from the analytical data with

restricted access. Access to the linkage file is granted exclusively to selected members of the research group who have an operationally justified need to access identifiable data in connection with data linkage, registry follow-up, or opt-out management.
Other analytical data are processed in a pseudonymized format. Access to project data is restricted to members of the research group with an operationally justified need for data access. Data processing, data extractions, and modifications within the database are logged in the respective systems in accordance with current security protocols.
Research data are stored within approved and access-restricted research server environments at Aarhus University and the Central Denmark Region, including regional research server environments such as MidtX or equivalent approved research platforms. Any potential sharing of data will only occur in accordance with approved data sharing agreements, data protection requirements, and the underlying legal permissions governing the project.
The project data are retained in compliance with the current rules for the storage of research data at the Central Denmark Region and Aarhus University. Upon project completion, data will be archived or deleted in accordance with applicable institutional and regulatory requirements.
Patients may object to the use of data concerning them in the research project, as described in the section “Participant Information and Opt-Out Procedure.” Upon registration of an objection, no further data extraction, registry linkage, or continued data collection regarding the patient will be conducted. The management of data already collected prior to the objection will be handled in compliance with applicable data protection legislation.

Financial Disclosures

The project was initiated as a collaborative effort among researchers from the Prehospital Emergency Medical Services of the Central Denmark Region, the Center for Emergency Medicine Research, and the Research Unit for Geriatric Diseases. The project is funded by the Independent Research Fund Denmark (*Danmarks Frie Forskningsfond – DFF*) through a standard research grant. No commercial or industrial collaborators or funding parties are involved in the project.

The grant is used for the execution of the research project, including salaries for the PhD student and supervisors, research-related operations, methodological support, healthcare economic analyses, and patient and public involvement (PPI). The project funds are administered through Aarhus University.
The research group has no financial interests or financial affiliations with companies or other stakeholders related to the intervention or the project's outcomes. Patients receive no financial compensation or other financial benefits for participating in the project.

Publication of Research Findings

The results of the project are expected to be published in peer-reviewed scientific journals and presented at scientific conferences and academic professional meetings. Publication of the findings will be pursued regardless of the study's outcome.
The results will be published in an anonymized format, and no personally identifiable information concerning participating patients or ambulance personnel will be disclosed. Published research findings will be publicly accessible following publication.

Liability and Responsibility

The principal investigator (PI / *forsøgsansvarlig*) serves as the sponsor-investigator for the project and bears overall responsibility for the execution of the study. The project is planned and conducted within the Central Denmark Region in collaboration with Aarhus University (Department of Clinical Medicine) and the Center for Emergency Medicine Research (*Center for Akutforskning*) at Aarhus University Hospital.
The PhD candidate manages the day-to-day project coordination, data processing, and analysis under the supervision of the principal investigator and the project's co-supervisors. The project supervisors provide professional supervision and guidance within the relevant specialist fields of the project, as well as quality assurance of the study's execution, analysis, and reporting. The PhD candidate also acts as the primary contact person for the project, operating under the supervision of the principal investigator, who retains ultimate responsibility.
The principal investigator holds joint appointments at the Center for Emergency Medicine Research, Aarhus University Hospital, and an institution in the Netherlands, maintaining a

permanent employment and research affiliation with the Danish research environment of the project. Furthermore, as part of the appointment at the Center for Emergency Medicine Research, Aarhus University Hospital, the principal investigator is regularly physically present at the center for 14-day intervals.
The principal investigator provides continuous supervision to the PhD candidate. This supervision is maintained through a combination of in-person and virtual weekly supervisory meetings, ensuring consistent guidance and opportunity to discuss matters pertaining to the execution of the project. Consequently, the concurrent appointment in the Netherlands is deemed not to impede the principal investigator's ability to ensure necessary supervision and fulfill the responsibilities inherent to the role of principal investigator.
The project's co-supervisors possess extensive research experience and a proven track record in PhD supervision. The supervisory group is affiliated with the specific research environments where the PhD candidate is based on a daily basis, including the Prehospital Emergency Medical Services of the Central Denmark Region and the Center for Emergency Medicine Research at Aarhus University Hospital. Thus, local academic sparring and supervision are consistently accessible to supplement the supervision provided by the principal investigator.

Perspectives

Previous research has primarily investigated whether ambulance personnel can effectively apply the CFS and has highlighted the necessity for more structured assessments when encountering elderly patients with complex needs. However, there remains insufficient research on how a systematic prehospital frailty assessment combined with a structured, holistic conversation impacts clinical decision-making, subsequent patient pathways, and resource utilization.
Consequently, this project can generate clinically applicable knowledge regarding both the clinical significance and practical implementation of systematic frailty assessments among elderly patients, as well as the use of structured, holistic conversations for elderly patients with identified frailty.

For elderly patients living with frailty, an individualized approach may be uniquely relevant because their baseline functional capacity, overall health status, and personal treatment preferences can profoundly influence which subsequent pathway best suits the patient. Integrating these factors systematically can enhance patient involvement and help ensure that clinical decisions more accurately reflect both treatment needs and what matters most to the individual. When non-conveyance (treatment on scene) is clinically appropriate, certain elderly patients living with frailty can avoid a burdensome transport to the hospital and a potential admission.

Thus, the findings can establish a foundation for a more patient-tailored and value-based prehospital intervention for elderly patients. They can provide insight into how subsequent care pathways are best organized, ensuring that elderly patients requiring hospital-based treatment receive it, while elderly patients who—following a comprehensive clinical evaluation—do not require admission receive a course of care that better accounts for their overall situation and preferences. In this manner, acute healthcare resources can be utilized in accordance with the specific clinical needs of the individual elderly patient.

Appendices and Supplementary Documentation

The following appendices and supplementary information are integrated as part of the protocol. The written participant information is attached in two versions, one for the intervention clusters and one for the control clusters, for distribution to patients.

Appendix 1. Written Participant Information
Two versions of the written participant information are attached: one version for patients in the intervention clusters and one version for patients in the control clusters. Both versions describe the project's purpose, its organization as a cluster trial, what data are utilized and from which data sources, that the patient is included upon receipt of the written information, and how the patient can decline the research-related use of data by contacting the project coordinator.
The intervention version describes the nature of the intervention, while the control version describes participation under standard prehospital assessment and treatment.
Furthermore, both versions specify that this does not affect the patient's current or future treatment, rights, or access to healthcare services.

Appendix 2. Brief Verbal Information Script for Ambulance Personnel
Ambulance personnel may utilize the following brief verbal information when the patient's condition and the prehospital situation permit. The script corresponding to the relevant written participant information for either the intervention or control clusters must be used:

Intervention Clusters

> "The ambulance service is participating in a low-risk research project concerning the assessment of elderly patients in the ambulance. The project involves a systematic assessment of frailty and a structured conversation to support the standard clinical evaluation. It does not alter your rights or your access to treatment.
> More information about the project is provided in the written document you are receiving here. Unless you choose to opt out, your data will be included in the research project. If you do not want your information to be used in the project, please inform us now, or contact the project contact person later. The contact details are provided in the information sheet you have been given. Choosing to opt out will have no impact on your care or treatment."

Control Clusters

> "The ambulance service is participating in a low-risk research project concerning elderly patients receiving emergency medical care. The project investigates how frequently elderly patients are transported to the hospital following an ambulance contact and evaluates their subsequent patient pathways. It does not alter your rights or your access to treatment.
> More information about the project is provided in the written document you are receiving here. Unless you choose to opt out, your data will be included in the research project. If you do not want your information to be used in the project, please inform us now, or contact the project contact person later. The contact

details are provided in the information sheet you have been given. Choosing to opt out will have no impact on your care or treatment."

Appendix 3. Assessment of Notification Requirements by the Regional Committee on Health Research Ethics

Prior to submission to the National Center for Research Ethics (VMK / *Videnskabsetisk Medicinkomité*), the project was presented to the Regional Committee on Health Research Ethics (RVK-M / *Regional Videnskabsetisk Komité*) for an assessment of notification requirements. On February 2, 2026, the assessment was forwarded to VMK by Lena Bjerregaard Danvøgg, Legal Department, Central Denmark Region. It stated that the chairman of RVK-M had initially assessed that the project in its entirety is not subject to notification requirements before the regional committee.
This assessment was subsequently confirmed during dialogue with the Regional Committee on Health Research Ethics and encompasses the project's overall implementation and quality improvement components, including the planned questionnaire section. The questionnaire component does not involve clinical intervention, alterations to treatment, or additional diagnostic or therapeutic procedures, and has thus been evaluated as not being independently subject to notification requirements before the regional committee.
The project's application of simplified informed consent under Section 5a of the Committee Act (*Komitéloven*) was subsequently clarified in dialogue with VMK via Johannes Nyled Madsen, Officer, MSc (*Fuldmægtig, cand.scient.*), Unit for Science and Ethics (*Enhed for Videnskab og Etik*). In this dialogue, VMK accepted that the project can be processed under Section 5a, provided that the questionnaire component is not independently subject to notification requirements before the Regional Committee on Health Research Ethics. This prerequisite has been met via the regional committee's comprehensive assessment of the project.

Appendix 4. Supplementary Literature Regarding Brief Research-Related Information Procedures in Acute Clinical Contexts

The following article describes the feasibility and perceived patient burden of a brief research-related information and assessment procedure among elderly patients in an acute clinical context:

> Lucke, J. A., Lubbers, E., Stralen, K. V., & de Groot, B. (2025). Disease Severity, Volume Status, Cognition and Delirium in Older Patients in the Emergency Department, a Pilot Study. *The Global Emergency and Critical Care*, 4(3), 130-138. https://doi.org/10.4274/globecc.galenos.2025.13007

This study was a prospective pilot study among emergency department patients aged 70 years or older hospitalized with a suspected infection or hip fracture. Among other objectives, the study aimed to evaluate the feasibility and experienced burden of a brief research-related procedure in an acute clinical setting. The procedure encompassed research-related information gathering along with assessments of cognition, frailty, and acute disease severity, among other factors.

The study reported that the procedure could be completed within 20 minutes. Furthermore, patients experienced no participation-related burden, and healthcare professionals evaluated the procedure as feasible and non-disruptive to acute emergency treatment. This study thus provides an empirical example demonstrating that brief research-related procedures among elderly patients in an acute clinical context can be successfully executed with low perceived patient burden and without interrupting acute clinical care.

Appendix 5. Matching of Ambulances

This appendix describes the historical, aggregated activity data from the prehospital dispatch and logistics system, LOGIS, utilized for the characterization and matching of ambulance clusters prior to randomization. These data did not contain electronic health record information, personal data, or personally identifiable data. The dataset covers the period from June to November 2025 and is compiled at the ambulance cluster level.
The variables utilized were the total number of prehospital contacts, the distribution across urgency tiers A and B, and the proportion of patients managed on scene (defined as contacts completed without transport to a hospital). Ambulance clusters were matched to establish balance between the intervention and control groups regarding activity volume, urgency tier distribution, and the baseline proportion of patients managed on scene. Minor residual differences were accepted, provided that the overall group-level data and the proportions of patients managed on scene remained comparable. The final matched ambulance clusters establish the cluster framework utilized in all subsequent statistical analyses.

Baseline Characteristics of Ambulance Clusters (June–November 2025)

Study Group	Total Prehospital Contacts (\(n\))	Urgency Tier A (\(n\))	Urgency Tier B (\(n\))	Total Proportion Managed on Scene (\(\%\))
Intervention	6,980	3,720	3,260	22.3
Control	7,250	3,600	3,650	21.9

Matched Ambulance Pairs (Intervention \(\rightarrow \) Control)

The final matched ambulance pairs established in the study are as follows:

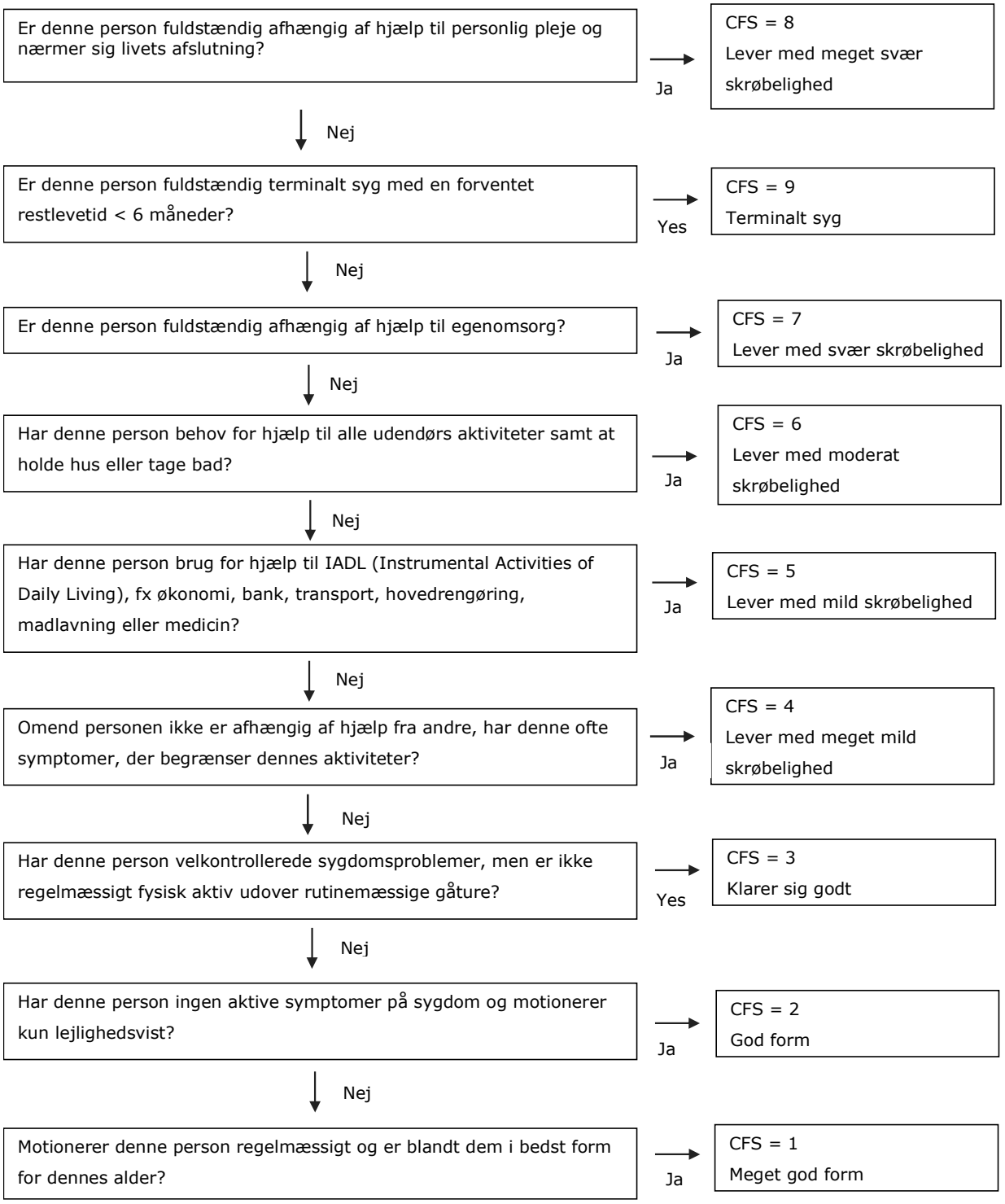
- Str-Am-da1 \(\rightarrow \) Hol-Am-da1
- Aac-Am-do3 \(\rightarrow \) Aac-Am-do2
- All-Am-do1 \(\rightarrow \) Ras-Am-do3
- Ham-Am-do1 \(\rightarrow \) Sil-Am-do3
- Hed-Am-do1 \(\rightarrow \) Hor-Am-do2
- Her-Am-do3 \(\rightarrow \) Her-Am-do1
- Hol-Am-do3 \(\rightarrow \) Hol-Am-do1
- Ika-Am-do1 \(\rightarrow \) Bra-Am-do1
- Kje-Am-do1 \(\rightarrow \) Vib-Am-do3
- Ran-Am-do2 \(\rightarrow \) Ras-Am-do2
- Ris-Am-do1 \(\rightarrow \) Ras-Am-do1
- Roe-Am-do1 \(\rightarrow \) Hin-Am-do1
- Ska-Am-do1 \(\rightarrow \) Sil-Am-do1
- Ska-Am-do2 \(\rightarrow \) Sil-Am-do2
- Tar-Am-do2 \(\rightarrow \) Vib-Am-do1

Appendix 6. The Geriatric 5Ms Framework

A structured framework to identify the most critical factors that can affect care and treatment in older adults.

Focus Area	Key Questions / Observations	Clinical Reflection
Matters Most *(Mest betydningsfuldt)*	• What is most important to the patient and their relatives right now? • What do the patient/relatives wish to avoid? • Is there a discrepancy between the patient's wishes and those of their relatives?	Is the plan aligned with what matters most to the patient and, if applicable, their relatives?
Mind *(Mentalt)*	• Confused, decreased attention/alertness, dementia? • Unsafe behavior (acting without awareness of safety risks)? • Poor hygiene, spoiled food, hoarding, or lack of self-care?	• Are there signs of cognitive impairment or altered mental status? • Is the patient capable of understanding the situation and making decisions regarding their treatment?
Mobility (Functional Capacity) *(Mobilitet / Funktionsevne)*	• Uses a walking aid? • Walks/moves slowly? • Seldom leaves the home? • Recent falls?	Are there signs of a decline in functional capacity or physical reserve?
Medications *(Medicin)*	• Recent changes in medication? • Medication not taken as prescribed (e.g., unopened medication, medication left lying around)? • Polypharmacy (>5 medications)?	Are there medication-related issues that should be considered?
Multi-complexity (Complex Illness and Life Situation) *(Multikompleksitet)*	• Multiple chronic conditions / multimorbidity? • Weekly home care or other forms of support? • Frequent or recent hospitalizations? • Recently widowed or lives alone?	Are there factors contributing to the overall complexity of the patient's situation?

Appendix 7. The Clinical Frailty Scale



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