Title	Video-assisted TELEmedecine for medical dispatch of adult patients calling to an Emergency Medical Communication Centre for acute DYSpnea: a multicentre stepped-wedge cluster randomised controlled study.
Acronym	TELEDYS
NCT number	NCT07726628
Date of the document	13 August 2026

The Statistical Analysis Plan of the TELEDYS Study

This Statistical Analysis Plan (SAP) was written according to the guidelines proposed by Yuan et al. [1] and by Gamble et al. [2] for randomized clinical trials.

1. SAP versions, dates and reasons for revision

Version #1: August 13th, 2026.

2. Trial registration number

NCT07726628 (Clinical trials Number)

3. Study title

Video-assisted TELEmedecine for medical dispatch of adult patients calling to an Emergency Medical Communication Centre for acute DYSpnea: a multicentre stepped-wedge cluster randomised controlled study.

4. SAP contributors with roles and responsibilities

Camille ALLEYRAT (camille.alleyrat@chu-poitiers.fr): Methodologist, document writing.

Sabrina GARNIER-KEPKA (sabrina.garnier-kepka@chru-strasbourg.fr): Medico-economist, document writing.

Nicolas MARJANOVIC (nicolas.marjanovic@chu-poitiers.fr): Principal investigator, document proofreading.

5. Background and rationale of study

Dyspnoea accounts for 8% of calls to emergency medical communication centers (EMCCs), and its triage is challenging, which may lead to inappropriate medical decisions, including under-triage — that is, a decision level below what is clinically required — which is associated with an increased risk of short- and medium-term mortality, and over-triage — that is, a decision level exceeding the actual medical need — leading to unnecessary consumption of healthcare resources and contributing to the disorganization of the emergency care system.

We hypothesize that direct visualization of clinical signs (cyanosis, respiratory struggle, exhaustion…) will enhance medical decision-making. This stepped-wedge randomized trial aims to demonstrate that the use of video-assisted telemedicine via the caller's smartphone camera during the medical dispatch of adult patients calling an EMCC for acute dyspnea as their primary complaint enhances medical decision-making by reducing the proportion of under-triage and over-triage.

6. Study type

This is a superiority, multicentric, open-label, stepped-wedge cluster randomized controlled trial.

7. Objectives and related endpoints (units and calculations used to derive outcomes)

7.1. Primary objective

The primary objective is to assess the impact of telemedicine on the quality of the medical decision.

The primary outcome is the proportion of incorrect triaging (under-triage and over-triage).

Under-triage will be defined:

- either as a patient having received a medical advice alone or referred to a consultation at the initial call and, within 24 hours of the initial call, at least one of the following situations:
    - referred to an emergency department (ED) after a second call to the EMCC or after a general consultation,
    - non-scheduled hospitalization,
    - death of the patient (whatever the cause),
    - secondary emergency medical service (EMS) unit dispatched.
- either as a patient being dispatched to an ED (not with an EMS) after the initial call and, within 3 hours of the initial call, at least one of the following situations:
    - required ventilatory support,
    - cardiac arrest,
    - death of the patient (whatever the cause),
    - secondary emergency medical service (EMS) unit dispatched.

Over-triage will be defined as an EMS unit being dispatched or a patient being referred to an ED after the initial call to an EMCC and, at the end of emergency management, no additional examination (computed tomography, chest radiography, pulmonary scintigraphy), no specific treatment (aerosol therapy, ventilatory support, intravenous treatment, oxygen therapy, anticoagulants, cardiotropic agents, chest drainage, apart from the patient's usual treatments), no hospitalisation being required within 24 hours of the call to the EMCC.

7.2. Secondary objectives

The secondary objectives are to compare the following outcomes in the two groups:

- The proportion of patients in under-triage situation, according to the definition given for primary outcome.
- The proportion of patients in over-triage situation, according to the definition given for primary outcome.
- The proportion of patients requiring an oxygenation support (other than conventional oxygen therapy) or a ventilatory support (invasive or non-invasive mechanical ventilation, or heated and humidified high-flow nasal cannula oxygen therapy) within 3 hours, 24 hours and 28 days following the call to the EMCC.
- The proportion of patients hospitalized in a critical care unit within 24 hours following the call to the EMCC.
- The proportion of patients with cardiac arrest within 3 hours, 24 hours and 28 days following the call to the EMCC.
- The proportion of deceased patients within 3 hours, 24 hours and 28 days following the call to the EMCC.
- The duration of the call to the EMCC, defined by the time between the beginning of the call and the medical decision (in minutes).

We also plan a cost-effectiveness analysis to evaluate the health-economic impact of each strategy (medical regulation with or without telemedicine). The corresponding outcomes are the costs and the effectiveness for each strategy. Cost data concern the human resources for the regulation interview (time spent for the patient), the hospital resources (cost related to hospitalizations) and the extra-hospital resources (transports, biology, imaging, medical consultations, paramedical procedures).

Effectiveness criterion will be the proportion of patients without serious complication (institution of in-hospital ventilatory support, occurrence of cardiac arrest, or death from any cause). The corresponding estimand is the incremental cost-effectiveness ratio (ICER) at day 28, defined by the difference in mean costs divided by the difference in mean effectiveness (cost per avoided serious complication).

8. Inclusion criteria

- Patient aged 18 years or older.
- Patient calling the EMCC for acute dyspnea or respiratory distress as the primary reason for the call, regardless of the underlying cause.
- Patient or witness possessing a mobile phone equipped with a camera and capable of making a video call.
- Emergency consent during the call to EMCC.

9. Non-inclusion criteria

- Extreme life-threatening emergency situations requiring an immediate dispatch of emergency resources (firefighters or EMS unit) according to local protocols.
- Patient in end-of-life care or with a known decision to limit therapeutic interventions at the time of the call.
- Refusal to use telemedicine.
- Lack of telephone network allowing for telemedicine call with camera.
- Patient previously included in the study.
- Person benefiting from enhanced protection, namely minors, persons deprived of their liberty by a judicial or administrative decision, adults under legal protection.

10. Exclusion criteria (post-inclusion)

- Refusal to pursue the study (patient or relative consent withdrawal).
- Patient not benefiting from a social security system.
- Free subject, without guardianship nor subordination.

11. Definition of the two compared groups

- The experimental group is defined by traditional medical regulation in an EMCC with the addition of telemedicine. The medical dispatcher will transmit an internet link from a text message to the smartphone used for telemedicine. At the same time, the medical dispatcher will carry out a medical examination, taking a medical history, clinical patterns and severity of symptoms. Once the patient or witness have validated the link, the video stream received by the camera on the smartphone will be transmitted live to the medical dispatcher computer screen.
- The control group is defined by traditional medical regulation in an EMCC. The medical dispatcher will carry out a medical interview, taking a medical history, clinical patterns and severity of symptoms.

12. Randomization details

This is a stepped-wedge cluster randomized trial (10 centers). Each of the participating center begin the study according to the usual care (control group- CTL). Then, every 2 weeks, 1 center cross over from

usual care to medical regulation with telemedicine (experimental group- EXP), after a wash-out (WO) period to train the staffs on the telemedicine software. Patients will not be recruited during the wash-out period. With this design, each center will contribute both for control and experimental group at the end of the study.

Each center will be allocated to a predefined sequence before the beginning of the study.

Center	T0	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10	T11
A	CTL	WO	EXP	EXP	EXP	EXP	EXP	EXP	EXP	EXP	EXP	EXP
B	CTL	CTL	WO	EXP	EXP	EXP	EXP	EXP	EXP	EXP	EXP	EXP
C	CTL	CTL	CTL	WO	EXP	EXP	EXP	EXP	EXP	EXP	EXP	EXP
D	CTL	CTL	CTL	CTL	WO	EXP	EXP	EXP	EXP	EXP	EXP	EXP
E	CTL	CTL	CTL	CTL	CTL	WO	EXP	EXP	EXP	EXP	EXP	EXP
F	CTL	CTL	CTL	CTL	CTL	CTL	WO	EXP	EXP	EXP	EXP	EXP
G	CTL	CTL	CTL	CTL	CTL	CTL	CTL	WO	EXP	EXP	EXP	EXP
H	CTL	CTL	CTL	CTL	CTL	CTL	CTL	CTL	WO	EXP	EXP	EXP
I	CTL	CTL	CTL	CTL	CTL	CTL	CTL	CTL	CTL	WO	EXP	EXP
J	CTL	CTL	CTL	CTL	CTL	CTL	CTL	CTL	CTL	CTL	WO	EXP

13. Sample size calculation

A prospective study [3] estimated the proportion of over-triage at 5%. Data from a retrospective [4,5] study (not published) estimated the proportion of under-triage at 12%. We hypothesize that 17% of the calls to EMCC for a dyspnea concludes with a decision not adapted (incorrect triage) and that telemedicine could reduce this proportion by 2/3 (absolute reduction of 11%). Considering a two-sided type I error of 5%, a power of 90%, we need to include 344 patients in case of individual randomization.

According to the stepped-wedge design proposed [6], with 10 centers for 11 inclusion periods (including baseline period), for an intra-class correlation coefficient set to 0.01, we need to recruit 778 patients (including 10% of missing data for consent withdrawal, lost to follow-up, no phone coordinates…), which represents 14 patients to include per month per center over 5.5 months (22 weeks).

14. Interim analysis (timing, person, adjustment of the significance level)

No interim analysis was planned.

15. Guidelines for an early stop of the study

The study may be prematurely suspended in the event of unexpected adverse events. On the same token, in the event of unexpected developments or new information and showing that the objectives of the study or the clinical program are unlikely to be reached, the sponsor may be persuaded to prematurely suspend the study.

No statistical discontinuation criteria have been drawn up.

16. Timing of the study

- Inclusion duration: 6 months = 22 weeks for recruitment + 2 weeks for wash-out period (no recruitment),
- Follow-up duration: 28 days.

17. Timing for assessing each collected parameter

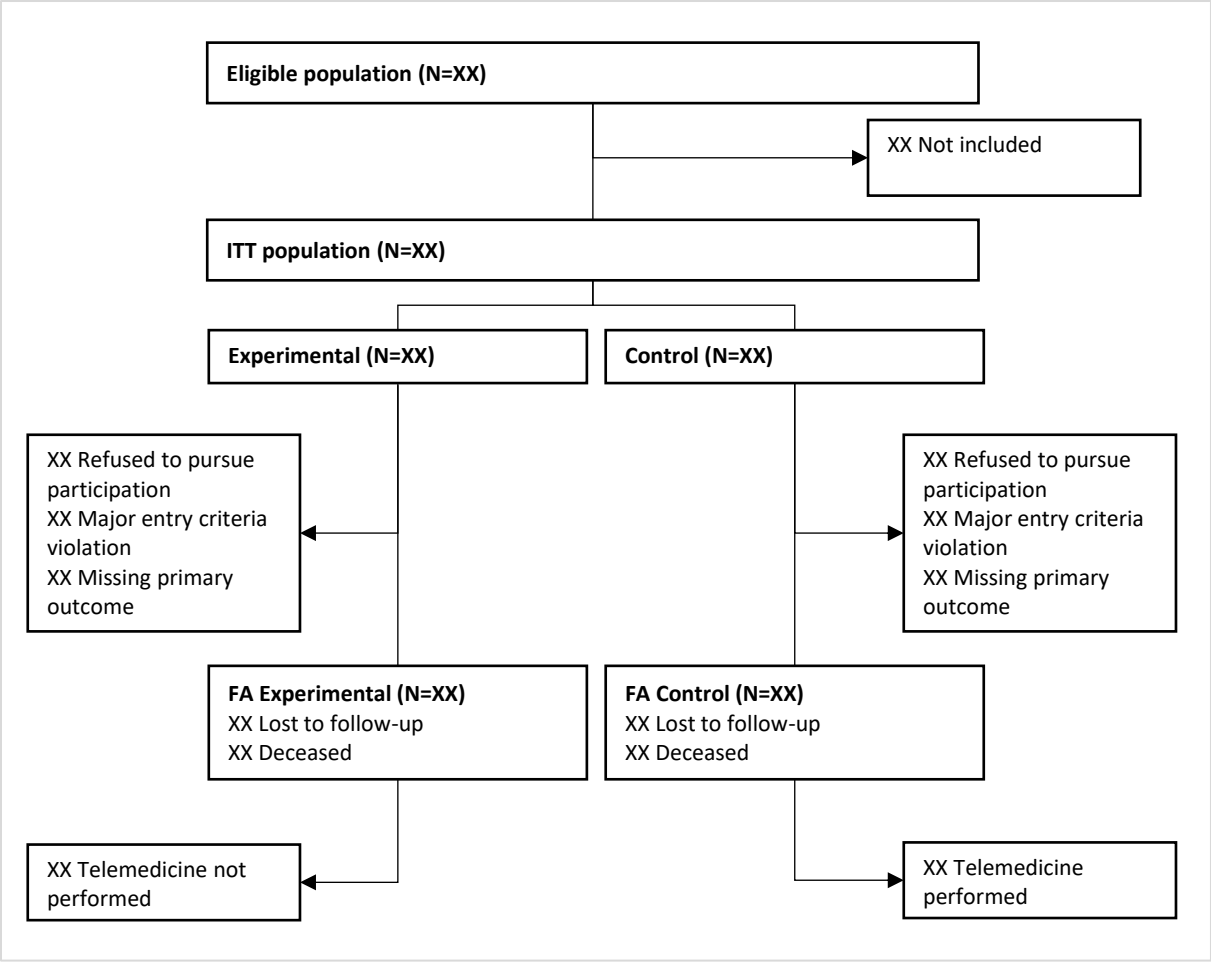
	Inclusion	Follow-up		
	Visit 0 (V0)	V0 + 24 hours	V0 + 14 days	V0 + 28 days
Emergency consent	X			
MRA interview	X			
Clinical exam (regulation doctor interview) with or without phone camera	X			
Medical decision of the regulation doctor	X			
Follow-up data: ventilatory support, hospitalization, cardiac arrest, additional examination or treatment, vital status		X Medical record		X Phone call
Oral consent (pursue study)			X	

MRA: Medical Regulation Assistant

18. Reporting the representativity of the studied population

A flowchart will be decomposed according to the following sets. The effectives and the related differences in-between two consecutive sets will be reported. The causes of the related differences will also be listed.

- **The intention-to-treat (ITT) analysis set.** The patients who were included and considered according to their allocated group, regardless of their adherence to the entry criteria, regardless of the intervention they received, and regardless of subsequent withdrawal from intervention or deviation from the protocol.
- **The full analysis (FA) set**. The previous ITT population, excluding participants who failed to meet major entry criteria [7], participants who withdrew consent and participants with missing primary outcome (whatever the reason).



19. Withdrawals and follow-up data

Patients may be withdrawn early from the clinical study for several reasons, including but not limited to consent withdrawal, exclusion criteria, lost to follow-up, death. The investigator will document the reasons for premature study discontinuation. The withdrawals will be exhaustively described in the flowchart.

20. Definition of the studied population

All the analyses will be performed based on the full analysis set.

If a patient or relative decline to give their consent within 14 days following inclusion, he/she will be asked for permission to use data obtained prior to withdrawal and to collect the primary outcome. If this is achieved, the patient will be included in the final analyses. If the patient or relative declines, all data from that patient will be destroyed (except for safety data).

21. Level of statistical significance (p-values, confidence intervals, one- or two-sided)

For the primary and secondary objectives, statistical significances will be achieved for p-values < 5% by using two-sided alternative hypotheses and two-sided 95% confidence intervals.

22. Plan and rationale for controlling the type I error (multiplicity of tests)

We will not consider the inflation of the type I error. The level of the proof will be the higher for the primary outcome. The statistical analyses related the secondary outcomes will be consider as exploratory results with a risk of false positive.

23. Sub-group analyses and/or tests of interactions

No sub-group analyses or test of interactions are planned.

24. Description of baseline patient characteristics

Demographic variables and other baseline characteristics will be summarized for the full analysis set.

The means, the standard deviations and the number of missing values will be presented for each arm and marginally for the following quantitative variables: age (years), time since onset of the symptoms (in days).

The effectives, the percentages of patients in each category and the number of missing values will be presented for each arm and marginally for the following categorical variables: gender (male/female), chronic respiratory failure (yes/no), chronic cardiac failure (yes/no), coronaropathy (yes/no), chronic kidney disease (yes/no), hepatic insufficiency (yes/no), active smoker (yes/no), central neurological disorder or sequelae of a central neurological disorder (yes/no), time of the call (day/night).

The standardized difference will be used to assess the baseline comparability of the two arms [8]. Unbalances will be considered for absolute values higher than 10%.

Underlined covariates are baseline potential risk factors for primary outcome and analyses will be adjusted on these factors (section 26).

25. Description of the outcomes

The outcomes of the patients will be compared for the full analysis set.

The mean, the standard deviation and the number of missing values will be presented for each arm and marginally for the following continuous outcomes: duration of the call to EMCC and the cost of the strategy. Student t-test will be performed to obtain the p-value.

The other outcomes are binary. The effectives, the percentages of patients in each category and the number of missing values will be presented for each arm and marginally. Pearson's Chi2 tests will be performed to obtain the p-values. Only when at least one theoretical effective under the null assumption will be lower than 5, a Fisher exact test.

26. Adjustments and estimands

Adjusted analyses on the risk factors of the outcome may increase power and give correct type I error rates and confidence intervals [9,10]. The following analyses will be performed for the full analysis set, with each outcome analyzed on a complete case basis (no imputation for the outcome). To avoid the exclusion of patients with missing values on the baseline predictors, multivariate imputation by chained equations will be performed 5 times on the full analysis set. For each imputed dataset, 1,000 bootstrap samples will be generated. We will use the G-computation to estimate the average treatment effect (ATE) for each bootstrap sample.

Firstly, we will estimate the outcome models: a mixed linear regression for the duration of the call to EMCC, and mixed logistic regressions for the binary outcomes, with center considered as random effect and study period, intervention and baseline predictors considered as fixed effect in the outcome models. Among the potential predictors, we will consider the risk factors highlighted in the section 24. No

interaction between the intervention group (experimental or control) and the predictors will be tested. The BIC minimization will be used for variables selection.

Secondly, based on the outcome models, we will predict the outcomes if all participants were assigned to the experimental group and then if all participants were assigned to the control group. For each outcome, the ATE will be the difference between the two adjusted individual predictions (difference of the means of the duration call and the differences of the proportions for the binary outcomes). The confidence intervals of the ATE will be estimated non-parametrically from the 5,000 imputed bootstrap samples [11].

For the cost-effectiveness analysis (CEA), we will follow guidelines from the Haute Autorité de Santé and CHEERS methodology [12,13]. CEA will be conducted in a collective perspective with a time horizon of 28 days. Costs and benefits will not be discounted in the context of a time horizon of less than 12 months. Cost data will be collected in the electronic case report form (eCRF), in the national health data system (NHDS) and also based on microcosting. CEA will be performed for the FAS population, on a complete case basis (no imputation for the efficacy or the costs).

The estimand for the CEA will be the ICER as defined in the secondary outcomes corresponding to the percentage of patients without serious complications. Complications will be assessed in both groups, with and without telemedicine, at day 28 by the occurrence of one of the following serious events:

- Initiation of in-hospital ventilatory support
- Occurrence of cardiorespiratory arrest
- Death from any cause

Only directs costs will be considered in the reference analysis:

- the costs of initial hospitalization and readmissions
- the costs of care management with and without telemedicine
- the costs associated with outpatient care (out-of-hospital medical consultations, paramedical procedures, biology, imaging, transportation).

In a secondary analysis, we will add the indirect costs corresponding to costs of per diem to value sick leave.

The robustness of the results will be assessed using deterministic sensitivity analysis to take into account the uncertainty of the parameters studied by varying their values.

In order to represent the variability of the results, we will perform nonparametric bootstrapping with 5,000 resamples and the result of the bootstrap replications will be presented on the cost effectiveness plane and on the acceptability curve showing the probability that the strategy with telemedicine is cost-effective as a function of societal willingness to pay.

27. The assumptions of the statistical methods, and alternative methods if they are false

There is no reason to suppose that the missing values of the baseline predictors will not be missing at random in such a randomized clinical trial. Therefore, the only assumption is the good specification of the outcome models.

The respect of the linearity and log-linearity assumptions will be assessed by comparing the Akaike information criterion (AIC) of the univariate model where the variable is not transformed versus the AIC of the model with B-splines transformation. If the criterion is lower for the model with B-splines, this transformation will be used in the multivariate model.

28. References

[1] Yuan I, Topjian AA, Kurth CD, Kirschen MP, Ward CG, Zhang B, et al. Guide to the statistical analysis

plan. Paediatr Anaesth. mars 2019;29(3):237-42

[2] Gamble C, Krishan A, Stocken D, Lewis S, Juszczak E, Doré C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 19 déc 2017;318(23):2337-43.

[3] Zhou J, Nehme E, Dawson L, et al. Epidemiology, outcomes and predictors of mortality in patients transported by ambulance for dyspnoea: A population-based cohort study. Emerg Med Australas 2023; 35: 48–55.

[4] Balen F, Lamy S, Fraisse S, et al. Predictive factors for early requirement of respiratory support through phone call to Emergency Medical Call Centre for dyspnoea: a retrospective cohort study. European Journal of Emergency Medicine 2023; published online Dec 9. DOI:10.1097/MEJ.0000000000001066

[5] Marjanovic N, Autin M, Violeau M, Mimoz O, Guenezan J. Telemedicine for the management of patients calling an Emergency Medical Communication Centre for dyspnea: a before-after study. European Journal of Emergency Medicine 2023; 30: 445–7

[6] Hemming K, Taljaard M. Sample size calculations for stepped wedge and cluster randomised trials: a unified approach. J Clin Epidemiol. 2016 Jan;69:137-46.

[7] Fergusson D, Aaron SD, Guyatt G, Hébert P. Post-randomisation exclusions: the intention to treat principle and excluding patients from analysis. BMJ. 2002 Sep 21;325(7365):652-4.

[8] Austin PC. Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples. Stat Med. 10 nov 2009;28(25):3083-107.

[9] Kahan BC, Morris TP. Reporting and analysis of trials using stratified randomisation in leading medical journals: review and reanalysis. BMJ. 14 sept 2012;345:e5840.

[10] Morris TP, Walker AS, Williamson EJ, White IR. Planning a method for covariate adjustment in individually randomised trials: a practical guide. Trials. 18 avr 2022;23(1):328.

[11] Schomaker M, Heumann C. Bootstrap Inference When Using Multiple Imputation. Stat Med. 30 juin 2018;37(14):2252-66.

[12] Haute Autorité de Santé. Choix méthodologiques pour l'analyse de l'impact budgétaire à la HAS. 2020.

[13] Husereau D, Drummond M, Augustovski F, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value in Health 2022; 25: 10–31.