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Effectiveness of a home-based telesurveillance program in reducing hospital readmissions in older patients with chronic disease: The eCOBAHLT randomized controlled trial

Achille Tchalla[1,2,3], Delphine Marchesseau[1,2], Noëlle Cardinaud[1,2], Cécile Laubarie-Mouret[1,2], Thomas Mergans[2], Patrick-Joël Kajeu[2], Sandrine Luce[4], Patrick Friocourt[5], Didier Tsala-Effa[1], Isabelle Tovena[1], Pierre-Marie Preux[4,6] and Caroline Gayot[1,2,3]

Abstract

Introduction: Given that chronic, long-term conditions are increasingly common in older patients, the impact of telesurveillance program on clinical outcomes is uncertain. This study aimed to evaluate the feasibility and effectiveness of a 12-month remote monitoring program in preventing rehospitalizations in older patients with two or more chronic diseases returning home after hospitalization.

Methods: We conducted a multicenter randomized controlled trial in two parallel groups to evaluate the remote monitoring system. Elderly patients with chronic diseases (at least two comorbidities) aged 65 years or older and discharged home after acute hospital care for a chronic disease were randomized to receive a home telemonitoring program (intervention group, n = 267) or conventional care (control group, n = 267). The remote home monitoring program was an online biometric home life analysis technology (e-COBAHLT) with tele-homecare/automation and biometric sensors. The eCOBALTH intervention group received the automation sensors containing chronic disease clinical factor trackers to monitor their biometric parameters and detect any abnormal prodromal disease decompensation by remote monitoring and providing geriatric expertise to general practitioners. The usual care group received no eCOBALTH program. In both groups, baseline visits were conducted at baseline and the final visit at 12 months. The primary outcome was the incidence of unplanned hospitalizations for decompensation during the 12-month period.

Results: Among 534 randomized participants (mean [SD] age, 80.3 [8.1] years; 280 [52.4%] women), 492 (92.1%) completed the 12-month follow-up; 182 (34.1) had chronic heart failure, 115 (21.5%) had stroke, and 77 (14.4%) had diabetes. During the 12-month follow-up period, 238 patients had at least one unplanned hospitalization for decompensation of a chronic disease: 108 (40.4%) in the intervention group versus 130 (48.7%) in the control group (P = 0.04). The risk of rehospitalization was significantly reduced in the intervention group (age- and sex-adjusted relative risk: 0.72, 95% 95% confidence intervals 0.51-0.94).

[1]Laboratoire VieSanté - UR 24134 (Vieillissement, Fragilité, Prévention, e-Santé), Institut OMEGA HEALTH, Université de Limoges, Limoges, France
[2]Service de Médecine Interne Gériatrique, Pôle Gérontologie Clinique, Centre Hospitalier Universitaire de Limoges, Limoges, France
[3]Unité de Recherche Clinique et d'Innovation (URCI) en Gérontologie, Pôle Gérontologie Clinique, Centre Hospitalier Universitaire de Limoges, Limoges, France
[4]Inserm U1094, IRD UMR270, Univ. Limoges, CHU Limoges, EpiMaCT - Epidémiologie des maladies chroniques en zone tropicale, Institut d'Epidémiologie et de Neurologie Tropicale, OmegaHealth, Limoges, France
[5]Service de Gériatrie, Centre Hospitalier de Blois, Loir-et-Cher, France
[6]CHU Limoges, Centre de Données Cliniques et de Recherche, Limoges, France

Corresponding author:
Achille Tchalla, Geriatric Medicine, University of Limoges, CHU Limoges; Laboratoire VieSanté – UR 24134 (Vieillissement, Fragilité, Prévention, e-Santé), Institut OMEGA HEALTH, Université de Limoges, Limoges, France.
Email: Achille.tchalla@unilim.fr

Conclusion: A 12-month home telemonitoring program with online biometric analysis using Home life technology combining telecare and biometric sensors is feasible and effective in preventing unplanned hospitalizations for chronic disease decompensation in elderly patients with chronic diseases at high risk for hospitalizations.

Keywords
Telesurveillance, remote monitoring, chronic disease, prevention, hospital readmission, older adults

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Introduction

Despite improvements in life expectancy and advances in medical therapies, individuals residing in rural areas face increasing disparities in healthcare delivery.[1,2] Remote and distant communities demonstrate higher rates of the five leading causes of death in the United States and Europe, attributed in part to the lack of resources in the ambulatory setting, limited access to specialists and specialized resources, fewer transportation options, and socioeconomic disparities. Rural healthcare is especially problematic in vulnerable populations including persons with disabilities specifically older adults.[3]

The incidence and prevalence of chronic diseases have steadily increased over the past few decades and continue to rise.[4] Patients with chronic diseases, such as chronic heart failure (CHF), chronic obstructive pulmonary disease (COPD), hypertension, and diabetes, are becoming more numerous and living longer, resulting in a significant deterioration in the quality of life (QoL) of these patients and an increase in morbidity and mortality.[5] Telemedicine has been shown to reduce emergency department and hospitalization for Nursing Home residents,[6] but no randomized trial has evaluated the effect of remote monitoring in preventing rehospitalization in elderly patients with chronic diseases at high risk for recurrent hospitalizations.

Patients with chronic diseases, such as CHF, COPD, hypertension, and diabetes, are continually increasing in number and living longer.[7,8] To date, health care has been dominated by single disease approaches lacking coordination and integration.[9]

Although in real life, diseases often coexist in the same patient, the coexisting disease approach has been largely neglected.[10,11] In particular, in complex conditions COPD and CHF frequently coexist due to common risk factors, leading to a significant deterioration in the QoL of these patients and increased morbidity and mortality.[7,8] The prevalence of COPD in patients with CHF ranges from 20% to 32%, whereas CHF is prevalent in more than 20% of patients with COPD.[9,12] Patients with COPD and CHF are often frail and are characterized by a high risk of frequent exacerbations and often the need for rehospitalization, with the associated cost burden.[13] Each disease is an independent predictor of morbidity, mortality, impaired functional status, and health service utilization.[14,15] The combination of two chronic diseases presents many diagnostic challenges.[16] This study aims to demonstrate that home automation and remote monitoring can lead to the development of a home safety environment that could help elderly and disabled people live independently in their own homes. In this study, automation sensors containing devices track clinical factors of chronic diseases to monitor their biometric parameters and detect any abnormal decompensation of prodromal disease via remote monitoring and geriatric expertise. Given that multimorbidity (defined as $\geq$2 chronic long-term conditions) is common in older patients, the impact of a home-based telesurveillance program on clinical outcomes is uncertain.

This study primary objective was to determine the feasibility and effectiveness of a 12-month home telemonitoring program in preventing rehospitalizations in elderly patients with two or more chronic diseases returning home after hospitalization in older people residing in rural areas.

Methods

Study design and randomization

This was a randomized controlled trial with 12 months of prospective follow up. The institutional review board approved the study, which was registered on June 4, 2014, at http://www.clinicaltrials.gov (NCT02155686) and was conducted in accordance with CONSORT guidelines, the tenets of the Declaration of Helsinki,[17] and good clinical practice.

All patients aged 65 years or older and some them home was equipped with home automation pack ("Automated Light Path coupled with tele-assistance system"), who had been hospitalized in the year preceding inclusion for the following conditions: heart failure, COPD, diabetes, hypertension, repetitive fall disorders, chronic renal failure, stroke, neurodegenerative diseases, undernutrition (according to HAS (Haute Autorité de Santé), French acronym of Health Authority in France criteria); several chronic diseases (at least 2 comorbidities) and who had given free and informed consent were selected for

inclusion. Exclusion criteria were estimated life expectancy of less than 12 months and enrollment in another clinical trial.

Intervention group. Before discharge, patients in the intervention group received individual educational sessions, explaining the purpose and content of the nurse-led home telemonitoring program, which followed them during the 12-month program. The telemonitoring kit was present only in the intervention group (Figure 1). It consists of the e-GEROPASS software who is an algorithm-based software that analyzes the data for baseline then out of range data that then gets transmitted to the monitoring platform[18] and external biometric sensors that transmit data to a control center. By using a mobile multisensor biometric system (7 external sensors for measuring blood pressure, heart rate, body temperature, oximetry, capillary blood sugar, weight and electrical activity of the heart), the results of the measurements are transmitted via Bluetooth technology to a hub that transfers them securely via the Internet to the e-GEROPASS. The signals were transmitted 24/7. The user or their informal career or professional caregiver need to upload data manually. The e-GEROPASS software allowed the geriatrician to assess and monitor the patient's chronic diseases on a daily basis. The remote expertise was the healthcare provider but software allows for better signal design but the software is not a decision-making tool. The geriatrician transmitted feedback in the form of advice and/or changes to the therapeutic protocol, resulting from the remote expertise to the health personnel in order to optimize the intervention of the attending physician and the paramedical act of monitoring the home care nurse. The latter received an alert on their cell phone telling them to connect to the e-GEROPASS software to read the geriatrician's conclusions. Over all, two geriatricians were involved in the study with an average of 134 (100–150) patients/geriatrician.

Control group. Patients assigned to the control group received usual care from their general practitioner (GP).

For both groups, the usual practice after hospitalization is mainly to treat the consequences of a fall but does not systematically address the patient's risk behaviors. Before discharge, we also recommended that these patients perform exercises focused on improving balance and muscle strength and walk regularly at least twice a week for at least 30 min, and we provided written information about fall risk factors.

For data collection, once a month, participants of both groups received a telephone call from research staff to check the incidence of falls, hospitalizations, and associated complications.

Measures

Program feasibility was assessed in terms of Home-TeleHealth-related side effects and the proportion of patients who completed the program. Home-telehealth-related side effects were defined as an adverse effect related to the use of the telemonitoring system. For example: not calling their own referring GP in an emergency case or having been treated on the basis of geriatric referrals based on sensor outliers.

Outcome measures. The primary outcome measure is the cumulative incidence of rehospitalizations for functional decompensation at 12 months. The secondary objective was to describe the clinical outcomes of rehospitalisations.

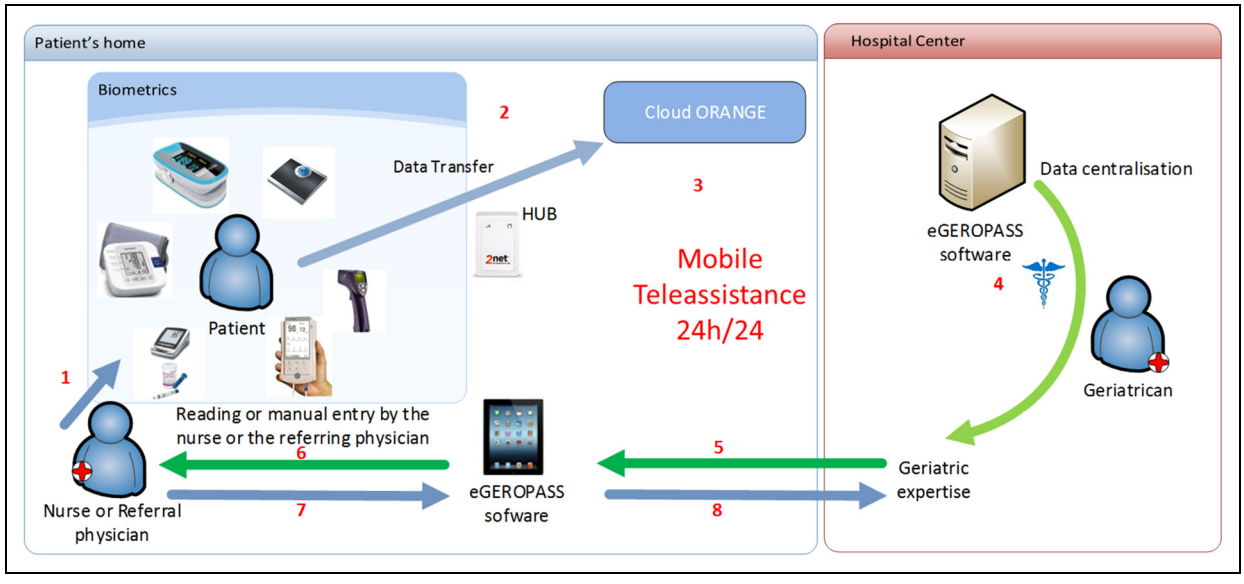

Figure 1. The eCOBAHLT telemonitoring intervention.

Sample size and statistical analysis

Data are presented as mean ± standard deviation (SD) or percentages, as appropriate. The comparison of the groups is based on this primary outcome measure. The test is a superiority test. Based on an alpha risk of 5%, a beta risk of 10%, and an estimated annual incidence of rehospitalization for functional decompensation in the polypathological elderly of 40% and assuming a 30% reduction in the risk of rehospitalization[19] in the intervention group, a minimum of 244 participants per group should therefore be recruited, for a total of 488 evaluable participants. To consider a 10% proportion of non-evaluable participants in this home-based research, a total of 536 individuals must be recruited, or 268 participants per group. We calculated the relative risk (RR) with 95% confidence interval (CIs). Calculation was performed using Nquery Advisor 7.0.

Results

A total of 534 patients were recruited between April 2014 and December 2015 and randomized: 237 to the intervention group and 237 to the control group. The follow up was completed in June 2016. Figure 1 shows the flow chart of the study. Patients had a mean age of 80.3 ± 8.1 years, were predominantly female (52.4%), and had a mean physical burden of disease as measured by the comorbidity index.[20] The distribution of major comorbidities was similar in the two groups except for heart failure ($p = 0.0035$). A total of 182 (34.1) had CHF, 115 (21.5%) had stroke, and 77 (14.4%) had diabetes. The baseline demographic and clinical characteristics of the patients are presented in Table 1. No home-telehealth-related side effects were recorded. And 19 (7.1%) of patients in intervention have not completed the program (Figure 2).

The proportion of unscheduled rehospitalizations was 40.4% (108 patients) in the intervention group and 48.7% (130 patients) in the control group. This difference was significant ($p = 0.043$) (Table 2). The risk of rehospitalization was significantly reduced in the intervention group (age-adjusted and sex-adjusted RR: 0.72, 95% CI 0.51–0.94) and still significant when adjust on the rate of CHF condition in the two groups. The proportion of emergency admissions without hospitalization was 6.0% (16 patients) in the intervention group and 2.2% (6 patients) in the control group. This difference was significant ($p = 0.027$). The main reasons of rehospitalization were CHF decompensation, COPD exacerbation, and recurrent falls (Table 3).

Discussion

The main result of this study was a significant reduction in the proportion of unscheduled hospitalizations or emergency room admissions followed by hospitalization. However, this remote monitoring generated more emergency room admissions without hospitalization.[21,22] Remote monitoring of biometric parameters significantly reduces the number of unscheduled hospitalizations. Thanks to the visualization of the biometric parameters' evolution curves and to the global gerontological evaluation performed in situ at the participant's home, the remote physician was able to manage the clinical situations before a decompensation in order to avoid a hospitalization. The objective of this remote monitoring is above all to anticipate, based on weak signals, any factors that could decompensate stabilized comorbidities. This is the example of the monitoring of the weight curve whose unexplained increase can allow early detection of a risk of future cardiac decompensation. This alert of the increase in weight transmitted to the attending physician allows him to adapt the diuretic treatment of the heart failure.

The unavailability of the attending physician leads to an increased admission to the emergency room for an adjustment of the treatments. This program therefore generates more emergency room visits without necessarily leading to hospitalizations. However, there are more emergency room visits without hospitalization. This result can be explained by the number of unscheduled hospitalizations, which was lower in the equipped group than in the control group. Indeed, while remote monitoring of biometric parameters decreases the rate of unscheduled hospitalizations, it increases the rate of patients admitted to the emergency room. This could be explained by the fact that the attending physician sometimes requires additional examinations and therefore the technical platform to carry out, for example, pulmonary imaging in the event of early cardiac decompensation. It is also conceivable that participation in the research protocol induces a bias in the attending physician who may feel observed by the tele-expert geriatrician and who wishes to be reassured in the care he or she provides, hence more frequent admissions with a return home without hospitalization. He wants to be reassured. The question then arises of training attending physicians in the management of complex polypathological situations in the elderly. It has been shown that a structured physician-directed, nurse, a physiotherapist-managed telemonitoring program for chronic patients can be better than the standard of care. Disabled older adults, if supported by a structured program, and even with limited prior experience using computers, are not resistant to using technology to access new types of healthcare service.[23,24]

We acknowledge several limitations. The memory bias could be possible because elderly patients were recalled over the past month to collect how many falls and complications they had but we also ask this question to informal carers or patient referral physician. Here it's possible that we had underestimate falls rate in the two groups. The population studied in eCOBAHLT is mostly (>50%)

Table 1. Demographic and clinical characteristics of patients at baseline, the eCOBAHLT randomized controlled trial; N = 534.

Characteristics at baseline	Population (N = 534)	Intervention group N = 267	Control group N = 267
Age (years) mean ± SD	80.3 ± 8.1	80.3 ± 8.3	80.3 ± 7.9
Female gender	280 (52.4)	147 (55.0)	133 (49.8)
Marital status			
Widow(er)	259 (48.5)	129 (48.3)	130 (48.7)
Married	198 (37.1)	99 (37.1)	99 (37.1)
Single	77 (14.4)	39 (14.6)	38 (14.3)
Educational level			
Can read, write, count	151 (28.3)	74 (27.7)	77 (28.8)
Certificate of primary education	216 (40.4)	104 (39.0)	112 (41.9)
College certificate	75 (14.0)	39 (14.6)	36 (13.5)
Secondary/higher education	92 (17.2)	50 (18.7)	32 (15.7)
Housing			
Individual housing	429 (80.3)	215 (80.5)	214 (80.1)
Residential home	105 (19.7)	52 (19.5)	53 (19.9)
Living area			
Urban	306 (57.3)	162 (60.7)	144 (53.9)
Rural	228 (42.7)	105 (39.3)	123 (46.1)
Functional independence			
Dependent on assistance in basis ADL	290 (54.3)	141 (52.8)	149 (55.8)
Dependent on assistance in IADL	306 (57.3)	162 (60.7)	144 (53.9)
SMAF (score) mean ± SD	23.4 ± 15.8	24.3 ± 16.5	22.5 ± 15.1
Domotic and Teleassistance devices	44 (8.2)	20 (7.5)	24 (9.0)
Presence of caregiver	178 (33.3)	90 (33.7)	88 (33.0)
Previous hospitalization in last year	534 (100)	267 (100)	267 (100)
Medical condition			
Chronic heart failure*	182 (34.1)	107 (40.1)	75 (28.1)
COPD	37 (6.9)	16 (6.0)	21 (7.9)
Diabetes	77 (14.4)	36 (13.5)	41 (15.4)
Hypertension	14 (2.6)	7 (2.6)	7 (2.6)
Chronic kidney failure	61 (11.4)	34 (12.7)	27 (10.1)
Recurrent falls*	36 (6.7)	13 (4.9)	23 (8.6)
Stroke	115 (21.5)	50 (18.7)	65 (24.3)
Neurodegenerative disease	8 (1.5)	2 (0.7)	6 (2.2)
Denutrition	4 (0.7)	2 (0.7)	2 (0.7)

*p-Value significant for medical condition. There are significative difference from chronic heart failure between the two group in favor of intervention group $p = 0.0035$). No significant difference from the other parameters. But also, for recurrent falls in favour of control group. ADL: Activity of Daily Living; IADL: Instrumental ADL; SD: standard deviation; SMAF, Système de mesure de l'autonomie fonctionnelle.

dependent on assistance in basis Activity of Daily Living (ADL)[25] or Instrumental ADL.[26] The average score found in the control group and the equipped group is considered equivalent. It corresponds to a loss of autonomy requiring the implementation of aids (human and/or technical). This characteristic is found in the literature, but as it's expected to be evaluated with other tools of functional independence the comparison is not relevant.[27,28] We selected the conditions identified in the inclusion criteria as predominant in the elderly population. In the top six diseases that resulted in hospitalization in the year before inclusion, we found the order of prevalence in the literature in the homebound elderly, with the exception of COPD and renal failure, which were under-represented in the study population: heart failure, stroke, diabetes, falls, COPD, and renal failure. It is important that the risk of chronic disease decompensation or falling be perceived as a problem that needs to be faced when the patient is still at home.[29] Multifactorial personalized interventions need to be undertaken, as well as prevention and education programs involving all in a proactive way, from the patient to the GP.[30,31] Despite limitations in this study, our approach had a number of strengths supporting our conclusions.

Conclusions and implications

This 12-month home telemonitoring program with online biometric sensor analysis is feasible and effective in preventing unscheduled hospitalizations for chronic disease decompensation in polypathological elderly patients at

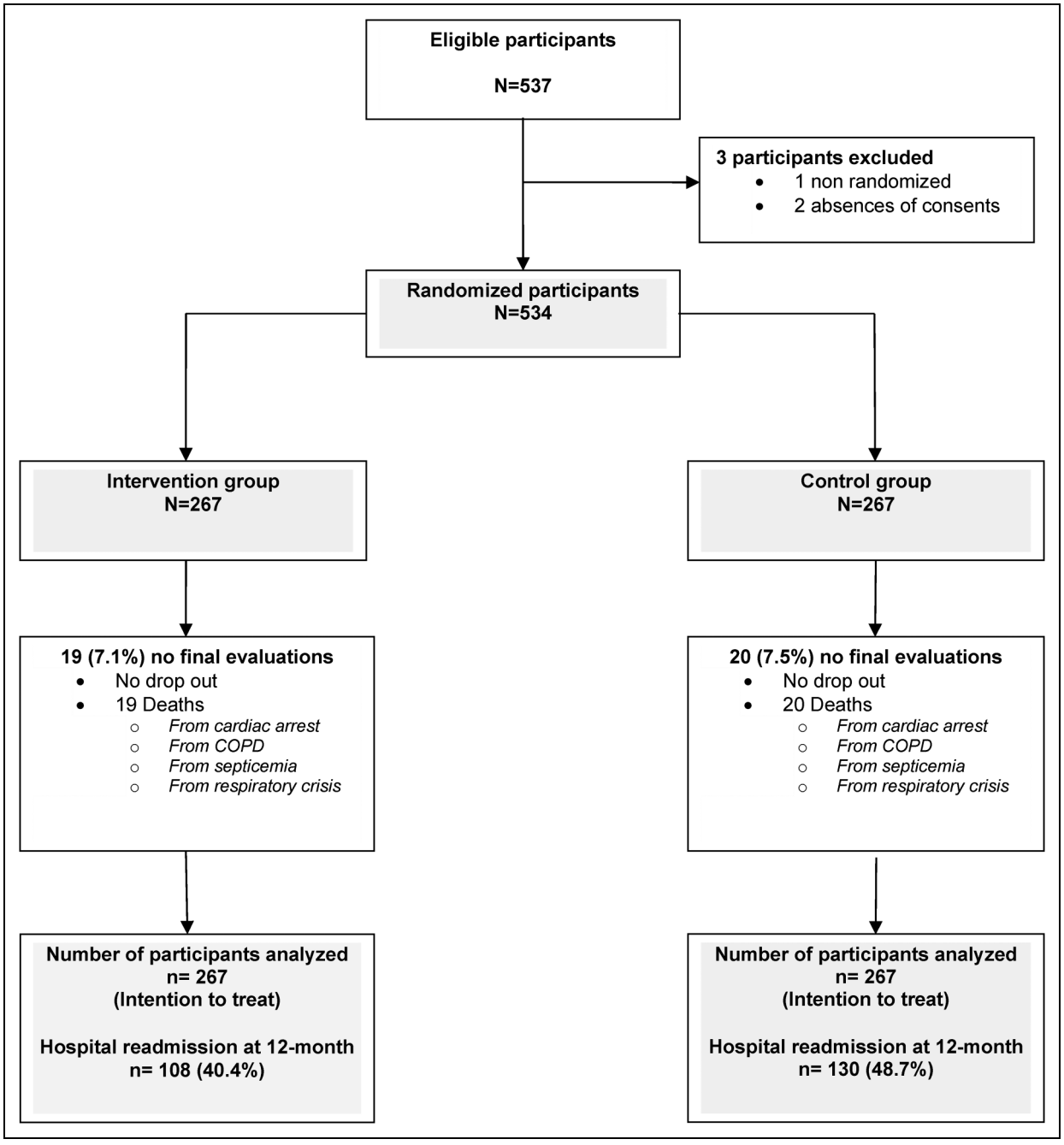

Figure 2. Flow chart of the eCOBAHLT randomized controlled trial.

Table 2. The 12-month outcomes of the eCOBAHLT randomized controlled trial; N = 534.

Outcomes	Total population (N = 534)	Intervention group N = 267	Control group N = 267	*p*-Value
ED visits without hospitalization, n (%)	22 (4.1)	16 (6.0)	6 (2.2)	0.027
Unplanned hospitalizations, n (%)	238 (44.6)	108 (40.4)	130 (48,7)	0.043

high risk for hospitalization. However, this effectiveness depends on the responsiveness of the treating physician to apply the recommendations of the remote monitoring center, which analyzes alerts from the patient's home. Remote monitoring of elderly patients with polypathology can be an opportunity to reduce over-medicalization of

Table 3. Adverse events with hospitalizations due to chronic disease decompensation in intervention group and control group, during the 12-month program, the eCOBAHLT randomized controlled trial; N = 534.

	Adverse events with hospitalization (N (%))		
Chronic diseases	Intervention group (n = 83)	Control group (n = 91)	*p*-Value
Cardiovascular system[a], n (%)	19 (22.9)	16 (17.6)	0.38
Respiratory system[b], n (%)	12 (14.5)	20 (22.0)	0.20
Metabolic disorders[c], n (%)	3 (3.6)	6 (6.6)	0.37
Hypertension, n (%)	2 (2.4)	0 (0)	0.14
Kidney system[d], n (%)	6 (7.2)	4 (4.4)	0.42
Neurovascular accidents[e], n (%)	6 (7.2)	4 (4.4)	0.42
Neurocognitive disorders[f], n (%)	4 (4.8)	4 (4.4)	0.87
Recurrent falls, n (%)	31 (37.3)	37 (40.7)	0.65

[a]Heart failure, cardiac decompensation.
[b]Bronchitis, bronchial superinfection, chronic obstructive pulmonary disease, respiratory failure, bronchial congestion.
[c]Diabetes, hypoglycemia, hyperglycemia.
[d]Pyelonephritis, renal failure.
[e]Hemorrhagic stroke, ischemic stroke.
[f]Cognitive disorders, Alzheimer's disease, delirium, behavioral disorders.

certain nonsymptomatic subclinical situations, but it is also effective in reducing more serious admissions requiring hospitalization.

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Authors' contributions

AT and CG drafted the manuscript. AT, CG, IT, DTE, and PMP read and revised the manuscript. SL, CG, PMP, and AT assisted with the statistical analysis. CG, CLM, NC, PK, TM, PF, and AT collected the data. CG, AT, SL, and PMP helped formulate the study methodology and draft the manuscript. All authors have read and approved the final manuscript.

Availability of data and materials

The datasets analyzed during the current study and the study protocol are available from the corresponding author on reasonable request.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethics approval and consent to participate

The trial received ethical approval from the local institutional review board (Comité de Protection des Personnes du Sud-ouest et Outre-mer IV) on 3 February 2014. The French "*Agence Nationale de Sécurité du Médicament et des Produits de Santé"* was notified. This research has been registered in http://www.clinicaltrials.gov/ on 02/06/2014 under the n° NCT02155686. Patients or their legal representatives gave written informed consent. We confirm that all experiments were performed in accordance with relevant guidelines and regulations.

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ORCID iD

Achille Tchalla https://orcid.org/0000-0003-3457-5219

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