Reduced use of healthcare services and increased social activities in COPD patients offered a telehealth service based on the Epital Care Model: “A pragmatic step-wedge controlled trial”

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Abstract

Background: Many healthcare systems confront considerable strain attributable to an escalating prevalence of older adults living longer leading to an increased number of people with chronic conditions. Concomitantly the numbers of trained professionals in the healthcare workforce is not keeping up with the increased numbers of people with chronic conditions. In this context, increased digitalization is considered one way to mitigate many of the challenges, but it remains to be documented whether this is of benefit to COPD patients. The Epital Care Model (ECM) constitutes a proactive and data-centric treatment paradigm that leverages patient-reported outcome data and 24/7 telehealth service to facilitate early detection of deteriorating conditions among patients with chronic diseases (1). This approach aims to reduce and address exacerbations early, thereby averting the need for extensive and resource-intensive interventions. It is noteworthy that the Epital frontline service is delivered by trained and certified staff consisting of students from health educations and not by health care professionals.

Objective: This clinical controlled trial was conducted to investigate the impact of the virtual component of the ECM framework in COPD on healthcare resource utilization and participants mental wellbeing and social activities.

Methods: A pragmatic step-wedged design was employed, involving the random allocation of 184 patients into either an intervention group (n=92) or a control group (n=92), with equitable distribution across four general practice clinics in Denmark. Participants were examined at an 8-month (T1) follow-up and 12-month (T2) follow-up. Healthcare service utilisation and participants’ social activity were assessed and compared using Poisson regression. Mental wellbeing was assessed by comparing the scores on the WHO-5 wellbeing index using an unpaired t-test.

Results: A significant reduction of healthcare utilization associated with COPD was found in the intervention group at T2, with reduced hospital admissions (56%), general practitioner visits (78%), on-call doctor consultations (73%), emergency room visits (49% reduction), and outpatient attendances (60% reduction) compared to the control group. Further, there was a significant increase in social activities ($p< 0.01$) and travel activities abroad ($p< 0.01$) at T2 in the intervention group, but no difference was found in well-being (WHO-5 index) between the two groups

Conclusions: The study highlights the value of the ECM virtual care model in COPD management, offering a potential solution to healthcare workforce shortages and resource constraints as it leads to both a significantly reduced use of healthcare services and at the same time introduces a new kind of workforce to complement the existing workforce. Further research using this model in other chronic conditions and other healthcare systems is warranted based on these findings. Clinical Trial: No trial registration has been performed. The protocol is available from: https://epital.com/temokap-protokol-2/

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Abstract:

Many healthcare systems confront considerable strain attributable to an escalating prevalence of older adults living longer leading to an increased number of people with chronic conditions. Concomitantly the numbers of trained professionals in the healthcare workforce is not keeping up with the increased numbers of people with chronic conditions. In this context, increased

digitalization is considered one way to mitigate many of the challenges, but it remains to be documented whether this is of benefit to COPD patients. The Epital Care Model (ECM) constitutes a proactive and data-centric treatment paradigm that leverages patient-reported outcome data and 24/7 telehealth service to facilitate early detection of deteriorating conditions among patients with chronic diseases (1). This approach aims to reduce and address exacerbations early, thereby averting the need for extensive and resource-intensive interventions. It is noteworthy that the Epital frontline service is delivered by trained and certified staff consisting of students from health educations and not by health care professionals.
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Methods: A pragmatic step-wedged design was employed, involving the random allocation of 184 patients into either an intervention group (n=92) or a control group (n=92), with equitable distribution across four general practice clinics in Denmark. Participants were examined at an 8-month (T1) follow-up and 12-month (T2) follow-up. Healthcare service utilisation and participants' social activity were assessed and compared using Poisson regression. Mental wellbeing was assessed by comparing the scores on the WHO-5 wellbeing index using an unpaired t-test.

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In conclusion: The study highlights the value of the ECM virtual care model in COPD management, offering a potential solution to healthcare workforce shortages and resource constraints as it leads to both a significantly reduced use of healthcare services and at the same time introduces a new kind of

workforce to complement the existing workforce. Further research using this model in other chronic conditions and other healthcare systems is warranted based on these findings.

Keywords:
COPD; telehealth, exacerbations, Epital Care Model; patient-reported outcomes; early interventions; management

Introduction

Western healthcare systems are under huge pressure around the globe with an ageing population, healthcare provider burnout, workforce shortages, supply chain disruptions and equipment shortages, lack of hospital beds and outdated facilities (2). Of these, the ageing population and its impact is by far one of the largest challenges for healthcare systems in high- and middle-income countries. The global population of the oldest seniors, 80 years of age or older, is expected to triple between 2020 and 2050 to reach 426 million by 2050 (3). Due, largely to ageing and its association with increased chronic disease, pressures on healthcare systems are substantial. In addition most healthcare systems are suffering from a shortage of healthcare professionals. These factors have led to a search for innovative and effective solutions.

In this context, digital health services and new technologies, including telehealth, may, if appropriately implemented, be of advantage to older people with long-term health conditions (LTHC) and may facilitate easier and more efficient access to health services (4).

One of the largest challenges of LTHC is chronic obstructive pulmonary disease (COPD) which is the third leading cause of death worldwide, causing 3.23 million deaths in 2019 (5,6). COPD is characterized by a gradual deterioration with progressive loss of pulmonary function over time, with intermittent episodes of exacerbations (5,7).

The treatment of COPD exacerbations (ECOPD) is a key area of focus when it comes to resource-saving efforts and quality improvement. ECOPD is known to be associated with high in-hospital mortality, deterioration in quality of life, increased decline in lung function over time, decreased expected lifetime and ECOPD is the largest component of the socioeconomic burden of living with COPD (8,9). To reduce the burden of COPD, it is critical to make an accurate diagnosis, manage the patient effectively, and detect the patient's symptoms early in the deterioration process (10).

The two important issues that need to be addressed are initiatives to postpone the progression of the disease - that is, to be able to keep the patients for as long as possible in the mild stages of the disease. This will have the effect of

saving resources and maintaining the individuals quality of life. Second, interventions directed toward therapies that more effectively prevent or treat ECOPD. Given that most exacerbations go unreported (11) and that early treatment results in better outcomes (12), the development of treatment models that enhance regular monitoring of changes in lung function over time, early detection of exacerbations with timely intervention with proven therapies should be targeted (13–15).

Numerous studies have reported the use of telehealth to monitor COPD to initiate early supportive and medical interventions, supervision of medical issues, care support through reassuring conversations, telerehabilitation, and prescription renewals, amongst others (16–21). There is, however, a lack of consensus in the research literature regarding the effect of telehealth, in the prevention of acute exacerbations, emergency room visits, hospitalizations, or quality of life. Nonetheless telehealth services are in widespread use and considered to be effective by professionals, health service providers and patients and not to cause any harm (18,22).

The Epital Care Model (ECM) is a person-centred, data-driven health service model (1), supporting the digital health service transformation informed by the WHO strategy to have integrated people-centred health services that empowers individuals to be self-managed and be more active in the patient pathway (23).

The ECM functions are mainly based on patient-generated health condition data (PRO) to which the underlying service organization responds synchronously, with a range of responses in the form of medical treatments or supervision, adapted to the patient's reported underlying change in health or mental state.

The ECM has been tested in a number of studies during the last decade in various municipalities in Denmark (22,24,25)). One study demonstrated that by using the Epital framework patients showed an increased understanding of their COPD, an increased self-management of their condition and concomitantly a reduction of their emotional distress (24). Another study reported that 69.4% of the severe exacerbations can be managed virtually in the patient’s own home (22). These findings have been confirmed in a further recent observational study in a Danish municipality (The PreCare study), which also build upon the ECM framework (25). These studies used a combination of observational methods,

surveys, and interviews.

To examine this approach with more robust methods we report on a randomized controlled trial to investigate the impact of applying the virtual components of the ECM approach on individuals with COPD. The study aimed to investigate outcomes in a group of COPD patients who received virtual support from an ECM set up as an adjunct to the generally available health services in comparison to a control group who received usual care.

We address the following research questions:

1. In what way does the combination of the virtual ECM service with a traditional service provided by general practitioners' impact on COPD patients' mental wellbeing and social activity?
2. How are the COPD-related use of of primary and secondary healthcare services impacted by patients participating in this virtual service?

Methods

Trial design

The TEMOKAP study is a pragmatic (modified stepped wedge) randomized control study (26,27), where the intervention group receives virtual health services defined by the ECM framework in addition to the usual practice as provided by GPs. The intervention is an examination of the impact of making health care more accessible through technology. There is no testing of technology or equipment, and all the telemedicine monitoring equipment used in the study were CE-marked.

The TEMOKAP study is reported according to the CONSORT checklist for reporting randomized trials (28). A detailed protocol is available in Danish on the internet (29).

Selection and Description of Participants

The patients were recruited from four GP clinics in Denmark (Kalundborg, Vordingborg, Aalborg and Brovst) affiliated with a larger organization of private clinics "allesLægehus" (30), and consecutively randomized in the period from Sept. 2020 to June 2021. The four clinics were geographically spread out in Denmark.

Inclusion criteria:

- Men and women aged ≥ 45 years
- COPD with risk score A, B, C or D according to the criteria of GOLD guidelines (7)
- Minimum three out of six points in cognitive screening test (The Clock Test + Three-Word Recall Memory Test) (31,32)
- Ability to provide oral or written informed consent
- Internet connection in own home (wireless)
- A phone/smartphone and able to use simple functions on the Internet.

Exclusion criteria:

- Significant co-morbidity;
  Unstable heart disease assessed by the investigator
  Poorly regulated diabetes assessed by the investigator
  Mentally debilitating disorders, including substance abuse
  Unable to comprehend spoken and/or written Danish
- Other illness or conditions which rendered the patient unsuitable for participation in the study (e.g., significant hearing or vision impairment).

Participants:

A primary care nurse from each of the four participating clinics sent out trial information to all eligible patients selected from the clinic's electronic patient record system or from the nurses' knowledge of potential candidates who might be suitable inviting them to participate in the study. Appointments were made with all interested patients to attend the clinic for an interview and a clinical examination with the principal investigator (PI).

The PI reconfirmed the diagnosis and the severity of COPD according to the GOLD guidelines, and all consenting participants meeting the eligibility criteria

were enrolled in the trial after reading the patient information and signing the informed consent form. All patients in both the intervention- and the control group were physically examined for the purposes of the study. In addition, to ensure homogeneity of the patients in the two groups, medication adjustments were made according to patients GOLD severity to ensure that all patients were correctly medicated at the outset of the study.

Randomisation

After giving their written consent, 184 patients were randomized using a computer-generated list of random numbers. Patients were randomized 1:1 to the intervention group or the control group, using fixed random block sizes of 10.

The intervention group

Those randomized to the intervention were connected to the ECM response and coordination centre (RCC) which provided the participants with 24/7/365 access to assistance from certified RCC staff who were supported by eDoctors (further details in Multimedia Appendix A). The intervention involved the organizational service and treatment setup from ECM 1 - 2 and the virtual part of ECM 4 that was used in the intervention group (see fig.1).

The participants were encouraged to perform their self-tracking activities daily (saturation, pulse, lung function, temperature and report on increased sputum, coughing, and shortness of breath). They were informed that the RCC would contact them and that they also would get information on their tablet in the event of signs of deterioration. To tackle the condition , the RCC staff together with the participant would make informed decisions, via phone or video call, on how to best manage the change in condition guided by the previous measures evaluated with graphs, including plotted trends. If there was a need for medical treatment, a treatment plan was drawn up with fixed follow-ups and a course plan. The self-monitoring activity was checked daily by the RCC and if there were participants who had not taken measurements for 7 days, they were called by the RCC to clarify the reason for this, remedy any technical problems and encourage future regular reporting of measurements.

Participants in the intervention group were equipped with an acute medicine box at home, to be used when exacerbations occurred to avoid delays in the

initiation of medical treatment. The content was prescribed by the eDoctor, provided directly to the participant by a local pharmacy, and used only in agreement with the RCC staff. For further details (1,22).

The control group

Patients randomized to the control group received the usual care provided by the general practitioner, emergency services from the hospital, outpatient clinics, and on-call doctors.

Figure 1.

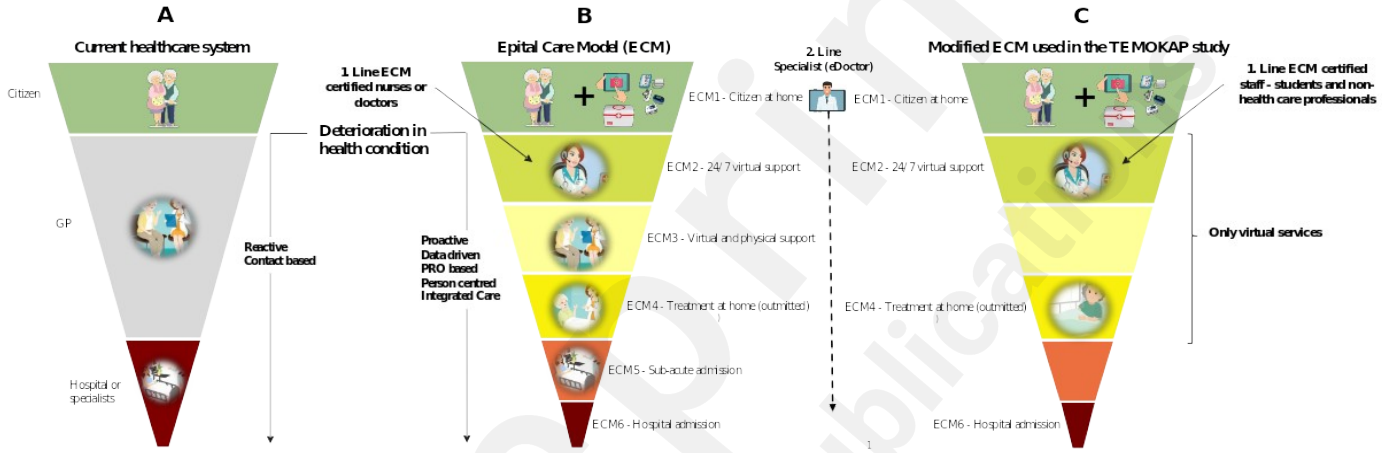

Figure 1. Principles and elements of the Epital Care Model (ECM) compared to a conventional HealthCare System. A: The conventional healthcare system, B: The Epital Care model with all service elements, C: The modified ECM used in the TEMOKAP study.

Upon medical deteriorations, a wide spectrum of health services are activated and organized in the ECM guided by the incoming PRO data from the patient and care activities are taken up by front line staff. All services in the ECM are designed to mitigate the patient back to ECM1. Via the established telehealth solutions deployed within patients' residences in the ECM, wherein patients can routinely report their health status, proactive intervention becomes feasible, allowing for the mitigation of potential exacerbations before they escalate into severe conditions. This stands in contrast to the conventional healthcare system, which is traditionally more reactive and thus has a longer latency period before the deterioration is recognized and treated.

In the TEMOKAP study, a modified version (C) of the ECM was used, which consisted entirely of the virtual elements of the ECM. Thus, there was no opportunity to establish physical contact with the patients from the intervention group, who therefore only received virtual services and help through the telehealth set-up.

The Data Collection

At baseline, all demographic and clinical data were collected at the physical examination. Subsequently, all patients were seen by a certified health IT student (RCC staff) who assisted and supervised the patients while they completed the planned

questionnaires; WHO-Wellbeing index, registration of patients' social and mobility activities and the Readiness and enablement index for health technology (READHY) questionnaire (Personal communication Palshof M 2024) . The RCC staff provided the tablet and monitoring equipment and who, together with the patient, went through a standardized training program in the use of the equipment. To ensure a high level of compliance, subsequent virtual follow-ups with the participant occurred after 1 week, 14 days and after 1 month, where the follow-up after 1 month included a conversation with the PI. The collection of data for the follow-up visits took place exclusively virtually.

Follow-up visits planned at 8 and 12 months (T1 and T2) were conducted over the telephone, where the participants were interviewed and filled in all questionnaires together with the RCC staff. The staff checked the supplemented data from postings in the clinic's EHR system, where the patient's contact patterns with the healthcare system are documented. In cases where there was a discrepancy between the patient's and the clinic system's counts, the clinic EHR system's data prevailed. As a further quality control, all the patients who had had hospitalizations were contacted an additional time by a co-investigator, to ensure that the total number of hospitalizations in the two groups was COPD-related.

Outcome measures

Primary outcome measure

The primary planned outcome was the patient’s mental well-being as assessed by the WHO-5 Well-Being Index. This is a validated questionnaire that examines patients' mental well-being and can also indicate anxiety, stress, and depression. The well-being index was measured at T0, T1 and T2 in both groups to examine potential differences over time (33).

A second primary outcome was the patients' COPD related contacts to healthcare services. This included general practice (GP), out-of-offices services, outpatient clinics and hospital admissions at T0, T1 and T2 in both groups. Baseline information on hospital admissions was also examined retrospectively 12 months from the date of inclusion.

In parallel the participants technology readiness was assessed using the READHY instrument (34) at T0, T1 and T2, data to be reported elsewhere.

Data are only self-reported but were verified by the clinical co-investigators with

interviews to ensure that the COPD-related outcomes were accurate.

Secondary outcome measures

As part of the value creation for the patients, we examined social and mobility activities within the two groups. Participants were asked about their social activities in the form of participation in entertainment and cultural events at T1 and T2 in both groups. Further, they were asked about their activities outside of Denmark in connection with holidays or visits to friends or family.

Ethics

The project was conducted in accordance with the Helsinki Declaration. A signed consent was obtained from all participants after information about the project was given orally as well as text and were informed that participation was voluntary and that they could withdraw from the study at any time. Participants did not receive any financial compensation for their participation. Accordingly to Danish practice, projects that do not involve testing of technical equipment or drugs and not involves sampling of diagnostic material or tissues do not require an approval from an ethical committee.

The intervention in this study does not differ from the usual practice from services provided by the Epital (the ECM Clinic). The clinic is regularly monitored by the Danish Patient Safety Authority and was latest accredited April 20th 2023.

Statistics

Sample size calculations

The number of required participants was calculated using "power.t.test" in RStudio using the "Two-sample t-test power calculation" option and a fixed analytical power of 0.8 and significance level of 0.05. The WHO well-being index has been chosen as the effect parameter. The background data used to determine the standard deviation (SD) of the effect parameter was used from a population of 67 COPD patients with GOLD status B, C or D, who were part of a pilot project that was a precursor to the TEMOCAP study. In the pilot project, the mean value was calculated to be 61.79 with an SD = 20.59.

Since previous studies have estimated that a difference of 10 points in the WHO well-being index is clinically relevant (35), the following variables were used for

the calculation: (Mean = 61.79, SD = 20.59, Delta = 10, Power = 0.8 and Significance Level = 0.05). The two-sided t-test power calculation thus gives a result with n= 68 in each group. The sample has been increased by 10% to ensure analytical power to accommodate an additional explanatory variable in an analysis model in addition to intervention, as well as a further 20% for a potential dropout during the study, a total of 30% increased number of patients (Estimated patients necessary for the study in total = (2 x 68) + (68/100 x 30) = 178 patients).

Data analysis

The baseline data included demographic data (sex, age) , FEV1 %pred., GOLD severity and risk factor classifications, number of comorbidities, body mass index (BMI) , smoking status (smoking/non-smoking/never smoked), "number of packages smoked per year", MRC dyspnea score (36), admission within the last year and WHO-5 Wellbeing Index.

A Two-Sample unpaired t-test (Welch) and Fishers exact test were used to determine whether differences existed between the two groups (intervention vs control).

We report primary data for WHO-5 Well-being Index and for admissions, out-of-office service, out-patient clinics, and general practitioners (GP), activities outside Denmark and participation in cultural events.

deviations.

We conducted two separate analyses; an intention to treat and a per protocol analyses. For the analysis of the differences between the intervention-group and the control-group of the use of health care services and social activities respectively, we calculated a rate ratio with corresponding 95% CIs using Poisson regression models. Two models were tested for each exposure variable: Model 1 was unadjusted; Model 2 was adjusted for age, GOLD severity, time at risk and co-morbidities.

For the analysis of differences between the intervention-group and the control-group within the WHO Wellbeing Index, we performed an un-paired T-test of within differences between the groups and a paired T-test comparing at T0, T1 and T2 (data presented as CIs and T-value).

For all tests, a significance level of .05 was used. The open-source statistical

program R version 1.4.1717 was used for the analysis.

Results

Participants

Figure 2 shows the flow of the patients through the 12-month trial period. A total of 197 patients were invited to one of the four clinics. Out of these, four patients did not attend and nine did not meet the inclusion criteria with the result that 184 patients were randomized to either the intervention group (n=92) or the control group (n=92), equally distributed from the four GP clinics. Fifteen patients randomised to the control group withdrew after being informed that they were not going to receive an intervention. Four patients were excluded after randomisation due to lack of access to Wi-Fi at home (n=3) and cognitive difficulties (n=1).

At T1, there were a total of 142 participants (77 in the intervention group and 65 in the control group), data was missing from two participants: one in each group.

At T2, a total of 138 participants completed the study (76 in the intervention group and 62 in the control group). One participant died before completing the telephone interview.

Figure 2. Flow chart

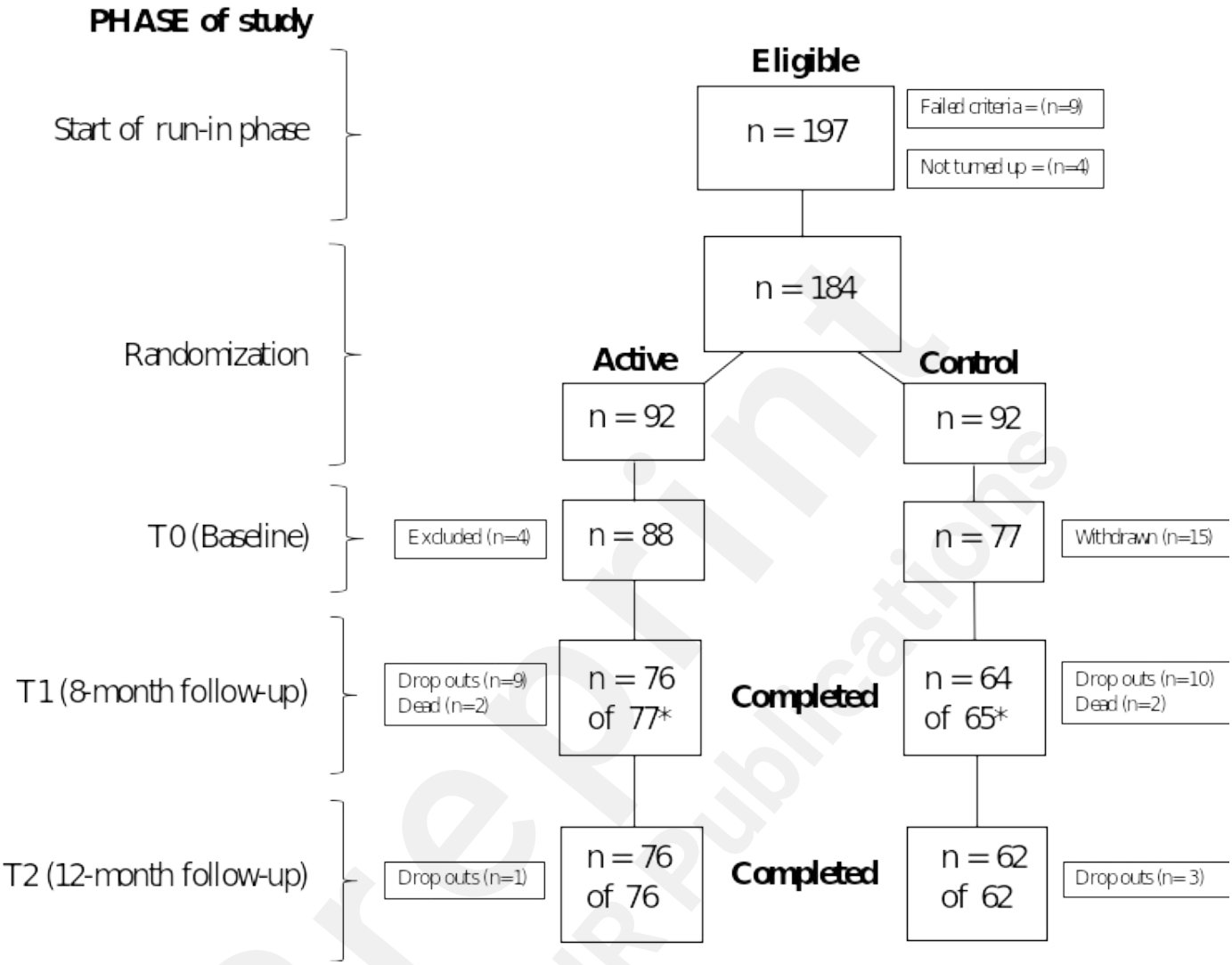

Figure 2. The TEMOKAP study flow chart; shows the profile of the number of patients (ITT) at each phase of the study period of 12 months. T0 = Baseline at inclusion, T1 = 8-month follow-up, T2 = 12- month follow-up.
**Data at T1 missing from two participants, one in each group*

Table 1: Demographics and baseline parameters including the WHO well-being index

	Intervention (N=92)			Control (N=92)			Two sample T-test
	Mean (SD)	n	%	Mean (SD)	n	%	
Age (years)	67.96 (9.33)			69.39(10.11)			0.32
<50		3	3		3	3	
50-59		12	13		13	15	
60-69		32	35		29	32	
70-79		38	41		35	38	
80-89		7	8		11	12	
>90		0	0		1	1	
FEV_1PRED%	54.37 (18.31)			52.30(18.35)			0.45
<30		8	9		8	9	
30-49		29	32		37	40	
50-79		50	54		40	43	
>80		5	5		7	8	
Co- and multimorbidity	1.68 (1.22)			1.75 (1.31)			0.73
BMI	27.40 (5.82)			26.50 (6.08)			0.31
<18.5		4	4		2	2	
18.5-24.9		30	33		43	47	
25-29.9		27	29		25	27	
>30		31	34		22	24	
Pack-year	40.40 (17.79)			38.27(16.90)			0.41
MRC	1.78 (0.99)			1.75 (0.97)			0.82
0		1	1		4	4	
1		46	50		40	43	
2		25	27		28	30	
3		12	13		15	16	
4		8	9		5	5	
Admissions (one year prior)	0.26 (0.72)			0.22 (0.46)			0.63
WHO well-being index	65.13 (18.55)			61.26(21.48)			0.19
							Chi-squared Test
Sex, n (%)							
Female		47	51		43	47	0.66

Male	45	49	49	53	
Smoke Status, n (%)					
Smoker	36	39	42	46	
Nonsmoker	55	60	46	50	0.22
Never smoked	1	1	4	4	
Risk score, n (%)					
AB	58	63	65	71	0.35
CD	34	37	27	29	

Table 1, Demographics, and baseline parameters including the WHO well-being index.

Sociodemographic characteristics at T0 were similar with no significant difference between the intervention and control group.

WHO-5Well-being index (WHO-5)

WHO-5 index was measured at baseline, at T1 and T2 (table 2.a, table 2.b). No differences were found between the two groups at baseline, T1 or T2 (Table 2a). There were neither a change at T1 or T2 for the intervention or control groups (Table 1).

Table 2.a: Unpaired t-test analyses at baseline, T1and with WHO-5 as outcome variable.

	Intervention, Mean (SD)	Control, mean (SD)	Estimate, [CI]	P-value
Baseline	65.13 (18.55)[a]	61.26 (21.48)[a]	-3.87 [-9.71;1.97]	0.19
Follow-up (T1)	63.94 (21.00)[b]	61.93 (21.65)[c]	0.15 [-7.42;7.71]	0.97
Follow-up (T2)	68.76 (17.29)[b]	59.70 (19.51)[d]	-4.12 [-10.75;2.51]	0.22

a: n = 92
b: n = 68
c: n = 60
d: n = 53

Table 2.b: Paired t-test analyses at 8- and 12-month follow-up (T1 and T2) with WHO-5 as outcome variable.

	Intervention		Control	
	Estimate, [CI]	P-value	Estimate, [CI]	P-value

Follow-up (T1)	-0.41 [-4.88;4.06]	0.85	-0.27 [-6.45;5.92]	0.93
Follow-up (T2)	3.59 [-0.66;7.84]	0.10	-0.53 [-5.70;4.65]	0.84

Contact to healthcare services

Results from the intention to treat are presented below. Per protocol analyses are provided as Multimedia Appendix B.

COPD-related contact with health care services

Table 3 shows the unadjusted and adjusted differences in the contact patterns with the healthcare services of the intervention group compared to the control groupat both T1 (Table 3a) and T2 (Table 3b). .

At T1 there was a reduction in COPD-related admissions of 65%, 70% in contacts to out-of-office services and 79% in GP visits. At T2 there was a reduction COPD-related admissions of 56%, 73% in contacts to out-of-office services, 60% in visits to outpatient clinics and 78% in GP visits. There was a non-significant reduction of 49% in contacts to out-of-office service at T1. After adjustment for age, GOLD, risk time and comorbidities, out-of-office service at T2 was not significant

Table 3a: COPD-related contact to healthcare services at T1 (Intention to Treat)

	Intervention (N=76)	**Control (N=64)**	**Estimate, [CI]**	**P-value**	**Adjusted estimate[a], [CI]**	**P-value**
Admissions	8	19	0.35 [0.15;0.78]	0.01	0.38 [0.16;0.85]	0.02
Out-of-office service	5	14	0.30 [0.10;0.79]	0.02	0.26 [0.08;0.71]	0.01
Outpatient clinics	12	20	0.51 [0.24;1.02]	0.06	0.59 [0.27;1.21]	0.16
General practitioner	30	120	0.21 [0.14;0.31]	<0.01	0.24 [0.16;0.37]	<0.01

Table 3b: COPD-related contact to healthcare services at T2 (Intention to Treat)

	Intervention (N=77)	Control (N=65)	Estimate, [CI]	P-value	Adjusted estimate[a], [CI]	P-value
Admissions	14	27	0.44 [0.22;0.82]	0.01	0.51 [0.26;0.96]	0.04
Out-of-office service	9	28	0.27 [0.12;0.55]	<0.01	0.49 [0.21;1.07]	0.09
Outpatient clinics	18	38	0.40 [0.22;0.69]	<0.01	0.49 [0.27;0.87]	0.02
General practitioner	44	172	0.22 [0.15;0.30]	<0.01	0.25 [0.17;0.35]	<0.01

[a]Adjusted for age, GOLD, risk time, and comorbidities.

Table 3a and table 3b, shows the outcome reduction in admissions, out-of-office services, visits to outpatient clinics and GP visits in the intervention group compared to the control group at T1 and T2. The outcome reduction was significant (p<0.05) on all parameters in the intervention group except for the outpatient clinic visit at T1 and the out-of-office services at T2. A Poisson regression was used to calculate the estimate, CI, and p-values. The estimate indicates the likelihood of an event occurring for those not receiving the intervention.

Cultural events and travel abroad

Table 4 shows differences in the engagement in cultural events and travel abroad in the intervention and control groups. In both the adjusted and unadjusted analyses at both Time 1 and Time 2 the intervention group engaged in more cultural events and travels abroad in comparison to the Control Group.

At T1 there was an increase in the number of participations in cultural events of 190% and 345% in the number of travels abroad Table 4a). At T2 there was an increase in the number of participation in cultural events of 69% and 193% in the number of travels abroad (Table 4b). The number of travel days is not reported here. The adjustment for age, GOLD, risk factor and comorbidities did not influence the level of significance. There were no changes after adjustments*.

Table 4a: Cultural events and travels at T1 follow-up (ITT)

	Intervention (N=76)	Control (N=64)	Estimate, [CI]	P-value	Adjusted estimate[a], [CI]	P-value
Cultural	169	49	2.90	< 0.01	2.84	< 0.01

events			[2.13;4.03]		[2.07;3.97]	
Travel abroad	37	7	4.45 [2.11;10.90]	< 0.01	3.82 [1.79;9.44]	< 0.01

Table 4b: Cultural events and travels at T2 follow-up (ITT)

	Intervention (N=77)	Control (N=65)	Estimate, [CI]	P-value	Adjusted estimate[a], [CI]	P-value
Cultural events	296	148	1.69 [1.39;2.06]	< 0.01	1.73 [1.42;2.13]	< 0.01
Travel abroad	52	15	2.93 [1.69;5.38]	< 0.01	2.50 [1.43;4.65]	< 0.01

[a]Adjusted for age, GOLD, risk factor, and comorbidities.

Table 4 shows the number and the differences in cultural events (participation in entertainment and cultural events outside of home) and travels abroad (outside Denmark) in the periods T0-T1 and T1-T2. A poisson regression was used to calculate the estimate, CI, and p-values. The estimate indicates the likelihood of an event occurring for those not receiving the intervention.

Discussion

While the ECM intervention did not seem to influence participants self-reported well-being other outcomes showed both a reduction in COPD related contacts to health care services and an increase in social activity.

We found a reduction in the intervention group in almost all of the four measures of contact with the healthcare services. Hospital admissions, visits to

general practitioners, on-call doctors, emergency room visits, and outpatient attendances were all significantly lower in the intervention group. The data supports that health services can, when supported by technology with a second level of health professionals, be efficient even when manned with trained and certified non-health professionals. Another important finding is that the intervention resulted in a higher level of engagement in social activity and more days spend on holiday trips abroad compared to the control group. Surprisingly this did not result in an increase in the WHO wellbeing index but this may be dues to the transient and intermittent feature of social activities and the small sample size.

Our findings are in alignment with several other observational Danish studies using equivalent technology (25). In the Danish PreCare study (PPC), the number of acute COPD-related contacts fell by 41% after inclusion in the study for at least one year, and in a subgroup of patients with severe COPD, costs fell by 87% (approx. 20,000 euro before inclusion to approx. 2700 euro after inclusion) (25). Similar findings were obtained in another observational study by Phanareth et al from 2021, 87 COPD patients (mean observation time 345 days) using the same components of the ECM as in this study, it was found that 69% of severe exacerbations were reversed in ECM2 without any physical contact or use of conventional health services (22). These reductions in usage of conventional health services in our study and in the above mentioned studies, may partly be due to the freely accessible RCC providing proactive timely responses. The immediate contact in case of deteriorations also provide an opportunity to educate the participants in how to recognise and respond to changes in their condition. Overall, the data provide evidence of an efficient alternative way to managing COPD.

Interestingly the immediate contact for participants in this study is in contrast to most other tele-health services which had a registered nurses or other authorised health professional as their initial contact. In this study initial contact was to health education students trained and certified in the basics of COPD and also to communicate with the participants. This supportive approach may lead to an increase the COPD patients feelings of trust, safety and being understood, which in Scandinavian language can be gathered to the concept of “Tryghed”.

This may ultimately result in an increased level of self-efficacy and empowerment, which also results in participation in more social activities.

The use of trained undergraduate students from health educations taking responsibility for patient care has been assessed in other studies. In a systematic review by Schutte et al from 2015, 42 articles were reviewed on student outcomes of participating in Student-run clinics (SRC). The quality of care provided by students appeared adequate and was comparable with that of regular care (37). In a recent systematic review, student learning outcomes associated with participation in SRCs were investigated. It was concluded that participation in SRCs provided students with the opportunity to develop clinical skills, foster leadership, and cultivate empathy (38). Our study contributes with further evidence for this approach and that it should be considered as a tool to solve the challenges of the healthcare system with a shrinking workforce and a lack of resources.

The role of telehealth in COPD has been a topic of interest in recent years, with various studies exploring the potential benefits (18–20,39–41).Tele-health is not the solution by itself, but may be a valuable component as part of a framework as the ECM. A Cochrane review by Poot et al from 2021 reported on 26 RCT studies comparing integrated disease management (IDM) programs for COPD versus usual care. Interventions consisted of multi-disciplinary (two or more health care providers) and multi-treatment (two or more components). In the analysis, it was found that different IDM components had different effects. For example, telemonitoring had a positive effect on quality of life and physical endurance, while self-management had the best effect on COPD exacerbations. The authors concluded that an IDM programme with a combination of exercise training, self-management, telemonitoring, and personalized education implemented in the right context should result in the best outcomes (42).

In a study by Casas et al from 2006, 155 COPD patients were recruited after hospital discharge and randomized to either a standardized IDM intervention with the support of information technology or to usual care. The primary end-point was the number of readmissions during the follow-up year and the study showed a significant decrease in admission rate in the intervention group compared to the usual care group (43).

These findings have recently been supported in an RCT by Iversen et al from 2021. The authors investigated the effect of affiliation to a cross-sectorial lung team (CLT) on hospitalization and length of hospital stay for 144 patients with severe COPD. The CLT was available for telephone calls and home visits day and night at the request from patients, and the CLT could initiate home treatment. In total, 56 patients were affiliated to the CLT, and 57 patients received usual care (UC). The results of a one-year affiliation to a CLT compared with a control group showed a statistically significant decrease in both the number of hospitalizations due to exacerbations as well as the length of hospital stay in the intervention group. No significant difference in number of severe adverse events, including death, was observed between groups (44).

Strengths and limitations

A strength of this study is the standardized procedure for recruitment which involved an initial examinations and standardisation of medication appropriate to the patients severity optimizing the condition for both participants at in both the control and intervention group at baseline. Not conducting a physical examination and optimising medication in all participants prior to randomisation is a potential confounding factor if only the intervention group receives additional medical input.

Another strength and in particular during a period with seasons and variable exposure to the pandemic, the stepped-wedge approach was used as it ensured an even recruitment over the seasons thereby avoiding seasonal-related deteriorations as a confounder. Finally, it should be noted that the number of deaths occurring in both the intervention and control groups are low. This may be due to the participants being recruited from general practices and in particular the number of people in GOLD severity group 4 may be lower than reported in other studies.

A limitation of the study is that consumption of healthcare resources and of social activities were self-reported and only gathered at T1 and T2 which may introduce some recall errors. To limit this bias, one of the authors (LS) contacted all participants by telephone and rigorously examined the history of each participant with respect to hospitalization. It was planned to extract patient data from national systems, but this turned out to not be feasible.

Perspectives

The study adds to the increasing literature with two important findings; one is that a primarily virtual service can reduce contacts to other health services and provide a feeling of confidence or “Tryghed” resulting in increased social activities and secondly, the front-line staff can consist of trained and certified individuals without extensive education in health care thereby reducing the burden of people with LTHC on health care services along with reducing costs.
These findings should be confirmed in larger scale studies and in more general populations of older adults with LTHC

Conclusion

A tele-health clinic organised in accordance with the ECM1 and ECM2 levels of the ECM model which provided services to patients with COPD was shown to both reduce the number of contacts to other healthcare services and also increase the social activity. It remains to be understood why it does not have a significant impact on the experienced mental well-being. The data supports that the health care service can be provided efficiently and at reduced costs and burden of health care staff as the front line staff can be trained and certified non health professionals.
The study, thereby contributes to the growing body of knowledge on virtual healthcare and digital transformation in the field of COPD care.

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Conflict of interest

The RCC telehealth service is provided by Epital Health Ltd.
The first author KP holds a share position in Epital Health Ltd. which provides the

ECM services used in this study.
There are no other intervention or contact to the other shareholders in relation to the conduction of the study or the writing of the article
The authors GTP, ATB, EFN og LS have in a period of the study been employde by the RCC
The organisation have provided access to the participants but have not been involved in the conduction and reporting of the study.

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Abbreviations

COPD: Chronic Obstructive Pulmonary Disease
ECM: Epital Care Model
ECOPD: COPD Exacerbations
EHR: Electronic Health Record
Epitalet: Epital Health Ltd.
FEV1: Forced Expiratory Volume during the first second
GP: General Practitioner
GOLD: Global Initiative on Chronic Obstructive Lung Disease
IDM: Integrated Disease Management
IT: Information technology
LTHC: Long-term Health Conditions
MRC: Medical Research Council dyspnea scale
PRO: Patient-Reported Outcome
RCC: Response and Coordination Center
READHY: Multidimensional Readiness and Enablement Index for Health Technology

Multimedia Appendix

Multimedia Appendix A
The Epital Care Model and the staff

The overall objective of the ECM is to ensure that patients, to the greatest extent possible and for the longest possible time, are in the state of "ECM 1", the first stage of the ECM model characterized by; the greatest possible freedom, independence, and self-control (active and independent living), regardless of whether at home or outside the home (see Fig 1). Even for patients with severe chronic disease, ECM 1 represents the level that the ECM service

will explicitly try to keep the patient in, or attempt to return the patient to. This provides the state of greatest independence for the patients. In addition the patients have the security of knowing that healthcare services are available 24/7 should a need for help arise. Another objective of the ECM is to be able to delegate as much responsibility and control to the patient as possible. This is supported by empowerment-promoting measures such as structured conversations and the provision of enabling technologies which may help the patient monitor themselves under continuous supervision. The patient is encouraged to act for themselves and respond appropriately to changes in conditions such that the classic passive patient role is reduced as much as possible. If their condition worsens, the patients are supported virtually in ECM 2 by specially trained staff from a Response and Coordination Centre (RCC). All patients in ECM are equipped with "emergency medicine" (broad-spectrum antibiotics plus oral prednisolone), which is kept by the patient at home and which is only used in consultation with the ECM staff. If the deterioration requires urgent medical treatment, the eDoctor is involved, and a plan is drawn up for a treatment course, that is carried out by the patient under supervision and monitoring by the RCC staff. In rare cases in which virtual support is not sufficient, a physical visit to the patient's home from health care professional will be arranged to clarify the situation in the context of ECM 3-6 (1).

This study is focussed on examining the effects of the virtual part of ECM. This therefore involved the organizational service and treatment setup from ECM 1 - 2 and the virtual part of ECM 4 that was used in the intervention group (se fig.1).

The eDoctor

The eDoctor is primarily responsible for patient care within the ECM Clinic. This responsibility is delegated to specific areas of the clinic's RCC staff through detailed instructions and delegated authority.

The eDoctor conducts pre-qualification of individual COPD patients in connection with the initiation of treatment at the ECM Clinic.

RCC staff work under the delegation and responsibility of the eDoctor and perform tasks related to ongoing monitoring of patient measurements, prescription medication management, initiation of exacerbation treatments,

follow-ups, ensuring compliance with medication and devices, care and support conversations, technical support, and ongoing documentation.

A crucial prerequisite for consistently performing work according to current healthcare guidelines is that RCCstaff have the opportunity to consult with the eDoctor on an ongoing basis, and that the eDoctor continuously supervises the work at the ECM Clinic.

eDoctor's tasks:

- Pre-qualifies patients who wish to be affiliated with the ECM Clinic
- Conducts virtual "ward rounds"
- Is available to ECM Clinic staff 24/7
- Is responsible for treating patients affiliated with the ECM Clinic
- Is responsible for initiating medical treatments
- Is responsible for certification and supervision of the ECM Clinic's RCC staff
- Is available to the patient when relevant.

The RCC-staff in the ECM Clinic

RCC staff are employed by the ECM Clinic and work under the instructional authority of the ECM Clinic's managing physician, who may also act as an eDoctor.

Contact with telemedicine patients is based on telephone or video contact, in combination with the patient's own condition measurements. The RCC staff conducts a thorough and precise assessment of the patient's condition based on the patient's measurements and status. The combination of RCC staff's personal contact with the individual patient in connection with inclusion and TM certification for the ECM Clinic, telemedicine contact in connection with changes in the patient's condition, and background information about the patient in the ECM Clinic's journal system enables RCC staff to work holistically in their approach to patients affiliated with the ECM Clinic. This also makes it possible to assess which interventions best serve the individual patient in the specific situation.

This means that RCC staff in the ECM Clinic handle a combination of nursing tasks of an instrumental clinical nature, and simultaneously assess needs that cover the patient's entire health and social situation.

In other words, RCC staff in their work with early detection, timely intervention, and treatment management, including complex and unforeseen patient cases, draw on knowledge and skills that extend beyond acute nursing care and contribute to ensuring quality, consistency, and patient safety in the ECM Clinic. RCC staff work, as mentioned, on delegation and with the instructions and job descriptions that cover the healthcare tasks performed under the auspices of the ECM Clinic's various functions.

The frontline staff at the RCC were not trained physicians or registered nurses but students from health-related programs at the faculty of health and medicine at the University of Copenhagen and Danish Technical University. All staff were certified with both a practical and theoretical test after four weeks of hands-on training in the RCC function. RCC's frontline staff worked under the authority of the eDoctor, who was available 24/7/365 and in all contexts the person responsible for the treatment of the patients in the intervention group. Further details on the system and the organization have been reported earlier elsewhere (1,22).

Certification of the RCC staff

A prerequisite for being an RCC staff member in the ECM Clinic is to be a student or graduate in one of the healthcare programs (e.g., health IT or nursing) at a University of Applied Sciences or a University, and to have completed ECM certification.

ECM certification consists of a hands-on training lasting between 5-7 days, as well as a theoretical and practical exam. The certification takes place in collaboration with examiners from the University of Copenhagen, ensuring a uniform and adequate level of competence.

Curriculum – ECM Certification

All written materials and instructions for the following curriculum are collected in the ECM Clinic's instruction folder in Dropbox (EH-instructions 2022), which only ECM Clinic employees are invited to and may access. It is assumed that ECM-certified employees understand and are familiar with all clinical, technical, and administrative instructions and have knowledge of the articles and documents in the instruction folder.

General Healthcare

The certified employee must be able to:

- Account for the healthcare system's most significant challenges
- Account for the healthcare system's sector division and explain the individual sectors' work areas and tasks they perform
- Explain the healthcare system's payment methods and how they affect the individual sectors
- Describe the difference between the system-centric and the person-centered healthcare system

General about ECM

The certified employee must be able to:

- Account for the ECM model's 6 domains (content, activities, and staffing)
- Account for the ECM model's dynamic and adaptive response based on PROM
- Explain how ECM can facilitate a paradigm shift toward a person-centered healthcare system
- Explain the ECM model's proactive elements and how patient involvement promotes empowerment
- Explain the most important elements that distinguish ECM from a conventional healthcare system

ECM-relevant Disease Areas

Chronic Obstructive Pulmonary Disease (COPD)

- General about COPD
    - Account for the causes of COPD and the clinical presentation
    - Account for the symptoms of COPD
    - Explain how the diagnosis of COPD is made
    - Account for the GOLD guideline classifications of severity levels (1,2,3,4 and A,B,C,D)
    - Describe the most important comorbidities of COPD

Treatment of stable COPD

- Explain the medical treatment principles for the different severity levels of COPD
- Account for the content and effect of inhalation medication SABA, SAMA, LABA, LAMA, ICS

- Account for the different types of devices for inhalation medication
- Describe the different formulations of inhalation medication (powder, spray, liquid) and account for the advantages and disadvantages of the different types
- Account for the possibilities of other medical treatment of COPD, in addition to inhalation treatment - i.e. oral prednisolone, Daxas, fixed low-dose antibiotics, home oxygen therapy, etc.
- Be able to advise and guide patients in the use of the different device types (pMDI, pMDI + spacer, DPI and nebulizer systems)
    - Be able to advise and guide patients regarding the most important side effects of the medication
    - Have knowledge of non-pharmacological treatment options for COPD
    - Know the Danish guidelines and care pathways for COPD

Treatment of acute COPD

- Account for the symptom picture in acute exacerbation
- Account for the principles of medical treatment of acute COPD (exa1,2,3)
- Explain the treatment process (procedures, workflows, start of treatment, monitoring, follow-up, and completion) for initiated exacerbation treatments

COPD comorbidities

- Describe the most important comorbidities of COPD (heart failure, diabetes, anxiety/depression, osteoporosis,cancer)
- Most important manifestations
- Overall treatment principles
- Account for how the EECM Clinic supervises in relation to comorbidities

Asthma

The ECM Clinic has a number of asthma patients affiliated, and it is therefore important that ECM certified employees have an overall knowledge of the disease, the clinical manifestations, and the most common treatment principles (curriculum: Read Asthma-Epitalinfo in the folder "Clinical instructions").

General about asthma

- Account for the causes of asthma and the clinical presentation
- Account for the symptoms of asthma
- Describe GINA guideline classifications of severity levels (1,2,3,4,5)

Treatment of acute asthma

- Account for the symptom picture in acute asthma exacerbation
- Account for the principles of medical treatment of acute asthma (exa1,2,3)
- Explain the treatment process (procedures, workflows, start of treatment, monitoring, follow-up, and completion) for initiated exacerbation treatments

IT support for the RKC function

The certified employee must have a basic understanding of the ECM Clinic's underlying two IT systems (Appinux and EH) regarding the most important functionalities. It is also expected that the certified employee can navigate both systems, understand and use the treatment applications, be familiar with the documentation systems, and be able to navigate the graphical representations of patient data to assess and act on patients' condition changes.

Appinux – the patient-oriented part

The certified employee must have a basic knowledge of:

- The ECM patient's monitoring equipment (tablet, spirometer, pulse oximeter, temperature meter, acute medication)
- The elements included in the ECM, EH-lite subscription
- The applications on the patient's tablet

Appinux – the healthcare professional part

Be familiar with all the following service catalogs in Appinux:

- Service response
- Decision basis
- Medication status
- Onboarding - members Be familiar with and able to extract the following customer-specific reports in Appinux:
- "Member control stats in date interval"
- "Patient without measurements today"

ECM – Website and back-office platform

The certified employee must have a basic knowledge of:

- The content of the clinic's website
- Functions and applications for the patient
- All tools and applications dedicated to "Staff":
    - Create patient
    - Alarms
    - Journal notes
    - Registrations
    - Reports
    - Mental training

Processes and Workflows

The certified employee must be able to:

- Create a new member
- Conduct an onboarding guided by the service catalog
- Guide the patient in conducting daily measurements
- Adjust medication according to severity guided by "Medication status"
- Ensure legal formalities (consent form, etc.)
- Handle acute calls from patients
- Handle red measurements
- Handle multiple and repeated yellow measurements
- Handle follow-ups
- Handle missing measurements
- Understand the indication for and initiate exa-treatments
- Plan exa-processes, follow-ups, and conclude processes
- Register and document in "Service response"

Technical Procedures

- Configure tablets
- Start Quick support
- Guide patients in the log-in procedure
- Be able to guide patients with technical problems with:
    - Spirometer
    - Pulse oximeter
    - Tablet

- Internet connection via Wi-Fi

Communication and Empowerment

It is expected that certified employees know the elements of good communication and have trained in communication with our patients. Know the definitions and principles of empowerment and the empowerment-promoting approach in communication and services (listen to the empowerment podcast on the website). The following are guidelines for what is expected to be learned.

The certified employee is expected to:

- Be able to master communication at eye level
- Be service-minded and solution-oriented in all situations
- Know their limitations and understand when and how to get help and support to perform their tasks with patients
- Continuously develop the empowerment-promoting approach in their communication

Certification

The certification consists of a theoretical and practical exam, scheduled for 30 and 20 minutes, respectively. The practical exam will be based on a case, with the possibility that it can take place in a live session with a "real citizen" - alternatively, it will be a constructed case.

- The ECM Clinic's managing physician is responsible for the examination in collaboration with an external examiner invited to the certification
- A guiding grade is given that is for internal use only (can be informed individually if desired)
- Externally, the certification will be assessed as passed or failed
- All certified persons will be issued an ECM certification certificate
- Upon passing the certification, a document on Delegated Prescribing Right is signed (see instruction folder)

Formalities

- The certified person must be able to present a signed employment contract with the ECM Clinic
- The certified person must have signed EH's current confidentiality

statement

- The certified person must have signed a document on delegated prescribing rights (see instruction folder)

Multimedia Appendix B
Per Protocol Analyses

The process of determining whether the patients failed to qualify to be included in the per protocol analysis was according to the following criteria; 1) If no measurement was made within the first month,

2) If the patient indicated that they did not want to continue in the study,

3) If the patient had not treatment contact with the RCC,

4) If the home monitoring kit was returned (with or without notice).

Table 2.a: Unpaired t-test analyses at T0, T1 and T2 with WHO-5 as outcome variable – per protocol analysis.

	Intervention, Mean (SD)	Control, mean (SD)	Estimate, [CI]	P-value
Baseline	65.13 (18.55)[a]	61.26(21.48)[a]	-3.87 [-9.71;1.97]	0.19
Follow-up T1	63.50(21.53)[b]	63.33(21.55)[c]	-3.14 [-10.55;4.27]	0.40
Follow-up T2	68.68(17.40)[d]	61.94(19.10)[b]	0.76 [-6.09;7.60]	0.83

a: n = 92
b: n = 64
c: n = 72
d: n = 65

Table 2.b: Paired t-test analyses at T1 and T2 with WHO-5 as outcome variable.

	Intervention		Control	
	Estimate, [CI]	**P-value**	**Estimate, [CI]**	**P-value**
T1	-0.75 [-5.37;3.87]	0.75	2.39 [-3.48;8.26]	0.42
T2	3.57 [-0.85;7.99]	0.11	2.81 [-2.50;8.12]	0.29

Table 2 shows the mean values for WHO-5 at T1 and T2. There was a significant reduction between the groups at T2. The rest of the parameters were insignificant.

Table 3: COPD related contact to healthcare services T0-T1– Per-protocol analysis

	Intervention (N=71)	Control (N=64	Estimate, [CI]	P-value	Adjusted estimate[a],	P-value

		)			[CI]	
Admissions	8	19	0.38 [0.16;0.84]	0.02	0.41 [0.17;0.91]	0.04
Out-of-office service	5	14	0.32 [0.10;0.84]	0.03	0.28 [0.09;0.76]	0.02
Outpatient clinics	12	20	0.54 [0.26;1.09]	0.09	0.63 [0.29;1.29]	0.21
General practitioner	29	120	0.22 [0.14;0.32]	< 0.01	0.25 [0.16;0.38]	< 0.01

COPD related contact to healthcare services T0-T2 – Per-protocol analysis

	Intervention (N=72)	**Control (N=65)**	**Estimate, [CI]**	**P-value**	**Adjusted estimate[a], [CI]**	**P-value**
Admissions	14	27	0.47 [0.24;0.88]	0.02	0.54 [0.27;1.02]	0.07
Out of office service	9	28	0.29 [0.13;0.59]	< 0.01	0.52 [0.22;1.12]	0.11
Outpatient clinics	18	38	0.43 [0.24;0.74]	< 0.01	0.52 [0.24;0.93]	0.03
General practitioner	35	172	0.18 [0.13;0.26]	< 0.01	0.21 [0.14;0.30]	< 0.01

[a]Adjusted for age, GOLD*, risk time, and comorbidities.

Table 3, shows the outcome reduction in admissions, out-of-office services, visits to outpatient clinics and GP visits in the intervention group compared to the control group at T1 and T2. The outcome reduction was significant (p<0.05) on all parameters in the intervention group except for the outpatient clinic visit at T1 and the out-of-office services and admissions at T2. A poisson regression was used to calculate the estimate, CI, and p-values. The estimate indicates the likelihood of an event occurring for those not receiving the intervention.

Table 4: Cultural events and travels after 8-month follow up Per-Protocol Analysis

	Intervention (N=71)	**Control (N=64)**	**Estimate, [CI]**	**P-value**	**Estimate Adjusted[a], [CI]**	**P-value**
Cultural events	165	49	3.04 [2.23;4.22]	< 0.01	2.93 [2.13;4.11]	< 0.01
Travel	37	7	4.76	< 0.01	4.11	< 0.01

abroad			[2.26;11.67]		[1.92;10.19]	

Cultural events and travels after 12-month follow up Per-Protocol Analysis						
	Intervention (N=72)	**Control (N=65)**	**Estimate, [CI]**	**P-value**	**Estimate Adjusted[a], [CI]**	**P-value**
Cultural events	290	148	1.77 [1.45;2.16]	< 0.01	1.80 [1.48;2.21]	< 0.01
Travel abroad	52	15	3.13 [1.81;5.76]	< 0.01	2.66 [1.52;4.95]	< 0.01

[a]Adjusted for age, GOLD, risk time, and comorbidities.

Table 4 shows the number and the differences in cultural events (participation in entertainment and cultural events outside of home) and travels abroad (outside Denmark) in the periods T0-T1 and T1-T2. A poisson regression was used to calculate the estimate, CI, and p-values. The estimate indicates the likelihood of an event occurring for those not receiving the intervention.

Supplementary Files

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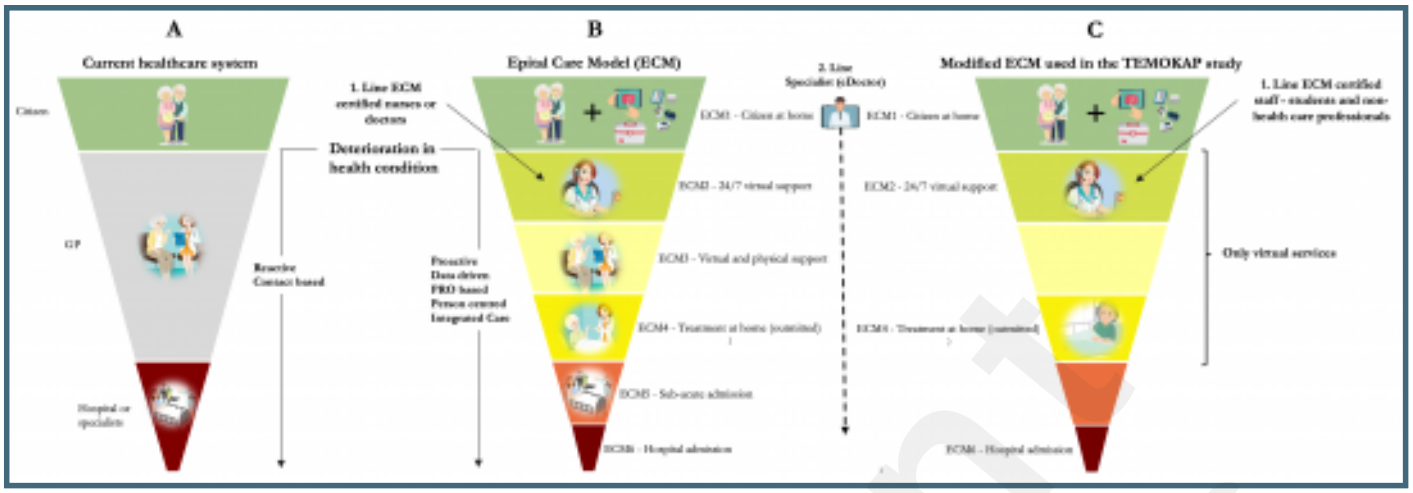

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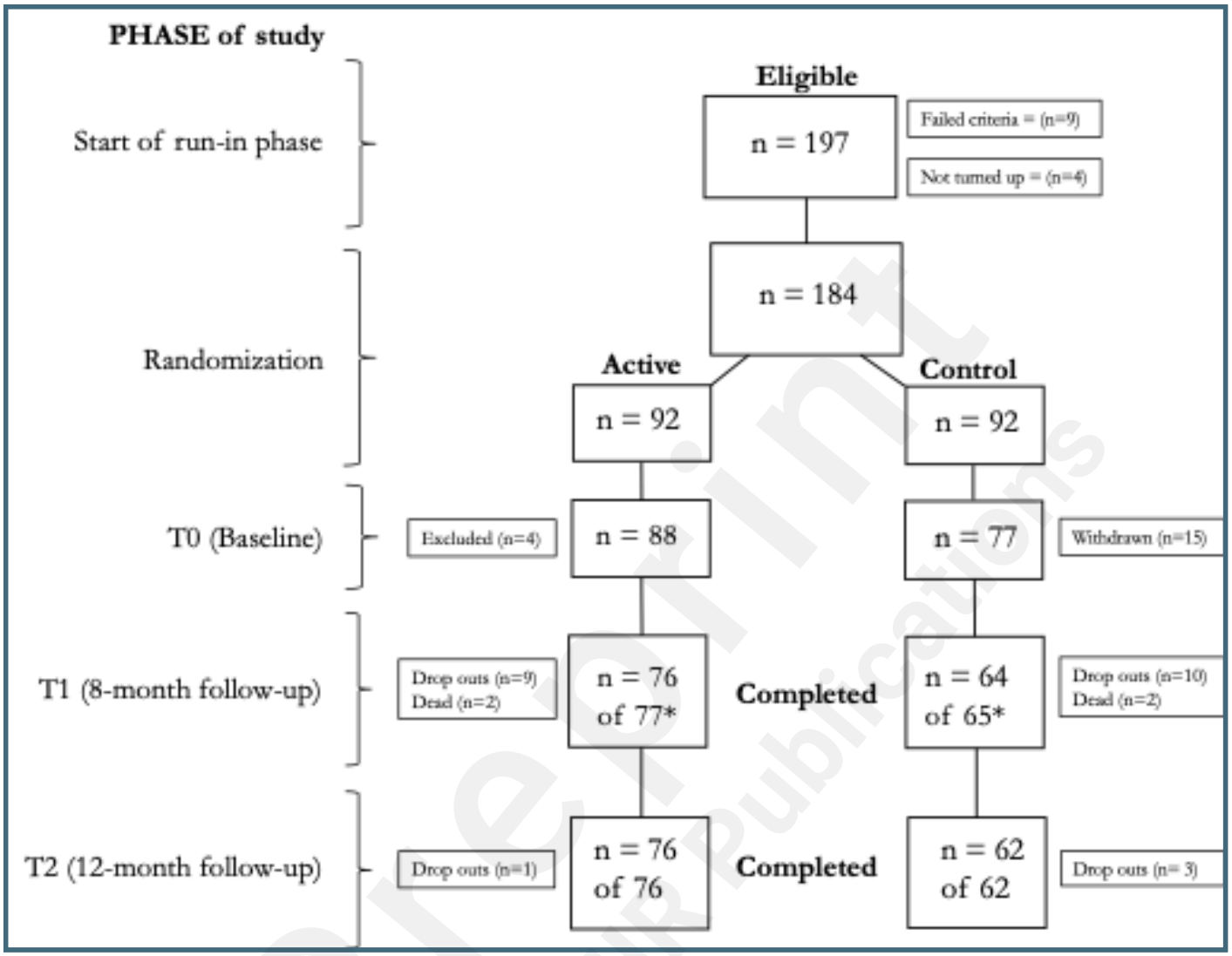
Figures

Flow Chart.


PHASE of study
Start of run-in phase
Eligible
n = 197
Failed criteria = (n=9)
Not turned up = (n=4)
Randomization
n = 184
Active
n = 92
Control
n = 92
T0 (Baseline)
Excluded (n=4)
n = 88
n = 77
Withdrawn (n=15)
T1 (8-month follow-up)
Drop outs (n=9)
Dead (n=2)
n = 76
of 77*
Completed
n = 64
of 65*
Drop outs (n=10)
Dead (n=2)
T2 (12-month follow-up)
Drop outs (n=1)
n = 76
of 76
Completed
n = 62
of 62
Drop outs (n= 3)

TOC/Feature image for homepages

The Epital Care Framework with Context Layers.