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Improving community-based COPD care in general practice in Poland – a cluster randomized controlled trial

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article

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Abstract

Introduction and Objective. Chronic obstructive pulmonary disease (COPD) is the third leading cause of death worldwide. The aim of the study was to evaluate the impact of intervention on exacerbations of COPD in elderly patients compared to those receiving usual care.

Materials and method. A 12 month, multicentre, three-arm, pragmatic, cluster randomized controlled trial was performed (CRCT). The 97 largest PHC clinics with at least 46 COPD registered patients in the Łódź Province, in central Poland. In total, 27,534 COPD patients aged 65 and over were identified from the National Health Fund (NFZ) electronic health records. A checklist of selected, recommended COPD interventions sent to GPs once or twice by post and shown on their desk in their clinics, in the intervention arms.

Results. A primary outcome was the difference in exacerbations or deaths between the 3 arms at 12 months. The amounts of specific short- and long-acting drugs purchased by patients were also assessed as secondary outcomes. Only 0.44% (122 of 27 534) COPD patients demonstrated exacerbations after the one-year study period. No statistically significant associations were found between interventions and exacerbations (p=0.1568, Chi-Square) or deaths (p=0.8128, Chi-Square) at 12 months.

Conclusions. As this study coincided with the pandemic period, the results should be interpreted with care. The intervention had no association with exacerbations. Future research on interventions aimed at improving chronic illness care are needed.

Key words

electronic health records, intervention, primary health care, Big Data, COPD Exacerbations, Cluster randomized controlled trial.

Abbreviations

COPD – Chronic Obstructive Pulmonary Disease; **CRCT** – Cluster Randomized Controlled Trial; **EHRs** – Electronic Health Records; **GP** –General Practitioner; **ICD-10** – International Classification of Diseases; **NFZ** – National Health Fund; **PHC** – Primary Health Care

INTRODUCTION

A great deal of research has been carried out on interventions related to the implementation of health care delivery [1], particularly concerning common conditions. One such condition is chronic obstructive pulmonary disease (COPD), the third leading cause of death worldwide [2]. Its burden is estimated to increase over the coming decades due to increased exposure to COPD risk factors and the gradual aging of the global population [3].

Clinical guidelines for the management of COPD are available for primary and specialist healthcare. Basic care is provided by general practitioners (GPs), who are the gate keepers for public health care systems, managed in Poland by the National Health Fund (NFZ). GPs take care of the patients registered on their list, referring them to specialist consultations if necessary. However, despite increased risk awareness, and the creation of established guidelines for the diagnosis and management of the condition, COPD remains a considerable problem for GPs and health care systems.

It is widely recognised that clinicians seldom consult guidelines when making clinical decisions. Additionally, when addressing the current medical problem of a patient, general practitioners may overlook the possibility of underlying chronic disease, such as COPD, possibly missing the opportunity to improve long-term management. A desktop reminder may stimulate additional activates and improve total outcomes. Missing such reminders may lead to unintended under-treatment of COPD, resulting in a greater frequency of exacerbations and hospitalizations [4]. This is particularly the case in elderly patients, who require special attention due to the increased prevalence of COPD and systemic comorbidities.

Primary care physicians are at the forefront of managing patients with COPD and are usually the first point of contact for patients experiencing an exacerbation which negatively affects the quality of life and can be fatal [5]. Therefore, it seems essential that GPs understand the importance of

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prompt diagnosis, and are aware of the steps to take in the management of COPD exacerbations [6, 7], as detailed in readily-available guidelines.

A randomized cluster study by Makatun et al. in 2018 found that providing a COPD care intervention package for family physicians (GPs) and assistants increased the implementation of key elements of COPD patient care in general practice after one year of intervention, compared to the control group receiving usual care [6]. However, no studies have examined the possible improvements in care for COPD exacerbations by primary care in Poland.

This study evaluates the effect of intervention on patient care by locating a compact chart with a friendly design on the GPs' desk, listing selected recommended COPD interventions, with the aim of focusing attention on long-lasting chronic problem underlying patient consultations. The protocol for the study was published in Trials in 2021 [8].

OBJECTIVE

The aim of the study was to determine the effect of the described intervention on COPD exacerbations in elderly patients, compared to those receiving usual care.

MATERIALS AND METHOD

The study was designed as a three-arm pragmatic, cluster randomized controlled trial (CRCT); a number of PHC clinics were randomised to three study arms according to a protocol.

The study was conducted between 1 March 2020 – 28 February 2021 in the Łódź Province, central Poland, with a population of 2,485,323 inhabitants. In the province, 84 PHC clinics with at least 30 COPD patients aged 65 years and over were randomly selected from NFZ electronic health records (EHR). Patients with COPD were identified by the ICD-10 code J-44 in NFZ electronic health records; exacerbations were defined as cases hospitalized with the J-44 code as the main reason for admission.

Power analysis. The sample size was calculated before the study and included in the protocol [8]. *Post hoc* power analysis was performed for one-way ANOVA, fixed effects for 3 groups. The control group comprised 8,807 subjects with J44, intervention 1 comprised 9,379, and intervention 2: 9,081. The average group size was 9,089. Mean values for exacerbations (as dependent/target variable) were: intervention 1: 0.0036, intervention 2: 0.0054 and control: 0.0041; common standard deviation: 0.0735. The root mean square standardized effect (RMSSE) was calculated as 0.0128. The calculated power was only 32%. This was less than the minimum power of 80% needed to correctly detect a statistically significant difference between groups; hence, to achieve this power, the study required 29,426 subjects in each group (details given in APPENDIX section 2.5. Power analysis).

Among the total number of 27,534 patients aged 65+ with COPD, only 0.44% demonstrated one or more COPD exacerbations (122 patients) after the one-year study period. This low value may have been affected by the COVID-19 pandemic.

To account for unforeseen circumstances, such as lack of response, clinic withdrawal, recording error, patient drop-out, change of clinic by the patient, increased risk of death in this population, and a small percentage of patients with exacerbations in this population, the number of COPD patients per clinic was increased by 52%, leading to at least 46 COPD patients per clinic [9, 10, 11]. Finally, the 97 largest PHC clinics with at least 46 (min. 46 – max. 173) COPD patients per clinic were randomized at baseline. The clinics were randomized by computer without repetition by a data scientist not involved in the trial.

Blinding. Participants in this trial were anonymized. Because of the nature of the interventions, it was not possible to blind the GPs in the clinics. Outcome assessment were not blinded as the researchers were aware of the allocation of clinics to the arms. The data scientist was independent of the research team and was therefore was not blinded.

Intervention. The checklists of selected-recommended interventions (Box 1) were prepared in the form of a desk-stand. These were sent to GPs in the intervention arms to be displayed on their desk in the clinics.

In the first intervention arm, the checklist was delivered at the beginning of the study (March 2020); in the second arm, it was delivered at the beginning of the study and then again after 9 months. In the control arm, the clinics did not receive the COPD management checklist, and GPs treated all patients according to standard care.

The checklist was developed by authors on the basis of GOLD guidelines [3] and the 2015 Physician Quality Reporting System (PQRS) Implementation Guide Centers for Medicare & Medicaid Services [12].

Outcomes. The primary outcome of the study was the effect of the interventions on the proportion of COPD exacerbations and the proportion of deaths of elderly COPD patients, registered within PHC clinic after one year.

- Primary outcome at the patient level was assessed as the proportion of cases between the 3 arms (intervention 1, intervention 2 and control) at the end of the one-year study period. The proportion of cases (event rates) of binary variables of exacerbation outcome was assessed based on 'hospitalization with the J-44 code as a main reason for admission', and the proportion of deaths of elderly COPD patients.
- Additional findings at the patient level were the specific short- and long-acting drugs purchased by patient. This was calculated as mean (±SD) numbers of packages purchased per patient between the control and intervention arms after one year.

Data collection and management. Anonymized patient data were obtained from the NFZ patient electronic health record system after the one-year study period.

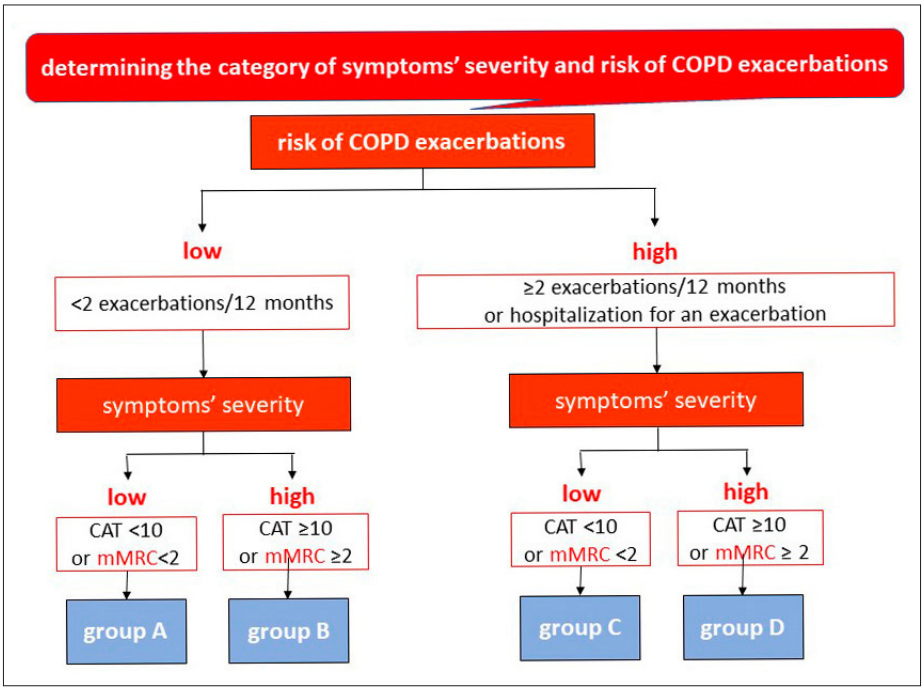
- Depersonalized data were obtained and subjected to quality control and cleaning.
- The structure of the obtained data was hierarchical. Individual patient data were anonymized. – Patients were nested within PHC clinics.
- Data cleansing was performed according to SAS Data Cleansing Methodology.

GP COPD CHECKLIST

Think and remember about COPD

I. Check diagnosis and patient condition

Classification of COPD



II. Patient check

1. Smoking cessation → stop smoking
2. Vaccinations (i.e. influenza, pneumonia) → advise vaccination
3. Importance of physical exercises → advise physical exercises
4. Medication adherence (i.e. know how work short- and long-term medications) → advise proper use
5. Proper use of inhalers → check the technique, instruct
6. Recognition and treatment of exacerbations → advise when and where ask for help
7. Follow-up visits → schedule next visit

III. Quality Measures Check

1. Spirometry evaluation: percentage of patients aged ≥18 years with a diagnosis of COPD with documented spirometry results.
2. Inhaled bronchodilator therapy: percentage of patients aged ≥18 years with a diagnosis of COPD and who have an FEV1/FVC <60% and have symptoms who were prescribed an inhaled bronchodilator.
3. Influenza immunization: percentage of patients seen for a visit during influenza period who received an influenza immunization.
4. Pneumonia vaccination: percentage of patients aged ≥65 years who have ever received a pneumococcal vaccine.
5. Documentation of current medications in the medical record: percentage of visits for patients aged ≥18 years for which the list of current medications were reported.
6. Tobacco use: percentage of patients aged ≥18 years who were screened for tobacco use within 24 months, and who received counseling for quitting if identified as a tobacco user

BOX 1. Desktop Stand Additional File (translated from Polish)

Statistical analysis. As only 0.4% of the elderly COPD patients reported at least one COPD exacerbation, no multilevel models with practice effect were created.

After the one-year study period, only 0.44% (122 of 27534) COPD patients demonstrated one or more exacerbations. Therefore, the statistical analysis was limited to examining the relationship between variables and intervention using non-parametric tests, such as Chi-squared test, Savage test, and Kruskal-Wallis test, after one year. The missing data were not included in the analysis. Post-intervention analysis was performed. The level of statistical significance was $p < 0.05$. Analysis was performed with the SAS V.9.4 statistical package and STATISTICA V.13.1.

Additional detail on the method for making these measurements is provided in an online data supplement.

RESULTS

The results were written in line with the CONSORT standard [13].

A flow diagram of the study is given in Figure 1**.**

Baseline data. It is important to note that the study began around the time of the COVID-19 pandemic lockdown when there was initially no access to PHC. The EHR analysis found the percentage of exacerbations in the COPD patient group (N = 27534 patients) to be 1.16% (n=319) at baseline.

97 PHC clinics were randomly assigned to 3 arms (2 PHC clinics of the 97 had no data). The clinics in the intervention arms (32 in intervention 1 and 33 in intervention 2) received interventions, and were then analyzed for primary and secondary outcomes. Less than 1% of the total cases (n=267; 0.97%) were missing and not included in the statistical analysis. After one year of the study, 95 PHC clinics with data remained: 29 clinics in the control arm, 32 in intervention arm 1, 33 in intervention arm 2, and one which was not assigned to any arm. Further data is available from the authors on request.

Outcomes and estimation. A total of 27,534 (100%) 65+ COPD eligible patients were identified, nested within 95 PHC clinics: 8,807 (31.99%) in the control group, 9,379 (34.06%) in intervention arm 1, and 9,081 (32.98%) in intervention arm 2, and 267 (0.97%) patients in the missing arm. Of the total number of patients, 15,749 (57.2%) were female. There was a statistically significant difference in patient age between the 3 arms ($p = 0.0052$, Kruskal-Wallis Test): with the median age of 74 years in the control arm (70–80, min. 65 – max. 100), 73 years in intervention arm 1 (69–80, min. 65 – max. 104) and 74 years in intervention arm 2 (69–80, min. 65 – max.103). The median age of all patients was 74 years (IQR: 70–80, min. 65 – max. 104).

Primary outcome at patient level. No statistically significant associations were found between exacerbation and intervention (Tab. 1) (p=0.1568).

1) After one year, 0.44% of patients demonstrated one or more exacerbation (n= 122 / 27,534): 0.54% in intervention arm 1 (n=51 / 9,379), 0.41% (n=37 / 9,081) in intervention arm 2, and 0.36% (n=32 / 8,807) in the control arm.
2) The percentage of patients with COPD exacerbations ranged from min.: 0.36% to max.: 0.54% after the one year study period.
3) No statistically significant associations were found between mortality of the patients 65+ with COPD and intervention (p=0.8128).
4) In total, 0.66% of the COPD patients died over the one-year study period: 0.64% (n=60/9,379) in intervention 1, 0.70% (n=64/9,081) in intervention 2, and 0.64% (n=56/8,807) in the control arm.
5) The percentage of patients who died ranged from 0.64% – 0.70% after the one-year study period.

Additional findings at patient level. Statistically significant associations were found between intervention and the drugs purchased by a patient in the study period: Aspulmo, Sabumalin, Ventolin (p=0.0011); Buventol Easyhaler, Ventolin Dysk (p<0.0001); Atimos (p=0.024); Atrodil, Atrovent N, Atrovent (p<0.0001); Airbufo Forspiro, Bufomix Easyhaler, DuoResp Spiromax, Symbicort Turbohaler (p=0.0045); Comboterol, Seretide, AirFlusal Forspiro, Asaris, Salflumix Easyhaler, Salmex, Seretide Dysk, Symflusal (p=0.0362); Euphyllin long, Theospirex retard, Theovent (p=0.0124) (). Indakaterol: Onbrez Breezhaler was not purchased by any patient. Wilanterol: Relvar Ellipta had mean (SD) number of packages: 0 (0.01) per patients in total: 0 (0.00) in control, 0 (0.00) in intervention 1, and 0 (0.02) in intervention 2.

Table 1. Characteristics of patients and PHC clinics by arms. Date of extracting data as of 28 February 2021, considered period: 1 March 2020 – 28 February 2021)

Characteristics [3]	MISS n(%)	Control n(%)	Intervention1 n(%)	Intervention2 n(%)	Total n(%)	Value	DF	p-value [1]
Number of PHC clinics	1	29	32	33	95 [2]			
Gender: Female	149 (55.81)	5118 (58.11)	5277 (56.26)	5205 (57.32)	15749 (57.2)			
Gender: Male	118 (44.19)	3689 (41.89)	4102 (43.74)	3876 (42.68)	11785 (42.8)	6.4042	2	0.0407
Age of the person 65+ [years]:								
Median (Lower Quartile-Upper Quartile)	76 (72–83)	74 (70–80)	73 (69–80)	74 (69–80)	74 (70–80)			0.0052#
Number of J44 Patients nested within PHC clinic	267 (0.97)	8 807 (31.99)	9 379 (34.06)	9 081 (32.98)	27 534 (100)			
Exacerbations number (binary, Yes=1)	2 (0.75)	32 (0.36)	51 (0.54)	37 (0.41)	122 (0.44)	3.7056	2	0.1568
Whether patient died (Yes=1)	2 (0.75)	56 (0.64)	60 (0.64)	64 (0.7)	182 (0.66)	0.4146	2	0.8128
Total	267 (0.97)	8807 (31.99)	9379 (34.06)	9081 (32.98)	27534 (100)			

1. p-value – Chi-Square test; #Kruskal-Wallis Test 2. Total of 97 PHC clinics included: 95 clinics with data and 2 with no data; 3. Other data available from the authors

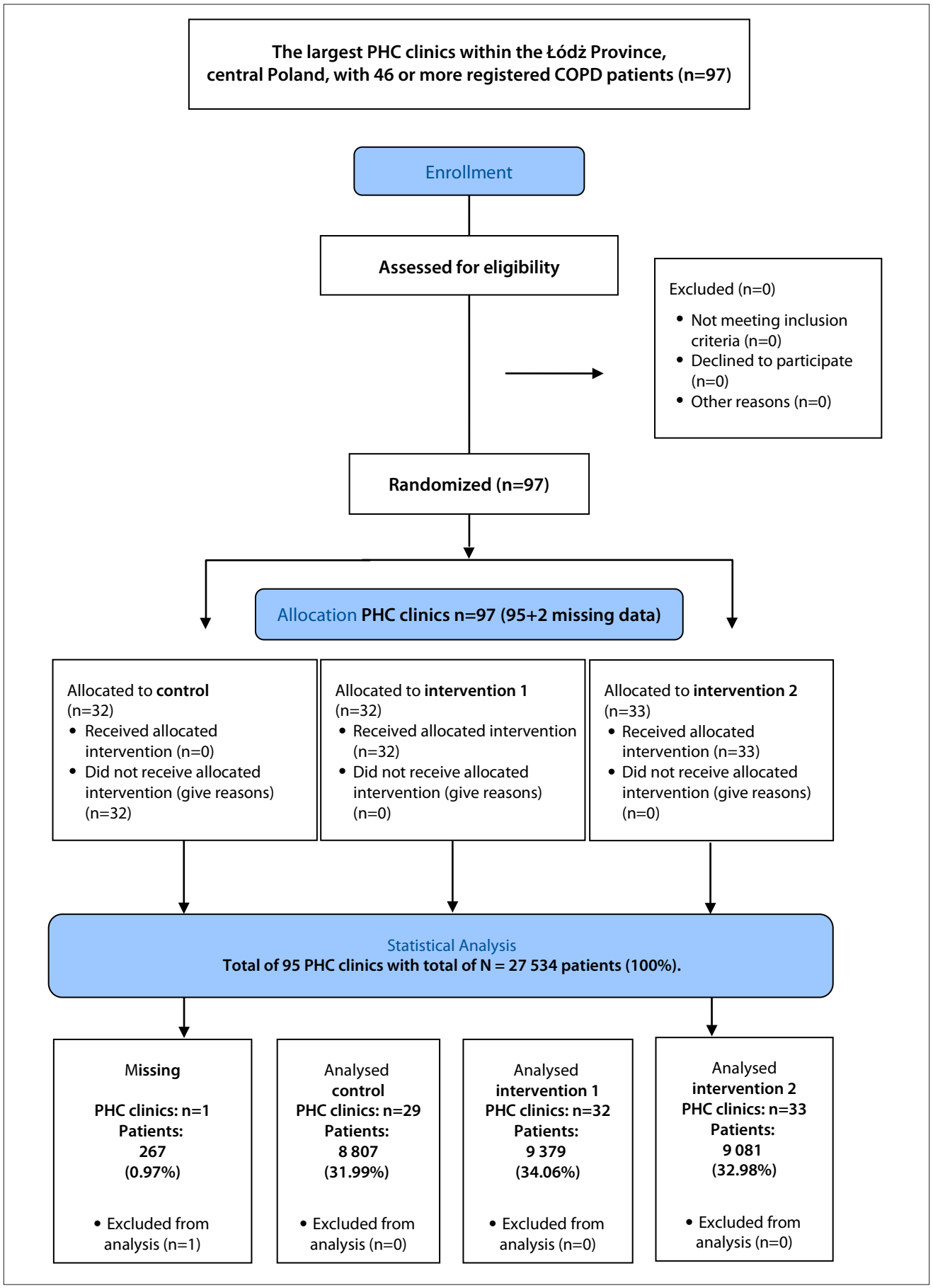


Figure 1. Participant flow according to CONSORT 2010

Other data available from the authors. Mean (±SD) – Number of drug packages with specific EAN codes purchased by the patient in a given period. Number of drug packages with specific EAN codes purchased by the patient in a given period. Thus, prescriptions for individual patients are selected based on the date of fulfillment.

A total of 782 doctors worked in the 95 PHC clinics, of whom 244 were family doctors: 249 (including 82 family doctors) in control, 259 (including 66 family doctors) in intervention arm 1, 268 (including 95 family doctors) in intervention arm 2; 6 (including 1 family doctors) in missing arm respectively.

A total of 165,177 patients aged 65 and over were registered in the 95 studied PHC clinics. Of these, 27,534 had COPD (Tab. 2).

DISCUSSION

The aim of the study was to determine the impact of an intervention consisting of an informative leaflet regarding COPD on reducing disease exacerbations among community-dwelling elderly COPD patients under the care of GPs. The intervention focused on specific long-term relationships between GP and patient, reminding the doctor to refer to patient's chronic condition at each visit.

The interventions for COPD patients in primary care has been studied elsewhere. Makatun et al. (2018) demonstrate that the COPD care intervention package provided to GPs and assistants increased the implementation of key elements of COPD patient care in general practice, compared to the usual care control group [6]. A Canadian study focused on integrated disease management (IDM), self-management, and structured follow-up intervention for high-risk patients with COPD in primary care, found that significantly fewer IDM patients had a severe exacerbation, required an urgent primary care visit for COPD, or had an emergency department visit compared to usual care [14].

In the current study, providing a COPD care checklist for display on the GP's desk while consulting patients did not produce the expected effect, possibly because the doctors were not able to notice the checklist due to their engagement in the consultation.

Unfortunately, the study period coincided with the COVID-19 outbreak, which could also have had a strong influence on the results. The current findings indicate that the prevalence of exacerbations in the group of COPD patients (N=27,534 patients) was only 0.44%. (122 patients). This could be related to exacerbations being coded as COVID (U07) instead of J44 during admission to hospital.

No statistically significant association was observed between the presented intervention and number of exacerbations (p=0.1568) or deaths (p=0.8128). The percentage of elderly COPD patients who died was 0.66%.

It is also possible that the studied intervention was susceptible to external factors, such as the pandemic, or that it has limited effects.

The relationship between intervention and exacerbations was found to be insignificant; however, this observation should be interpreted with care because data collection coincided with the pandemic period, and an almost

Table 2. Characteristics of PHC clinics by arms. Data collected from electronic health records

After 1 year study	**Total**				
Variable	**N**	**N Miss**	**Sum**	**Mean (Std Dev)**	**(Min. - Max.)**
Number of doctors working in 95 PHC clinics	95	2	782	8.23 (4.19)	(2 -20)
Including family doctors	95	2	244	2.57 (2.06)	(0 -13)
Total number of 65+ patients in total studied PHC clinics	95	2	165177	1738.71 (806.61)	(442 -3937)
Total number of 65+ COPD patients in PHC totl studiedclinics	95	2	27534	289.83 (147.97)	(78 -764)
After 1 year study	**Arms=missing (Miss)**				
Variable	**N**	**N Miss**	**Sum**	**Mean (Std Dev)**	**(Min. - Max.)**
Number of doctors working in 95 PHC clinics	1	1	6	6 (.)	(6 -6)
Including family doctors	1	1	1	1 (.)	(1 -1)
Total number of 65+ patients in total studied PHC clinics	1	1	1800	1800 (.)	(1800 -1800)
Total number of 65+ COPD patients in total studied PHC clinics	1	1	267	267 (.)	(267 -267)
After 1 year study	**Arms=Control**				
Variable	**PHC clinics, N = 29**	**N Miss**	**Sum**	**Mean (Std Dev)**	**(Min. - Max.)**
Number of doctors working in 95 PHC clinics	29	1	249	8.59 (4.34)	(2 -20)
Including family doctors	29	1	82	2.83 (2.42)	(0 -13)
Total number of 65+ patients in total PHC clinics	29	1	51232	1766.62 (813.77)	(556 -3604)
Total number of 65+ COPD patients in total studied PHC	29	1	8807	303.69 (161.04)	(93 -764)
After 1 year study	**Arms=Intervention1**				
Variable	**N**	**N Miss**	**Sum**	**Mean (Std Dev)**	**(Min. - Max.)**
Number of doctors working in 95 PHC clinics	32	0	259	8.09 (4.62)	(2 -19)
Including family doctors	32	0	66	2.06 (1.56)	(0 -5)
Total number of 65+ patients in total studied PHC clinics	32	0	57626	1800.81 (923.97)	(442 -3937)
Total number of 65+ COPD patients in total studied PHC	32	0	9379	293.09 (160.89)	(78 -763)
After 1 year study	**Arms=Intervention2**				
Variable	**N**	**N Miss**	**Sum**	**Mean (Std Dev)**	**(Min. - –Max.)**
Number of doctors working in 95 PHC clinics	33	0	268	8.12 (3.76)	(2 -17)
Including family doctors	33	0	95	2.88 (2.1)	(0 -8)
Total number of 65+ patients in total studied PHC clinics	33	0	54519	1652.09 (701.63)	(478 -3260)
Total number of 65+ COPD patients in total studied PHC	33	0	9081	275.18 (127.01)	(80 -590)

complete absence of exacerbations in the studied group. In addition, the study has other limitations. Mainly, the observed numbers of patients who visited the GP for COPD treatment may have been influenced by the short period of observation and initial lack of access to PHC clinics during the pandemic. In addition, some selection bias may exist in the study, since practices with fewer than 40 COPD patients were not included.

Furthermore, future studies should include additional time points for data collection to account for the impact of COVID-19. However, the study has 2 key advantages: the involvement of practicing GPs providing care to ageing patients with multiple comorbidities, and the fact that data collection took place in the 'real world' of general practice.

CONCLUSIONS

Use of the tested intervention appeared to have no significant influence on the chance of exacerbation or death during the pandemic. Future research is needed to evaluate strategies aimed at reducing COPD exacerbations in elderly patients, especially in periods without any external turmoil, such as a pandemic. Most importantly, it appears that the target for COPD has not been met, and further efforts are needed for its achievement.

Contribution to the literature. This paper describes the design and implementation of a pragmatic study to assess the effectiveness and implementation of a strategy based on a structured checklist in primary care. The impact of the applied checklist on COPD care was determined using Big Data methods.

A methodology for the clinical efficacy of repeated exposure to the COPD checklist in primary care was presented.

SUMMARY BOXES

What is already known on this topic. Many interventions are available to manage patients with COPD; however, implementing these strategies to improve outcomes may be difficult [15].
- Primary care interventions in COPD patients have enhanced the delivery of key elements of COPD care.
- No studies on improving primary care in terms of COPD exacerbations have been found in Poland.

What this study adds. This study assessed the effect of providing GPs with a COPD care checklist to decrease the number of COPD exacerbations in elderly primary care patients.
- The impact of the checklist on COPD care was determined by using Big Data methods in primary care.
- The study presents a methodology for the clinical effectiveness of repeated intervention in primary care.
- The originality of this study is related to the analysis of non-hospital-based intervention.

Additional information

Trial status
The trial is currently completed.

ClinicalTrial.gov identifier: NCT04301505. Registered on 10 March 2020,
https://clinicaltrials.gov/ct2/show/NCT04301505
Protocol Version 10: 28 July 2022.
Recruitment start date: March 2020; **Recruitment completed:** March 2021.
Data and materials available from the authors on request.

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APPENDIX

Additional detail on the method for making these measurements is provided in the online data supplement below.

Power analysis

Descriptive statistics

Variable	No division into groups Descriptive statistics (t1idpo_kopia.sta)		
	N	Mean	Std Deviation
_5__LbHhospJ44_binPO	27534	0.004431	0.066418

Variable	Aggregated results Descriptive statistics (t1idpo_kopia.sta)			
	ArmsPO	N	Mean	Std Deviation
_5__LbHhospJ44_binPO		267	0.007491	0.086386
_5__LbHhospJ44_binPO	Control	8807	0.003633	0.060172
_5__LbHhospJ44_binPO	Intervention1	9379	0.005438	0.073544
_5__LbHhospJ44_binPO	Intervention2	9081	0.004074	0.063705

Power analysis

	Power(t1idpo_kopia.sta) One-way ANOVA Fixed Effects
	Value
Number of groups	3.0000
Sample size (N)	9089.0000
RMSSE	0.0128
Parameter of decentrality (Delta)	2.9761
Probability type I error (Alpha)	0.0500
Df for effect	2.0000
Df for error	27264.0000
Critical Value F	2.9961
Power	0.3192

Sample size calculations

	Sample size (t1idpo_kopia.sta) One-way ANOVA Fixed Effects
	Value
Number of groups	3.0000
RMSSE	0.0128
Parameter of decentrality (Delta)	0.0033
Probability type I error (Alpha)	0.0500
Target power	0.8000
Power for required sample size N	0.8000
Sample size required (N)	29426.0000