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Effect of care transfer model led by the hospital clinical pharmacist on reduction of hospital readmissions in the elderly

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Transfer of care is a critical point for patient safety and requires an optimal care transfer model in order to ensure safe pharmacotherapy transfer. Polypharmacy among elderly is associated with adverse health consequences such as hospital readmissions. Hospital readmissions represent priorities in health care research and are one of the measures for assessing patient safety. Medication-related problems among elderly are associated with polypharmacy. The aim of the study was to show the impact of a developed model of care transfer led by a hospital clinical pharmacist on the number of hospital readmissions in the 12-months period in the elderly. A randomized controlled study of patients aged 65 or more was conducted at Dubrava University Hospital, Community Health Centre Zagreb – East and community pharmacies in the City of Zagreb and Zagreb County, Croatia. An intervention group received specially designed care transfer led by the hospital clinical pharmacist. Model included high-intensity pharmacotherapy interventions delivered at admission, during hospital stay and discharge, transition to primary care and post-discharge and cooperation between all healthcare professionals. In all, 182 patients in the intervention and 171 in the control group were analysed. The total number of hospital readmissions and emergency readmissions, within one year from the hospital discharge, was lower in the intervention group than in the control group (41.7% *vs.* 58.3%, p=0.005; 40.8% *vs.* 59.2%, p=0.008). The model of the health care transfer applied in this research thus significantly reduced hospital readmissions in the 1-year period in elderly patients. Therefore, the hospital clinical pharmacists should design and coordinate the transfer between hospital and primary care.

1. Introduction

Transfer of care is as critical point for patient safety and requires an optimal care transfer model for reducing potential harm (WHO 2019). The patient journey across health-care systems is a complex, multi-step process that requires integrated communication and coordination between different health-care points (Li et al. 2016). In particular, the transition between the hospital and primary health care is associated with an increase in the number of medication errors due to omnipresent polypharmacy and communication gaps (Coleman et al. 2004; Li et al. 2016; Alqenae et al. 2020).

It is important to consider polypharmacy as a separate medical issue in the transfer of care. Polypharmacy is a feature of modern medicine, especially in elderly patients with multimorbity. Incidence of multimorbidity is significantly higher in the elderly and reaches 50% (Chowdhury et al. 2023). Elderly patients consume a large amount of acute health care resources, having an up to 5-fold increase in the likelihood of hospital admissions (Koehler et al. 2009; Leppin et al. 2014; Brunner-La Rocca et al. 2020). Lack of a transitional care model can be a serious problem for safe pharmacotherapy transfer, frequently apostrophized in the literature (Redmond et al. 2018). Taking into account the diversity of drugs, indications and doses, contraindications, need for dosage adjustment, drug-drug interactions, potentially inappropriate drugs, side effects, non-adherence and elderly vulnerability for drug applications, polypharmacy can generate a whole range of potential pharmacotherapy problems that require optimal models of care transfer.

Medication reconciliation has been proposed as a solution for reduction of medication errors between patients' medication lists across transitions in care (WHO 2014; Mekonnen et al. 2016a; Grimes et al. 2016; IHI 2018). Health care accreditation institutions determined medication reconciliation as indispensable part of patient safety and should be established as routine safety protocol (NICE 2015; Ministry of health 2019; Joint Commission 2020). Unintentional discrepancies in pharmacotherapy can be harmful, leading to adverse drug events and an increase in hospital readmissions that are also associated with high financial burden (Mueller et al. 2013; Redmond et al. 2018). Even though unintentional discrepancies are most often observed as an effect of a successfully implemented care transfer model, other harmful clinical consequences such as readmissions needs to be observed (Redmond et al. 2018). Hospital readmissions are one of the indicators of heath care quality. They represent priorities in health care research and are one of the measures for assessing patient safety (Krumholz et al. 2017; Redmond et al. 2018). The use of polypharmacy was identified as prominent risk factor for readmission (Prasad et al. 2024). To reduce the potential polypharmacy burden and readmissions, approaches focused on medication reconciliation and other pharmacotherapy interventions should be implemented in care transfer process.

Medication reconciliation along with other pharmacotherapy interventions has a potential to reduce the post-discharge health-care utilization but the research combine different approaches and results are ambiguous (Kwan et al. 2013). Among other things,

evidence supports integration of pharmacists during hospital admission, discharge and post-discharge in care transfer model (Ensing et al. 2015; Rodrigues et al. 2017). Transfer of care should be a well-coordinated process with high-intensity pharmacotherapy interventions delivered in hospital and following discharge in order to maximize its effectiveness and long-term effect on readmissions (Ravn-Nielsen et al. 2018; Daliri et al. 2021; Uitvlugt et al. 2021). Observing the frequency of hospital readmissions over a longer period can show the scale of the model's effectiveness. Tailoring and planning of the care transfer model should also incorporate specificity of the healthcare system and target population (Mueller et al. 2013; Zazzara et al. 2021).
The aim of this paper was to show the impact of a specifically developed transfer of care model led by a hospital clinical pharmacist on the number of readmissions in the 12-months period in elderly.

2. Investigations and results

2.1. Setting and participants

A randomized controlled study was conducted at Dubrava University Hospital in collaboration with the Community Health Centre Zagreb – East and community pharmacies in the City of Zagreb and Zagreb County, Croatia. Dubrava University Hospital provides hospital health care for the eastern part of Zagreb with approximately 350,000 inhabitants. The study included elderly patients (65 years and older) admitted to the Internal Medicine Clinic and treated at the primary care physician from the Health Centre Zagreb – East. The Internal Medicine Clinic consisted of eight departments: Department for Cardiovascular Medicine, Department of Endocrinology, Diabetes, Diseases of Metabolism and Clinical Pharmacology, Department of Gastroenterology, Hepatology and Clinical Nutrition, Department of Rheumatology and Clinical Immunology, Department of Nephrology and Dialysis, Department of Pulmonology, Department of Haematology and Department of Intensive Care Medicine.

2.2. Description of care transfer model

The study implemented a care transfer model organised and led by a hospital clinical pharmacist in collaboration with healthcare professionals that are involved in pharmacotherapy management: hospital specialists, hospital clinical pharmacists, primary care physicians, community pharmacists. Model development included various experts and the preparatory activities of the study that made up a large part of this research. Preparatory activities, among others, included training of health care professionals. During this training process the role for each healthcare provider was well established. The educational courses were organized in Dubrava University Hospital and The Community Health Centre Zagreb – East. The Agency for Quality and Accreditation in Health Care and Social Welfare, the Clinical Pharmacy Section of the Croatian Pharmaceutical Society, the Croatian Society for Quality Improvement of Health Care of the Croatian Medical Association and City Pharmacies Zagreb also participated in the educational courses. Representatives of all healthcare institutions involved in the research cooperated well and agreed on the method of communication and exchange of information. They were informed about the study protocol and the process of medication reconciliation.
The integrated medication reconciliation model in transfer of care which encompassed different activities is presented in the Fig. The intervention group received high-intensity pharmacotherapy interventions while patients in the control group received standard medical care. High-intensity pharmacotherapy interventions were categorised in four groups:

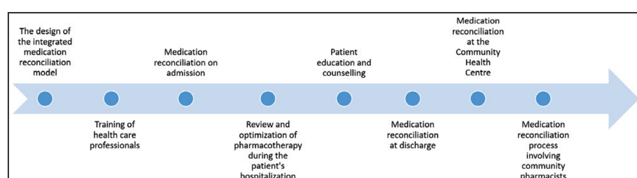

Fig.: The integrated medication reconciliation model that included high-intensity pharmacotherapy interventions

2.2.1. High-intensity pharmacotherapy interventions at admission

Medication reconciliation at admission: A hospital clinical pharmacist obtained an accurate and complete list of medications, BPMH within 24 h from the admission in accordance with the Protocol on Medication Reconciliation and Implementation Guide (WHO 2014). Obtaining the BPMH included an interview with the patient and obtaining information from other sources (contacting community pharmacist and primary care physician, consulting patient's medication list and medical documentation, inspecting patient's pill organizer, communicating with the caregiver). Unintentional discrepancies between the BPMH and inpatient medication chart were identified and resolved in collaboration with hospital specialists.

2.2.2. High-intensity pharmacotherapy interventions during hospital stay and at discharge

Medication review: A hospital clinical pharmacist provided medication review during hospitalisation at daily basis.
Creating the BPMDP, patient counselling and education: When planning the hospital discharge, a hospital clinical pharmacist created the Best Possible Medication Discharge Plan (BPMDP) intended for outpatient healthcare professionals while the patient received adjusted form of the BPMDP listing all discharge medication and their purpose. Before discharge, a hospital clinical pharmacist provided counselling focused on patient's medications, directions on how to use medications and changes in pharmacotherapy that have been made during hospitalizations. The patient had an educational session covering the important aspects of the participant's current medications and making sure new medications were fully understood by the participant.

2.2.3. High-intensity pharmacotherapy interventions during transition – communication with outpatient health professionals

The pharmacist electronically sent the BPMDP to the primary care physician. In addition, a simplified BPMDP was given to the patient, who was advised to bring it to every visit to their primary care physician and community pharmacist.

2.2.4. Post-discharge high-intensity pharmacotherapy interventions

In order to detect possible unintentional discrepancies, the discharge medication list was compared to medications prescribed at the Community Health Centre Zagreb East. In case there were any discrepancies, they were revised and corrected in collaboration with primary care physicians. After an evaluation and consultation with a primary care physician the patient pharmacotherapy status was determined and afterwards confirmed by community pharmacists. Patients were advised to obtain all medications from one pharmacy.

2.3. Results

A total of 353 elderly patients were analysed (182 in the intervention and 171 in the control group). All 353 patients were followed up for the predefined period of 12 months. Overall, 10 participants were excluded from further analyses in the intervention group and 20 participants in the control group. There were no statistically significant differences in the baseline characteristics of the intervention and control groups (Table 1). The median age of patients in the intervention group was 75.5 (IQR 71 – 80) while in the control group it was 75 (IQR 70 – 80.5) (p=0.470). The most represented status was living with family or caregiver for 148 patients (81.3 %)

Table 1: Patient characteristics

Patient characteristics	Intervention group (n=182)	Control group (n=171)	**Statistical significance (p value)**
Age, years, median (IQR)	75.5 (71-80)	75 (70-80.5)	0.470
Gender			0.242
Male, n (%)	82 (45.1)	88 (51.5)	
Residence, n (%)			0.886
Living alone	30 (16.5)	31 (18.1)	
Living with family/caregiver	148 (81.3)	137 (80.1)	
Nursing home	4 (2.2)	3 (1.8)	
Initial admission to hospital, n (%)			0.501
Emergency	164 (90,1)	150 (87.7)	
Elective	18 (9.9)	21 (12.3)	
Recent hospitalization, n(%)	56 (30.8)	55 (32.2)	0.959
History of adverse drug events, n(%)	52 (28.6)	47 (27.5)	0.820
Mean number of comorbidities, median (IQR)	9 (6-12)	9 (6-12)	0.423
Mean number of prescription medications (discharge), median (IQR)	9 (7-11)	9 (7-12)	0.328
The most common principal diagnosis of initial hospitalization			/
I21 Acute myocardial infarction			
I50 Heart failure	18	10	
N18 Chronic kidney disease	14	9	
I20 Angina pectoris	7	10	
J18 Pneumonia	8	9	
K80 Cholelithiasis	7	6	
E11 Type 2 diabetes mellitus	8	5	
I26 Pulmonary embolism	7	4	
I10 Essential (primary) hypertension	5	3	
N17 Acute renal failure	8	1	
	5	4	

*IQR, interquartile range

Table 2: Patients' comorbidities according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision

The most common comorbidities (ICD-10)	Intervention group (182 patients)	Control group (171 patients)
I10 Essential (primary) hypertension	100 (54.9 %)	78 (45.6 %)
E10-E14 Diabetes mellitus	83 (45.6 %)	83 (48.5 %)
D50-D64 Anaemia	84 (46.2 %)	74 (43.3 %)
I25 Chronic ischaemic heart diseases	70 (19.8 %)	74 (43.3 %)
I48 Atrial fibrillation	75 (21.2 %)	63 (36.8 %)
K29 Gastritis and duodenitis	65 (18.4 %)	71 (20.1 %)
E78 Disorders of lipoprotein metabolism and other lipidaemias	66 (18.7 %)	65 (38 %)
Z95.5 Presence of coronary angioplasty implant and graft	60 (17 %)	59 (16.7 %)
N18 Chronic kidney disease	44 (12.5 %)	36 (21.1 %)
I50 Heart failure	34 (9.6 %)	43 (25.1 %)

Table 3: Number of hospital readmissions in the intervention and control group (12 months of follow-up after index hospitalization)

Variable	Intervention group (182 patients)	Control group (171 patients)
Number of hospital readmissions	125	168
Number of hospital admissions/patients/year	0.69	0.98
Max. number of hospital readmissions per patient	7	11
Number of emergency readmissions	95	126
Number of emergency readmissions/patients/year	0.52	0.74
Max. number of hospital readmissions per patient	6	11

in the intervention group and 137 (80.1 %) in the control group. The mean number of comorbidities in both observed groups was 9 (IQR 6-12) (p=0.423). The most common principal diagnoses of initial hospitalizations were acute myocardial infarction, heart failure, chronic kidney disease, angina pectoris and pneumonia.

Table 2 shows comorbidities according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision. Among the top ten individual comorbidities there were four cardiovascular diagnoses (essential hypertension, chronic ischaemic heart diseases, atrial fibrillation and heart failure). These diagnoses belong to the group I00-I99 – diseases of the circulatory system (30.1 % in the intervention group *vs*. 29.3 % in the control group). The next most common groups of diagnoses were Z00-Z99 – factors influencing health status and contact with health services (19.1 % in the intervention group *vs.* 16.0 % in the control group) and E00-E90 – endocrine, nutritional and metabolic diseases (12.4 % in the intervention group *vs.* 14.7 % in the control group).

The number of hospital readmission data in 12 months post discharge is presented in Table 3. Overall, 87 patients in the control group were readmitted at least once within 12 months from the discharge. These 87 patients had 168 hospital readmissions. The number of hospital readmissions per person per year in the control group was 0.98. In the intervention group 76 patients were readmitted at least once within 12 months from the discharge. These 76 patients had 125 hospital readmissions. The number of hospital readmissions per person per year in the intervention group was 0.69. Table 4 shows the total number of hospital readmissions in the intervention and control group after the group equalization procedure has been completed. The fundamental analysis is the goodness-of-fit test. The total number of hospital readmissions, within one year of hospital discharge, in the intervention group was lower than in the control group (41.7% *vs.* 58.3%; p=0.005).

Table 4: Comparison of the total number of hospital readmissions between the control and intervention groups after the group equalization procedure has been completed

Group	N	Observed		Expected		χ^2	**p**
		Number	Share	Number	Share		
Control	171	168	58.3%	144	50.0%		
Intervention	171	120	41.7%	144	50.0%	8.000	**0.005**
Total	342	288	100%	288	100%		

p – statistical significance

Table 5: Comparison of the total number of emergency admissions between the control and intervention groups after the group equalization procedure has been completed

Group	N	Observed		Expected		χ^2	p
		Number	Share	Number	Share		
Control	171	126	59.2%	106.5	50.0%		
Intervention	171	87	40.8%	106.5	50.0%	7.141	**0.008**
Total	342	213	100%	213	100%		

p – statistical significance

The number of hospital emergency readmission data in the 12 months post discharge is presented in Table 3. Overall, 69 patients in the control group had emergency readmission at least once within 12 months from the discharge. These 69 patients had 126 emergency readmissions. The number of emergency readmissions to hospital per person per year in the control group was 0.74. In the intervention group 57 patients had emergency readmissions at least once within 12 months from the discharge. These 57 patients had 95 emergency readmissions. The number of emergency readmissions to hospital per person per year in the intervention group was 0.52. Table 5 shows the total number of emergency readmissions in the intervention and control group after the group equalization procedure has been completed. The fundamental analysis is the goodness-of-fit test. The total number of emergency admissions to hospital, within one year of hospital discharge, was lower in the intervention group than in the control group (40.8% *vs.* 59.2%; p = 0.008).

3. Discussion

Pharmacotherapy is an important cause of hospital readmissions. A systematic review of El Morabet et al. (2018) reported that 21% of readmissions were directly associated with drug-related problems, and 69% of them were potentially preventable. The number of hospital readmissions represents a health care quality indicator and should be observed as a measure of delivered interventions (Krumholz et al. 2017). The reduction of hospital readmissions generates considerable health care savings and enables better disposal of health system capacity (Jencks et al. 2009). A recent study found that 30% of the potentially preventable readmissions were due to transition errors and failure to communicate medication changes to the patient and/or the next healthcare providers (Uitvlugt et al. 2021).

Although polypharmacy is a reflection of modern medicine, it carries its own risks like rehospitalisation. Polypharmacy in transfer of care represents a special problem for elderly patients. Nearly half of older adults are exposed to polypharmacy (Morin et al. 2018). Due to unintentional discrepancies, drug-drug interactions and adverse drug events, elderly patients are more prone to rehospitalisation. Also, elderly patients are particularly vulnerable to the application of drug due to changes caused by the aging process. Deterioration of renal and liver function, cognitive impairment and other functional deficits complicate pharmacotherapy management (Zazzara et al. 2021).

The health care system requires a well-designed transfer of care model, especially in the elderly with polypharmacy in order to ensure safe pharmacotherapy transfer. Our transfer model included a thoroughly organised collaboration of all healthcare professionals involved in the pharmacotherapy management. This way an organised care transfer model contributed to a lower number of readmissions in the intervention group compared to the control group (p=0.005). The connectivity of the health system at all levels of care is crucial for care transfer effectiveness. Model effectiveness also requires implementation of medication reconciliation at every stage of care (admission, discharge, post-discharge) completed with other pharmacotherapy interventions (Greenwald et al. 2010). Further, Ensing et al. (2015) emphasized that there is a need for a greater presence of pharmacists at all levels of health care pharmacotherapy transfer. Pharmacists have specific knowledge about wide scope of drugs and therefore they need to take more proactive role in the process of transfer of care and be a pillar of safe pharmacotherapy. Pharmacists are well trained and qualified to more accurately reconcile medications. The optimal transfer of care model should be organized and led by a hospital clinical pharmacist in collaboration with all healthcare professionals including community pharmacists.

Another crucial model component is organizing primary care follow-up. Special efforts should be made in clarifying specific roles of individual health professionals in the care transfer process with a special emphasis on community pharmacist follow-up. The health system seeks for a more active role of the community pharmacist in the process of transfer of care due to its specific position in the health care system (Nazar et al. 2015; Rodrigues et al. 2017; Lussier et al. 2020). A community pharmacist is one of the most accessible health care professionals and the last professional link before the medicine reaches the patient. Integrating a community pharmacist in these multifaceted programs across the health care settings ensures continuity of care (Ensing et al. 2015). Models that improve communication between community pharmacists and inpatient care teams have the potential to positively affect transfer of care (Wright et al. 2019). A study by Wright et al. (2019) found that engagement of community pharmacists after discharge significantly reduced 30-day hospital readmission rate. The concept of a "family" pharmacist would facilitate even more the transfer of the care process. Heterogeneity of the community pharmacy network may be the cause of weakening the model effectiveness that imposes the need for a "family" pharmacist similar to the obligation to have a primary care physician. A "family" pharmacist enables a better follow up process and insight in the pharmacotherapy changes. This concept requires the dispensing of drugs in one pharmacy and ensures constant pharmaceutical supervision of the patient.

The transfer of care model also needs to establish high-intensity pharmacotherapy interventions which will be delivered through model. Intensity of delivered medication-related interventions are warranted to provide positive outcomes (Daliri et al. 2021; Ravn-Nielsen et al. 2018). Research focus either on interventions performed in hospital or out of hospital and limited evidence is available on medication reconciliation delivered both in hospital and following discharge (Daliri et al. 2021). Isolated interventions are less successful as compared with interventions that are initiated in the hospital and continued following discharge (Ravn-Nielsen et al. 2018; Dautzenberg et al. 2021). The readmission rates are reduced by 9–25 % with every component added to the intervention bundle (Daliri et al. 2021). Interventions across settings are needed with specific recommendations to the patient and the next healthcare provider (Uitvlugt et al. 2021). One of the main advantages of our model are delivered high intensity interventions at admission, hospital stay and discharge, transition to primary care and post-discharge period which included medication reconciliation, pharmacotherapy review, counselling, education, creation of the BPMD, communication with outpatient health care professionals and follow-up.

Studies that evaluated the effect of the transfer of care models on reducing hospital readmissions have shown different results (Lehnbom et al. 2014; Mekonnen et al. 2016b; McNab et al. 2018; Redmond et al. 2018). For most studies, the duration of follow-up was short, at 30 days (Mekonnen et al. 2016b). Koehler et al.

(2009) stressed the need to incorporate additional outpatient transitional care support to sustain favourable long term effect. Kwan et al. (2020) imposed the need to consider a longer window of observation to demonstrate benefit as the specific effect of medication reconciliation in multifaceted interventions may not become apparent until much later than 30 days after discharge. Davies et al. (2010) determined 1-year time for the identification of ADRs, which may not be immediately apparent. Our model observed the long-term effect on hospital readmissions in the 12-month period and showed a positive effect. Therefore, our model included primary health care professionals: primary care physicians and community pharmacists in order to ensure a longer effect on hospital readmissions. Hospital clinical pharmacist established a communication chain between hospital and primary care settings, which made the model more sustainable.

Optimal transfer of care model also requires more active involvement of the patient (Coleman et al. 2004; Leppin et al. 2014). Our model empowered patient role in the process of transfer of care. The patient should have a greater role in the care transfer process through education, counselling and patient-centred documentation. This enables better pharmacotherapy outcomes and increases the safety of the transfer of care process. Further, the patient is the single constant in the patient care (WHO 2019). Health care providers must optimise medication reconciliation process and incorporate patient engagement. WHO highlights patient involvement and the topic of the patient safety day in the year 2023 is "*Engaging Patients for Patient Safety*" (WHO 2023).

Limitations of this study should be observed through its non-absolute applicability. This model was applied to a specific patient group, included specific departments and it was designed considering the specifics of the health care system. The clinical pharmacist should design the care transfer model according to its department, health target population and include all available options of the accessible health care system. Patients were excluded if they were not able to answer the questions needed to complete the structured interview or did not have a caregiver who could be interviewed and therefore patients with cognitive impairment were underrepresented in our study population. As the drug market increase and guidelines changes regular evaluation of model effectiveness should be consider. Further research should accelerate and upgrade the process of care transfer. A well-organized model should have accompanying IT platform to support the application of the model. As health care evolves with the adoption of more sophisticated systems (such as centralized databases for prescribing and collecting medication information), the effectiveness of these processes will grow (Joint Comission 2020). Today, digitalization is a priority in the healthcare system. It is important that process of digitalization doesn't omit the transfer of care.

Conclusion: The complexity of managing pharmacotherapy in elderly requires specifically designed model in the transfer of care. Model of the health care transfer applied in this research significantly reduced hospital readmissions in the 1-year period in elderly. The hospital clinical pharmacists should coordinate the transfer of care between the hospital and the primary care. The model should include cooperation between all healthcare professionals and high-intensity pharmacotherapy interventions at all levels of healthcare in order to maximize effectiveness of safe pharmacotherapy transfer.

4. Experimental

4.1. Participants

Patients were excluded if they were not able to answer the questions needed to complete the structured interview or did not have a caregiver who could be interviewed in case the patient was unable to participate in the interview and were unable or unwilling to give their consent. Patients meeting the eligibility criteria were randomly assigned, using a computer-generated sampling table of random numbers. Patients were randomized 1:1 to a control and an intervention group. The patients were enrolled consecutively. All respondents who met the inclusion criteria and/or family members/caregivers signed an informed consent to participate in the study. Patients were enrolled from December, 2018 to March, 2020, and followed up for 12 months. Final follow-up was completed in March, 2021. The study was approved by The Hospital Ethics Committee (Number 2018/2602-6).

4.2. Data collection

All patients were analysed as originally assigned during randomization (i.e., *intention to treat*) and were included in all the analyses provided that data were available. Data on patient demographics and diagnoses were extracted from patients' Best possible medication history (BPMH) and hospital records. Patients' diagnoses were classified according to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10).

4.3. Outcome measures

The outcome measures were the differences in the number of hospital readmissions and emergency readmissions between the intervention and control group. The follow-up lasted for 12 months after patients' discharge. Data on numbers of hospital readmissions and emergency readmissions were collected using a hospital information system and by contacting patients, caregivers and patients primary care physicians. Study personnel, clinical pharmacists, reviewed medical records to quantify 12-months rehospitalisation at the study institution. All study subjects received a phone call 3, 6 and 12 months after discharge to report hospitalizations.

4.4. Statistical analysis

All statistical analysis was performed using the statistical program e R 4.0.3 (R Core Team, 2020). Data distribution was analysed using the Shapiro-Wilk test. For non-normal numerical variable distributions, the median and interquartile range (IQR) were calculated, and the differences between the groups were tested using the Mann-Whitney's test. Categorical data were presented as a share or percentage and were analysed with the chi-square test. The fundamental analysis is the goodness-of-fit test. Data were analysed based on the intention-to-treat analysis. P values smaller than 0.05 were considered statistically significant.

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Data availability statement: The data were used exclusively for the research conducted as part of this study and were kept confidential.

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