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Improving care coordination for patients with cardiac disease: Study protocol of the randomised controlled new healthcare programme (Cardiolotse)

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ABSTRACT

Introduction: A lack of effective coordination and communication between ambulatory care physicians and hospitals, including the lack of follow-up care, poses a challenge to the recovery process of patients suffering from cardiac disease, often resulting in rehospitalisation and adverse outcomes. This innovative care programme aims to bridge the gap between ambulatory and hospital care. A key element of this programme is specifically trained care managers (Cardiolotse) who provide post-discharge support, access to additional resources and help the patient to navigate successfully through the healthcare system.

Material and methods: The study is set up as a prospective, randomised, controlled trial. Allocation to intervention group (support of care managers) and control group (usual care) follows an allocation ratio of 1:1 using block randomisation. Sample size calculations resulted in 1454patients per group after adjusting for potential non-compliance. All participants are surveyed at discharge, after 3 and 12 months. The primary outcome of the study is the 12-month rehospitalisation rate. Secondary outcomes include differences in length of hospital stay, mortality, quality-adjusted life years, costs and patient satisfaction. Statistical analysis and economic evaluation will be complemented by a process evaluation.

Discussion: The new healthcare programme is designed to support patients when leaving hospital with cardiac conditions by easing the transition between sectors through access to Cardiolotses and individualised care plans. We hypothesise that the programme reduces rehospitalisation and improves clinically relevant patient outcomes. *Trial registration:* German Clinical Trial Register, DRKS00020424. Registered 2020-06-18, http://www.drks. de/DRKS00020424

List of abbreviations

		HIS	Hospital information system
AOK	Allgemeine Ortskrankenkasse (Health Insurance Fund)	LoS	Length of hospital stay
CEAC	Cost-effectiveness acceptability curves	MI	Myocardial infarction
CD	Cardiac disease	MRC	Medical Research Council
CL	Cardiolotse	SAPS	Short Assessment of Patient Satisfaction
CL-ID	Unique study identification number	SES	Socio-economic status
GLM	Generalised linear models	SHI	Social health insurance
GP	General practitioner	QALY	quality-adjusted life years
HF	Heart failure		

(continued)

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1. Introduction

The transition from hospital to ambulatory care is a vulnerable phase in the care process. Patients who suffer from severe illness or need permanent medication and continuous health monitoring are particularly affected by a potential fragmentation of the healthcare system, as it exists in Germany. Information exchange between hospitals and ambulatory care providers mainly based on discharge letters may not guarantee adequate end-to-end information transmission, hence resulting in the patient missing important parts of post-discharge therapy as suggested by the hospital physicians. This lack of effective coordination and communication among hospitals and ambulatory care providers, including the lack of follow-up care, hamper the recovery process or may worsen patients' health, often resulting in rehospitalisation and adverse outcomes [1]. Especially for patients suffering from cardiovascular disease, rehospitalisation rates shortly after hospital discharge remain high, putting them at increased risk of poor health outcomes [2]. Thus, rehospitalisations not only impose considerable burden on patients and their relatives but also on healthcare systems, as a large proportion of the financial burden can be attributed to potentially avoidable rehospitalisations.

Evidence suggests that comprehensive discharge management can reduce rehospitalisation rates and follow-up medical care and improve health outcomes such as quality of life [3–6]. It has also been suggested that the adoption of personalised care plans can promote self-care management and enhance patient satisfaction [7,8]. However, coping with an illness is a complex process, often requiring a permanent change in health behaviour. It involves health educational measures and strategies to increase patients' adherence to preventive programmes including diet changes or regular exercise. Especially after hospital discharge, patients often feel unsettled and unable to cope with their situation because of the lack of health education [9]. This poses a challenge to effective self-care management. Thus, innovative care approaches need to span healthcare sectors, linking healthcare providers who focus on patient-centred activities.

In Germany, hospitals are required by law to provide discharge services to their patients (§39 Abs.1a SGB V). However, due to shortened hospital stays and an increase in chronic diseases, current measures often do not prove satisfactory in supporting patients post-discharge [10,11]. An effective care coordination that goes beyond insufficient discharge management could pose an essential element in order to overcome the boundaries between sectors and disciplines and to facilitate the transition from hospital to ambulatory care.

Many studies that evaluate rehospitalisation rates focus on patients with acute myocardial infarction (MI) or heart failure (HF) [12–14]. However, patients suffering from other heart diseases such as atrial fibrillation or chronic ischemic heart disease face similar challenges posed by the discontinuity of care and may thus also benefit from integrated care approaches in terms of reduced readmission rates [15–17].

The present study is designed to develop, implement and test a new healthcare programme that aims to bridge the gap between hospital and ambulatory care providers. A key element of the programme will be a specifically trained care manager, so-called Cardiolotse (CL), which translates as *cardiac guide*, providing post-discharge support to patients with cardiac disease (CD) and helping them to access resources and navigate the healthcare system.

2. Material and methods

This study is designed as a prospective, randomised, two-group parallel study. Recruitment of patients started in January 2019 and enrolment was expected to last until March/April 2020.² All evaluations

are planned to be completed by the end of May 2022.

Participants will be recruited within the Department of Internal Medicine at eight participating sites of the Vivantes Hospital Group in the city of Berlin.

2.1. Study aims

The main objective is to evaluate whether the new healthcare programme can bridge the care gap for patients suffering from CD through access to personal care managers (CLs) and personalised healthcare plans. The primary hypothesis is that the innovative healthcare programme leads to a significant reduction in the rehospitalisation rate 12 months after discharge compared with usual care.

To this end, we evaluate the effectiveness of the new healthcare programme on patient-centred outcomes such as mortality, qualityadjusted life years (QALYs), patient satisfaction and adherence to treatment recommendations in comparison to standard discharge services. In addition, we contrast marginal cost and effects in order to establish the cost-effectiveness and cost-utility ratio of the intervention compared with usual care. Process indicators such as contextual factors affecting the implementation of the intervention will be evaluated to identify and address potential organisational and individual-level barriers and/or facilitators.

2.2. Study population/eligibility criteria

Inclusion criteria for patients are age \geq 18 years, who were admitted to an inpatient unit of the Vivantes Hospital Group (Berlin) with the following cardiovascular admission diagnosis codes, ICD 10-GM I20–I25, I47–I50, including all patients with coronary artery disease, cardiac arrhythmias and heart failure (Appendix). All patients were asked to give written, informed consent. Only patients carrying insurance with AOK Nordost, a statutory health insurance provider in the north-eastern part of Germany, were recruited. Patients with preexisting cognitive or severe psychiatric diseases (ICD 10-GM F20–29; F33.3), with care level four or more or residing in long-term care facilities were excluded.

2.2.1. Identification of eligible patients and randomisation

Eligible patients are recruited by CLs in the hospital before discharge during the recruitment period with the help of the hospital information system (HIS). CLs will visit potential participants to provide detailed information on the study and answer questions regarding enrolment, participation and the withdrawal process. Informed consent is taken by study personnel in hospital during the initial stay. Patients who had given their written, informed consent to participate were attributed a unique study identification number (CL-ID) through a specifically designed module in the HIS and, subsequently, were randomly assigned to either the treatment or the control arm on a 1:1 basis. The web-based Randoulette randomisation tool of the Institute for Medical Information Processing, Biometry and Epidemiology, LMU Munich, Germany, is used for simple block randomisation with a block size of 10. The CLs receive the allocation result of the patient immediately after entering the CL-ID, the year of birth and sex of the patient in Randoulette. The recruiting CLs are blinded to the underlying allocation sequence of Randoulette. After assignment to either of the two arms, it is no longer feasible to blind patients or healthcare providers to randomisation status. The participant can withdraw from the study within 2 weeks after giving informed consent through the AOK Nordost without giving reasons. All data of these individuals is removed and prohibited to be used for the analysis.

2.3. Intervention

The two-group parallel design compares usual care with the new healthcare programme. A key element of the intervention will be the care manager (CL) assisting a patient's transition from inpatient to

 $^{^2\,}$ Recruitment was stopped/put on hold on 16 March 2020 due to the ongoing COVID-19 pandemic.

ambulatory care. During the hospital stay, the CL will initiate the first face-to-face contact with the patient in order to build and maintain a personal relationship post-discharge via telephone. No additional contact in person is allowed after hospital discharge.

Medical staff (nurses or qualified medical employees) received additional training of up to 2 months to acquire the skills necessary to qualify as a CL. Elements of the curriculum include communication training, training on physical and psychosocial health needs of people with CD, preventive and rehabilitative treatment options, important aspects about care services and care delivery mechanisms as well as basic training on ethical and legal issues. The theoretical part is complemented with practice training to ensure high quality services. The curriculum was developed by medical specialists at the Vivantes Hospital Group, operator of the community hospitals in Berlin, in cooperation with employees of AOK Nordost. Training is offered at the clinic site.

2.3.1. Intervention group

In addition to recommendations for follow-up care, patients assigned to the intervention group will receive tailored preventive programmes based on their needs. Additionally, patients will receive a booklet on CD that offers some practical information, for example how and when the CL or the patient hotline can be reached by telephone. If necessary, the CL will also consult family members or relatives during the patient's hospital stay to promote active participation and include them in postdischarge care planning. Finally, together with a discharge summary report, patients will receive a letter for both their general practitioner (GP) and their cardiologist that conveys information about the patients' study participation and the possibilities for engagement in the study (Fig. 2).

After discharge, patients will be contacted by the CL at a priori defined intervals via telephone during the intervention period: within the first quarter following discharge, once a month; within the second quarter following discharge, every 6 weeks; in the third and fourth quarters after discharge, every 3 months.

At all regular telephone encounters, a standardised questionnaire is employed for follow-up questions. These include enquiry regarding selected vital parameters (e.g. blood pressure, body weight); compliance with the medication plan; any adjustment of medication initiated by the primary care provider/specialist. The CL will also ask about the patient's adherence to health behaviour recommendations, assist the patient in meeting his or her specific care needs, facilitate access to health information and educational material, motivate the patient to overcome barriers and establish goals to self-manage her/his illness and

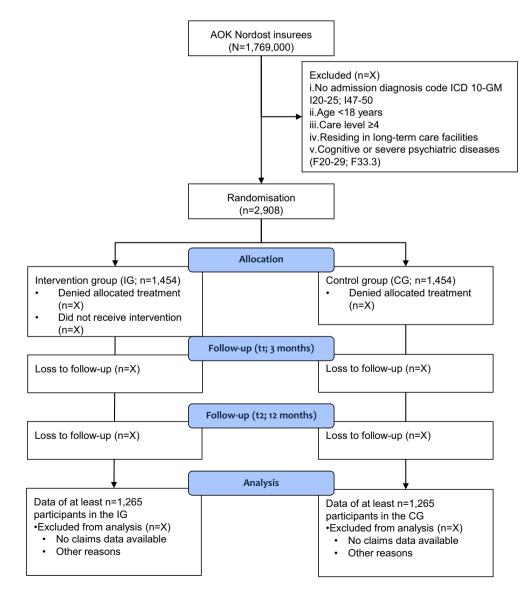


Fig. 1. Study flow chart.

recommend referral to specialist care if any warning signs occur. Before getting in touch with the patient's primary care provider or a medical specialist, the CL will consult the trial medical director at the hospital site to confirm the urgency of a physician visit.

If deemed necessary, the CL will also help in scheduling appointments with primary care physicians or specialists, making contact with other healthcare providers, therapists or (re)connecting with community care services.

In case of any healthcare questions or concerns, the patient is able to contact the CL for assistance directly. In addition, a telephone hotline has been made available to answer health-related questions from patients and relatives during the intervention period. The telephone hotline is also available to medical professionals who are involved in the medical treatment of participating patients and seek consultation on certain aspects of treatment with the CL.

The intervention will be complete after a minimum of 12 months of follow-up after hospital discharge (Fig. 1). Depending on the time of recruitment, the follow-up period lasts between 12 and 27 months, meaning that all patients will receive the intervention until the last patient has reached the 12 months follow-up. Thus, patients recruited

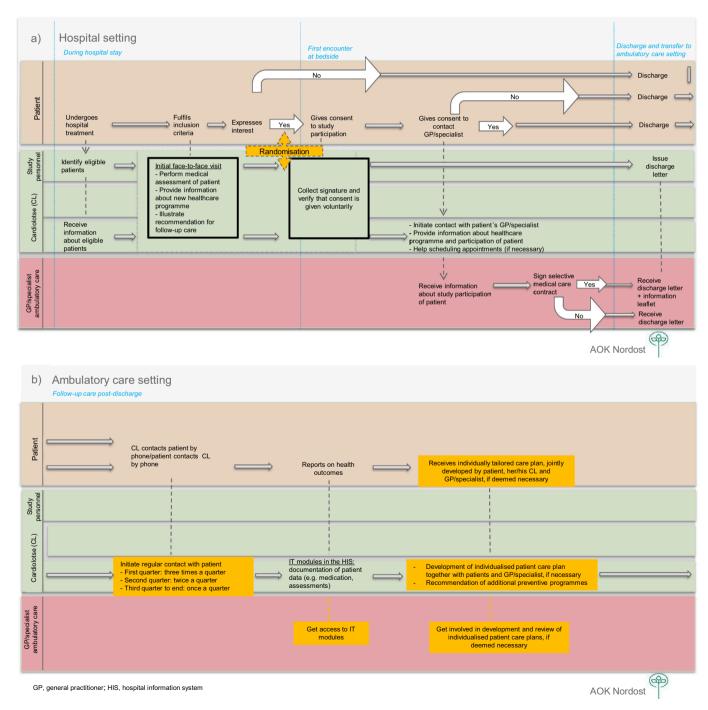


Fig. 2. Description of intervention.

earlier in the study will have a longer follow-up period, which will allow us to check whether the CL has a long-term beneficial effect. However, the primary study endpoint, i.e. rehospitalisaton rate, will be evaluated after 12 months of follow-up under the hypothesis that the effect of the CL is greatest within one year after the initial hospital stay.

2.3.2. Control group

Patients allocated to the control group continue to receive treatment as usual at and following hospital discharge. In addition, the control group is asked to complete follow-up questionnaires (EQ-5D-5L and patient satisfaction) identical to the intervention group 3 months and 12 months post-discharge by telephone. In order to avoid any potential

Table 1

Outcome measures and times of assessment.

bias, trained assistants instead of CLs will record the follow-up questionnaires of the control group. The patients of the control group receive no further telephone calls and their physicians do not receive a letter that conveys information on the patient's participation in the study to avoid bias in the outcome, e.g. based on altered behaviour of either the patient or the physician. However, all GPs and cardiologists in the area of Berlin are invited to engage in the study.

2.4. Data collection and outcome measures

All outcomes are collected through a combination of patient surveys/ questionnaires, review of certain medical records and telephone

Outcome measures and times o					
	STUDY PERIOD				
	BASELINE FOLLOW-UP				
Timoroint	to	t1	t ₂	t3	t4
Timepoint	enrolment	30 d	3 mos	6 mos	12 mos
	ENROLM	1ENT			
Eligibility screen	Х				
Informed consent	Х				
	COMPARA	ATORS			
Intervention (CL)	+				
Care as usual	+				
	ASSESSM	IENTS			
	PRIMARY O	UTCOM	E		
Rehospitalisation		X	Х	X	X
S	SECONDARY (DUTCON	1ES		
LoS					Х
Mortality					Х
QALY	Х		Х		Х
SAPS			Х		X
	PROCESS INI	DICATOF	RS		
Guideline adherence	\				
Calls to CLs*					Х
Contextual factors	+				
	ECONOMIC PA	RAMETI	ERS		
Implementation costs	+				
Treatment costs					
(Confounding	G FACTO	ORS		
SES	Х				
DMP					Х

Abbreviations: *CL* Cardiolotse, *DMP* Disease Management Programmes, *LoS* Length of (hospital) Stay, *SAPS* Short Assessment of Patient Satisfaction, *SES* Socio-Economic Status, *QALY* Quality-Adjusted Life Year.

*Calls to CLs can be measured in the intervention group only.

interviews in specifically designed IT modules through the HIS of the Vivantes study sites and administrative claims data, which will be provided by AOK Nordost.

In addition to the primary outcome, secondary outcomes including process indicators, economic parameters and potential confounding factors are also collected at given intervals from both the intervention and the control group (see Table 1).

2.4.1. Primary outcome measure

The primary outcome is the 12-month rehospitalisation rate for all causes. Additionally, we examine the 12-month rehospitalisation rate resulting from one of the study inclusion diagnoses (ICD-10-GM I20–I25, I47–I50). Rehospitalisation is assessed 30 days, 3 months, 6 months and 12 months after hospital discharge using administrative claims data (see Fig. 1 and Table 1).

2.4.2. Secondary outcome measures

Mortality of patients and length of hospital stay (LoS) in case of a rehospitalisation are evaluated at the end of the study using administrative claims data. QALYs are derived from interviews through the German telephone version of the EuroQol questionnaire (EQ-5D-5L) [18]. Satisfaction with the treatment of the CD is obtained using an adapted version of the Short Assessment of Patient Satisfaction (SAPS) [19].

2.4.2.1. Cost measures of the economic evaluation. Cost data for the costeffectiveness and cost-utility analysis include the implementation costs of the intervention and overall treatment costs associated with CD. The parameters for treatment costs comprise costs of medication, inpatient and ambulatory care as well as medical remedies or aids, and are routinely collected for provider reimbursement by AOK Nordost. To compare marginal effects with marginal costs, we use rehospitalisation rate and QALYs as effect measures to establish the cost-effectiveness and the cost-utility of the new healthcare programme.

2.4.2.2. Measures of the process evaluation. In accordance with Medical Research Council (MRC) guidance [20], the study is accompanied by a process evaluation to identify any unintended pathways and their consequences at every stage of the intervention. Semi-structured interviews and questionnaires with CLs, physicians at the study sites, GPs and medical specialists are used to identify relevant contextual factors and the mechanisms of impact of the intervention. Additionally, adherence to treatment recommendations is derived from administrative claims data for both groups. To test whether the patients of the intervention group adhere with all recommendations received from the CLs, records of the follow-up calls are stored in the IT modules of the Vivantes Group. For the intervention group, the frequency of calls to a CL are also recorded at an individual level.

2.4.2.3. Confounding factors. Data on socio-economic status (SES) including marital status, level of education, migration history, ethnic background and employment status at baseline are collected as potential confounding factors in the analysis. Additionally, data on the participation in disease management programmes provided by the AOK Nordost is used as a confounding factor.

2.5. Sample size calculation

The sample size calculation is based on an assumed significance level of 5%, power of 80% to detect at least 20% reduction in the rehospitalisation rate over a 12-month follow-up after discharge. According to internal claims data from AOK Nordost, the rehospitalisation rate of patients with CD in usual care is estimated to be 25%. Based on these assumptions, a minimum of 2188 patients, 1094 per group, are needed for the analysis. According to estimations from an interim analysis of the Vivantes Group, non-compliance in terms of lack of possibility of the CL supporting his/her patient is expected to be approximately 2% on account of the close relationship between CLs and the intervention group. We further assume that about 5% of the control group might be influenced by concomitant care programmes in the region of Berlin. Following the statistical approach of Wittes (2002), the sample size of 2188 needs to be multiplied by a factor of 1.16 to account for the aforementioned influences [21]. Given that the expected loss to follow-up is up to 13%, we needed to include 2908 patients (1454 in each group).

A review of comparable prior intervention studies found reductions in rehospitalisation rates that vary from 0% to 80% [8]. However, these studies primarily focus on patients with heart failure (HF). No comparable recent studies were found that examined different forms of heart diseases that are included in our study. Two studies including ischaemic heart disease and myocardial infarction (MI) report no significant differences in rehospitalisation rates between intervention and control groups [6,22], although reductions in the event rate for MI of 48% within 3 years have been found [22]. Owing to the limited comparability of prior research, we expect our study population to be similar to patients with HF regarding rehospitalisation rates and conservatively assume a 20% reduction in the rehospitalisation rate .

2.6. Statistical analysis

The evaluation of the intervention will be performed as intention to treat. Although the block randomisation of the patients to intervention and control group aimed at unbiased results, it cannot guarantee perfect comparability of the two groups. Hence, adjusted generalised linear models (GLM) are used to analyse differences in rehospitalisation rates between intervention and control group. In a second analysis, we test whether differences in time-to-rehospitalisation exist between the two groups using cox proportional hazard models.

Secondary outcomes are analysed using standardised regression models. Differences in time of death and overall mortality between the intervention and control groups are measured through survival analyses. Missing values are completed, if possible, through multiple imputations using chained equations. All analyses are carried out using R and STATA.

2.6.1. Economic evaluation

The economic evaluation of the new healthcare programme will determine the cost-effectiveness and cost–utility of the intervention compared with usual care. Findings are expressed as incremental cost-effectiveness and cost–utility ratios, which illustrate the additional costs in Euros [ϵ] incurred in relation to the additional unit of effectiveness (rehospitalisation) or utility (QALY).

Treatment costs are calculated through standardised costing of sickness fund data (AOK Nordost). The perspective of the sickness fund is adopted to test whether the results can be transferred to the general publicly insured population. The statistical uncertainty of the estimates is described using bootstrapping methods and estimating costeffectiveness acceptability curves (CEAC).

2.6.2. Process evaluation

Structured questionnaires and semi-structured interviews with relevant stakeholders are screened using Mayring's (2014) content analysis approach [23]. Thus, contextual factors that facilitate or hinder the effectiveness of the intervention can be identified, which is necessary to understand the underlying mechanisms of impact. Other process measures are summarised descriptively and, if applicable, used for sensitivity analyses.

2.7. Sensitivity analysis

Extensive sensitivity analyses are planned to test the dependence of

the results on selected parameters such as differences in the results based on the primary admission diagnosis of the recruited patients. Moreover, parameters of the process evaluation are used to examine if adherence with the recommendations of the CL correlates with a decrease in rehospitalisation rates. That way, we can approximate whether the observed effect is attributable to the intervention or may be subject to the increased attention. In addition, the statistical uncertainty of the economic evaluation is estimated using CEAC.

2.8. Data management and data reporting

The collection and processing of data is carried out under strict compliance with legal regulations, in particular regulations concerning data protection and medical confidentiality.

Consent forms will be stored as scanned documents at the Vivantes Hospital Group. Clinical data will be stored in the clinical information system at the hospital.

Paper questionnaires and interview transcripts will be stored at the responsible institutions (LMU/Vivantes Group), and access is only possible by authorised individuals.

For data protection reasons, an independent trust centre merges the clinical data of the patients from the Vivantes Hospital Group and administrative claims data from AOK Nordost. Thus, all datasets will be pseudonymised twice before they are made available for analysis. Data analysis is conducted by independent researchers employed by the LMU and appointed for this task. Data management, analysis and reporting will be in compliance with Good Clinical Practice and Good Practice of Secondary Data Analysis [24].

The primary investigator reports study progress to the executing organisation of the funding body on a quarterly basis and submits a detailed financial and technical report once per year. Any modification of the protocol or milestones is reported to the funding body and, if applicable, to the trail registry and participants.

In biannual meetings with an external advisory board consisting of medical experts and a patient representative, study progress (recruitment, outcome parameters, data security) is discussed and recommendations on further proceeding of the study is given. No additional data monitoring committee is employed as the study is evaluated by an independent institution. Thus, the primary investigators have no influence on the study evaluation or results. Moreover, the main data components of the evaluation are claims data of the insurance company that cannot be influenced by the primary investigators. Study results will be published in a peer-reviewed, international scientific journal.

3. Discussion

Healthcare systems face unique challenges when patients transit from hospital to the ambulatory care sector. The new healthcare programme (Cardiolotse) has been developed to improve this transition, providing access to personal care managers (CLs) and individualised care plans that support patients with CD. The new healthcare programme is designed as a bridging element in a fragmented healthcare system to facilitate continuity of care and care coordination posthospital discharge. Patients are supported to effectively self-manage their illness – independent of their educational level or social status. We expect the programme to achieve a reduction in rehospitalisations and to improve other relevant clinical parameters.

Previous research has shown that comprehensive intervention studies found reductions in rehospitalisation rates that varied from 0% to 80%. Thus, there is no simple, uniform approach that can be implemented to reduce rehospitalisation rates. Instead, integrated care approaches need to be established that are tailored to the context they are implemented in [5]. Our intervention combines patient-centred care through patient empowerment that enhances continuous care fostered through the additional individually tailored support of the CLs. Thereby the CLs try to overcome the challenges posed by discontinuous information exchange between hospitals and ambulatory care providers. Additionally, GPs and cardiologists are included in the study to ensure common care strategies and avoid double-barrelled structures.

Recent new healthcare programmes try to support patients through digital solutions, providing e.g. educational material through apps or other technologies. However, the effectiveness of these interventions is thought to decrease with age because of barriers to computer use in older populations [25]. In addition, many patients with a migration background in the first or second generation may have additional problems with the complexity of the German healthcare system and electronic devices provided for healthcare management. Conversely, prevalence rates of CD increase with the patient's age, stipulating the need for additional support. Personalised healthcare plans such as those provided by the CLs are designed in close dialogue with the patient to empower self-management at all ages, complementary to effective digital solutions. Ethnic diversity of the CLs also lowers cultural and language barriers in comparison with highly standardised healthcare plans.

The results of the economic and process evaluation may offer healthcare actors and policy-making bodies guidance for implementation in area-wide clinical practice and hence for intensifying the exchange between care providers from both the hospital and the ambulatory care sector for the benefit of patients. Provided that the new healthcare programme proves to be effective, it may also serve as a role model to support future implementation of similar healthcare programmes.

One limitation of the study design lies in the restriction to one health insurance company and one hospital group, which may hamper the generalisability of the study results to the entire social health insurance (SHI)-insured population. However, our results may well be generalisable to the SHI-insured population living in urban areas with similar socio-demographic characteristics and that are hospitalised with cardiovascular disease as defined above. Although the limitations inherent to administrative claims data apply here as well, we linked these data source with primary data to gain a more comprehensive picture.

Ethics

All procedures conducted during the study are carried out in compliance with federal and institutional ethical standards. Ethics approval has been provided by the ethics committee of Berlin Medical Council ('Ethik-Kommission der Ärztekammer Berlin'), chaired by PD Dr. Hans-Herbert Fülle. The regulations of the Data Security Law applicable to Berlin, Germany, are also met. A separate data protection and security concept, which details responsibilities concerning data management, data access and analysis, has been set up and agreed upon between the study group comprising AOK Nordost, Vivantes Hospital Group and LMU.

Consent to participate

Informed, written consent was obtained from all participants.

Consent for publication

Not applicable.

Data sharing and dissemination

Data and material will be published in peer-reviewed journals after completion of the study. Additionally, results will be presented at national scientific conferences.

Funding statement

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review by the scientific board of the governmental funding body and the Innovation Fund Committee. The funder had no role in study design, data collection, data analysis or the preparation of the manuscript.

Author contributions

[IG, KCR] drafted the original manuscript and contributed equally to this work. *[LS, IG, KCR, SK, AS, SL]* reviewed and edited the original draft. *[PR, HD, AH]* planned the study and developed the intervention. All authors provided input, read and approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no competing interests.

Appendix A. Appendix

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ICD-10 GM	Categories (German original)	Categories (English)	
I20	Angina pectoris	Angina pectoris	
I21	Akuter Myokardinfarkt	Acute myocardial infarction	
I22	Rezidivierender Myokardinfarkt	Subsequent myocardial infarction	
123	Bestimmte akute Komplikationen nach akutem Myokardinfarkt	Certain current complications following acute myocardial infarction	
I24	Sonstige akute ischämische Herzkrankheit	Other acute ischaemic heart diseases	
I25	Chronische ischämische Herzkrankheit	Chronic ischaemic heart disease	
I47	Paroxysmale Tachykardie	Paroxysmal tachycardia	
I48	Vorhofflimmern und Vorhofflattern	Atrial fibrillation and flutter	
I49	Sonstige kardiale Arrhythmien	Other cardiac arrhythmias	
150	Herzinsuffizienz	Heart failure	

References

- C. van Walraven, M. Mamdani, J. Fang, P.C. Austin, Continuity of care and patient outcomes after hospital discharge, J. Gen. Intern. Med. 19 (2004) 624–631, https://doi.org/10.1111/j.1525-1497.2004.30082.x.
- [2] A. Gößwald, A. Schienkiewitz, E. Nowossadeck, M.A. Busch, Prävalenz von Herzinfarkt und koronarer Herzkrankheit bei Erwachsenen im Alter von 40 bis 79 Jahren in Deutschland: Ergebnisse der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1), Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 56 (2013) 650–655, https://doi.org/10.1007/s00103-013-1666-9.
- [3] M.D. Naylor, D.A. Brooten, R.L. Campbell, G. Maislin, K.M. McCauley, J. S. Schwartz, Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial, J. Am. Geriatr. Soc. 52 (2004) 675–684, https://doi. org/10.1111/j.1532-5415.2004.52202.x.
- [4] W.P. Wong, J. Feng, K.H. Pwee, J. Lim, A systematic review of economic evaluations of cardiac rehabilitation, BMC Health Serv. Res. 12 (2012) 243, https://doi.org/10.1186/1472-6963-12-243.
- [5] K. Dharmarajan, Comprehensive strategies to reduce readmissions in older patients with cardiovascular disease, Can. J. Cardiol. 32 (2016) 1306–1314, https://doi. org/10.1016/j.cjca.2016.01.030.
- [6] P. Giannuzzi, P.L. Temporelli, R. Marchioli, A.P. Maggioni, G. Balestroni, V. Ceci, et al., Global secondary prevention strategies to limit event recurrence after myocardial infarction: results of the GOSPEL study, a multicenter, randomized controlled trial from the Italian cardiac rehabilitation network, Arch. Intern. Med. 168 (2008) 2194–2204, https://doi.org/10.1001/archinte.168.20.2194.
- [7] S. Nickel, B. Thiedemann, O. von dem Knesebeck, The effects of integrated inpatient health care on patient satisfaction and health-related quality of life: results of a survey among heart disease patients in Germany, Health Policy 98 (2010) 156–163, https://doi.org/10.1016/j.healthpol.2010.06.012.
- [8] M. Adib-Hajbaghery, F. Maghaminejad, A. Abbasi, The role of continuous care in reducing readmission for patients with heart failure, J. Caring Sci. 2 (2013) 255–267, https://doi.org/10.5681/jcs.2013.031.
- [9] S. Ludt, F. Heiss, K. Glassen, S. Noest, A. Klingenberg, D. Ose, J. Szecsenyi, Die Patientenperspektive jenseits ambulant-stationärer Sektorengrenzen - Was ist Patientinnen und Patienten in der sektorenübergreifenden Versorgung wichtig? Gesundheitswesen 76 (2014) 359–365, https://doi.org/10.1055/s-0033-13482260
- [10] Redaktion Deutsches Ärzteblatt, Entlassmanagement bereitet Krankenhäusern Probleme. https://www.aerzteblatt.de/nachrichten/88826/Entlassmanagement -bereitet-Krankenhaeusern-Probleme, 2018 (Accessed 11 Dec 2020).
- [11] E. Nagel, B. Neukirch, A. Schmid, G. Schulte, Wege zu einer effektiven und effizienten Zusammenarbeit in der ambulanten und stationären Versorgung in Deutschland. https://www.zi.de/fileadmin/images/content/Gutachten/Zi -Gutachten_ambulant_vor_station%C3%A4r_Mai_2017.pdf, 2017.

- [12] K. Dharmarajan, A.F. Hsieh, Z. Lin, H. Bueno, J.S. Ross, L.I. Horwitz, et al., Diagnoses and timing of 30-day readmissions after hospitalization for heart failure, acute myocardial infarction, or pneumonia, JAMA 309 (2013) 355–363, https:// doi.org/10.1001/jama.2012.216476.
- [13] F. Koehler, K. Koehler, O. Deckwart, S. Prescher, K. Wegscheider, B.-A. Kirwan, et al., Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial, Lancet 392 (2018) 1047–1057, https://doi.org/10.1016/S0140-6736(18)31880-4.
- [14] P. Jepma, G. ter Riet, M. van Rijn, C.H.M. Latour, R.J. Peters, O.P. Scholte, W.J. M. Reimer, B.M. Buurman, Readmission and mortality in patients ≥70 years with acute myocardial infarction or heart failure in the Netherlands: a retrospective cohort study of incidences and changes in risk factors over time, Neth. Heart J. 27 (2019) 134–141, https://doi.org/10.1007/s12471-019-1227-4.
- [15] G. Hindricks, T. Potpara, N. Dagres, E. Arbelo, J.J. Bax, C. Blomström-Lundqvist, et al., 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS), Eur. Heart J. (2020), https://doi.org/10.1093/eurheartj/ ehaa612.
- [16] D.C. Gonçalves-Bradley, N.A. Lannin, L.M. Clemson, I.D. Cameron, S. Shepperd, Discharge planning from hospital, Cochrane Database Syst. Rev. (2016), CD000313, https://doi.org/10.1002/14651858.CD000313.pub5.
- [17] P.M. Ho, D.J. Magid, F.A. Masoudi, D.L. McClure, J.S. Rumsfeld, Adherence to cardioprotective medications and mortality among patients with diabetes and ischemic heart disease, BMC Cardiovasc. Disord. 6 (2006) 48, https://doi.org/ 10.1186/1471-2261-6-48.
- [18] M. Herdman, C. Gudex, A. Lloyd, M. Janssen, P. Kind, D. Parkin, et al., Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L), Qual. Life Res. 20 (2011) 1727–1736, https://doi.org/10.1007/s11136-011-9903-x.
- [19] G. Hawthorne, J. Sansoni, L. Hayes, N. Marosszeky, E. Sansoni, Measuring patient satisfaction with health care treatment using the Short Assessment of Patient Satisfaction measure delivered superior and robust satisfaction estimates, J. Clin. Epidemiol. 67 (2014) 527–537, https://doi.org/10.1016/j.jclinepi.2013.12.010.
- [20] G.F. Moore, S. Audrey, M. Barker, L. Bond, C. Bonell, W. Hardeman, et al., Process evaluation of complex interventions: Medical Research Council guidance, BMJ 350 (2015) h1258, https://doi.org/10.1136/bmj.h1258.
- [21] J. Wittes, Sample size calculations for randomized controlled trials, Epidemiol. Rev. 24 (2002) 39–53, https://doi.org/10.1093/epirev/24.1.39.
- [22] A.-D.O. Zwisler, A.M.B. Soja, S. Rasmussen, M. Frederiksen, S. Abedini, S. Abadini, et al., Hospital-based comprehensive cardiac rehabilitation versus usual care among patients with congestive heart failure, ischemic heart disease; or high risk of ischemic heart disease: 12-month results of a randomized clinical trial, Am. Heart J. 155 (2008) 1106–1113, https://doi.org/10.1016/j.ahj.2007.12.033.

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- [23] P. Mayring, Qualitative Content Analysis: Theoretical Foundation, Basic Procedures and Software Solution, 2014.
- [24] E. Swart, H. Gothe, S. Geyer, J. Jaunzeme, B. Maier, T.G. Grobe, P. Ihle, Gute Praxis Sekundärdatenanalyse (GPS): Leitlinien und Empfehlungen, Gesundheitswesen 77 (2015) 120–126, https://doi.org/10.1055/s-0034-1396815.
- [25] G.A. Wildenbos, M.W.M. Jaspers, M.P. Schijven, L.W. Dusseljee-Peute, Mobile health for older adult patients: using an aging barriers framework to classify usability problems, Int. J. Med. Inform. 124 (2019) 68–77, https://doi.org/ 10.1016/j.ijmedinf.2019.01.006.