

Effects of care by advanced practice nurses for multi-morbid patients in general practices in rural areas. Results of a nonrandomized controlled trial

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Abstract

Background

Multimorbidity poses a significant challenge for primary care. In Germany shortage of primary care physicians hinders comprehensive assessments of patients and home visits. We aim to investigate the impact of incorporating Advanced Practice Nurses (APNs) into primary care in rural areas for patients with multiple chronic conditions on care quality, healthcare utilization and satisfaction.

Methods

We used a non-randomized, two-arm, multicentre intervention design. Nine APNs in nine general practices provided care to multimorbid patients in the Intervention Group (IG), while the Control Group (CG) received standard care. Quantitative and health economic analysis investigated the differences in utilization of the primary endpoints *outpatient emergency contacts* and *unplanned hospitalizations* between the IG and CG. Qualitative analysis was used for process evaluation based on semi-structured interviews with general practitioners, APNs, and patients.

Results

A total of 705 IG patients and 1410 CG patients were included. Both groups showed a similar average amount of out-of-hours emergency services (IG: 0.27; 95%CI 0.21–0.33; CG: 0.27; 95%CI 0.16;0.33) and of out-of-hours general practitioner contacts (IG: 0.23; (CG: 0.17). After adjusting for confounders, no statistically significant differences in the costs for emergency hospital stays (IG: 2592.76€; CG: 1537.89€), regular hospital stays (IG: 1399.23€; CG: 1054.33€), and home visits (IG: 59.88€; CG: 41.54€) were found between the two groups.

Trial registration

DRKS00026172 on DRKS (Deutsches Register Klinische Studien)

Background

Multimorbidity, defined as the coexistence of at least three chronic conditions, poses a significant challenge for primary care physicians in Germany (1). This complex issue is often accompanied by overlapping symptoms, treatment strategies, and psychosocial problems, primarily affecting older adults. The development of additional syndromes (e.g., mobility limitations, malnutrition, cognitive impairment, incontinence, pain, and chronic wounds) further complicates care. Effective management of these syndromes through continuous monitoring and coordinated care can reduce mortality and improve health outcomes for patients with conditions like diabetes, coronary heart disease, heart failure, and chronic obstructive pulmonary disease (2). However, Germany's shortage of primary care physicians, with an average consultation time of 7 to 8 minutes, hinders comprehensive assessments of patients and home visits (3). Insufficient coordination of care exacerbates the issue. The growing patient population and

impending physician shortage necessitate innovative solutions (4–6). The World Health Organization (WHO) and the German Society of General Practitioners and Family Physicians (DEGAM) guidelines emphasize person-centred care as crucial for optimizing healthcare (1, 7). This approach prioritizes patients' needs, perspectives, and autonomy, moving away from a purely biomedical focus. Key elements include: Therapeutic Alliance, fostering strong patient-provider relationships; Shared Decision-Making, involving patients in treatment decisions; Care Continuity, ensuring seamless transitions between care settings; Self-Management Support, empowering patients to manage their conditions; And health Literacy Promotion: Enhancing patients' understanding of their health.

The Role of Advanced Practice Nurses (APNs)

Given the special needs of patients with multimorbidity APNs are well suited to addressing the associated challenges and thereby reducing the time pressures faced by General practitioners. APNs, typically holding a clinical Master's degree (M.Sc.), are academically trained to provide high-quality, person-centred care. International examples (e.g., USA, Canada, Australia, and Sweden) demonstrate that APNs can achieve outcomes comparable to those of physicians, without compromising patient safety, and often increasing patient satisfaction (8, 9).

General practitioners form the backbone of Germany's outpatient healthcare system. Unlike in many other countries, APNs have so far played no role in primary care in Germany (10). The previous lack of advanced education pathways for nurses in Germany has hindered the adoption of APN roles. In the meantime, there are numerous Master's degree programmes in Germany that train APNs (11).

We aim to investigate the impact of incorporating APNs into primary care in rural areas for patients with multiple chronic conditions, focusing on enhanced care quality and alleviated workload for General Practitioners.

Methods

Design and setting of the study

The impact of incorporating APNs into primary care was evaluated using: (i) a quantitative epidemiological approach; (ii) a health economics approach; (iii) a qualitative approach.

The focus of the study was a two-arm, non-randomized, multicentre intervention study (Fig. 1). Patients in Arm 1 (Intervention Group, IG) received the new care model, which involves case-related care provided by an APN in the general practice setting. Patients in Arm 2 (Control Group, CG) received standard care.

Description of the intervention

During the intervention, nine APNs employed in nine general practices cared for multimorbid patients. Due to their employment at the practice, the APNs had unrestricted access to patient records. They largely provided care to participating people independently. They conducted an in-depth instrument-based assessment and drew up a person-centred, evidence-based treatment plan. The assessment

encompassed cognitive capabilities, nutritional status, pain status, mobility status, neuropsychiatric state, continence status, skin condition/wounds, medication management, psychosocial situation, self-management skills, home living situation and social situation around loneliness. They also conducted a clinical assessment. The APNs implemented the care plan themselves or called in other care service providers if needed. Their tasks also included monitoring, evaluating and documenting the treatment plan. An important strategy of the APNs was counselling. With the aim of increasing independence and self-management, promoting healthy behaviour and improving the current condition, the APNs counselled patients and their relatives. Cooperation with patients and relatives was based on the principle of shared decision making. The APNs conducted home visits and offered consultation hours at the practice. They were the point of contact in emergency situations and ensured that information was shared across sectors. In accordance with German law, the APNs consulted with GPs on measures requiring a prescription that they deemed necessary. To this end, they held weekly case conferences (12).

Data Collection

Primary outcomes included the number of outpatient emergency contacts and the number of unplanned inpatient hospital stays. Secondary outcomes collected and evaluated within the FAMOUS project are reported in details in Table 1.

Table 1
Outcomes in the intervention vs. control group

Outcome measures	Data sources	
	Intervention group	Control group
Primary Outcome Measures		
Number of outpatient emergency contacts	KV RLP§	BKK
Number of unplanned inpatient hospital stays	Health insurance companies&	BKK
Secondary Outcome Measures		
Utilization of additional healthcare institutions	Health insurance companies&	BKK
Number of home visits by general practitioners	KV RLP§	BKK
Utilization of nursing homes	Health insurance companies&	BKK
§ Regional Association of Statutory Health Insurance Physicians in Rhineland-Palatinate		
& BKK, AOK, TK, Barmer and DAK		
7		

Data for the intervention group’s outcome measures were provided through routine data from the KV RLP (Regional Association of Statutory Health Insurance Physicians in Rhineland-Palatinate) and the participating health insurance companies, as well as collected by the APNs and entered into a database.

Data on inpatient hospital stays for the intervention group were provided by the participating health insurance companies.

Routine data for the control group were provided by the BKK Landesverband Mitte health insurance.

Characteristics of participants

Inclusion criteria include:

- Medical Diagnosis: At least three chronic conditions, with three chronic conditions requiring primary care treatment in at least 3 out of 4 quarters over the past year.
- Minimum age of 18 years;
- Undergoing treatment at a participating general practitioner's practice; Willingness to participate in the Advanced Practice Nursing (APN) Program.

Exclusion Criteria include:

- Deemed to be in the terminal phase of life (as assessed by the primary care physician).

Based on these criteria, the participating GPs asked potentially suitable patients to take part in.

Sample size calculation and matching

Sample size calculation has been described in detail in the published study protocol (12). The planned sample size for this study comprised 817 for the intervention group (IG) and 1,634 for the control group (CG).

To ensure a fair comparison, patients in the IG were matched with two counterparts in CG based on key characteristics. This process unfolded in two stages:

1. First, individuals were matched exactly on gender and the number of chronic conditions, guaranteeing that these fundamental aspects were identical between the groups.
2. Next, to account for age, a more flexible approach was employed, seeking the closest matches within a ± 2 years range. This nuanced method, known as Nearest-Neighbour Matching, minimized age disparities between the groups.

For each IG patient, multiple potential matches in the CG were identified. When more than two suitable matches were found, the two with the most shared chronic conditions were selected to enhance the comparison's validity. Conversely, if fewer than two matches were initially identified, the age criterion was gradually relaxed (e.g., to ± 3 , ± 4 , or ± 5 years) to ensure that at least two comparable counterparts were found for each IG patient.

Analysis

(i) Quantitative epidemiological approach

Descriptive statistics were summarised by means, 95% bootstrap confidence intervals (13), standard deviations, and frequencies.

Median imputation was used to handle the missing information regarding participants' care levels. For participants with fewer than three documented chronic conditions in the health insurance data, a stepwise imputation process was applied:

1. we used APNs-documented ICD-10 codes to identify the relevant critical conditions and added to the documented chronic conditions.
2. If participants still had less than three critical conditions after this step, we used the minimum required number of chronic conditions for study inclusion—specifically, three critical conditions—for imputation.

To estimate the intervention effect of APN, we applied a Bayesian zero-inflated negative binomial (ZINB) model (14) to account for the excessive zero observations. In addition, we included in the model the following potential confounding variables: age, sex, the number of chronic conditions, and care levels. Interactions between these confounding factors and the intervention itself were also included in the model. To perform a Bayesian inference on the intervention events, a weakly informative prior, a normal distribution with a mean of 0 and a standard deviation of 4, was employed. We drew 10,000 samples from the posterior distribution of the intervention effects via the Markov Chain Monte Carlo (MCMC) algorithm with 10 parallel chains. The posterior intervention effects were summarized as mean incidence rate ratios accompanied by 95% credibility intervals.

For an additional plausibility assessment of the effects, a pre-versus-during comparison was performed for all participants who were insured with one specific health insurance with a high proportion of participating patients and who completed the project as planned, in addition to the primary analysis. The latter provided data for these participants covering the year preceding the start of the project (date of the first contact) and the year during project participation. These data were descriptively analysed with respect to the primary and secondary endpoints.

Statistical analysis was conducted using R (Version 4.4.1) and R package brms, MatchIt, marginal effects, and boot (15–18).

(ii) Health economics approach

The APNs were requested to document their hours worked. To calculate hourly costs for an APN, we used the hours worked only for those APNs who documented at least of 70% of their working hours indicated by their contract. Of the working hours 30 days of holiday, 15 days of sickness leave and 8 days for public holidays, - the standard absence rates for German employees - were deducted from the working time (19). The documented working time was now combined with the working hours in the contract and then the

hourly cost for an APN were calculated. In order to compare the costs between the IG and the CG, costs for emergency hospital stays, regular hospital stays, and home visits by the general practitioner were assessed for both groups. Cost data was provided by the participating health insurances. A two-part regression model using logistic regression and a generalized linear model with gamma distribution was used to adjust for age, sex, number of chronic diseases and care degree. Predicted margins adjusted mean values and associated 95% confidence intervals were calculated for both groups (20, 21).

To examine the pre- versus-during comparison from a health-economic perspective, the cost categories used in the primary cost analysis (planned inpatient hospital stays, unplanned inpatient hospital stays, and home visits) were employed. The analysis was performed descriptively, reporting means with 95% confidence intervals, medians, and the 25th and 75th percentiles (Q1 and Q3).

(iii) Qualitative evaluation

Semi-structured interviews (12) were conducted with the doctors participating in the IG before and after the intervention, with APNs at the end of their work in GP practices, and with patients after 12 months of APN treatment. These interviews were conducted to investigate satisfaction with and feasibility of APNs in rural GP practices. All interviews took place between autumn 2021 and spring 2024. All interviews were conducted via telephone by a trained researcher. All GP practices and APN were contacted while patients were contacted until saturation was reached. The interviews were audio recorded, transcribed verbatim and analysed using Mayring's qualitative content analysis with inductive and deductive category formation (22). Disagreements were resolved by consensus. The evaluating researchers were not involved in the organisation or delivery of the intervention.

Results

Quantitative analysis

In total 853 patients were enclosed from nine rural general practices in Rhineland-Palatinate, Germany.

709 patients (83.1%) completed the study as planned, with a minimum of 12 months of intervention (± 14 days). Data for four patients could not be found by the KV RLP and were excluded. After this exclusion, 705 patients proceeded for analysis. (Table 2).

Table 2
Characteristics of the study population

	Control group	Intervention group		
	Matched participants* N = 1,410	Planned Completion N = 705 (82.6%)	Non-Planned Completion N = 148 (17.4%)	p-value**
Age				
Mean (SD)	80 (10.2)	80.1 (10.3)	81.4 (10.1)	0.18
≤ 69	190 (13.5%)	92 (13.1%)	17 (11.5%)	
70–79	321 (22.8%)	164 (23.3%)	28 (18.9%)	
80–89	715 (50.7%)	348 (49.4%)	72 (48.6%)	
≥ 90	184 (13.0%)	100 (14.2%)	31 (20.9%)	
Sex				
Male	520 (36.9%)	260 (36.9%)	64 (43.2%)	
Female	890 (63.1%)	445 (63.1%)	84 (56.8%)	0.16
Number of chronic conditions				
Mean (SD)	9.7 (5.1)	9.7 (5.1)	9.8 (5.3)	0.83
2–5	304 (21.6%)	152 (21.6%)	35 (23.6%)	
6–10	578 (41.0%)	289 (41.0%)	60 (40.5%)	
11–15	348 (24.7%)	174 (24.7%)	36 (24.3%)	
≥ 15	180 (12.8%)	90 (12.8%)	17 (11.5%)	
Nursing home				
No	39 (2.8%)	22 (3.1%)	17 (11.5%)	
Yes	1,371 (97.2%)	683 (96.9%)	131 (88.5%)	0.000078
Care levels				
Without	72 (5.1%)	84 (11.9%)	15 (10.1%)	
Age and number of chronic diseases were summarized using the mean (standard deviation).				
* Only patients in the intervention group who completed the study as planned were matched.				
** The estimated p-values are the results of hypothesis tests between the planned termination and unplanned termination groups in the intervention group.				

	Control group	Intervention group		
	Matched participants* N = 1,410	Planned Completion N = 705 (82.6%)	Non-Planned Completion N = 148 (17.4%)	p-value**
1	175 (12.4%)	137 (19.4%)	31 (20.9%)	
2	110 (7.8%)	102 (14.5%)	36 (24.3%)	
3	39 (2.8%)	25 (3.5%)	17 (11.5%)	
4	9 (0.6%)	7 (1.0%)	5 (3.4%)	
5	1,005 (71.3%)	350 (49.6%)	44 (29.7%)	0.00050
Age and number of chronic diseases were summarized using the mean (standard deviation).				
* Only patients in the intervention group who completed the study as planned were matched.				
** The estimated p-values are the results of hypothesis tests between the planned termination and unplanned termination groups in the intervention group.				

Mean age was 80.1 years (range: 19–100 years) and approximately two-thirds (66.7%) of the patients were female. The number of chronic conditions for 15 patients was imputed due to an initial count of less than three. On average 9.7 chronic conditions per patient (maximum: 36 conditions) were observed. Approximately 3% of patients resided in nursing homes (Table 2).

50% of patients were not assigned a care level, 10.6% were in care level 1, 19.9% in level 2, 14.4% in level 3, and 4.5% in level 4 or higher (Table 2).

148 patients (17.4%) did not complete the intervention as planned, citing reasons such as death, change of general practitioner, withdrawal from APN, relocation, or unknown reasons. Statistically significant differences were found between “Planned Completion” and “Non-Planned Completion” groups for nursing home status and care levels. A discrepancy in care level distribution between CG and IG was observed (Table 2).

Primary endpoint I: Number of emergency contacts

Following the exclusion of four unidentifiable patients from the IG, the analysis proceeded with 705 IG patients and 1,410 CG patients. Limited health insurance data further reduced the dataset for hospital stays to 577 IG and 1,154 CG patients (Table 3).

Table 3
Summery of the results

Endpoint	Outcome variable	Control group (mean [95% bootstrapped confidence interval])	Intervention group (Mean [95% bootstrapped confidence interval])	Unadjusted incidence rate ratio (95% credibility interval)	Adjusted incidence rate ratio (95% credibility interval)
Primary endpoint I: Number of emergency contacts ($N_{IG}=705$, $N_{CG}=1410$)					
Cumulative number of emergency contacts over the 12-month intervention period	on-call duty	0.25 [0.22, 0.30]	0.27 [0.21, 0.33]	-	-
	Out-of-Hours general practitioner contacts	0.17 [0.16, 0.33]	0.23 [0.13, 0.21]	-	-
	Total sum	0.42 [0.37, 0.48]	0.49 [0.40, 0. 60]	1.18 [0.90, 1.56]	1.02 [0.68, 1.46]
Primary endpoint II: Unplanned hospital admissions ($N_{IG}= 577$, $N_{CG}=1154$)					
Cumulative number of unplanned hospital admissions over the 12-month intervention period		0.29 [0.25, 0.33]	0.44 [0.37, 0.54]	1.48 [1.12, 1.99]	1.37 [0.98, 1.89]
Secondary endpoint I: Use of additional healthcare facilities ($N_{IG}=577$, $N_{CG}=1154$)					
Cumulative number of additional healthcare facilities used during the 12-month intervention period	Hospital admissions	0.46 [0.41, 0.51]	0.73 [0.62, 0.84]	-	-
	Specialist visits	5.20 [4.92, 5.49]	4.87 [4.48, 5.3]	-	-
	hospital outpatient clinic	0.16 [0.13, 0.21]	0.20 [0.15, 0.27]	-	-
	Total sum	5.82 [5.47, 6.13]	5.80 [5.31, 6.26]	1.00 [0.87, 1.16]	1.01 [0.88, 1.17]

Endpoint	Outcome variable	Control group (mean [95% bootstrapped confidence interval])	Intervention group (Mean [95% bootstrapped confidence interval])	Unadjusted incidence rate ratio (95% credibility interval)	Adjusted incidence rate ratio (95% credibility interval)
Secondary endpoint II: Number of home visits by general practitioners ($N_{IG}=705$. $N_{CG}=1410$)					
Cumulative number of home visits by general practitioners over the 12-month intervention period.		2.47 [2.14, 2.83]	3.44 [3.05, 3.90]	1.19 [0.81, 1.80]	1.96 [0.65, 1.42]

Out-of-Hours Emergency Service Utilization

In the IG, over the 12-month intervention period, an average cumulative utilization of 0.27 (95% CI: [0.21, 0.33]) was observed. In comparison, the CG exhibited an average cumulative utilization of 0.25 (95% CI: [0.22, 0.30]).

Out-of-Hours General Practitioner Contacts

In the IG, an average cumulative utilization of 0.23 (95% CI: [0.13, 0.21]) was recorded. The CG showed a comparatively lower average cumulative utilization of 0.17 (95% CI: [0.16, 0.33]).

An increase in emergency contacts was observed with advancing age, a higher number of chronic conditions, and elevated care levels (Table 3).

Patients residing in nursing homes exhibited a heightened demand for emergency contacts (Table 3).

No statistically significant difference in emergency contact utilization was found between male and female patients.

Approximately 80% and 90% of patients in the IG and CG, respectively, did not utilize out-of-hours emergency services or general practitioner contacts. About 75% of patients in both groups had no emergency contacts throughout the intervention period.

A mean adjusted Incidence Rate Ratio (IRR) of 1.02 was estimated (95% Credibility Interval: [0.68, 1.46]), indicating a 2% higher average incidence rate of emergency contacts in the IG.

Primary Endpoint II: Unplanned Hospital Admissions

Over the 12-month intervention period, IG patients exhibited an average of 0.43 unplanned hospital admissions (95% CI: [0.36, 0.52]). In comparison, CG patients had an average of 0.29 unplanned hospital admissions. IG: Approximately 70% of patients did not require unplanned hospital admission throughout the intervention period, while about 80% of patients in the CG did not experience unplanned hospital admissions.

We observed an incidence rate ratio (IRR) of 1.37, indicating a 37% average higher incidence rate of unplanned hospital admissions in the IG. However, the analysis revealed no statistically significant difference in unplanned hospital admissions in the IG compared to the CG.

Pre vs. During

For 300 patients who completed the study as scheduled, data were available for the year preceding the intervention and for the study year itself. The descriptive analyses reveal no substantial differences between the two periods in terms of mean utilization rates or changes in the numbers of utilizations for the primary and secondary endpoints. In the domain of routine general-practice visits (i.e., non-emergency), a higher mean was observed during the intervention (mean-difference = 0.68). An overview of the pre-versus-during comparison results is presented in Table 4.

Table 4
pre vs. during comparison

	Mean (SD)			Share (%)		
	Before the intervention	During the intervention	Mean difference	Higher before the intervention	No difference	Higher during the intervention
Primary endpoints						
On-call-duty	0.33 (0.77)	0.26 (0.77)	-0.07 (0.80)	48 (23.4%)	205 (68.3%)	47 (22.9%)
Contacts with GP outside the working hours	0.15 (0.46)	0.15 (0.72)	0 (0.81)	28 (9.3%)	246 (82.0%)	26 (8.7%)
unplanned inpatient hospital stays	0.54 (0.92)	0.53 (1.21)	-0.01 (1.26)	74 (24.7%)	167 (55.7%)	59 (19.7%)
Secondary endpoints						
Specialist visits	4.80 (4.80)	4.95 (5.01)	0.15 (3.15)	114 (38.0%)	66 (22.0%)	120 (40.0%)
inpatient hospital stays	0.74 (1.13)	0.79 (1.42)	0.04 (1.41)	77 (25.7%)	151 (50.3%)	72 (24.0%)
Hospital outpatient clinic	0.10 (0.46)	0.15 (0.59)	0.05 (0.51)	14 (4.7%)	264 (88.0%)	23 (7.7%)
home visits by GP (regular)	3.03 (4.82)	3.71 (5.57)	0.68 (4.40)	84 (28.0%)	106 (36.3%)	107 (35.7%)
home visits by GP (emergency)	0.15 (0.46)	0.19 (0.78)	0.04 (0.83)	28 (9.3%)	248 (82.7%)	24 (8.0%)

Regarding care level, however, a marked change was detected. An increase in care level was documented during the intervention period for 83 participants (27.7%). In the year before the intervention, no participant experienced an increase in care level.

Health economics

Almost 75% of the working hours of an APN was spend on treating patients. This resulted in in average costs of 59.26€ per APN hour. After adjusting for age, sex, number of chronic diseases and care degree no statistically significant differences in the costs for emergency hospital stays (IG: 2592.76€, 95%CI [1833.61;3351.91]; CG: 1537.89€, 95%CI [1183.11;1892.67]), regular hospital stays (IG: 1399.23€ 95%CI [986.87;1811.59]; CG: 1054.33€ 95%CI [789.47;1319.18]), and home visits (IG: 59.88€ 95%CI [49.00;70.76]; CG: 41.54€ 95%CI [34.35;48.74]) were found between the two groups.

Regarding the costs in the pre vs. during comparison, no differences were observed in any of the cost categories: (1) unplanned inpatient hospital stays, (2) planned inpatient hospital stays, and (3) home visits. An overview of the costs is presented in Table 5.

Table 5
pre vs. during comparison for the health economic analysis

Kategorie	pre	during
unplanned inpatient hospital stays		
Median (Q25;Q75)	0 (0;3593.33)	0 (0;2414.48)
Mean [95%CI]	2967.83 [2290.66;3645.00]	3348.33 [2420.39;4276.26]
planned inpatient hospital stays		
Median (Q25;Q75)	0 (0;0)	0 (0;0)
Mean [95%CI]	1113.91 [653.73;1574.09]	1290.50 [830.73;1750.28]
Home visits by GP		
Median (Q25;Q75)	33.48 (0;111.60)	22.32 (0;111.60)
Mean [95%CI]	68.85 [57.12;80.58]	82.51 [67.71;97.31]

Qualitative approach

Semi-structured interviews were conducted with GPs before (n = 6) and after (n = 10) the intervention, with APNs at the end of their work in GP practices (n = 9), and with patients after the intervention period (n =

26; data collection stopped upon reaching thematic saturation). General Practitioners described their work as being characterized by two main factors. Firstly, they reported a lack of time. Secondly, they reported high demands due to nonmedical tasks, such as social care for patients. APNs are regarded as a crucial support system, capable of addressing gaps in care, providing patients with more intensive care, and offering physicians relief through collegial feedback and the assumption of routine tasks (23).

The patients expressed satisfaction with their interactions with the APN, citing the reliability of the contact person, the ease of access, the consideration given to their needs, and the comprehensive support provided, both medically and socially.

The APNs reported encountering a wide variety of patient situations, which they generally manage to improve, irrespective of the initial condition. While the respondents expressed a high degree of job satisfaction, they also reported a lack of time due to the allocation of time to bureaucratic tasks.

Discussion

Multimorbidity is associated with old age and leads to a high burden in terms of symptoms, treatment and care needs. The project presented here aims to investigate the employment of APNs to address this difficult situation. With an average age of 81.1 and an average of 9.7 chronic conditions, this project has succeeded in reaching elderly multimorbid patients with a particularly high need for outpatient care. However quantitative analysis shows no significant results for the primary and secondary endpoints. This means that emergency contacts, unplanned hospital admissions, use of additional health care facilities and number of home visits by GPs have not decreased significantly. These results are consistent with a Cochrane Review. Laurant et al. (2018) (24) also found little or no difference between nurses and doctors in terms of the number of emergency room visits, referrals and hospital admissions. In contrast, an OECD paper confirms indications that the use of APNs helps to reduce hospital (re-) admissions (25). In the FAMOUS project the health economic analyses show no significant effects. The Cochrane review mentioned above also concluded that the impact of APN care on costs is unclear (24).

The results of the qualitative interviews point in a different direction. They show that patients viewed the use of APNs positively and often regretted that the project was limited to only one year. Patients emphasised that APNs also perform advisory activities that go beyond the purely medical field, such as social law advice or support in obtaining medical aids. Various reviews show that patient satisfaction with care provided by APNs is high and probably even higher than when care is provided by doctors or doctors alone (24, 26). In line with the literature, the participating GPs confirmed that the APNs enabled improved and needs-based care for people with multimorbidity (24). The more holistic approach of the APN care was positively highlighted by the interviewed GPs. APNs and GPs treated each other with respect and trusted one another (27). This is also evident in the kind of collegial communication in the reported study. The shared philosophy of care, mutual trust and respect and effective communication are essential prerequisites for the successful co-management of patients (24).

The GPs interviewed report that APNs have eased their workload. This was in line with the expectations of the GPs expressed before the intervention began (23). A large-scale British study found that the autonomous working methods of highly qualified APNs reduce the workload for GPs, whereas less qualified staff require additional effort in terms of delegation, monitoring and supervision. The main motivation for GPs to employ APNs was to increase the availability of appointments (28).

With regard to the quantitative results, which show no effects various factors that may have influenced this outcome must be mentioned. We adjusted in the regression model for the potential confounding effect of the level of care. However, residual confounding cannot be ruled out.

Even taking into account the level of care required, it is questionable whether the variables age, gender, number of chronic diseases and level of care are really sufficient to adequately represent the current health status or the burden of disease caused by chronic diseases. There are indications that patients in the IG had a higher health burden than patients in the CG or that the CG represents a 'healthier' patient collective, which may affect the results.

Indications for this assessment is provided by

- the higher care level classification in the IG
- The statements made by general practitioners in the qualitative interviews. They stated that they refer patients with particularly high care needs and a higher burden of disease to APNs for care.
- the basis of the CG patients. These were drawn from a broader and thus more representative collective. This means that the IG patient collective does not necessarily reflect the entire multimorbid patient collective of a general practitioner's practice.
- The different proportion of deceased persons in the IG and CG groups. Internal analyses have shown that 10% of patients in the IG group died during the observation period, compared to 5% in the CG population. This may also be an indicator that the CG is 'healthier' than the IG and that this is why no differences between the two groups could be found.

The before-during comparison with patients included in the project and who completed it regularly also shows no differences with regard to the primary and secondary endpoints. However, the number and level of care levels increased significantly during the intervention period. As it is unlikely that the patient's health status has changed to such an extent, the significant increase in the care level can be seen as an indication of the successful counselling and support provided by the APNs.

Strengths and limitations

One strength of this study lies in its mixed method design. This allows the key questions to be examined from multiple perspectives. Another strength of this study is that the number of patients required according to the power calculation was not only duly achieved but exceeded. A key limitation of this study is the non-randomised design. The selection and allocation of patients to the project was carried out by the GPs, as specified in the study protocol. They recruited patients with particularly high and complex care

needs as study participants. On the one hand, this approach reflects the GPs' conviction of the quality of care provided by the APNs, but on the other hand, it is likely to have caused considerable selection bias. Data from health insurance companies was used for the control group. Routine data from health insurance funds is primarily collected for billing and documentation purposes within the fund and not for evaluation or healthcare research purposes (29). Data that is not relevant to revenue provides less incentive for complete documentation. For example, the coding of diagnoses in the outpatient sector has little influence on billing, so that a lower quality of documentation must be assumed here (30). A well-known problem with the use of routine data from health insurance is the lack of information on patient-centred and patient-reported outcomes such as quality of life, treatment satisfaction, diagnostic measures and treatment outcomes. Another significant limitation associated with this is the limited ability to map disease severity in routine data. The examination of a change in symptom burden or disease severity is also an important parameter, which can currently only be examined to a very limited extent with routine data (e. g. via ICD10 coding). Whether this is possible depends heavily on the quality of the diagnosis coding (31).

One possible criticism is that the doctors interviewed may have a positive attitude towards the study, which could have influenced the results of the interviews in a positive direction. A French cross-sectional survey of 251 general practitioners shows mixed results regarding their assessment of the usefulness of APNs as primary care providers for patients (32).

Implications of the findings in context of existing research

The qualitative data show a high level of acceptance of APN care for people with multimorbidity. In order to investigate the effects on the primary and secondary endpoints defined in this study, the study should be repeated using an RCT design that avoids selection bias. In addition, the quality of life of patients should be tested using standardised valid and reliable instruments.

Conclusions

Although there are no differences in the primary and secondary endpoints (also for the reasons mentioned above) compared to standard care, APNs can possibly help to compensate for gaps in care in rural areas. They reduce the workload on GPs and their practices, thereby helping to counteract the shortage of GPs in rural areas. Furthermore, they offer chronically ill patients the necessary support tailored to their needs in many areas that are not covered by standard care. As in many other European countries (33), Germany lacks recognition, regulation, professional development and structural positioning of APNs in the healthcare system. Successful implementation of APNs in GP practices in Germany requires that these issues be addressed.

Abbreviations

APN	advanced practice nurse
CG	control group

CI	confidence interval
GP	general practitioner
IG	intervention group
IRR	incidence rate ratio

Declarations

Ethics approval and consent to participate

The protocol, informed consent forms, recruitment materials, and other requested documents were approved by the Ethics Committee of the German Society of Nursing Science. The ethical reference issued (No. 21 – 012). All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all subjects or their legal guardian. The study was carried out following Good clinical practice as well as in accordance with the Declaration of Helsinki.

Consent for publication

All authors reviewed the manuscript and gave their consent for publication.

Author Contribution

RS, EG, and MB conceptualized the study and obtained the funding. GS-R, IHR, SP, OW, RS and SK participated in the project implementation and data collection. JK, BB, SS, OB, MB, RH, TE and LP participated in the data collection. RH, MB, and BB performed the analysis. EG, BB, RH, MB, and RS wrote the first draft of the manuscript. All authors reviewed and commented on the manuscript. All authors read and approved the final manuscript.

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Data Availability

The data is not publicly available but can be obtained upon reasonable request from the FAMOUS Consortium. Data can be requested at Renate.Stemmer@kh-mz.de.

References

1. Scherer MW, Hans-Otto Lühmann, Muche-Borowski D, Schäfer C, Duben I, Thiesemann HH, Rüdiger, et al. Multimorbidität. S3-Leitlinie. Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM); 2017.
2. Path-Theta Collaboration. Optimizing chronic disease management mega-analysis. economic evaluation. Ont health Technol Assess Ser. 2013;13:1–148.
3. Reif S, Schubert S, Köhler J. Behandlungsgespräche in der Arztpraxis – Ein Europäischer Vergleich. Mannheim (Germany); 2023.
4. Irving G, Neves AL, Dambha-Miller H, Oishi A, Tagashira H, Verho A et al. International variations in primary care physician consultation time: a systematic review of 67 countries. *Bmj Open*. 2017;7(10).
5. Klakow-Franch R. Patientensteuerung und Koordinierung der Versorgung. 2016 [Available from: <https://www.barmer.de/presse/infothek/studien-und-reports/gesundheitswesen-aktuell/gwa-2016-69654>]
6. Rheinland-Pfalz KV. Versorgungsatlas Rheinland-Pfalz 2016 2016 [Available from: https://www.kv-rlp.de/fileadmin/user_upload/... KVRLP_Versorgungsatlas_2016.pdf]
7. Organization WH. Towards people-centered health systems. An innovative approach for better health outcomes 2013 [Available from: http://www.euro.who.int/__data/assets/pdf_file/0006/186756/Towards-people-centred-health-systems-an-innovative-approach-for-better-health-outcomes.pdf]
8. Everett CM, Morgan P, Jackson GL. Primary care physician assistant and advance practice nurses roles: Patient healthcare utilization, unmet need, and satisfaction. *Healthc (Amst)*. 2016;4(4):327–33.
9. Gysin S, Sottas B, Odermatt M, Essig S. Advanced practice nurses' and general practitioners' first experiences with introducing the advanced practice nurse role to Swiss primary care: a qualitative study. *BMC Fam Pract*. 2019;20(1):163.
10. Maier C, Aiken L. R. B. Nurses in advanced roles in primary care: Policy levers for implementation. Paris; 2017.
11. Müller N. Masterstudiengänge in der Pflege mit direktem Versorgungsbezugb. Zusammenfassung der Befunde zur Sondererhebung 1/2024 im BIBB- Pflegemonitoring. Bonn: Bundesinstitut für Berufsbildung; 2024.
12. Stemmer R, Büchler B, Büttner M, Dera-Ströhm C, Klein J, Gianicolo E. Effects of care of multimorbid patients in general practices by advanced practice nurses (FAMOUS): study protocol for a nonrandomized controlled trial. *BMC Health Serv Res*. 2023;23(1):501.
13. Wood M. Bootstrapped confidence intervals as an approach to statistical inference. *Organizational Res Methods*. 2005;8(4):454–70.
14. Rose CE, Martin SW, Wannemuehler KA, Plikaytis BD. On the use of zero-inflated and Hurdle models for modeling vaccine adverse event count data. *J Biopharm Stat*. 2006;16(4):463–81.

15. Bürkner PC. Bayesian Item Response Modeling in R with brms and Stan. *J Stat Softw.* 2021;100(5):1–54.
16. Ho D, Imai K, King G, Stuart EA. MatchIt: Nonparametric Preprocessing for Parametric Causal Inference. *J Stat Softw.* 2011;42(8):1–28.
17. Arel-Bundock V, Greifer N, Heiss A. How to Interpret Statistical Models Using margineffects for R and Python. *J Stat Softw.* 2024;111(9):1–32.
18. Canty A, Ripley B, Boot. Bootstrap R (S-Plus) Functions. R Package Version 1.3–28.1.; 2022.
19. DESTATIS FSOoG. Labour market 2026 [Available from: <https://www.destatis.de/DE/Themen/Arbeit/Arbeitsmarkt/Qualitaet-Arbeit/Dimension-2/krankenstand.html>]
20. B LC, McGuire TG, Lock K, Zaslavsky AM. Comparing methods of racial and ethnic disparities measurement across different settings of mental health care. *Health Serv Res.* 2010;45(3):825–47.
21. Manning WG, Basu A, Mullahy J. Generalized modeling approaches to risk adjustment of skewed outcomes data. *J Health Econ.* 2005;24(3):465–88.
22. Mayring P, Fenzl T. Qualitative Inhaltsanalyse. *Handbuch Methoden der empirischen Sozialforsch.* Wiesbaden,: SpringerVS; 2019. pp. 633–48.
23. Büchler B, Pfrommer L, Gianicolo E, Singer S, Stemmer R. Erwartungen von Hausärzten im ländlichen Raum an Advanced Practice Nurses. *Z für Allgemeinmedizin.* 2025;101(5):257–63.
24. Laurant M, van der Biezen M, Wijers N, Watananirun K, Kontopantelis E, van Vught AJ. Nurses as substitutes for doctors in primary care. *Cochrane Database Syst Rev.* 2018;7(7):CD001271.
25. Brownwood I, Lafortune G. Advanced practice nursing in primary care in OECD countries: Recent developments and persisting implementation challenges. Paris: OECD; 2024.
26. Htay M, Whitehead D. The effectiveness of the role of advanced nurse practitioners compared to physician-led or usual care: A systematic review. *Int J Nurs Stud Adv.* 2021;3:100034.
27. Norful AA, de Jacq K, Carlino R, Poghosyan L. Nurse Practitioner-Physician Comanagement: A Theoretical Model to Alleviate Primary Care Strain. *Ann Fam Med.* 2018;16(3):250–6.
28. McDermott I, Spooner S, Goff M, Gibson J, Dalgarno E, Francetic I, et al. Health and Social Care Delivery Research. Scale, scope and impact of skill mix change in primary care in England: a mixed-methods study. Southampton (UK): National Institute for Health and Care Research; 2022.
29. Veit C, Bierbaum T, Wesselmann S, Stock S, Heidecke CD, Apfelbacher C, et al. [Routine Practice Data for Health Care Analyses: Part 3 of the Manual]. *Gesundheitswesen.* 2023;85(8–09):718–24.
30. GmbH II. Bewertung der Kodierqualität von vertragsärztlichen Diagnosen. Eine Studie im Auftrag des GKV-Spitzenverbands in Kooperation mit der BARMER GEK. 2012.
31. Neumann A, Kliemt R, Baum F, Seifert M, Kubat D, March S, et al. [An Experience Report on the Evaluation of New Forms of Care for People with Mental Illness: Pros and Cons of the Use of SHI Claims Data]. *Gesundheitswesen.* 2024;86(S 03):S212–23.
32. Goddaert C, Gerard PA, Kessler C, Leblanc M, Barbe C, Chrusciel J, et al. Perceptions of general practitioners towards the services provided by advanced practice nurses: a cross-sectional survey in

France. BMC Health Serv Res. 2023;23(1):1442.

33. Sara MG, Jocelyn S, Sebastien C. Advanced practice nursing in the European Union: A scoping review. Nurs Outlook. 2025;73(6):102588.

Figures

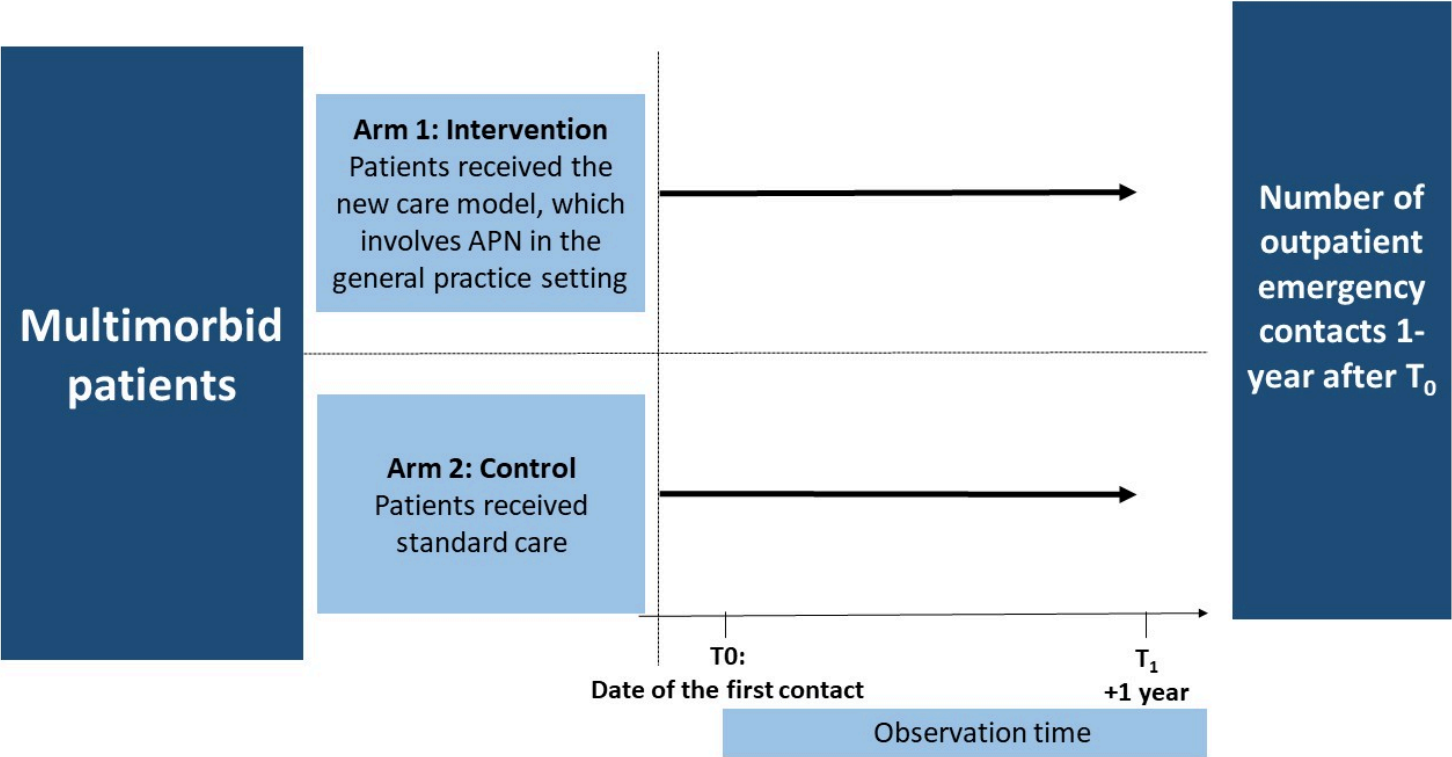


Figure 1

Study Design