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Implementation and the effects of a Parkinson Network Therapy (PaNTher) on activities of daily living and health-related quality of life in Parkinson's disease patients: study protocol of an mixed-method observational cohort study in outpatient care

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ABSTRACT

Introduction Parkinson's disease (PD) represents the fastest growing neurodegenerative disease with an increasing prevalence worldwide. It is characterised by complex motor and non-motor symptoms that lead to considerable disability. Specialised physiotherapy has been shown to benefit patients with PD. The *Parkinson Netzwerk Therapie* (PaNTher) was created to improve access to specialised physiotherapy tailored to care priorities of PD patients. This study aims to evaluate the effectiveness, acceptability and needs of the PaNTher network by neurologists and physiotherapists involved in the network in outpatient care.

Methods and analysis This is a mixed-method, prospective, pragmatic non-randomised cohort study of parallel groups, with data collection taking place in Bavaria, Germany, between 2020 and 2024. Patients with PD insured by the *Allgemeine Ortskrankenkasse Bayern* (AOK Bayern) living in Bavaria will be recruited for study participation by network partners. Patients in the intervention group must reside in Munich or the surrounding area to ensure provision of specialised physiotherapy in close proximity to their place of residence. Controls receive care as usual. Six and 12 months after baseline, all patients receive a follow-up questionnaire. Mixed-effect regression models will be used to examine changes in impairment of activities of daily living and quality of life of patients with PD enrolled in the programme over time compared with usual care. Qualitative interviews will investigate the implementation processes and acceptability of the PaNTher network among neurologists and physiotherapists. The study is expected to show that the PaNTher network with an integrative care approach will improve the quality and effectiveness of the management and treatment of patients with PD.

Ethics and dissemination The study has been approved by the ethics committee at the medical faculty of the Ludwig-Maximilians-University Munich (20-318). Results will be published in scientific, peer-reviewed journals and presented at national and international conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The PaNTher project is a promising approach for people with PD as it provides access to more effective physiotherapy tailored to symptoms and all stages of PD.

⇒ Another strength of this study is its mixed-methods design, as qualitative interviews will allow deeper insights into success and needs of the PaNTher network in daily practice.

⇒ The prospective cohort study will provide comprehensive data on patient-individual determinants of impairment of activities of daily living and health-related quality of life in patients with PD at multiple time points.

⇒ This study uses validated and well-established outcome measures.

⇒ Potential limitation is that currently only patients from Munich and surrounding areas can be treated according to the PaNTher programmes, so generalisability of the results is limited to this urban area.

INTRODUCTION

Neurological diseases are associated with considerable disability, among these Parkinson's disease (PD) represents the fastest growing neurodegenerative disease with an increasing prevalence worldwide.[1] In Germany, PD is the second most prevalent neurodegenerative disease with more than 200 000 patients with PD.[2 3]

PD is a progressive disorder characterised by complex motor and non-motor symptoms.

Cardinal motor signs include rest tremor, rigidity, brady-/akinesia and postural instability.[4] Moreover, altered gait patterns, including freezing of gait, lead to an increased risk of falls and thus, to fractures, hospitalisations, long-term care or death.[5 6] With advanced PD, these symptoms lead to restrictions in activities of daily living (ADL) and a significant impact on the quality of life of patients and their social environment.[7 8] In spite of an optimal pharmacotherapy and neurosurgical treatment, motor symptoms and impairment of ADL can only be partially improved. Therefore, physiotherapy provides an important contribution to improve physical functions, activity, posture, gait patterns, balance and fear as well as risk of falling.[9] Recent studies and guidelines have supported a variety of physiotherapy techniques, such as conventional physiotherapy including active exercises targeting balance, fall prevention and walking speed as well as treadmill training, Cueing and Thai Chi.[10]

PD patients often receive inappropriate and ineffective treatment.[11 12] One reason for this is that in Germany prescription of physiotherapy—regulated in the catalogue of remedies—is traditionally concept-based (eg, Bobath, Vojta, PNF).[13] This means that only therapy based on these concepts are billable services paid by the health insurance providers. However, these concepts were originally developed for the treatment of spasticity and paresis after lesions of the central nervous system, and thus they do not correspond to the recommendations of the European Physiotherapy Guideline for Parkinson's Disease.[10] Another reason might be the fact that in Germany, at present hardly any training opportunities tailored to the needs of PD patients are offered to physiotherapists.

Traditionally, physiotherapy has been prescribed in advanced stages of PD, when balance constraints or risk of falling have already occurred.[14] Patients in the early stages of the disease have rarely been included in clinical trials concerning physiotherapy.[15] Following the National Guideline, all patients with PD in all stages of the disease should have access to physiotherapy within an appropriate time period.[16] In Germany, physiotherapy is typically prescribed by a neurologist. Although most PD patients consult an outpatient neurologist at least once a year,[12] it has been shown by a research consortium that only 36% among 22 000 PD patients receive physiotherapy in Germany.[11] One reason might be that outpatient neurologists are not always highly qualified for PD treatment and therefore might be unaware of PD-specific therapeutic approaches even in the early stages.[17] Another reason is that they often face constraints in referrals due to budgeting.

To overcome this insufficient access to physiotherapeutic PD specialists and to interdisciplinary consultation, integrated and multidisciplinary care concepts have been proposed.[18 19] A leading role in integrated PD networks was the *ParkinsonNet* in the Netherlands, which led to improved quality of life and a reduced mortality.[20–22] Another Canadian programme showed a significant improvement in health-related quality of life and motor function if treated in a PD network.[23] Ypinga *et al* compared PD patients treated with specialised physiotherapy within the *ParkinsonNet* against usual physiotherapy. They found a lower rate of complications related to PD and reduced mortality.[24] There are also similar PD networks in Germany.[25] Some of them also incorporate the physiotherapy sector (eg, *Satellitennetzwerk Hamburg, Parkinsonnetz Münsterland +, Parkinson Netzwerk Rhein Neckar, Parkinson Netz Jena* and *Parkinsonnetzwerk Bremen*); however, the provision of specialised physiotherapy within a network is not common and is only offered regionally.

Therefore, a multiprofessional team of physicians and physiotherapists of the Schoen Clinic München Schwabing initiated the model project '*Parkinson Netzwerk Therapie*' (PaNTher) in 2019 to improve access to specialised therapy tailored to care priorities of PD patients in collaboration with a statutory health insurance fund (*Allgemeine Ortskrankenkasse (AOK) Bayern*). Being part of the network allows an outpatient neurologist to offer patients the model project and prescribe physiotherapy programmes, which are tailored to the specific symptoms and stages of the disease. Physiotherapists are specially trained to carry out these programmes.[26]

We hope that the PaNTher network will improve the practice of treatment and outcomes of patients with PD in outpatient care. Therefore, the objective of this study is to evaluate the implementation of a pragmatic network for the care of PD, Parkinson's Network Therapy (PaNTher). Specifically, we want to examine the effectiveness of PaNTher on impairment of ADL and health-related quality of life in patients with PD. Second, we want to examine the acceptability and needs of the network by neurologists and physiotherapists involved in the network in outpatient care. Third, we want to analyse costs of care as an indicator for health service utilisation.

METHODS AND ANALYSIS
The study protocol follows the Recommendations for International Trials (SPIRIT).

Study design
This is a mixed-method, longitudinal evaluation study, that is, a pragmatic, naturalistic design conducted within the context of ongoing healthcare provision. The quantitative component investigates the change of ADL impairment and quality of life of patients with PD inscribed into the programme over time as compared with usual care. The qualitative part of the study investigates implementation processes and acceptability of the PaNTher network among neurologists and physiotherapists.

Qualitative methods
We use semistructured interviews with purposively sampled outpatient neurologists and physiotherapists who are members of the network.

Participants and recruitment
From all members of the network, neurologists and physiotherapists are invited via email and phone to

participate. Physiotherapists are invited after completion of the training and initial experience with the application of the specialised therapy programmes.

Sample size is determined by saturation,[27] recruitment is stopped when interviews do not provide any new themes. Interviews are conducted via telephone.

Research team and reflexivity

Interviews are conducted by project scientists with formal training in quantitative and qualitative research.

Analysis and findings

Audio recordings are transcribed verbatim and entered into MAXQDA software[28] to support analysis. The interview transcripts are not returned for review by the interviewees. The analysis is iterative using the structured content analysis approach according to Mayring.[29] A deductive approach allows to allocate statements from the interviews in predefined categories and codes. An inductive approach allows identifying new categories and codes, which expand the coding tree by adding or removing codes in a more meaningful way.

Guiding questions for the neurologists' interviews are the satisfaction and the benefit as a network partner as well as the reflection on success and needs arising in daily medical practice, for example, related to prescriptions for the specialised physiotherapy or invoicing with the health insurance company. Needs include challenges and barriers in the processes within the network on a structural, organisational and content-related level.

Guiding questions for the physiotherapists' interviews are the satisfaction and the benefit as a network partner. We focus on success and needs arising in daily physiotherapeutic practice and improvement of the training programme.

Quantitative methods

The quantitative component of PaNTher is a prospective, pragmatic non-randomised cohort study of parallel groups—a physiotherapy intervention specifically adapted to the needs for PD or care as usual among patients with PD.

Participants and data collection procedures

Table 1 gives an overview of the data collection processes developed within the PaNTher project. In order to reduce implementation complexity, PaNTher is initially restricted to Munich and the surrounding area. The training for physiotherapists only takes place in Munich and all physiotherapists work in outpatient practices, which are located in Munich or the surrounding area.

Patients with a confirmed diagnosis of PD (ICD 10: G20.0, G20.1) and at Hoehn and Yahr I-IV, who are insured by the *Allgemeine Ortskrankenkasse Bayern (AOK*

Table 1 Cohort study flow diagram gives an overview of the study processes for recruitment, enrolment, allocation and assessment for the control group (column 1) and the intervention group (column 2) developed within the PaNTher project

	Control group	Intervention group
Recruitment	Assessed for eligibility ▶ Morbus Parkinson (ICD 10: G20.0, G20.1) ▶ Off state Hoehn and Yahr I-IV ▶ Insured by the AOK Bayern ▶ Not living in a care facility ▶ Living in Bavaria (except Munich and surroundings)	Assessed for eligibility ▶ Morbus Parkinson (ICD 10: G20.0, G20.1) ▶ Off state Hoehn and Yahr I-IV ▶ Insured by the AOK Bayern ▶ Not living in a care facility ▶ Living in Munich and surroundings
	Strategies ▶ Letters to all insured persons meeting the inclusion criteria by the AOK Bayern ▶ Application by network partners (outpatient neurologists, professional and patient associations)	Strategies ▶ Letters to all insured persons meeting the inclusion criteria by the AOK Bayern ▶ Application by network partners (outpatient neurologists, professional and patient associations) ▶ Application by inpatient and outpatient centre for movement disorders, Schoen Clinic Munich Schwabing
Enrolment		Residential neurologist and Schoen Clinic movement disorder outpatient department ▶ Information of eligible patients ▶ Inscription into the model project ▶ Prescription of specialised physiotherapy (PaNTher)
	LMU/IBE ▶ Information and study enrolment of eligible patients, who have been interested and have contacted the research team	LMU/IBE ▶ Information and study enrolment of patients, who have been prescribed PaNTher physiotherapy
Allocation	Control group ▶ Receive care as usual	Intervention group ▶ Receive PaNTher physiotheray
Assessment	Questionnaire ▶ Baseline ▶ Six and 12 months after baseline	Questionnaire ▶ Baseline ▶ Six and 12 months after baseline

AOK Bayern, *Allgemeine Ortskrankenkasse Bayern*; IBE, Institute for Medical Information Processing, Biometry and Epidemiology; LMU, Ludwig-Maximilians-University; PaNTher, *Parkinson Netzwerk Therapie*.

Table 2 Overview of the prescribable basis and special packages for each stage-specific physiotherapy programme developed within the PaNTher project

Therapy programme I		Therapy programme II		Therapy programme III	
Hoehn and Yahr 1		Hoehn and Yahr 2		Hoehn and Yahr 3 and 4	
Basis package I	Special package 1	Basis package II	Special package 1	Basis package III	Special package 1–4
Frequency, duration, extent: 2×30 min/ week; 4 weeks	Hypo bradykinesia: 4×60 min/ week; 4,5 weeks	Frequency, duration, extent: 2×30 min/week; 6 weeks 1×30 min/months; 10 months	Hypo bradykinesia: 4×60 min/week; 4,5 weeks	Frequency, duration, extent: 2×30 min/week; 20 weeks (over four quarters)	Hypo bradykinesia: 4×60 min/week; 4,5 weeks
					Fall Prevention: 3×60 min/week; 4 weeks 2×60 min/ week; 4 weeks
Follow-up prescription: 1×30 min per quarter (4 x)		Follow-up prescription: 2×30 min/week; 6 weeks			Posture: 3×30 min/week; 4 weeks
Aims: a. Maintaining activity b. Prevent fear of falling c. Pain reduction		Aims: a. Maintaining activity b. Prevent falling c. Improving/ d. maintaining – Walking – Transfer – Balance – Arm and hand functions		Aims: a. Maintaining: – Walking – Transfer – Balance – Arm and hand functions	Freezing: 3×30 min/week; 2 weeks

PaNTher, *Parkinson Netzwerk Therapie*.

Bayern), are not living in a nursing home and do not have a care dependency of 4 or higher are invited to participate. Patients of the intervention group have to have their residence in Munich or the surrounding areas to ensure provision of specialised physiotherapy in close proximity to their place of residence. Patients with a confirmed diagnosis of PD (ICD 10: G20.0, G20.1) and at Hoehn and Yahr I–IV from other areas and large cities in Bavaria, Germany (for instance, Nürnberg, Fürth, Erlangen, Regensburg, Ingolstadt, Augsburg) are invited as controls. They do not participate in the specialised therapy programmes and receive care as usual.

Eligible patients are addressed by network partners (*AOK Bayern*, *Schoen Clinic Munich Schwabing*, outpatient neurologists, physiotherapists, patient associations) by means of letters, personal approach, flyers, meetings and articles in lay journals.

Intervention

The intervention consists of three stage-specific and symptom-specific physiotherapy programmes developed within the PaNTher project, which involved neurologists and physiotherapists specialised in movement disorders with experience in treating PD (table 2). The intervention and its development have been described in detail elsewhere.[26] In brief, each programme comprises one basic and up to four special therapy packages. Therapy duration, frequency and extent as well as content and aims depend on the stage of the disease and are based on the European physiotherapy guidelines.[10] Physiotherapeutic therapy sessions are mostly longer and at higher frequency than usual care.

Physiotherapists are invited to participate if they have a specific and certified expertise in the treatment of patients with neurological disease, for example, proprioceptive neuromuscular facilitation, Bobath, Vojta. The training is developed and organised by the *Schoen Clinic Munich Schwabing*,[30] and funding for the training is provided by one of the largest professional physiotherapy associations, *Physio Deutschland*.[31] Participating physiotherapists are trained in a 2-day workshop by experts from the PaNTher network. Contents of the workshop include current assessment and treatment standards according to guidelines.[10] Training is based on principles of problem-based learning and includes practical hands-on sessions. On successful participation, physiotherapists receive the PaNTher certificate that allows additional remuneration. Besides, they can access supervision and any support for the management and implementation in practice, therefore a telephone hotline is provided.

The health insurance company spends an enhanced fee for service according to PaNTher compared with existing payments for therapeutic prescriptions. The refunds are independent of the catalogue of remedies, but they are fixed for each therapy programme and package within PaNTher.

Data collection procedures

Data will be collected at patient level via paper-based questionnaires. For the linkage of survey data to the health insurance claims data, a temporary pseudonym based on the participants' insurance number is provided.[32] Based on the temporary pseudonym, primary data are linked to the health insurance claims data by a third independent person providing a second pseudonym. The linkage process is monitored by a data protection trustee, who saves the allocation list with the first and second pseudonyms.

Data management will follow the General Data Protection Regulation.

Measures

Participants will be assessed at baseline as well as six and 12 months after baseline using validated questionnaire-based instruments. The primary outcome of the study is ADL impairment in patients with PD. We use the *Movement Disorder Society—Unified Parkinson Disease Rating Scale*, motor aspects of experiences of daily living, section part two (MDS-UPDRS II, composed of 13 patient-based items rated from 0 (normal) to 4 (severe)).[33] It rates impairment (speaking, salivating/drooling, chewing/swallowing, tremor and freezing) and difficulties in ADL (eating, dressing, personal hygiene, handwriting, hobbies/activities, turning in bed, getting up/getting out and walking/balance). The lower the total score, the fewer are the impairments in ADL.

Secondary outcomes are generic and disease-specific health-related quality of life (HRQoL) as well as falls, concerns of falling and freezing of gait if present.

Disease-specific HRQoL is measured using the *Parkinson's Disease Questionnaire* (PDQ-8),[34] the short version of the PDQ-39.[35–37] It measures eight aspects of functioning and well-being: mobility, activities of daily living, emotional well-being, stigma, social support, cognition, communication and physical discomfort. It rates disease-specific health status by providing a single score ranging from 0 (good health) to 100 (poor health).

Generic HRQoL is measured using the *EuroQol Five-Dimensional Five-Level Questionnaire* (EQ-5D-5L)[38] including the *Visual Analogue Scale* (EQ-VAS) assessing self-rated health. It comprises five dimensions (with one 5-point Likert-scaled item each): mobility, self-care, usual activities, pain/discomfort and anxiety/depression ranging from no problems (1) to extreme problems (5). The EQ-5D-5L utility score ranges between death (−0.661) and perfect health (1) and is calculated based on the value set devised by Ludwig *et al*.[39] In the EQ-VAS, the self-rated health is visualised on a continuous VAS with end points labelled the worst imaginable health (0) and the best imaginable health (100).

Falls are assessed using a *patient fall diary*.[40] Fear of falling is assessed using the *Falls Efficacy Scale International* (FES-I).[41]

Freezing if present is accessed using the *Freezing of Gait Questionnaire* (FOG).[42]

All outcomes are listed in table 3.

Third, we analyse the overall disease-related care as an indicator for health service utilisation using health insurance claims data. Here, we focus on cost of care, for instance pharmaceutical costs for PD-related drugs, costs of disease-related outpatient and inpatient care

Table 3 Overview of research outcomes and instruments used

	Instrument, items	Baseline	Follow-up 1	Follow-up 2
Primary outcome measures				
Impairment of activities of daily living	MDS-UPDRS II	x	x	x
Secondary outcome measures				
Disease-specific health-related quality of life	PDQ8	x		x
Generic health-related quality of life	EQ5D		x	
Falls/Concerns of falling	FES-I	x	x	x
Freezing of Gait	FOG	x	x	x
Tertiary outcome measures				
Satisfaction with physiotherapy		x	x	x
Medication intake	Insurance claims data based on exact prescription dates			
Impatient treatment	Insurance claims data based on exact prescription dates			
Confounding variables				
Age, sex, highest education, occupation, marital status, living conditions		x	x	x
Medications related to Parkinson's disease	Insurance claims data based on exact prescription dates			

EQ5D, 5-level EQ-5D version; FES, Falls Efficacy Scale; FOG, Freezing of Gait Questionnaire; MDS-UPDRS, Movement Disorder Society's (MDS) revision of the Unified Parkinson's Disease Rating Scale (UPDRS); PDQ, Parkinson's Disease Questionnaire.

and therapy costs. Measurements of costs include recent German measurement standards.[43]

In order to consider potential confounding, sociodemographic data, for instance, age, sex, highest educational level, are assessed.

Sample size

Sample size calculation is based on a clinically relevant difference of three points improvement measured with the MDS-UPDRS II.[44] Assuming a power of 80% and a significance level of 0.05, a total of 348 patients (174 patients per group) is needed. Assuming a loss to follow-up of 25% between baseline and follow-ups, we need to include 436 patients (218 patients per arm) at baseline. A prior analysis of the insurance data of the AOK Bayern showed that there is a potential of 3400 eligible PD patients (intervention: 680, control: 2720) in Bavaria.

Data analysis

Outcome measures are analysed descriptively. Means and SD are used for continuous variables and absolute and relative percentages for categorical variables. For comparisons between the intervention and control group, bivariate non-parametric and parametric tests stratified by sociodemographic variables are conducted at baseline. We will perform subgroup analyses based on therapy programmes to investigate whether the impacts of different therapy programmes vary across groups and specific severity levels.

The association of the dependent variable of change in motor functioning over time and the PaNTher intervention is analysed using mixed-effects regression models. Models will be adjusted for sociodemographic variables and medications related to PD. They will allow to control for time-dependent confounders. Interaction with time and follow-up is included to observe significant group differences. As there is no randomised group assignment, Propensity Score Matching will be employed to estimate the probability of allocation to the treatment or control group, thereby balancing potential confounding variables.

To estimate the group differences in healthcare utilisation, we use Generalised Linear Models (GLM) with gamma-distributed cost variables (ie, the responses are non-negative). Additionally, a cost-effectiveness and a cost-utility analysis might be performed. For the cost-effectiveness analyses, costs associated with health-care utilisation are computed by multiplying health service units (for instance, consults) and medication costs are calculated as the average cost price per standard daily dose. For the cost-utility analyses, HRQoL will be expressed in Quality Adjusted Life Years (QALY), derived from utility scores and to determine the incremental costs per QALY.

Patient and public involvement

Individuals diagnosed with PD actively participated in the initial conceptualisation of the study design, providing additional insights derived from their personal experiences and preferences regarding the PaNTher intervention. The study benefits from a close partnership with Parkinson's self-help groups, contributing to a notable enhancement in patients' willingness to participate.

DISCUSSION

We expect that the PaNTher network with an integrative care approach will improve the quality and effectiveness of the management and treatment of patients with PD. Additionally, the cost-effectiveness of the intervention and the potential for improvement will be investigated.

The study is expected to improve access to more effective physiotherapy tailored to symptoms and all stages of PD. Therefore, it has the potential for relevant gains in functioning and health-related quality of life. One strength of the study is its mixed-method approach. Qualitative interviews will detect the strength, challenges and future needs of the network.

Potential limitations are that currently only patients from Munich and surrounding areas can be treated according to the PaNTher programmes and that all patients are insured of a specific health fund, so results may not be generalisable. However, we assume that our results will contribute to a long-term professional network, which might be extended to other regions or other health insurance funds.

ETHICS AND DISSEMINATION

The study has received approval from the ethics committee at the medical faculty of the Ludwig-Maximilians-University (LMU) Munich. Patients receive sufficient information about their participation in the study and are only included if written informed consent is present. Participants are not exposed to any medical risk as a result of their participation in the study. The study is conducted in accordance with the Declaration of Helsinki.[45] All questionnaires are pseudonymised. The list linking the pseudonym and the person-identifying information is destroyed after study completion. Conclusion about the actual patient will then no longer be possible and data will be de facto anonymised. Data are double pseudonymised before analysis.

Results are published in scientific, peer-reviewed journals and presented at national and international conferences. Results are disseminated via newsletters, the project partners' websites and conferences.

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