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Mixed-methods process evaluation of a proactive approach to healthcare in Parkinson's disease—ParkProReakt: a protocol of a hybrid efficacy-implementation study

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ABSTRACT

Introduction People with Parkinson's disease (PwPD) experience a wide range of motor and non-motor symptoms that have a significant impact on their health and quality of life. Effective care management for PwPD involves monitoring symptoms at home, involving specialised multidisciplinary care providers and enhancing self-management skills. This study protocol describes the process evaluation within a randomised clinical trial to assess the implementation and its impact on patient health outcomes of ParkProReakt—a proactive, multidisciplinary, digitally supported care model for community-dwelling PwPD.

Methods and analysis The hybrid efficacy-implementation study will assess key implementation outcomes using the Medical Research Council framework for complex interventions alongside a randomised controlled trial. A combination of quantitative and qualitative methods will be used to assess process data from care providers and patients. The main process outcomes are fidelity, dose, feasibility and context. Context will be analysed through semistructured interviews and focus groups using the Consolidated Framework of Implementation Research. To elucidate potential facilitators and barriers to implementation and to gain deeper insights into the efficacy outcome data, quantitative and qualitative process data will be integrated at an interpretative level using mixed methods. In addition to process evaluation, potential indirect mechanisms of impact will be measured.

Ethics and dissemination Ethical approval for this study was obtained from the responsible state medical ethics committees in Hesse and Hamburg, Germany. Results will be communicated to the funding body and disseminated through scientific publications.

Trial registration This study was registered with the German Registry for Clinical Studies (DRKS)—number: DRKS00031092.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous research has demonstrated that people with Parkinson's disease benefit from support for self-management, enhanced interdisciplinary collaboration and a dedicated case manager to optimise individualised care. Despite these findings, the comprehensive implementation of these elements in clinical practice remains insufficient. To address this gap, it is recommended that hybrid designs be employed, which simultaneously analyse changes in patient health status and the quality of implementation.

WHAT THIS STUDY ADDS

⇒ The mixed-methods approach enables an in-depth understanding of the context in which process and health outcomes data are used. By analysing detailed qualitative and quantitative data, the study identifies factors that facilitate the scaling up and dissemination of the intervention. Furthermore, it provides a nuanced understanding of intervention success by analysing health outcomes in relation to process data.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study may demonstrate the efficacy of integrated care models and encourage further exploration of hybrid designs in clinical studies. In practice, the findings could lead to the development of comprehensive and patient-centred care strategies for the management of chronic diseases such as Parkinson's disease. It emphasises the significance of interdisciplinary collaboration and dedicated case management, which could inform healthcare policies aimed at improving patient outcomes and the overall quality of care.

INTRODUCTION

People with Parkinson's disease (PwPD) exhibit a heterogeneous and complex combination of motor and non-motor symptoms, which progressively increase in severity throughout the course of the disease.[1 2] The

complexity of symptom profiles contributes to a significant burden on patients' physical and mental health, adversely affecting their health-related quality of life (HRQoL).[3] This highlights the importance of a tailored, multidisciplinary treatment approach that addresses the individual symptoms and requirements of each patient, particularly in cases where the disease has persisted for several years and the PwPD are in their mid or late disease stages.[2 4]

Integrated and person-centred care models aim to deliver comprehensive care that is tailored to the individual needs of PwPD.[5 6] One goal is to provide ongoing symptom monitoring and treatment in the patient's home environment to avoid long-distance travel to specialised clinics and assess patient symptoms during their normal daily activities.[7 8] Regular monitoring of motor and non-motor symptoms in the home environment allows a proactive response to changes in symptoms and could lead to a reduction in clinic visits, thereby reducing resource demands.[7]

The complexity of symptoms in PwPD requires coordination among different medical, psychological and social disciplines for comprehensive treatment. This treatment should be coordinated according to individual life situations and across healthcare settings.[6 9] Specialist Parkinson's nurses are recommended to provide this care management, collecting patient information and coordinating treatment within a care network.[7] Another pertinent aspect of care for PwPD is the reinforcement of self-management capabilities, thereby enabling patients to cope with the disease independently or more effectively in their daily lives.[9]

The positive impact of integrated care models on HRQoL of PwPD has already been demonstrated.[5 10] However, the specific mediators of this effect remain unclear. In addition to the previously established correlation between symptom severity and quality of life (QoL),[3] the perceived improvement in care, mediated by enhanced care coordination and continuity or by improved individual satisfaction with care, could also be a contributing factor to changes in HRQoL.[11]

Integrated care models are complex interventions comprising multiple components and involving various care providers working collaboratively.[12] Randomised clinical trials (RCTs) are considered the gold standard for evaluating the efficacy of interventions in comparison to standard care. However, the 'one size fits all' approach does not apply to a heterogeneous population such as PwPD. Consequently, it is critically important to understand the mechanisms and circumstances under which an intervention produces change.[13] The complexity of integrated care models further complicates the identification of the most effective components and their interactions in influencing outcomes.[12] Additionally, the quality of intervention implementation, which may depend on the implementation strategies employed, plays a critical role in understanding its impact on patient health outcomes.[14]

Therefore, hybrid designs are recommended to simultaneously analyse changes in patient health status and implementation quality.[15] A hybrid design, which combines an RCT with process evaluation, helps to understand how the intervention produces change and what the underlying mechanisms of change might be. The UK Medical Research Council framework for designing and evaluating complex interventions recommends that the effectiveness of an intervention should be evaluated in terms of *what* is implemented and *how* implementation is archived.[16] In conjunction with a contextual analysis (eg, factors that affect implementation or outcomes), the patient health outcomes can be interpreted in relation to process data.[16 17]

The objective of this study protocol is to describe the methods of the process evaluation within an RCT aimed at assessing the efficacy of a proactive healthcare approach for PwPD—'ParkProReakt'. A separate protocol is available for efficacy outcome evaluation.[18]

ParkProReakt—a proactive approach to healthcare in Parkinson's disease

The ParkProReakt project aims to improve the multidisciplinary care of PwPD in a sustainable manner. This will be accomplished through an integrated care model that is cross-sectoral, proactive, demand-driven and technology-enabled. The main objectives are to improve the QoL of PwPD and alleviate the burden on informal carers. The programme is structured as a complex care initiative, where medical care coordination is facilitated by case management and the individual needs of patients are addressed by a multidisciplinary team. The efficacy of ParkProReakt will be assessed in an RCT at two sites in Germany (Marburg, Hamburg), with the results being compared with those obtained from a standard care group. For a detailed description of the care model, see van Munster *et al*.[18] In summary, ParkProReakt uses a smartphone application and wearable devices to consistently monitor patient symptoms. Patients employ these tools for daily symptom recording, weekly motor tests (eg, hand rotation) and the completion of a well-being questionnaire (WHO-5[19]). The collected data are reviewed by specialised Parkinson telenurses (PTNs) and translated into a treatment requirement using a status traffic light. The status traffic light changes colour (green/yellow/red) at defined critical events (online supplemental material). In the event of a deterioration in symptoms, the PTNs contact the patient and initiate further measures in consultation with the PwPD and the care team. In addition to the PTN, the ParkProReakt care team includes on-site Parkinson study nurses (PSNs), specialised neurologists and a community nursing service responsible for home visits. All patient symptoms and care measures are documented and stored on a care-provider platform to facilitate care organisation and to assist communication between care providers. Additionally, a Parkinson self-management tool is accessible for the PwPD via the smartphone application. The self-management tool contains

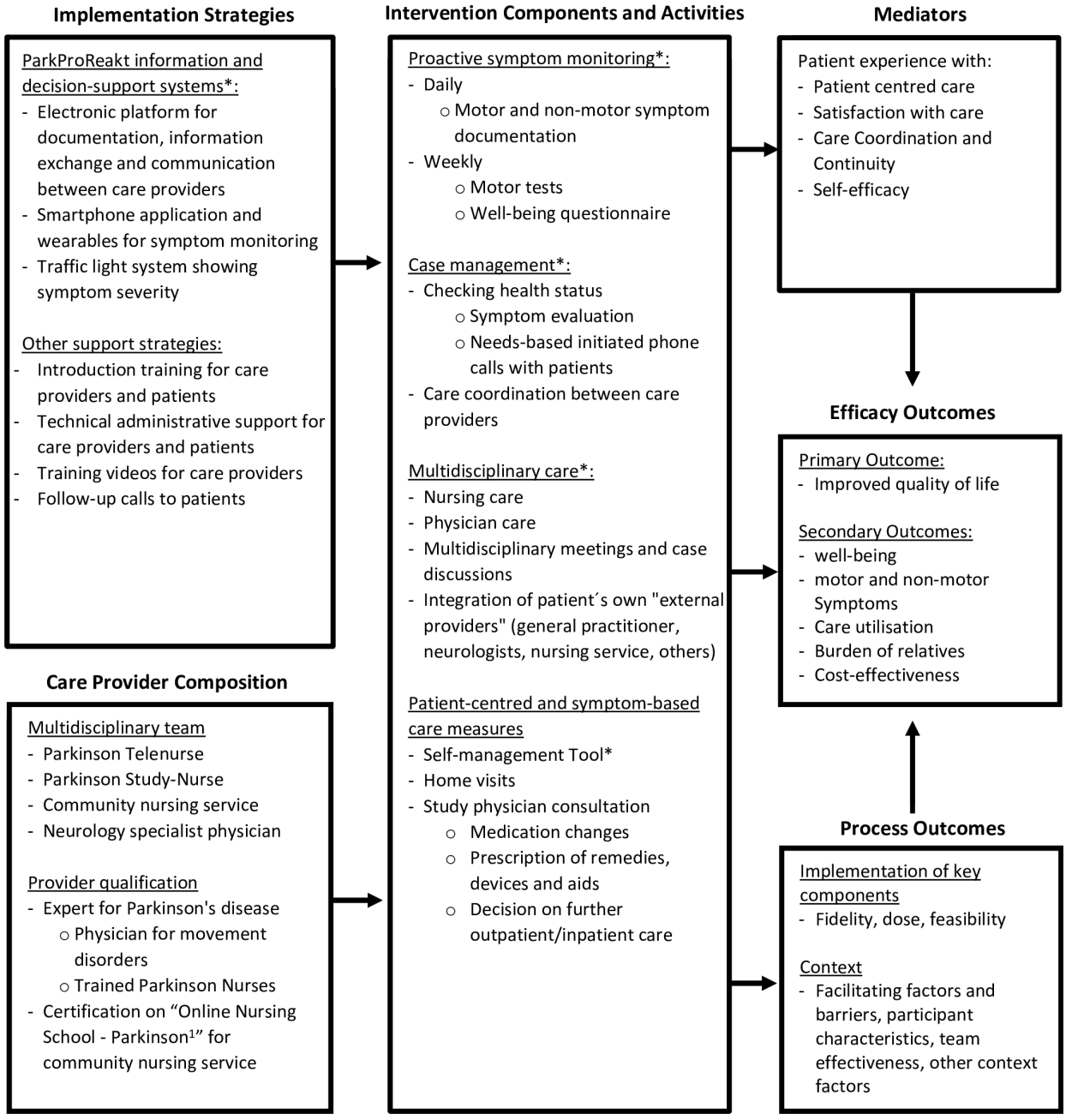

Figure 1 ParkProReakt logic model. *ParkProReakt Key components; [1](https://www.online-pflegeschule.de/pflegeschule-parkinson/hauptseite).

information about the disease and special management advice for PwPD.

Specifying key components for process evaluation in ParkProReakt

It is necessary to specify key components of this complex intervention, in order to derive appropriate process-related questions and outcomes. The key components are an integral part of ParkProReakt (eg, proactive symptom monitoring).[20] In addition, there are other elements that can be applied depending on the needs of the PwPD or the preferences of the care providers (eg, appointment to clinic). The key components are divided into (a) intervention components and (b) implementation strategies (see figure 1).

To define the key components, the Chronic Care Model (CCM) was employed as a framework,[21 22] and the following ParkProReakt key intervention components were delineated based on the CCM elements 'delivery system design' and 'self-management support':

1. Monitoring of symptoms in the patient's home environment
2. Case management (CM), which is defined here as patient-oriented, continuous and coordinated care
3. Multidisciplinary care
4. Self-management tool

The implementation strategies of ParkProReakt are applied to support the implementation of the key intervention components. These key implementation strategies are:

1. The care-provider platform (CCM element 'clinical information system')
2. The smartphone application and wearables (CCM element 'delivery system design')
3. The traffic light system (CCM element 'decision support').

Additional implementation strategies involve providing training for care providers. Since not all community nursing service providers have experience with Parkinson's disease (PD), they will participate in the 'Online Parkinson's Care School', a collaborative initiative by Deutsche Parkinson Hilfe e.V. and the Parkinson Centre Beelitz-Heilstätten,[23] which includes certification. Further training courses are offered to prepare all care providers for their specific tasks and roles as well as to enable them to apply the planned procedures, including symptom evaluation and documentation processes. Additionally, care providers have access to specific training videos on topics such as care home assessment and documentation on the care-provider platform. Technical support is available via email to assist with any issues encountered.

After included in the study and randomised to the intervention group, all PwPD and their accompanying relatives receive instructions on how to use the technical components (smartphone application, wearables) and their functions from the on-site PSNs. A flyer with a written and illustrated summary of how to use the technical components is provided to the PwPD. The aforementioned technical support via email is also accessible for the PwPD. For reminding and assisting the PwPD to implement recommended care measures by care providers during the intervention period, regular follow-up calls are conducted by the PTN 2 weeks after the recommendations.

All implementation strategies and intervention components are illustrated in a logic model (see figure 1).

Objectives of process evaluation

The objective of the ParkProReakt process evaluation is to explore the implementation of the intervention, identify potential facilitating factors and barriers that may influence implementation and analyse how the process data may affect patient outcomes. Consequently, the study will analyse the context of ParkProReakt implementation and examine the key components in terms of feasibility, fidelity, dose delivered by care providers and dose received by patients.

The detailed research questions are as follows:

1. To what extent are the key intervention components implemented?
2. How feasible are the key components of ParkProReakt?
3. What are the potential contextual factors that facilitate or inhibit the implementation of ParkProReakt?
4. What are the potential factors that affect patient outcomes?

Mediating effects of ParkProReakt on patients' HRQoL are additionally measured alongside the process evaluation to gain insights into possible indirect mechanisms of impact.[24] Integrated care models such as ParkProReakt aim to enhance patients' perceived QoL.[7] This subjective experience of improved care may have a significant impact on patients' QoL. To investigate the indirect mediation, the enhanced patient experience within ParkProReakt will be evaluated using parameters such as continuity of care, care coordination and patient satisfaction. In addition, the self-management tool, as a key intervention component of ParkProReakt may indirectly influence QoL through its impact on patient self-efficacy.[25]

Therefore, the last research question is:

5. What are the potential indirect mechanisms of impact of ParkProReakt on the patient's HRQoL?

The study is designed as a hybrid efficacy-implementation trial with a mixed-methods process evaluation.

METHODS

The current protocol for process evaluation (PE) provides a detailed description of the methodology employed and should be read together with the efficacy outcome evaluation protocol.[18] This will help to understand the patient inclusion/exclusion criteria, sample size calculation, recruitment and randomisation strategies. The trial is registered at Deutsches Register Klinischer Studien (DRKS), Germany (DRKS00031092.). All collected data during the intervention will be managed by a data integration centre at the University of Giessen. On completion of the intervention, the data will be pseudonymised and transferred to the data integration platform (DIP) as fast healthcare interoperability resources (FHIR). Access to the DIP is provided through a virtual private network (VPN) connection to the Giessen research network. Evaluators have personalised access points to access the pseudonymised data and download it in the form of FHIR resources or excel files for further analysis. All care providers, PwPD and their relatives gave written informed consent for trial participation and data utilisation. Patient recruitment began in January 2024 and is expected to conclude in January 2025.

The PE protocol is developed in accordance with the SPIRIT guidelines.[26] Planning, design and analysis of the PE are based on the Medical Research Council framework for complex interventions.[16] The main element of the framework includes the implementation of the intervention, the mechanisms of impact and the context in which the intervention is implemented and produces the desired effect. The Consolidated Framework for Implementation Research (CFIR) is used to structure the context analyses.[27]

Data collection

All care providers and patients in the intervention group will be included in the collection of process data. Quantitative measurements will be carried out, complemented

	Study Measures	Outcome	Timepoints					
			Baseline	3 months	6 months	9 months	End of study	At event
Quantitative	Platform documentation	Fidelity, Dose	←	—	—	—	→	
	Usability-Questionnaire	Feasibility		x	x	x		
	Contact to technical Support	Feasibility	←	—	—	—	→	
	Characteristic-Questionnaire	Context (Reach)	x					
	Team-effectiveness -Questionnaire	Context (Team-effectiveness)		x	x	x	x	
	Smartphone utilization data	Dose	←	—	—	—	→	
	Usability-Questionnaire	Feasibility			x			
	Contact to technical Support	Feasibility	←	—	—	—	→	
	Characteristic-Questionnaire	Context (Reach)	x					
	Drop-Out Questionnaire	Context (Reach)						x
Qualitative	Focus Groups	Context (facilitating factors and barriers)				x	x	
	Semi-structured Interviews	Context (facilitating factors and barriers)					x	

Figure 2 Schedule according to SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)—ParkProReakt timeline of process evaluation methods.

by focus groups with care providers and interviews with PwPD (see figure 2).

For research questions 1–4, a comprehensive survey of all PwPD and care providers will be used to assess the quantitative data. Focus groups will be conducted midway and at the end of the project with at least one representative from each care provider group (PTN, PSN, community nurse, study physician). The sampling strategy for patient interviews will be based on extreme cases of change in the primary outcome (HRQoL as measured by Parkinson's Disease Questionnaire (PDQ-39)[28]), in the pre/post comparison.[29] During the final medical examination of patients, care providers will invite PwPD who have experienced a change in HRQoL of more than five points (a clinically relevant difference[30]), as well as those who have not experienced any change or deterioration in HRQoL. This selection will provide a deeper insight into the facilitating factors and barriers to change in HRQoL for these extreme responders. To analyse the indirect mediating effects (research question 5), patients in the intervention and control groups will be asked to complete a series of standardised questionnaires (see table 1).

The sequence and result-based integration of quantitative and qualitative data for mixed-methods analysis is employed to[31]:

1. Explain the context in which the quantitative process data were generated (result-based integration) (research question 3)

Table 1 Indirect effect measurements

Outcome	Questionnaire	Time points
Experience with:		
Patient-centred care and satisfaction	PACIC-S5	Postintervention
Care coordination and continuity	NCQ	Postintervention
Self-efficacy	SES6G	Preintervention and postintervention

NCQ, Nijmegen Continuity Questionnaire[37]; PACIC-S5, Patient Assessment of Chronic Illness Care—short version[39]; SES6G, Self-Efficacy for Managing Chronic Disease 6-item Scale[40].

Table 2 Process indicators of ParkProReakt

Outcome	Questions	Instrument	Indicator
Fidelity	Is symptom-related continuous care being provided? (Continuity of Care)	Care-provider platform documentation	a. Number of consultations for discussing symptom deterioration/number of symptom deteriorations documented through monitoring (%) b. Time until consultations to discuss a symptom deterioration documented through monitoring
	Is the prescribed home care provided by the team? (Care Coordination)	Care-provider platform documentation	a. Number of home visits conducted/number of recommendations for home visits (%) b. Time between recommendation and implementation (days) c. Number of consultations between patient and study physician conducted/number of recommendations for study physician consultations (telephone/video) (%) d. Time between recommendation and implementation (days)
	Is the prescribed out-of-home care realised? (Care Coordination)	Care-provider platform documentation	a. Number of patient visits to a practice or clinic/number of recommendations for appointments in a practice or clinic (%) b. Time between recommendation and implementation (days)
	Were all designated care provider types represented during the case discussions?	Care-provider platform documentation	Designated care provider types (PTN, PSN, community mobile nurses) per case discussions
Dose delivered and received	How frequently is the SMT used?	Smartphone utilisation data	Average frequency of data views per patient per month (first to sixth)
	Are all monitoring instruments being used by the patients with the intended regularity?	Smartphone utilisation data	a. Motoric tests (7-day): Number of weeks conducted the test/number of weeks in intervention b. Well-being Questionnaire (7-day): Number of weeks conducted test/number of weeks in intervention c. Symptom report (daily): Days used/total days in intervention
	Were the recommended self-management (SM) measures implemented by the patients?	Care-provider platform documentation	Number of (completely/partially/not) implemented SM measures/number of recommended SM measures
	Were the recommended nursing care measures after the home visits implemented by the patients?	Care-provider platform documentation	Number of (completely/partially/not) implemented nursing care measures/number of recommended nursing care measures
	Were the recommended measures after the consultation with the study physician implemented by the patients?	Care-provider platform documentation	Number of (completely/partially/not) implemented measures after study physician consultation/number of recommended measures after study physician consultation
	How many contacts between the PTN and the patient occurred?	Care-provider platform documentation	Number of contacts between PTN and patient
	How many home visits by the community care service occurred?	Care-provider platform documentation	Number of home visits per patient
	How many contacts between the study physician and the patient occurred?	Care-provider platform documentation	Number of contacts between study physician and patient
	How many care team consultations (between PTN, PSN, community nursing service) occurred?	Care-provider platform documentation	Number of care team consultations per patient

Continued

Table 2 Continued

Outcome	Questions	Instrument	Indicator
	How many whole team consultations (between PTN, PSN, community nursing service, study physician) occurred?	Care-provider platform documentation	Number of whole team consultations per patient
	How many case discussions between the study physician and the PTN occurred?	Care-provider platform documentation	Number of case discussions between the study physician and the PTN
Feasibility	Are all care providers capable of carrying out the intervention as intended?	a. Contact to technical support b. Usability Questionnaire	a. Frequencies of contacts to technical support b. Median of Likert scales
	Are the patients capable of using the technical components?	a. Contact to technical support b. Usability Questionnaire	a. Frequencies of contacts to technical support b. Median of Likert scales
Context (reach)	What patient characteristics are associated with participation in the study?	Patient Characteristics Questionnaire	Description of the existing characteristics: for example, age, gender, nationality, marital status, disease severity
	What patient characteristics are associated with study dropout?	Patient Characteristics Questionnaire, dropout list	Description of the existing characteristics: for example, age, gender, nationality, marital status, disease severity
	What are the provider characteristics?	Care Provider Characteristics Questionnaire	Description of the existing characteristics: for example, ParkProReakt introduction training, PD certificates, work experience, academic degree
Context (facilitating factors and barriers)	What are the potential factors that facilitate or inhibit the implementation of ParkProReakt?	Focus groups	Deductive and inductive codes and themes
	What are the potential factors that affect patient outcomes?	Semistructured Interview	Deductive and inductive codes and themes

PSN, Parkinson study nurse; PTN, Parkinson telenurse; SM, self-management; SMT, self-management tool.

2. Facilitate in-depth interpretation of the quantitative outcome data (sequence and result-based integration) (research question 4).

Question 1: To what extent are the intervention components implemented?

For evaluating question 1, the outcomes fidelity and dose are employed in care providers on the basis of structured and unstructured text documentation data on the care-provider platform and in patients based on smartphone utilisation data.

Fidelity is defined as the degree of adherence to the protocol for the delivery of the key intervention components (done yes/no and duration until delivery). Dose is defined by frequency of contacts between care providers and patients, frequency of delivered care measures by care providers and applied care measures by patients and the frequency of smartphone usage by patients.

A detailed overview of all process indicators can be found in table 2.

Platform documentation data: Care providers document all identified changes in patient symptoms, contacts between care providers and patients, additional patient symptoms assessed during contacts, provider activities and all medical recommendations on the care-provider platform.

Special indicators (see table 2) derived from platform documentation were defined to enable the analysis of fidelity for the key intervention components of 'case management' and 'multidisciplinary care'. The indicators for case management are defined by the quality-of-care continuity (eg, prompt contact with the patient in response to a deterioration of symptoms) and care coordination (eg, an explicit care measure is promptly implemented). Multidisciplinary care is reflected by the presence of various specialist disciplines during the case discussions.

The number of care measures or recommendations delivered by care providers, the actual implementation of these measures or recommendations by patients and the frequencies of contacts between patients and care providers or among care providers are documented to determine the dose indicators. To examine the type of

Table 3 Classification of delivered ParkProReakt care measures and recommendations

Category of care measures	Definition	Examples of recommendations and actions	Identified by	Delivered by
Self-management recommendation	Actions that can be carried out by the patient independently and without the assistance of medical professionals	Information on nutrition or physical activity	PTN	PTN
Home visits by nursing service	Need for a home visit	Conducting a (partially) standardised assessment to identify care needs in home environment	PTN, study physician	Community nursing service
Study physician consultation	Phone or video meetings between PwPD and ParkProReakt physician	Adjusting medication dosages, prescribing new medication or medical aids	PTN, study physician, community nursing service	Study physician
Admission to external medical specialists	Referring the PwPD to other (external) specialists	Physical therapist, nutritionist, neurologist, etc	Study physician	Care providers outside ParkProReakt care team

PTN, Parkinson telenurse; PwPD, people with Parkinson's disease.

delivered care measures, they are categorised as follows: self-management recommendations, home visits by nursing service, study physician consultation and admission to external medical specialists. For detailed definitions, see table 2. The care measures are documented as structured or unstructured free text inputs. The free text entries are categorised by the type of recommended care measures and the type of applied care measures by patients based on the definitions provided in table 3.

The implementation of recommendations applied by the PwPD is determined through telephone follow-up calls (recommendation based on self-management measures, study physician consultation and admission to external medical specialists) and documented on the platform. The follow-up calls take place at least 2 weeks after the recommendations are given, and the patient's implementation is documented and categorised as complete, partial, or not implemented.

The frequencies of the care measures and recommendations, as well as the duration (in days) between the recommendation and its implementation, are employed for the analyses of fidelity and dose.

Smartphone utilisation data: The smartphone log data are employed to quantify the dose parameters for the app-based key intervention components 'symptom-monitoring' and 'self-management tool' (SMT). While the symptom report and the SMT are used based on the individual patient needs and preferences, it is recommended that the motoric tests and the well-being questionnaire be applied on a weekly basis. The frequency and recommended regularity will be analysed (see table 2).

Question 2: How feasible are the key components of ParkProReakt?

Training sessions, additional video material and technical support should enable care providers and PwPD using the key components of ParkProReakt. The feasibility is analysed by quantitative survey data and contacts with the technical support team (see figure 2).

Usability Questionnaire for care providers: All care providers will be invited to complete online questionnaires to evaluate the quality of information provided during training sessions or through videos on applying the key components. The survey is divided into two sections: a general section for all care providers and a special section containing statements regarding the application of key components for specific care provider groups (eg, PTN, study physician). The general section of the survey includes statements about the respondents' awareness of the project's objectives, the role of each care provider type and the project's overall workflow. It also covers topics such as the ability to document on the care-provider platform, the usefulness of the information provided on the platform in understanding the patient's needs and to deliver care measures. The specific sections present statements for each care provider type regarding their knowledge and perceived ability to perform care activities, as well as any issues or uncertainties that may arise in their care delivery processes. Respondents are asked to indicate their level of agreement with the statements on a four-point Likert scale, with the options 'fully agree', 'agree', 'partially disagree' and 'disagree'. The initial questionnaire survey (online supplemental material) will be conducted 3 months after the intervention begins. Further online questionnaires will be developed sequentially,[16] taking into account the knowledge gained from the PE up to that point and are conducted in the mid phases of the ParkProReakt project to analyse changes in the ability of care providers to deliver the intervention.

Usability Questionnaire for PwPD: At the end of the intervention period, a modified version of the German

mHealth App Usability Questionnaire (MAUQ) will be sent to the PwPD to quantitatively assess their ability to use the smartphone application (App).[32] The MAUQ is a questionnaire that measures the perceived usability of a mobile health App. It consists of 18 statements answered on a seven-point Likert scale ('completely agree' to 'completely disagree') and includes the following three domains: 'Ease of use', 'Interface and satisfaction' and 'Usefulness'.

Contact to technical support: Care providers and PwPD can contact a support team via email to report any issues with the care-provider platform or smartphone App and to receive prompt assistance. The technical support team will document the nature of the problems and, whenever possible, provide solutions. The frequency and reasons for these contacts will be analysed to assess the feasibility of the care-provider platform and App. Additionally, this documentation will serve as a basis for potential further development of the technical components.

Question 3: What are the potential contextual factors that facilitate or inhibit the implementation of ParkProReakt?

To explain contextual factors in which ParkProReakt is implemented and the quantitative process data are generated, qualitative and quantitative methods will be employed. Context is defined as a set of circumstances or unique factors that may influence the implementation of the intervention.[14] Consequently, person-based questionnaires for describing who provides and receives the intervention (sometimes this factor is called 'reach') and a questionnaire on the effectiveness of collaboration in the care provider team will be employed to collect quantitative context parameters. Furthermore, focus groups with care providers will be conducted in order to qualitatively explore the facilitators and barriers to implementation (see figure 2).

Characteristics Questionnaires: These questionnaires are designed to examine the characteristics of the participants, including PwPD, their relatives and all care providers. Our interest lies in the description of severity and duration of the disease (Hoehn and Yahr stage,[33] year of symptom onset) and in the distribution of characteristics that predict participation in the project or have been associated with study dropout. The data collection period begins immediately on the inclusion or dropout of the PwPD and their relatives. The care provider characteristics are assessed with a questionnaire in the first few weeks of the project.

Team Effectiveness Questionnaire: A modified version of the Integrated Team Effectiveness Instrument is employed to assess the perceived team efficacy of care providers. Originally, developed for care teams working with patients with chronic obstructive pulmonary disease,[34] a modified questionnaire for care teams working with PwPD was created.[35] The questionnaire will be administered quarterly through online surveys and analysed in relation to the subscales of 'perceived team effectiveness', 'team processes' and 'teams' psychosocial traits'. It consists of 24 statements, which are rated on a four-point Likert scale (from 'completely agree' to 'completely disagree') with the option to indicate that the statement is not applicable.

Focus groups with care providers: Two focus groups involving care providers will be conducted throughout the project duration. Each focus group will be facilitated by one interviewer and supported by a protocol assistant. The entire interview will be recorded with the participants' consent using audio means. Furthermore, responses and discussion points will be summarised in bullet points. Any particularities observed during the interviews will be documented at the conclusion of the focus groups.[36] A preliminary focus group with the care providers will be held midway through the project period. One individual from each category of care providers will be randomly selected from both treatment sites (HH, MR) and invited to focus group interviews to obtain the experiences of all types of care providers. In order to achieve a high participation rate, focus groups are conducted online. The semistructured interview guide was created according to Misoch.[29] The CFIR was employed as the foundation for the content development of the interview guide, which delineates specific domains that can either facilitate or impede the implementation of complex healthcare interventions.[27] The questions from the CFIR domains of 'Intervention Characteristics,' 'Outer and Inner Setting' and 'Characteristics of Individuals' were adapted to align with the specific characteristics of the ParkProReakt project. Furthermore, the perceived applicability of key components is integrated to discuss the components that are effective or usable, those that are not, and potential additional strategies that could facilitate implementation. While the interview guide is semi-structured, participants are encouraged to discuss additional issues.[36] Finally, at the conclusion of the project, another focus group will be conducted to ascertain potential changes in facilitating factors and barriers of implementation.

The first interview guide is included in the online supplemental material, while the second guide will be developed sequentially.[16]

Question 4: What are the potential factors that affect patient efficacy outcomes?

It is important to consider the context in which changes in patient health outcomes are generated, as well as the quality and quantity of process data during the implementation of the intervention.[16 17] The hybrid efficacy-implementation design of this study enables an in-depth analysis of changes in efficacy outcomes derived from the RCT.[18]

Once the intervention phase has been completed and the process data have been analysed, the two datasets (patient efficacy outcomes and process outcomes) will be merged in order to identify any dependencies and direct mechanisms of impact. To ascertain their influence on patient efficacy outcomes, the parameters fidelity, dose, feasibility and patient characteristics will be analysed and

interpreted in conjunction. Furthermore, semistructured interviews with PwPD will be conducted to assess the context qualitatively.

Semistructured interviews with PwPD: To facilitate in-depth interpretation of the quantitative outcome data, patients with extreme responses and those with non-responses in QoL (measured by PDQ-39), as well as their relatives, will be invited to participate in interviews after completing the ParkProReakt intervention. A semistructured interview guide allows for the elicitation of insights into the experiences and attitudes of patients towards ParkProReakt.[29] The guide includes inquiries regarding the utilisation of symptom-monitoring and SMT autonomously and within their daily routines, their satisfaction with care coordination and continuity, as well as issues encountered during care provision. One interviewer and a protocol assistant will be responsible for conducting and recording the interviews in accordance with the above-outlined methodology.[29 36] The interview guide is included in the online supplemental material. Furthermore, sociodemographic data, along with the year of PD diagnosis and the level of care dependency, were obtained via a questionnaire prior to the interview.

Question 5: What are the potential indirect mechanisms of impact of ParkProReakt on the patient's QoL?

Possible indirect mechanisms of impact between the intervention and patient's health outcomes will be evaluated through mediator analysis. The ParkProReakt integrated care model aims to improve continuity and coordination of care, patient-centred care and satisfaction with care. In addition, the integrated SMT for PwPD should improve their self-efficacy.[25] To analyse the effect of these potential mediators on HRQoL, we have selected standardised questionnaires and measurement times listed in table 1.

The Nijmegen Continuity Questionnaire is designed to assess continuity and coordination of care from the patient's perspective.[37] It can be used in different healthcare settings (outpatient/inpatient) and is applicable to all medical specialties (eg, general practitioner, cardiologist). The questionnaire covers the domains of 'personal continuity' and 'team and interdisciplinary continuity' and consists of 12 questions to be answered on a five-point Likert scale ('strongly agree' to 'strongly disagree').

The Patient Assessment of Chronic Illness Care (PACIC) is a questionnaire based on the CCM, designed to assess patient-centredness and satisfaction with the care of chronically ill patients.[38] The short German version of the PACIC consists of 11 statements regarding medical care received in the last 6 months and is rated on a five-point Likert scale from 'almost never' to 'almost always'.[39] The final question assesses satisfaction with care and is rated on a percentage scale.

The Self-Efficacy for Managing Chronic Disease 6-item Scale is used to assess self-efficacy in patients with chronic conditions.[40] Patient's confidence in managing disease-specific symptoms such as fatigue and pain and their impact on daily activities are rated using a Numerical Rating Scale ranging from 'not at all confident' to 'very confident'. The sum of the six items reflects the level of subjective self-efficacy.

The surveys for research question 5 will coincide with the assessment of efficacy outcomes and will be conducted simultaneously in both the intervention and control groups. This will allow a comparison between the care provided by ParkProReakt and the standard care group.

All patient questionnaires will be sent by post to the PwPD, along with prepaid envelopes.

Data analysis

The research questions 1, 2 and 5 will be analysed quantitatively. Research questions 3 and 4 will be analysed using a mixed-methods approach, which involves the integration of both quantitative and qualitative data. The results of the RCT evaluating the efficacy of ParkProReakt will be analysed after evaluating the process data. The same evaluation team is responsible for addressing all questions regarding process evaluation as well as outcome evaluation. Consequently, there will be no blinded analysis of the outcome data in relation to the process data. Data analysis for the outcome evaluation is reported elsewhere.[18]

Quantitative data analysis

The results of the process evaluation will be presented in a descriptive manner. The analysis of fidelity and dosage will be based on the frequency of interactions between stakeholders, the frequency of special care measures, the time duration between care recommendations and their delivery by care providers, and the frequency of recommendations actually implemented by patients.

The average regularity of App usage per week and the frequency of usage throughout the project by PwPD will be presented descriptively based on smartphone utilisation data. The Usability Questionnaires completed by care providers will be analysed in terms of the distribution of statement frequencies and their dispersion according to provider type. The MAUQ will be considered separately in terms of its three domains and overall score. The same approach will be taken with the team effectiveness questionnaire. Additionally, we will investigate whether there are differences in perceived team effectiveness according to the various types of care providers. This analysis will be purely descriptive due to the small sample size of some care provider types (study physician n=3). The frequency of contacts with technical support will be divided according to the technical system (symptom monitoring, SMT, care-provider platform) and stakeholders (care provider type, patient). The parameters in the characterisation questionnaires will be presented in accordance with the scaling used, which may be means, medians or frequencies, including measures of dispersion.

Given the association between symptom severity and the need for multidisciplinary care in PwPD,[2 4 41] process parameters will additionally be analysed across patients' Hoehn and Yahr stages. This analysis aims to identify

potential differences in the application of ParkProReakt in relation to motor symptom severity. Depending on the data structure, general linear models or the Friedman test will be applied. Post hoc tests will be adjusted for multiple comparisons.

To address research question 4, multivariate regression models will be employed. Following the analysis of process and efficacy outcomes, these datasets will be integrated and Pearson correlation coefficients will be calculated to assess the relationships between fidelity, dosage, patient feasibility (independent variables) and patient health outcomes (dependent variables). Based on the correlation results, multivariate regression models will be used to further analyse these relationships. Patient characteristics (eg, severity of condition, age) will be included as control variables to account for potential confounding effects. Assumptions of the regression analysis (linearity, normality of residuals, homoscedasticity and absence of multicollinearity) will be checked and addressed as needed.

The mediation analysis will be conducted to uncover a priori defined potential indirect mechanisms affecting HRQoL of PwPD. The initial stage of this investigation entails assessing of whether there are differences in the mediator outcomes between the two treatment groups and whether there is a difference in HRQoL (measured by PDQ-39[28]) between the treatment groups. If a statistically significant difference is identified between the groups using the t-test, a Pearson correlation analysis will be employed to examine the relationship between QoL and the mediator outcomes.

The significance level will be set at α=0.05. All quantitative data will be analysed using SPSS statistical software.

Qualitative data analysis

All focus groups and interview sessions will be audio-recorded and transcribed verbatim. The transcripts will be carefully checked for accuracy, and any necessary corrections will be made. Any identifiable remarks will be made anonymous before being imported into the qualitative analysis software MAXQDA. Thematic analysis will be employed for all qualitative data using a combination of deductive and inductive approaches.[42] The deductive codes focus on the feasibility and reach of the outcomes, as well as the CFIR domains addressed in the interview guide. In addition, inductive codes will be created to capture any contextual factors that may influence the implementation of the intervention or the results of ParkProReakt. All codes will be organised according to facilitators or barriers.[43]

A second reviewer will independently analyse a randomly selected sample of 25% of the transcript extracts to determine the inter-rater reliability of the coding system. If agreement is less than 70%, any conflicting decisions will be resolved through discussion until a consensus is reached. The reliability will be calculated using the kappa coefficient.[44]

All findings will be presented separately for each gender and other relevant characteristics (eg, sociodemographic, disease severity) whenever possible.

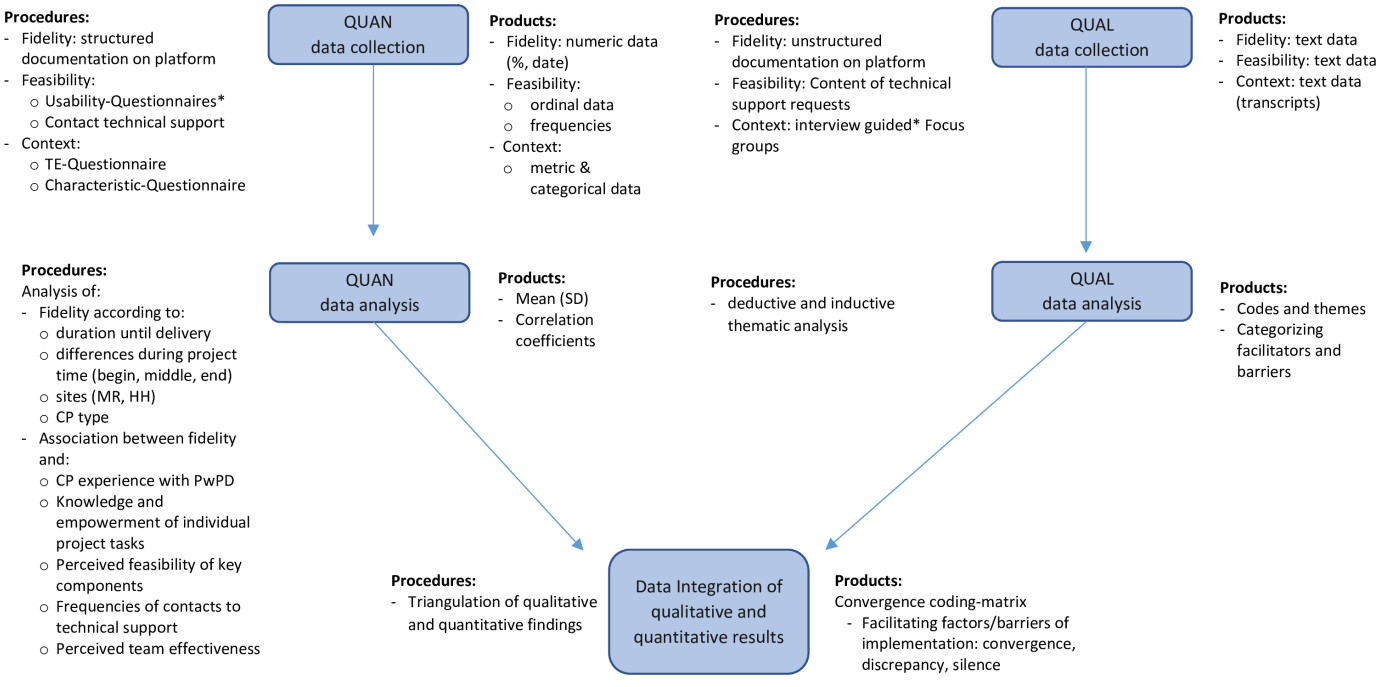

Figure 3 Parallel design of mixed-methods approach for research question 3. *Iterative development. CP, care provider type; HH, city Hamburg, Germany; MR, city Marburg, Germany; PwPD, people with Parkinson's disease; QUAL, qualitative; QUAN, quantitative; TE, team effectiveness.

Mixed methods

The mixed-methods approach is used to investigate research questions 3 and 4. These questions are addressed in a multiphase design, which combines a parallel design and an explanatory sequential design.[45]

To explain the potential facilitating factors and barriers of implementation (research question 3, see figure 3) and to gain further insights into the efficacy outcome data (research question 4, see figure 4), quantitative and qualitative process data will be integrated on an interpretative level using the triangulation method.[46] The quantitative data will be presented in a tabular structure alongside the summarised qualitative themes in a convergence coding matrix to identify convergence, discrepancy or silence in the results of the datasets. Convergence refers to a general agreement between the datasets regarding the element being compared (eg, feasibility of key components). Discrepancy, on the other hand, refers to a general disagreement between the datasets, and silence refers to one dataset addressing a particular issue or example, that the other dataset does not provide relevant data on.[47] The combined parallel and explanatory sequential design for analysing research question 4 allows for data interpretation in relation to patients with good and non-response of the PDQ-39 after intervention. Therefore, the convergence coding matrix will be additionally divided into thematic codes for these patient groups. This approach enables the identification

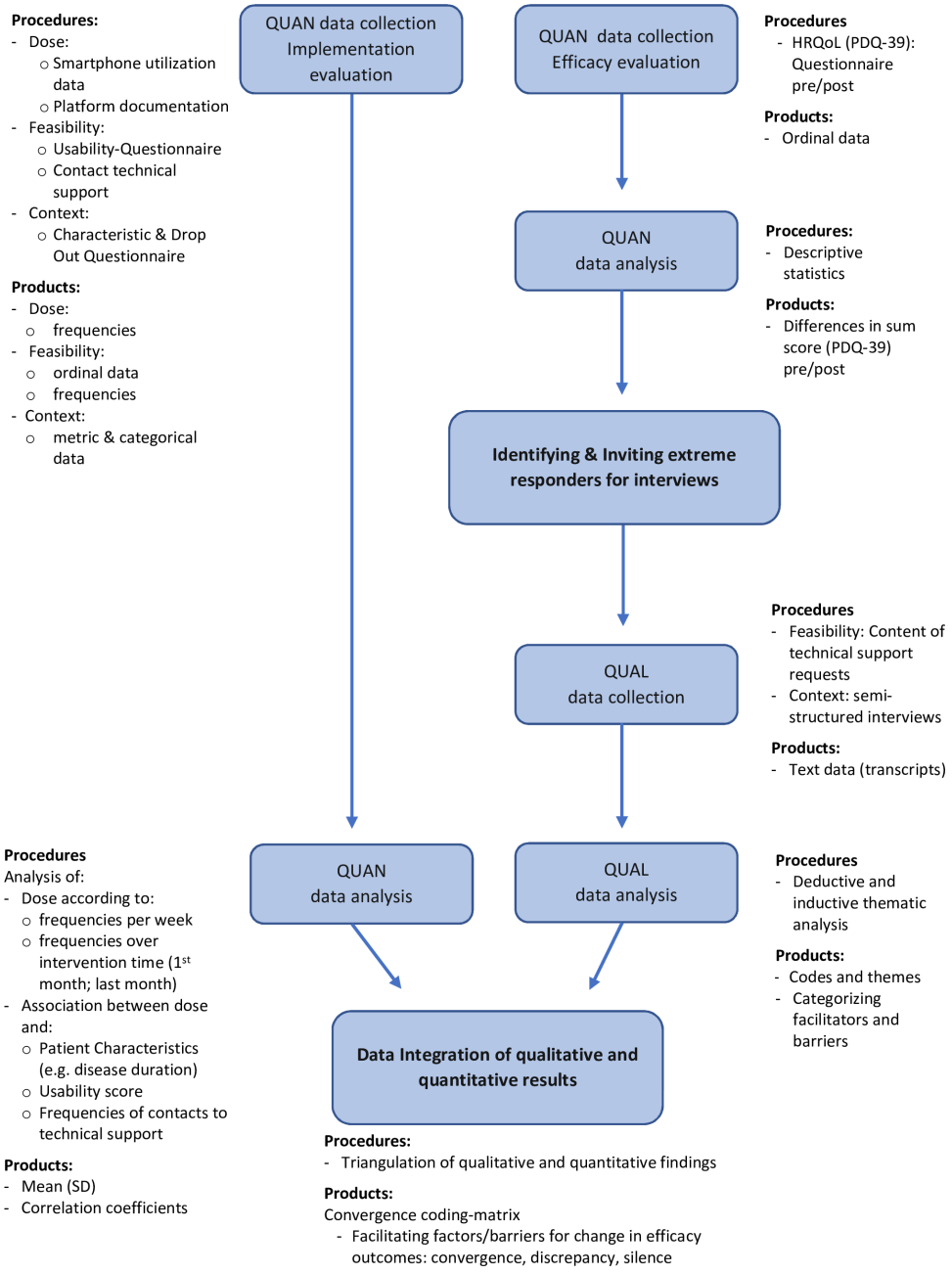

Figure 4 Combined parallel and explanatory sequential design of mixed-methods approach for research question 4. HRQoL, health-related quality of life; QUAL, qualitative; QUAN: quantitative; PDQ-39, Parkinson's Disease Questionnaire.

of potential obstacles to improving health status and the derivation of possible strategies for future improvement. Conversely, patients who demonstrate a clear improvement in health following the intervention can provide insights into potential support factors and unexpected mechanisms of impact.

Patient and public involvement

The ParkProReakt study design and care pathway were presented to and approved by patient representatives. In addition, patient representatives were actively involved in the development of the smartphone applications, as well as in the formulation of the research question of the RCT prior to the start of the project.

ETHICS AND DISSEMINATION

Ethical approval for this study was obtained from the responsible state medical ethics committees in Hesse and Hamburg, Germany (Ref. 2022-3139-evBO and 2023-200762-BO-bet). Before participating in the study, each subject will be asked to sign a consent form. This form will explicitly state that their decision to participate in the study is voluntary and that they are free to withdraw at any time. All personal data will be treated confidentially as described above. The applicable privacy policy will be consistently and strictly adhered to at all times. Participating patients, their relatives and any care providers will be informed of any intended use of their data and will be required to give their consent. Results will be disseminated through peer-reviewed publications and presented at national and international conferences. They will also be reported to the funding agency. Additionally, the results will be shared in close collaboration with national Parkinson's societies and patient organisations.

Trial status

Protocol Version 1.0.

Currently, the trial is ongoing, and the recruitment of participants continues. Recruitment began in January 2024 and is expected to be completed by January 2025.

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Contributors NA (guarantor) conceptualised the process evaluation methods. MG supervised the development of the process evaluation protocol and revised the first draft of the manuscript critically for important intellectual content. DJP is the principal investigator of ParkProReakt, responsible for ethical approvals. DJP, JS and MvM are in charge of overseeing the project. IW and HB were involved in the study conception and in close coordination with the principal investigator. IW was responsible for the ethical approval in Hamburg, Germany. All authors read and provided critical feedback on multiple drafts. All authors and the ParkProReakt Collaborator Group read and approved the final manuscript. The interview guides were translated from German to English using the DeepL translation software.

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Patient consent for publication Not applicable.

Ethics approval Ethical approval for this study was obtained from the responsible state medical ethics committees in Hesse and Hamburg, Germany (Ref. 2022-3139-evBO and 2023-200762-BO-bet). State medical ethics committee in Hesse: https://www.laekh.de/fuer-aerztinnen-und-aerzte/rund-ums-recht/ethik-kommission; state medical ethics committee in Hamburg: https://www.aerztekammer-hamburg.org/ethik_kommission.html. Participants gave informed consent to participate in the study before taking part.

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