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Healthcare provision, functional ability and quality of life after proximal femoral fracture - 'ProFem': Study protocol of a population-based, prospective study based on individually linked survey and statutory health insurance data

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Keywords:	proximal femoral fracture, healthcare provision, patient-reported outcomes, data linkage

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Study protocol

Healthcare provision, functional ability and quality of life after proximal femoral fracture - 'ProFem': Study protocol of a population-based, prospective study based on individually linked survey and statutory health insurance data

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Abstract

Introduction: Proximal femoral fractures (PFF) are among the most frequent fractures in older people. However, the situation of people with a PFF after hospital discharge is poorly understood. Our aim is to (1) analyse healthcare provision, (2) examine clinical and patient-reported outcomes (PROs), (3) describe clinical and sociodemographic predictors of these, and (4) develop an algorithm to identify subgroups with poor outcomes and a potential need for more intensive healthcare.

Methods and analysis: This is a population-based prospective study based on individually linked survey and statutory health insurance (SHI) data. All people aged minimum 60 who have been continuously insured with the AOK Rheinland/Hamburg and experience a PFF within one year will be consecutively included (SHI data analysis). Additionally, seven hundred people selected randomly from the study population will be consecutively invited to participate in the survey. Questionnaire data will be collected in the participants' private surroundings at three, six, and 12 months after hospital discharge. If the insured person considers themselves to be only partially or not at all able to take part in the survey, a proxy person will be interviewed where possible. SHI variables include healthcare provision, healthcare costs, and clinical outcomes. Questionnaire variables include information on PROs, lifestyle characteristics, and socio-economic status. We will use multiple regression models to estimate healthcare processes and outcomes including mortality and cost, investigate predictors, perform non-responder analysis, and develop an algorithm to identify vulnerable subgroups.

Ethics and dissemination: The study was approved by the ethics committee of the Faculty of Medicine, Heinrich-Heine-University Düsseldorf (approval reference 6128R). All participants including proxies providing written and informed consent can withdraw from the study at any time. The study findings will be disseminated through scientific journals and public information.

Registration details: The study has been registered with the German Clinical Trials Register (DRKS; DRKS00012554).

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Strengths and limitations of this study

- To the best of our knowledge, this is the first study to conduct an individual data linkage between statutory health insurance (SHI) data and questionnaire data in the field of research on proximal femoral fractures (PFF).
- Individually linked survey and SHI data is used to answer a variety of health service research, clinical, and patient-orientated questions in people with PFF.
- Vulnerable subgroups, such as people with dementia, are included in our study.
- Due to structural differences between populations insured with various SHI funds and regions, the generalisability of our findings might be limited.

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Introduction

Proximal femoral fractures (PFF) are among the most frequent fractures in older people (1, 2). However, knowledge about the situation of those affected by a PFF is scarce (3-5). Studies indicate poor outcomes following a PFF: 50% of those affected retained functional limitations (6), 15% were newly admitted to a nursing home (7), and around 20% died within one year (8). Although post-operative programmes showed positive effects (6-11), more than 60% of patients received no further treatment (6), suggesting shortcomings in the care provided. Specific aspects of healthcare provision, such as treatment in geriatric trauma centres or rehabilitation, have hardly been investigated. Existing international studies suggest a healthcare gap (6, 12). It is currently unclear as to which patients particularly benefit from specific care models (13). In addition to healthcare processes, patient-reported outcomes (PROs) such as health-related quality of life (HRQoL), functional ability, and social participation in older people following PFF have hardly been investigated. Subgroups characterised by particularly poor clinical and patient-reported outcomes, and by a potential need of more intensive care, have not yet been identified.

Therefore, the aims of this study are (1) to analyse healthcare provision after PFF, (2) to examine clinical outcomes (such as re-hospitalisation, occurrence of need for care, nursing home admission, death) and PROs (such as HRQoL, functional ability, social participation) after PFF, and (3) to describe clinical and sociodemographic predictors of these (such as comorbidity, age, sex, social support). In doing so, (4) the aim is to identify subgroups who have poor outcomes (e. g. people living at home with low social support, comorbidity, and high healthcare utilisation) and are potentially in need of more intensive healthcare. This will be done by developing an algorithm which generates a 'case finding'.

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Methods and analysis

Study design and population

This is a population-based prospective study based on statutory health insurance (SHI) data and questionnaire data collected from people insured with the AOK Rheinland/Hamburg. Overall, the AOK Rheinland/Hamburg covers more than 2.5 million insured people in North Rhine-Westphalia (NRW), which has the highest population of all German Federal States, with approximately 25% aged 60 or older. All people resident in NRW aged 60 or over and who have been continuously insured with the AOK Rheinland/Hamburg for at least 12 months prior to PFF and experience a PFF between January 2018 and January 2019 will be consecutively included in the study. People with PFF will be identified consecutively over one year along with their exact date of hospital discharge using SHI diagnoses (main or secondary diagnosis) and operational procedure keys. A fracture event is defined according to the 10th revision of the International Classification of Diseases (ICD-10) codes S72.0 (fracture of head and neck of femur), S72.1 (pertrochanteric femoral fracture), and S72.2 (subtrochanteric femoral fracture), and selected surgical, and procedural keys (OPS-Codes, see Appendix A).

This study comprises two populations: all identified people as described above belong to the 1) study population based on SHI data. For those, a comprehensive analysis of SHI data covering 12 months before and 12 months after the fracture event will be performed. Furthermore, a 2) random sample – drawn from the overall SHI study population – will be consecutively invited to additionally participate in a survey. An algorithm will be applied weekly to ensure a random selection of the survey sample. Questionnaire data collection is planned at three and 12 months after hospital discharge using Pen-and-Paper Personal Interviews (PAPI) with participants in a private surrounding, and at six months after discharge by means of a postal survey. Sufficient German language skills are a prerequisite for participation in the survey (Appendix B). If the insured person considers themselves to be only partially or not at all able to take part in the survey, e.g. due to dementia or reduced state of health, an attempt will be made to conduct the interview with a caregiving relative (person of trust) or a legal guardian either additionally or on behalf of the insured person. The following criteria will be used to identify an eligible proxy: they must know the insured person well, should visit the insured person twice a week on average, and support them in everyday life. The participation of the proxy is always voluntary. People no longer able to take part in the interviews themselves and with no eligible caregiving relative or legal guardian to perform a proxy interview with will be excluded (Appendix B).

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Figure 1 displays the flow through the study. The sample size calculation will be described further below.

Figure 1 Study design

Recruitment

First contact to arrange an appointment for the visit in the private surrounding will be made by postal letter. The letter contains a cover letter, information on the study and on data protection, and the consent form for participation for prior information. The letter will also ask the insured person (or their proxy) to contact the study centre to arrange an appointment. A written reminder will be sent to non-responders after approximately two weeks, followed by telephone contact as a next step. Where no telephone number is available, a second reminder will be sent. Response will be monitored consecutively and proportions will be calculated to describe participation behaviour (14, 15).

Data Collection - Data Sources and Variables

Data will be collected from the sources outlined above. SHI data collected from consenting individuals 12 months before and 12 months after the event will be individually linked to questionnaire data. The SHI data will be used to measure healthcare provision and clinical outcomes in the 12 months after PFF. Healthcare provision is described for various healthcare areas: inpatient and outpatient care, rehabilitation, nursing services, prescribed medication, remedies and medical aids as well as costs for the different healthcare areas, transportation, and costs in total. Clinical outcomes are re-hospitalisation, care dependency (including new occurrences), admission to a nursing home, and mortality. SHI data collected 12 months after PFF and 12 months before PFF will also be evaluated regarding predictors such as demographic characteristics and comorbidity. The questionnaire data will be used to record PROs, which focus on HRQoL, functional ability, social participation, pain, and fear of falling. Self-reported predictors include demographic characteristics as well as socio-economic status, social support, lifestyle, healthcare utilisation, and special health-related events. Questions on PROs should be answered by the insured person whenever possible. If the insured person is not able to respond to an abridged version of the questionnaire comprising the questions on the aforementioned PROs, the proxy will be asked to respond to the entire questionnaire except the questions on pain and fear of falling (please see Table 1). Interviews will be conducted by trained interviewers. An interviewer manual and standard operating procedures will be provided for quality assurance purposes and to ensure a standardised approach.

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Outcomes

The following variables will be recorded for the aforementioned purpose:

SHI data

Healthcare provision

Healthcare provision will be evaluated using the following variables: number of hospital admissions after PFF; length of hospital stay (LOS) for each hospital admission; admission to a specialist department; physician contact per billing quarter; number and kind of different specialists involved; number, duration and kind of inpatient and/or outpatient rehabilitation; number, duration and kind of nursing services; institutional long-term care or short-term care; number and kind of prescribed medications; and number and kind of remedies and medical aids. Furthermore, healthcare costs will include: inpatient costs; outpatient costs; rehabilitation costs; nursing services costs; medication costs; costs for remedies and medical aids; and costs for transportation. Healthcare costs will be shown in euro. Since outpatient data is only provided in quarters, these cost values will be equally distributed over the time span (e.g. in weeks).

Clinical Outcomes

Re-hospitalisation is addressed by the variables already named above (number of hospital admissions after PFF, LOS for each hospital admission, and admission to a specialist department). Care dependency (including new occurrences) is displayed in five care degrees according to the German Nursing Care Act (1 to 5) depending on the amount of care needed (16). The maximum level of care in the period before the PFF hospital stay will be considered. Admission to a nursing home is assessed by the type of service, including e.g. provision of short-term or long-term care along with the exact date. The date of death of people with PFF who died during the observation period will be recorded to assess mortality.

Questionnaire data

Patient-reported outcomes (PROs)

Health-related quality of life

Overall HRQoL will be measured using the 12-Item Short Form Health Survey (SF-12) covering the previous four weeks of a person's life (17). The SF-12 is the shorter version of the Short Form-36 Health Survey (SF-36) and contains one or two items for the following eight health dimensions: physical functioning; role functioning; bodily pain; general health

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perception; energy/vitality; social functioning; emotional functioning; and mental health. The SF-12 comprises two summary scores – a physical component summary score (PCS) and a mental component summary score (MCS). In the SF-12, a better health-related quality of life is denoted by higher values. The SF-12 is one of the best-known and most frequently used instruments to assess HRQoL and its measurement performance has been tested (18).

The European Quality of Life 5-Dimensions questionnaire (EQ-5D) is a generic preference-based measure of health status and consists of two parts – a questionnaire and a visual analogue scale (EQ-VAS) (19, 20). The questionnaire contains five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a 5-level (5L) scale. The result of the questionnaire can be summarised as perceived state of health (from best to worst state where "11111" is the best and "55555" the worst state). The EQ-VAS is a scale for rating health between 100 (best imaginable state of health) and zero (worst imaginable state of health), expressing health on the day of completion. The EQ-5D is a well-accepted and frequently used instrument with good psychometric properties (21).

Functional ability

Functional ability will be measured using three instruments.

The Oxford Hip Score (OHS) is a hip-specific 12-item questionnaire to assess activities of daily living (ADL) with six questions relating to pain (type and the resulting impairments in mobility) and six questions relating to functional ability (self-care, mobility, and independence), each referring to the last four weeks (22, 23). Answers to the questions are categorised in five dimensions, ranging from 0 (worst outcome) to 4 (best outcome). The sum of all values provides an overall score between 0 and 48. A high overall score indicates a better outcome with 48 being the best outcome. The reliability and validity of the OHS has been assessed in a German population with osteoarthritis of the hip (24).

The Heuschmann et al. (2005) (25) version of the Barthel Index (BI), a common measure of ADL, provides an interview and a paper and pencil form. The BI comprises ten domains which are divided into self-care and mobility. Self-care includes feeding, bathing, grooming, dressing, toilet use, and bowel and bladder control. Mobility consists of transfer, mobility, and stairs. The interview version comprises 17 questions. The postal survey includes ten questions – one for each domain. The person's overall ADL score is classified according to an ordinal scale where 0 is the lowest score and 20 indicates complete independence. Comprehensibility and reliability of both questionnaires were tested in stroke patients (25).

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Pre-fracture functional level will be assessed using the Mobility Parker Score (MPS) (26), which evaluates a person's ability to get about the house, out of the house, and to go shopping. Each item is rated from 0 ('no difficulty') to 3 ('not at all'). The answers result in a total score ranging from 'no walking ability at all' to 'total independence' (0-9).

Social Participation

The Index for Measuring Participation Restrictions (IMET) measures the restriction of participation of people with different chronic diseases (27, 28). Based on the dimensions of the International Classification of Functioning, Disability and Health (ICF), this tool covers nine aspects of everyday activities and participation. This includes self-care, daily duties, and responsibilities at and outside home, recreation, social activities, personal relations, sex, and stress and extraordinary strains. The impairment caused by a disease is evaluated for each item by means of an 11-level scale (0 - 10). Lower IMET values suggest better social participation. A summary score can be calculated. The psychometric properties have been tested for different patient groups (28).

Pain

Pain will be recorded as follows: the current level of pain, the average level of pain during the last four weeks and the highest level of pain during the last four weeks will be rated on a numerical rating scale (1 - 5) (29).

Fear of falling and falls

The assessment of fear of falling (30) includes a question about occurrence and frequency of fear (31), and a question about the occurrence and frequency of activities avoided due to fear of falling (31). The number and frequency of falls are recorded over the 12 months prior to the fracture as well as the period after the fracture (32, 33). A single question is used to determine whether it is the first fracture.

Overall, we considered the recent recommendations regarding core outcomes and appropriate instruments to be used in trials with older people with hip fractures (34, 35, 36). We selected instruments that are suitable for personal interviews, postal survey, and proxy assessments. We decided for the SF-12 instead of the SF-36 to reduce the length of the questionnaire (34).

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Predictors

SHI data

Demographic characteristics and comorbidity

Age, sex, and region of residence will be considered. Comorbidity, number of prescribed medications, number of inpatient stays in hospital, level of care, and healthcare costs for the year prior to the fracture will be considered as possible predictors 12 months before PFF. Age will be defined by the year of the fracture event and classified into five-year age groups. Region of residence will be denoted by the first two numbers of the postcode. Additionally, overall comorbidity-related disease burden will be assessed using the enhanced Charlson comorbidity index for ICD-10 codes (37, 38). In accordance with previous studies (39-42), the Charlson comorbidity index will be calculated using inpatient diagnoses 52 weeks before (<) the index week and outpatient diagnoses four quarters before (<) the index quarter. A score variable will sum up and categorise comorbidities from 0, 1, 2-3, 4-5, and 6+.

Questionnaire data

Demographic characteristics

The assessment of demographic characteristics comprises marital status, nationality, and country of birth.

Socio-economic status

The socio-economic status includes education and income. Education will be recorded based on the International Standard Classification of Education (ISCED). Education level is grouped into three categories ranging from low to high (43). Income will be determined by the equivalised disposable income. For this purpose, the net household income will be recorded by providing 15 categories of income, the household size, and the number of people living in the household including information regarding sex, age, and relationship to the participant (33). The number of children, professional position, indication of professional activity, and information on the current employment situation will also be assessed. Subjective social status will be rated using a 10 rung self-anchoring scale in the form of a ladder (44, 45).

Social support

Social support will be captured by using the Oslo Social Support Scale, which consists of three questions regarding close people to rely on; other people's concern and interest in the

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participant's life; and ease of obtaining help from neighbours (46). Answers will be scored from 1 to 4 or 5. The individual values will be added to a total score, which can have values between 3 and 14 with higher values indicating higher social support (47).

Lifestyle factors

Questions regarding lifestyle factors include: physical activity (33, 48); smoking status, and if applicable the amount of cigarettes, cigars, pipes, and cigarillos smoked per day (49, 50); alcohol consumption and binge drinking (33). Height and weight will be recorded as anthropometric measures.

Healthcare utilisation

Intake and use of medication will be recorded within five questions to assess healthcare utilisation beyond SHI data. Participants will be asked about their current intake of analgesics, use of over the counter medication, and the presence of a medication plan. Photographs will be taken of the plan or drug package(s) and a question asked about who is responsible for drug preparation. It will also be assessed if medications are administered long-term or prescribed as needed. Furthermore, the current pattern of use of remedies and medical aids and their possession before the fracture will be recorded using different pictures of remedies and medical aids (51).

Special health-related events

The assessment of special negative and positive health-related events as significant incidents comprises the previous six-month period and the last seven days. Participants will be asked if they experienced any positive or negative events and if so, which events can be named (52).

Table 1 provides an overview of all assessed parameters from SHI and questionnaire data.

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Category	Source of Data	Acquisition of	Instruments/Variables	12 Month before PFF	3 Month after PFF	6 Month after PFF	12 Month after PFF
Outcomes	Statutory Health Insurance Data (SHI data)	**Healthcare provision**			Continuous		
		Inpatient care	Number of hospital admissions, length of hospital stay, admission to a specialist department				
		Outpatient care	Physician contact per billing quarter (yes/no), number and kind of specialists involved				
		Rehabilitation	Number, duration and kind of inpatient/outpatient rehabilitation				
		Nursing services	Number, duration and kind of nursing services/institutional long-term care/short-term care				
		Prescribed medication	Number and kind of prescribed medication				
		Remedies and medical aids	Number and kind of remedies and medical aids				
		Costs	Inpatient costs, outpatient costs, rehabilitation costs, nursing services costs, medication costs, costs for remedies and medical aids, and costs for transportation				
		Clinical outcomes					
		Re-hospitalisation	Number of hospital admissions, length of hospital stay, admission to a specialist department		Continuous		
		Care dependency (including new occurrences)	Level of care				
		Admission to a nursing home	Type of service, date of admission				
		Mortality	Date of death				
	Questionnaire data	**Patient-reported outcomes**					
		Health-related quality of life	SF-12[1, 2, 3]		X	X	X
			EQ-5D[1, 2, 3]		X	X	X
		Functional ability	Oxford Hip Score[1, 3]		X	X	X
			Barthel Index[1, 3]		X	X	X
			Mobility Parker Score[1, 3]		X		
		Social participation	IMET [1, 2, 3]		X	X	X
		Pain	Numeric rating scale of the German Pain Society[1, 2]		X	X	X

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		Fear of falling and falls	Occurrence and frequency of fear of falling[1, 2], occurrence and frequency of fear-related avoidance of activities[1, 2], frequency of falls[1, 3]		X	X	X
Predictors	SHI data	**Demographic characteristics**	Age, sex, region of residence		X		
		Comorbidity	Number of prescribed medication	X			
			Number of inpatient stays				
			Level of care				
			Costs				
			Charlson comorbidity index				
	Questionnaire data	**Demographic characteristics**	Marital status[1, 3]		X		X
			Nationality[1, 3]		X		
			Country of birth[1, 3]		X		
		Socio-economic status	Level of education (ISCED) [1, 3]		X		
			Equivalised disposable income [1, 3]		X		X
			Subjective social status using MacArthur scale (German version) [1, 2, 3]		X		X
		Social support	Oslo Social Support Scale[1, 2, 3]		X		X
		Lifestyle factors	Physical activity, smoking status, alcohol consumption[1, 3]		X		X
			Height, weight (anthropometry) [1, 3]		X		X
		Health care utilisation	Intake and use of medication[1, 3], use of remedies and medical aids[1, 3]		X		X
		Special health-related events	Positive and negative health-related events[1, 3]		X		X

[1] = participant; [2] = participant who is only partially able to take part in the survey; [3] = proxy

Table 1 Overview of assessed parameters from SHI and questionnaire data

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Sample size

According to data from the year 2014 provided by the AOK Rheinland/Hamburg, at least 4,000 insured people aged 60 or over are expected to experience a PFF within 12 months. Of these, 700 randomly selected people will be consecutively invited to participate in the survey. The sample size should make it possible to show specific healthcare provision (rehabilitation, treatment, and medical care), and outcomes in relevant subgroups (age, sex, migration background, various social contexts). The data currently available from literature is insufficient for performing a detailed calculation of sample size. However, age and sex specific estimates are available for HRQoL (53), mortality (8), and rehabilitation (54). The precision of the estimates of these parameters has been examined a priori, assuming the expected 4,000 people with PFF and the random sample of n = 700 based on the age and sex distribution of the insured population of AOK Rheinland/Hamburg in 2014. The aim is to achieve a response of 80% of the target population. A dropout of 20% is expected after 12 months, including participants who die (approx. 20%) (8). This results in 448 (= 0.8*0.8*700) participants after 12 months. The precision of the estimators was evaluated by calculating the PCS and MCS for HRQoL based on the sample size stratified by age and sex. From the results presented in Table 2, it can be concluded that the sample size provides sufficient accuracy for estimating HRQoL. It will be possible to identify differences between men and women and age groups. If the observed response considerably differs from the expected response we will adjust the number of weekly contacted persons up to exhausting the whole SHI study population.

	N = 700*	**SD for PCS, MCS**	**Estimator PCS**	**95%-CI (PCS)**	**Estimator MCS**	**95%-CI (MCS)**
Age						
<80	163	10	41.6	(40.1-43.1)	41.7	(40.2-43.2)
>=80	285	10	35.3	(34.1-36.5)	38.8	(37.6-40.0)
Sex						
Men	126	10	41.2	(39.5-42.9)	41.0	(39.3-42.7)
Women	322	10	36.9	(35.8-38.0)	39.8	(38.7-40.9)

SD = standard deviation; PCS = physical component summary score; MCS = mental component summary score; CI = confidence interval; *n = 448 after 12 months

Table 2 Precision of the estimators of the physical and mental component summary score (SF-36)

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Planned statistical analysis

Depending on the research question, statistical analyses are carried out using either 1) SHI data or 2) SHI data and questionnaire data, which are combined to a linkage dataset. In general, the SHI population of all identified PFF patients and the survey sample will be described using baseline variables by prevalence (with 95% confidence interval (CI)), means, medians, standard deviations (SD) or percentiles depending on their distributions.

The variables of healthcare provision will be investigated using descriptive methods. Furthermore, healthcare provision will be evaluated by latent class analysis (LCA) and latent transition analysis (LTA). LCA is a modelling technique used to categorise participants into a number of unique (unobserved) classes. Participants are homogeneous with respect to their healthcare utilisation within each latent class and heterogeneous between classes. LCA typically uses cross-sectional data to identify subgroups at a single time point. LTA is an extension of LCA using longitudinal data where individuals transition between latent classes over time (55). Healthcare costs will be displayed in euro and categorised in approximately quintile classes. Calculations of total mean costs and mean costs per component and a 95% bootstrap CI will be performed.

Clinical outcomes will be analysed using Kaplan-Meier survival curves and Cox regression. Two analyses will be conducted regarding mortality, the first for the entire SHI study population, the second for the survey sample addressing the prognosis for people who have already survived at least three months. The mortality of the SHI study population will be compared to the German population ≥ 60 years. Age and sex-specific relative mortality rates will be calculated. Standardised mortality ratios (SMR) and comparative mortality figures (CMF) will be estimated together with 95% CI.

PROs will be studied using stratified descriptive analysis. Among others, outcomes related to PROs will be considered separately according to dementia status and state of health. Graphical or regression methods will be used to describe and exploratively estimate the association between paired self-reported and proxy values in the subpopulation of participants with dementia/reduced state of health.

Possible predictors to healthcare provision, clinical, and patient-reported outcomes will be investigated using mixed linear or logistic regression models, depending on the distribution of outcomes. Furthermore, two-part models (56-58) will be used to investigate associations within

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cost analysis. Repeated measurements per participant will be adjusted by random effects in the mixed models.

At least one binary indicator for 'severe cases' will be derived from the outcomes. Different competing definitions for 'severe cases' could be combined in order to choose the final indicator. Furthermore, a latent class or latent transition analysis including different variables might be considered. An algorithm will be derived from one half of the study population based on the binary case indicator using logistic regression models with independent variables selected from the baseline variables to classify the risk of a 'severe case' after PFF. A final selection of variables for the algorithm will be made using goodness of fit criteria and stepwise, forward, and backward selection procedures. A score will be derived via the final model and tested with the other half of the study population (randomly chosen).

Furthermore, a non-responder analysis will be performed based on individual SHI data, available for responders and non-responders. Descriptive statistics and corresponding statistical tests will be used to describe response at all observation intervals. Logistic regression analysis with subsequent multiple adjustment will be used to obtain (adjusted) odds ratios for belonging to the response group.

The study and the data linkage will be performed in line with Good Epidemiological Practice (GEP) (59), Good Practice of Secondary Data Analysis (GPS) (60), and in accordance with the REporting of studies Conducted Using Observational Routinely-Collected Health Data (RECORD) Statement (61), and the Standard for Secondary Data Analyses (62). The data linkage of questionnaire and SHI data will be performed on an individual level using suitable key variables.

Discussion and practical implications

The results of the study may contribute to improving older people's health-related quality of life, functional ability, and social participation as well as to the reduction of costs associated with the avoidable need of care, and hospitalisation after PFF.

Conclusion

To our knowledge this is the first study to investigate questions regarding healthcare provision, health-related quality of life, functional ability, and social participation after PFF. The strength of our study is the linkage of SHI and questionnaire data as well as the consideration of important vulnerable subgroups, such as people with dementia.

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Ethics and dissemination

The study was approved by the responsible ethics committee of the Faculty of Medicine, Heinrich-Heine-University Düsseldorf (approval reference 6128R). All participants will provide written and informed consent and can withdraw from the study at any time. All procedures performed will be in accordance with the Declaration of Helsinki and comparable ethical standards (e.g., GEP and GPS). The data protection agreement applied for this study does not cover posting data in public databases. Data will be held at the IVG and mediStatistica. The development of this study protocol was guided by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement and the SPIRIT-PRO Extension, where applicable (63-65). The results of the project will help to identify possible shortcomings in the care of older people with PFF and detect people with special needs of care. The findings of the study will be disseminated through scientific journals and public information.

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Authors contributions

SA, MR, and AI drafted the manuscript. SA, MR, GM, FH, AS, MB, JB, KJ, AF, BH, VG, WA, LT, DC, RH, ST, PF, CGGS, JW, CJR participated in the design and preparation of the study. BH and VG provided statistical analysis support. GM, FH, AS, MB, JB, KJ, AF, BH, VG, WA, LT, DC, RH, ST, PF, CGGS, JW, CJR critically revised the manuscript's drafts. All authors approved the final version of the manuscript.

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Competing interests statement

The authors declare that they have no competing interests.

Data sharing statement

Data are subject to national data protection laws and later on only available upon formal request.

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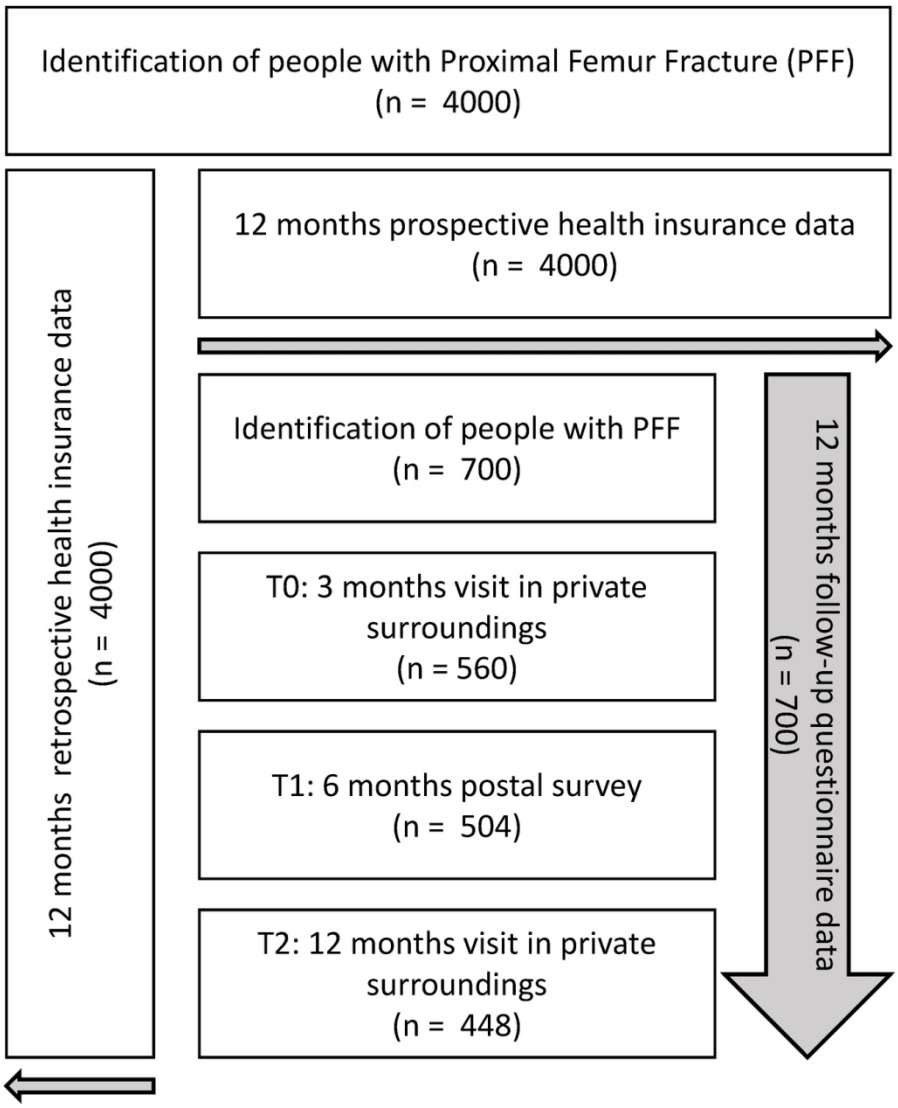

Figure 1 Study design

127x147mm (300 x 300 DPI)

Appendix A

OPS-Codes for:

- closed reduction and osteosynthesis with intramedullary nail, plate or dynamic hip screw:
  5-790.0e, 5-790.3e, 5-790.3f, 5-790.4e, 5-790.4f, 5-790.5e, 5-790.5f, 5-790.7e, 5-790.7f, 5-790.8e, 5-790.8f
- open reduction of a simple fracture on the proximal femur and osteosynthesis with intramedullary nail, plate or dynamic hip screw:
  5-793.2e, 5-793.2f, 5-793.4e, 5-793.4f, 5-793.5e, 5-793.5f, 5-793.ae, 5-793.af, 5-793.be, 5-793.bf
- open reduction of a multifragmentary fracture on the proximal femur and osteosynthesis with intramedullary nail, plate or dynamic hip screw:
  5-794.1e, 5-794.1f, 5-794.3f, 5-794.3e, 5-794.4f, 5-794.4e, 5-794.ae, 5-794.af, 5-794.be, 5-794.bf and,
- implantation of hip endoprosthesis:
  5-820

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Appendix B

Inclusion and exclusion criteria of the study population

Inclusion criteria:

- 60 years or older
- Resident in North Rhine-Westphalia
- Continuously insured with the AOK Rheinland/Hamburg at least 12 months prior to PFF
- PFF identified using ICD-10 codes S72.0, S72.1 and S72.2, and OPS-Codes (for OPS-Codes see Appendix A)

Exclusion criteria:

- Lack of German language skills
- People with e.g. dementia or reduced state of health who are no longer able to personally participate in the interview and for whom no eligible caregiving relative (person of trust) or legal guardian can be found to perform a proxy interview

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STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6-7, 27-28
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	no
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-14
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-14
Bias	9	Describe any efforts to address potential sources of bias	15-17
Study size	10	Explain how the study size was arrived at	15
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	16-17
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	16-17
		(*b*) Describe any methods used to examine subgroups and interactions	16-17
		(*c*) Explain how missing data were addressed	No
		(*d*) If applicable, explain how loss to follow-up was addressed	No
		(*e*) Describe any sensitivity analyses	No
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7, 15, Study Design Mono-Image
		(b) Give reasons for non-participation at each stage	No
		(c) Consider use of a flow diagram	7, Study Design Mono-Image

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Descriptive data		14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	No
			(b) Indicate number of participants with missing data for each variable of interest	No
			(c) Summarise follow-up time (eg, average and total amount)	No
Outcome data		15*	Report numbers of outcome events or summary measures over time	No
Main results	16		(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	No
			(*b*) Report category boundaries when continuous variables were categorized	No
			(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	No
Other analyses	17		Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No
Discussion				
Key results	18		Summarise key results with reference to study objectives	No
Limitations	19		Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No
Interpretation	20		Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	No
Generalisability	21		Discuss the generalisability (external validity) of the study results	No
Other information				
Funding	22		Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	26

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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BMJ Open

Healthcare provision, functional ability and quality of life after proximal femoral fracture - 'ProFem': Study protocol of a population-based, prospective study based on individually linked survey and statutory health insurance data

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Study protocol

Healthcare provision, functional ability and quality of life after proximal femoral fracture - 'ProFem': Study protocol of a population-based, prospective study based on individually linked survey and statutory health insurance data

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Abstract

Introduction: Proximal femoral fractures (PFF) are among the most frequent fractures in older people. However, the situation of people with a PFF after hospital discharge is poorly understood. Our aim is to (1) analyse healthcare provision, (2) examine clinical and patient-reported outcomes (PROs), (3) describe clinical and sociodemographic predictors of these, and (4) develop an algorithm to identify subgroups with poor outcomes and a potential need for more intensive healthcare.

Methods and analysis: This is a population-based prospective study based on individually linked survey and statutory health insurance (SHI) data. All people aged minimum 60 who have been continuously insured with the AOK Rheinland/Hamburg and experience a PFF within one year will be consecutively included (SHI data analysis). Additionally, seven hundred people selected randomly from the study population will be consecutively invited to participate in the survey. Questionnaire data will be collected in the participants' private surroundings at three, six, and 12 months after hospital discharge. If the insured person considers themselves to be only partially or not at all able to take part in the survey, a proxy person will be interviewed where possible. SHI variables include healthcare provision, healthcare costs, and clinical outcomes. Questionnaire variables include information on PROs, lifestyle characteristics, and socio-economic status. We will use multiple regression models to estimate healthcare processes and outcomes including mortality and cost, investigate predictors, perform non-responder analysis, and develop an algorithm to identify vulnerable subgroups.

Ethics and dissemination: The study was approved by the ethics committee of the Faculty of Medicine, Heinrich-Heine-University Düsseldorf (approval reference 6128R). All participants including proxies providing written and informed consent can withdraw from the study at any time. The study findings will be disseminated through scientific journals and public information.

Registration details: The study has been registered with the German Clinical Trials Register (DRKS; DRKS00012554).

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Strengths and limitations of this study

- To the best of our knowledge, this is the first study to conduct an individual data linkage between statutory health insurance (SHI) data and questionnaire data in the field of research on proximal femoral fractures (PFF).
- Individually linked survey and SHI data is used to answer a variety of health service research, clinical, and patient-orientated questions in people with PFF.
- Vulnerable subgroups, such as people with dementia, are included in our study.
- Due to structural differences between populations insured with various SHI funds and regions, the generalisability of our findings might be limited.

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Introduction

Proximal femoral fractures (PFF) are among the most frequent fractures in older people (1, 2). However, knowledge about the situation of those affected by a PFF is scarce (3-5). Studies indicate poor outcomes following a PFF: 50% of those affected retained functional limitations (6), 15% were newly admitted to a nursing home (7), and around 20% died within one year (8). Although post-operative programmes showed positive effects (6-11), more than 60% of patients received no further treatment (6), suggesting shortcomings in the care provided. Specific aspects of healthcare provision, such as treatment in geriatric trauma centres or rehabilitation, have hardly been investigated. Existing international studies suggest a healthcare gap (6, 12). It is currently unclear as to which patients particularly benefit from specific care models (13). In addition to healthcare processes, patient-reported outcomes (PROs) such as health-related quality of life (HRQoL), functional ability, and social participation in older people following PFF have hardly been investigated. Subgroups characterised by particularly poor clinical and patient-reported outcomes, and by a potential need of more intensive care, have not yet been identified.

Therefore, the aims of this study are (1) to analyse healthcare provision after PFF, (2) to examine clinical outcomes (such as re-hospitalisation, occurrence of need for care, nursing home admission, death) and PROs (such as HRQoL, functional ability, social participation) after PFF, and (3) to describe clinical and sociodemographic predictors of these (such as comorbidity, age, sex, social support). In doing so, (4) the aim is to identify subgroups who have poor outcomes (e. g. people living at home with low social support, comorbidity, and high healthcare utilisation) and are potentially in need of more intensive healthcare. This will be done by developing an algorithm which generates a 'case finding' to detect those groups of people.

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Methods and analysis

Study design and population

This is a population-based prospective study based on statutory health insurance (SHI) data and questionnaire data collected from people insured with the AOK Rheinland/Hamburg. Overall, the AOK Rheinland/Hamburg covers more than 2.5 million insured people in North Rhine-Westphalia (NRW), which has the highest population of all German Federal States, with approximately 25% aged 60 or older. All people resident in NRW aged 60 or over and who have been continuously insured with the AOK Rheinland/Hamburg for at least 12 months prior to PFF and experience a PFF between January 2018 and January 2019 will be consecutively included in the study. People with PFF will be identified consecutively over one year along with their exact date of hospital discharge using SHI diagnoses (main or secondary diagnosis) and operational procedure keys. A fracture event is defined according to the 10th revision of the International Classification of Diseases (ICD-10) codes S72.0 (fracture of head and neck of femur), S72.1 (pertrochanteric femoral fracture), and S72.2 (subtrochanteric femoral fracture), and selected surgical, and procedural keys (OPS-Codes, see Appendix A).

This study comprises two populations: all identified people as described above belong to the 1) study population based on SHI data. For those, a comprehensive analysis of SHI data covering 12 months before and 12 months after the fracture event will be performed. Furthermore, a 2) random sample – drawn from the overall SHI study population – will be consecutively invited to additionally participate in a survey. An algorithm will be applied weekly to ensure a random selection of the survey sample. Questionnaire data collection is planned at three and 12 months after hospital discharge using Pen-and-Paper Personal Interviews (PAPI) with participants in a private surrounding, and at six months after discharge by means of a postal survey. Sufficient German language skills are a prerequisite for participation in the survey (Appendix B). If the insured person considers themselves to be only partially or not at all able to take part in the survey, e.g. due to dementia or reduced state of health, an attempt will be made to conduct the interview with a caregiving relative (person of trust) or a legal guardian either additionally or on behalf of the insured person. The following criteria will be used to identify an eligible proxy: they must know the insured person well, should visit the insured person twice a week on average, and support them in everyday life. The participation of the proxy is always voluntary. If a person is too ill to be interviewed at baseline but willing to stay in the study, we will try to arrange an interview at the next time interval. People no longer able to take part in the interviews

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themselves and with no eligible caregiving relative or legal guardian to perform a proxy interview with will be excluded (Appendix B).

Figure 1 displays the flow through the study. The sample size calculation will be described further below.

Figure 1 Study design

Recruitment

First contact to arrange an appointment for the visit in the private surrounding will be made by postal letter. The letter contains a cover letter, information on the study and on data protection, and the consent form for participation for prior information. The letter will also ask the insured person (or their proxy) to contact the study centre to arrange an appointment. A written reminder will be sent to non-responders after approximately two weeks, followed by telephone contact as a next step. Where no telephone number is available, a second reminder will be sent. Response will be monitored consecutively and proportions will be calculated to describe participation behaviour (14, 15).

Data Collection - Data Sources and Variables

Data will be collected from the sources outlined above. SHI data collected from consenting individuals 12 months before and 12 months after the event will be individually linked to questionnaire data. The SHI data will be used to measure healthcare provision and clinical outcomes in the 12 months after PFF. Healthcare provision is described for various healthcare areas: inpatient and outpatient care, rehabilitation, nursing services, prescribed medication, remedies and medical aids as well as costs for the different healthcare areas, transportation, and costs in total. Clinical outcomes are re-hospitalisation, care dependency (including new occurrences), admission to a nursing home, and mortality. SHI data collected 12 months after PFF and 12 months before PFF will also be evaluated regarding predictors such as demographic characteristics and comorbidity. The questionnaire data will be used to record PROs, which focus on HRQoL, functional ability, social participation, pain, and fear of falling. Self-reported predictors include demographic characteristics as well as socio-economic status, social support, lifestyle, healthcare utilisation, and special health-related events. Questions on PROs should be answered by the insured person whenever possible. If the insured person is not able to respond to an abridged version of the questionnaire comprising the questions on the aforementioned PROs, the proxy will be asked to respond to the entire questionnaire except the questions on pain and fear of falling (please see Table 1). Interviews will be conducted by trained

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interviewers. An interviewer manual and standard operating procedures will be provided for quality assurance purposes and to ensure a standardised approach.

Outcomes

The following variables will be recorded for the aforementioned purpose:

SHI data

Healthcare provision

Healthcare provision will be evaluated using the following variables: number of hospital admissions after PFF; length of hospital stay (LOS) for each hospital admission; admission to a specialist department; physician contact per billing quarter; number and kind of different specialists involved; number, duration and kind of inpatient and/or outpatient rehabilitation; number, duration and kind of nursing services; institutional long-term care or short-term care; number and kind of prescribed medications; and number and kind of remedies and medical aids. Furthermore, healthcare costs will include: inpatient costs; outpatient costs; rehabilitation costs; nursing services costs; medication costs; costs for remedies and medical aids; and costs for transportation. Healthcare costs will be shown in euro. Since outpatient data is only provided in quarters, these cost values will be equally distributed over the time span (e.g. in weeks).

Clinical Outcomes

Re-hospitalisation is addressed by the variables already named above (number of hospital admissions after PFF, LOS for each hospital admission, and admission to a specialist department). Care dependency (including new occurrences) is defined by a classification system for a person's impairment of autonomy and displayed in five care degrees according to the German Nursing Care Act. The five care degrees are depending on the amount of care needed and with a range from the level of care 1 (minor impairment of the person's autonomy) up to level 5 (heaviest impairment with special demands on nursing care) (16). The maximum level of care in the period before the PFF hospital stay will be considered. Admission to a nursing home is assessed by the type of service, including e.g. provision of short-term or long-term care along with the exact date. The date of death of people with PFF who died during the observation period will be recorded to assess mortality.

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Questionnaire data

Patient-reported outcomes (PROs)

Health-related quality of life

Overall HRQoL will be measured using the 12-Item Short Form Health Survey (SF-12) covering the previous four weeks of a person's life (17). The SF-12 is the shorter version of the Short Form-36 Health Survey (SF-36) and contains one or two items for the following eight health dimensions: physical functioning; role functioning; bodily pain; general health perception; energy/vitality; social functioning; emotional functioning; and mental health. The SF-12 comprises two summary scores – a physical component summary score (PCS) and a mental component summary score (MCS). In the SF-12, a better health-related quality of life is denoted by higher values. The SF-12 is one of the best-known and most frequently used instruments to assess HRQoL and its measurement performance has been tested (18).

The European Quality of Life 5-Dimensions questionnaire (EQ-5D) is a generic preference-based measure of health status and consists of two parts – a questionnaire and a visual analogue scale (EQ-VAS) (19, 20). The questionnaire contains five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a 5-level (5L) scale. The result of the questionnaire can be summarised as perceived state of health (from best to worst state where "11111" is the best and "55555" the worst state). The EQ-VAS is a scale for rating health between 100 (best imaginable state of health) and zero (worst imaginable state of health), expressing health on the day of completion. The EQ-5D is a well-accepted and frequently used instrument with good psychometric properties (21).

Functional ability

Functional ability will be measured using three instruments.

The Oxford Hip Score (OHS) is a hip-specific 12-item questionnaire to assess activities of daily living (ADL) with six questions relating to pain (type and the resulting impairments in mobility) and six questions relating to functional ability (self-care, mobility, and independence), each referring to the last four weeks (22, 23). Answers to the questions are categorised in five dimensions, ranging from 0 (worst outcome) to 4 (best outcome). The sum of all values provides an overall score between 0 and 48. A high overall score indicates a better outcome with 48 being the best outcome. The reliability and validity of the OHS has been assessed in a German population with osteoarthritis of the hip (24).

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The Heuschmann et al. (2005) (25) version of the Barthel Index (BI), a common measure of ADL, provides an interview and a paper and pencil form. The BI comprises ten domains which are divided into self-care and mobility. Self-care includes feeding, bathing, grooming, dressing, toilet use, and bowel and bladder control. Mobility consists of transfer, mobility, and stairs. The interview version comprises 17 questions. The postal survey includes ten questions – one for each domain. The person's overall ADL score is classified according to an ordinal scale where 0 is the lowest score and 20 indicates complete independence. Comprehensibility and reliability of both questionnaires were tested in stroke patients (25).

Pre-fracture functional level will be assessed using the Mobility Parker Score (MPS) (26), which evaluates a person's ability to get about the house, out of the house, and to go shopping. Each item is rated from 0 ('no difficulty') to 3 ('not at all'). The answers result in a total score ranging from 'no walking ability at all' to 'total independence' (0-9).

Social Participation

The Index for Measuring Participation Restrictions (IMET) measures the restriction of participation of people with different chronic diseases (27, 28). Based on the dimensions of the International Classification of Functioning, Disability and Health (ICF), this tool covers nine aspects of everyday activities and participation. This includes self-care, daily duties, and responsibilities at and outside home, recreation, social activities, personal relations, sex, and stress and extraordinary strains. The impairment caused by a disease is evaluated for each item by means of an 11-level scale (0 - 10). Lower IMET values suggest better social participation. A summary score can be calculated. The psychometric properties have been tested for different patient groups (28).

Pain

Pain will be recorded as follows: the current level of pain, the average level of pain during the last four weeks and the highest level of pain during the last four weeks will be rated on a numerical rating scale (1 - 5) (29).

Fear of falling and falls

The assessment of fear of falling (30) includes a question about occurrence and frequency of fear (31), and a question about the occurrence and frequency of activities avoided due to fear of falling (31). The number and frequency of falls are recorded over the 12 months prior to the

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fracture as well as the period after the fracture (32, 33). A single question is used to determine whether it is the first fracture.

Overall, we considered the recent recommendations regarding core outcomes and appropriate instruments to be used in trials with older people with hip fractures (34, 35, 36). We selected instruments that are suitable for personal interviews, postal survey, and proxy assessments. We decided for the SF-12 instead of the SF-36 to reduce the length of the questionnaire (34).

Predictors

SHI data

Demographic characteristics and comorbidity

Age, sex, and region of residence will be considered. Comorbidity, number of prescribed medications, number of inpatient stays in hospital, level of care, and healthcare costs for the year prior to the fracture will be considered as possible predictors 12 months before PFF. Age will be defined by the year of the fracture event and classified into five-year age groups. Region of residence will be denoted by the first two numbers of the postcode. Additionally, overall comorbidity-related disease burden will be assessed using the enhanced Charlson comorbidity index for ICD-10 codes (37, 38). In accordance with previous studies (39-42), the Charlson comorbidity index will be calculated using inpatient diagnoses 52 weeks before (<) the index week and outpatient diagnoses four quarters before (<) the index quarter. A score variable will sum up and categorise comorbidities from 0, 1, 2-3, 4-5, and 6+.

Questionnaire data

Demographic characteristics

The assessment of demographic characteristics comprises marital status, nationality, and country of birth.

Socio-economic status

The socio-economic status includes education and income. Education will be recorded based on the International Standard Classification of Education (ISCED). Education level is grouped into three categories ranging from low to high (43). Income will be determined by the equivalised disposable income. For this purpose, the net household income will be recorded by providing 15 categories of income, the household size, and the number of people living in the household including information regarding sex, age, and relationship to the participant (33).

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The number of children, professional position, indication of professional activity, and information on the current employment situation will also be assessed. Subjective social status will be rated using a 10 rung self-anchoring scale in the form of a ladder (44, 45).

Social support

Social support will be captured by using the Oslo Social Support Scale, which consists of three questions regarding close people to rely on; other people's concern and interest in the participant's life; and ease of obtaining help from neighbours (46). Answers will be scored from 1 to 4 or 5. The individual values will be added to a total score, which can have values between 3 and 14 with higher values indicating higher social support (47).

Lifestyle factors

Questions regarding lifestyle factors include: physical activity (33, 48); smoking status, and if applicable the amount of cigarettes, cigars, pipes, and cigarillos smoked per day (49, 50); alcohol consumption and binge drinking (33). Height and weight will be recorded as anthropometric measures.

Healthcare utilisation

Intake and use of medication will be recorded within five questions to assess healthcare utilisation beyond SHI data. Participants will be asked about their current intake of analgesics, use of over the counter medication, and the presence of a medication plan. Photographs will be taken of the plan or drug package(s) and a question asked about who is responsible for drug preparation. It will also be assessed if medications are administered long-term or prescribed as needed. Furthermore, the current pattern of use of remedies and medical aids and their possession before the fracture will be recorded using different pictures of remedies and medical aids (51).

Special health-related events

The assessment of special negative and positive health-related events as significant incidents comprises the previous six-month period and the last seven days. Participants will be asked if they experienced any positive or negative events and if so, which events can be named (52).

Table 1 provides an overview of all assessed parameters from SHI and questionnaire data.

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Category	Source of Data	Acquisition of	Instruments/Variables	12 Month before PFF	3 Month after PFF	6 Month after PFF	12 Month after PFF
Outcomes	Statutory Health Insurance Data (SHI data)	**Healthcare provision**			Continuous		
		Inpatient care	Number of hospital admissions, length of hospital stay, admission to a specialist department				
		Outpatient care	Physician contact per billing quarter (yes/no), number and kind of specialists involved				
		Rehabilitation	Number, duration and kind of inpatient/outpatient rehabilitation				
		Nursing services	Number, duration and kind of nursing services/institutional long-term care/short-term care				
		Prescribed medication	Number and kind of prescribed medication				
		Remedies and medical aids	Number and kind of remedies and medical aids				
		Costs	Inpatient costs, outpatient costs, rehabilitation costs, nursing services costs, medication costs, costs for remedies and medical aids, and costs for transportation				
		Clinical outcomes					
		Re-hospitalisation	Number of hospital admissions, length of hospital stay, admission to a specialist department		Continuous		
		Care dependency (including new occurrences)	Level of care				
		Admission to a nursing home	Type of service, date of admission				
		Mortality	Date of death				
	Questionnaire data	**Patient-reported outcomes**					
		Health-related quality of life	SF-12[1, 2, 3]		X	X	X
			EQ-5D[1, 2, 3]		X	X	X
		Functional ability	Oxford Hip Score[1, 3]		X	X	X
			Barthel Index[1, 3]		X	X	X
			Mobility Parker Score[1, 3]		X		
		Social participation	IMET [1, 2, 3]		X	X	X
		Pain	Numeric rating scale of the German Pain Society[1, 2]		X	X	X

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		Fear of falling and falls	Occurrence and frequency of fear of falling[1, 2], occurrence and frequency of fear-related avoidance of activities[1, 2], frequency of falls[1, 3]		X	X	X
Predictors	SHI data	**Demographic characteristics**	Age, sex, region of residence		X		
		Comorbidity	Number of prescribed medication	X			
			Number of inpatient stays				
			Level of care				
			Costs				
			Charlson comorbidity index				
	Questionnaire data	**Demographic characteristics**	Marital status[1, 3]		X		X
			Nationality[1, 3]		X		
			Country of birth[1, 3]		X		
		Socio-economic status	Level of education (ISCED) [1, 3]		X		
			Equivalised disposable income [1, 3]		X		X
			Subjective social status using MacArthur scale (German version) [1, 2, 3]		X		X
		Social support	Oslo Social Support Scale[1, 2, 3]		X		X
		Lifestyle factors	Physical activity, smoking status, alcohol consumption[1, 3]		X		X
			Height, weight (anthropometry) [1, 3]		X		X
		Health care utilisation	Intake and use of medication[1, 3], use of remedies and medical aids[1, 3]		X		X
		Special health-related events	Positive and negative health-related events[1, 3]		X		X

[1] = participant; [2] = participant who is only partially able to take part in the survey; [3] = proxy

Table 1 Overview of assessed parameters from SHI and questionnaire data

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Patient and Public involvement

Patients were not involved in the definition of the research questions and modelling of the design and outcome measures. They were also not engaged in the recruitment and conduct of the study. Our aim is to include patients in the interpretation of the study results if possible. Public involvement is achieved through the active role of the AOK Rheinland/Hamburg, a statutory health insurance company that represents the interests of its members. The results of the study will be disseminated to the study participants through public information such as the customer magazine *AOK Vigo*.

Sample size

According to data from the year 2014 provided by the AOK Rheinland/Hamburg, at least 4,000 insured people aged 60 or over are expected to experience a PFF within 12 months. Of these, 700 randomly selected people will be consecutively invited to participate in the survey. The sample size should make it possible to show specific healthcare provision (rehabilitation, treatment, and medical care), and outcomes in relevant subgroups (age, sex, migration background, various social contexts). The data currently available from literature is insufficient for performing a detailed calculation of sample size. However, age and sex specific estimates are available for HRQoL (53), mortality (8), and rehabilitation (54). The precision of the estimates of these parameters has been examined a priori, assuming the expected 4,000 people with PFF and the random sample of n = 700 based on the age and sex distribution of the insured population of AOK Rheinland/Hamburg in 2014. The aim is to achieve a response of 80% of the target population. A dropout of 20% is expected after 12 months, including participants who die (approx. 20%) (8). This results in 448 (= 0.8*0.8*700) participants after 12 months. The precision of the estimators was evaluated by calculating the PCS and MCS for HRQoL based on the sample size stratified by age and sex. From the results presented in Table 2, it can be concluded that the sample size provides sufficient accuracy for estimating HRQoL. It will be possible to identify differences between men and women and age groups. If the observed response considerably differs from the expected response we will adjust the number of weekly contacted persons up to exhausting the whole SHI study population.

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	N = 700*	SD for PCS, MCS	Estimator PCS	95%-CI (PCS)	Estimator MCS	95%-CI (MCS)
Age						
<80	163	10	41.6	(40.1-43.1)	41.7	(40.2-43.2)
>=80	285	10	35.3	(34.1-36.5)	38.8	(37.6-40.0)
Sex						
Men	126	10	41.2	(39.5-42.9)	41.0	(39.3-42.7)
Women	322	10	36.9	(35.8-38.0)	39.8	(38.7-40.9)

SD = standard deviation; PCS = physical component summary score; MCS = mental component summary score; CI = confidence interval; *n = 448 after 12 months

Table 2 Precision of the estimators of the physical and mental component summary score (SF-36)

Planned statistical analysis

Depending on the research question, statistical analyses are carried out using either 1) SHI data or 2) SHI data and questionnaire data, which are combined to a linkage dataset. In general, the SHI population of all identified PFF patients and the survey sample will be described using baseline variables by prevalence (with 95% confidence interval (CI)), means, medians, standard deviations (SD) or percentiles depending on their distributions.

The variables of healthcare provision will be investigated using descriptive methods. Furthermore, healthcare provision will be evaluated by latent class analysis (LCA) and latent transition analysis (LTA). LCA is a modelling technique used to categorise participants into a number of unique (unobserved) classes. Participants are homogeneous with respect to their healthcare utilisation within each latent class and heterogeneous between classes. LCA typically uses cross-sectional data to identify subgroups at a single time point. LTA is an extension of LCA using longitudinal data where individuals transition between latent classes over time (55). Healthcare costs will be displayed in euro and categorised in approximately quintile classes. Calculations of total mean costs and mean costs per component and a 95% bootstrap CI will be performed.

Clinical outcomes will be analysed using Kaplan-Meier survival curves and Cox regression. Two analyses will be conducted regarding mortality, the first for the entire SHI study population, the second for the survey sample addressing the prognosis for people who have already survived at least three months. The mortality of the SHI study population will be

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compared to the German population ≥ 60 years. Age and sex-specific relative mortality rates will be calculated. Standardised mortality ratios (SMR) and comparative mortality figures (CMF) will be estimated together with 95% CI.

PROs will be studied using stratified descriptive analysis. Among others, outcomes related to PROs will be considered separately according to dementia status and state of health. Graphical or regression methods will be used to describe and exploratively estimate the association between paired self-reported and proxy values in the subpopulation of participants with dementia/reduced state of health at fixed time points. It will be discussed, whether imputation of transformed proxy values in missing outcome values should be done. Further subpopulations will be considered for sensitivity analyses: participants without dementia / reduced state of health, participants with dementia / reduced state of health only with self-reported values resp. only with proxy values. Furthermore, participants changing between self-reported and proxy values during follow up will be described separately. Depending on frequencies and results, specific imputation methods for self-reported values will be discussed.

Possible predictors to healthcare provision, clinical, and patient-reported outcomes will be investigated using mixed linear or logistic regression models, depending on the distribution of outcomes. Furthermore, two-part models (56-58) will be used to investigate associations within cost analysis. Repeated measurements per participant will be adjusted by random effects in the mixed models.

At least one binary indicator for ‘severe cases’ will be derived from the outcomes. Different competing definitions for ‘severe cases’ could be combined in order to choose the final indicator. Furthermore, a latent class or latent transition analysis including different variables might be considered. An algorithm will be derived from one half of the study population based on the binary case indicator using logistic regression models with independent variables selected from the baseline variables to classify the risk of a ‘severe case’ after PFF. A final selection of variables for the algorithm will be made using goodness of fit criteria and stepwise, forward, and backward selection procedures. A score will be derived via the final model and tested with the other half of the study population (randomly chosen).

Furthermore, a non-responder analysis will be performed based on individual SHI data, available for responders and non-responders. Descriptive statistics and corresponding statistical tests will be used to describe response at all observation intervals. Logistic regression analysis

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with subsequent multiple adjustment will be used to obtain (adjusted) odds ratios for belonging to the response group.

The study and the data linkage will be performed in line with Good Epidemiological Practice (GEP) (59), Good Practice of Secondary Data Analysis (GPS) (60), and in accordance with the REporting of studies Conducted Using Observational Routinely-Collected Health Data (RECORD) Statement (61), and the Standard for Secondary Data Analyses (62). The data linkage of questionnaire and SHI data will be performed on an individual level using suitable key variables.

Discussion and practical implications

The results of the study may contribute to improving older people's health-related quality of life, functional ability, and social participation as well as to the reduction of costs associated with the avoidable need of care, and hospitalisation after PFF.

Conclusion

To our knowledge this is the first study to investigate questions regarding healthcare provision, health-related quality of life, functional ability, and social participation after PFF. The strength of our study is the linkage of SHI and questionnaire data as well as the consideration of important vulnerable subgroups, such as people with dementia.

Ethics and dissemination

The study was approved by the responsible ethics committee of the Faculty of Medicine, Heinrich-Heine-University Düsseldorf (approval reference 6128R). All participants will provide written and informed consent and can withdraw from the study at any time. All procedures performed will be in accordance with the Declaration of Helsinki and comparable ethical standards (e.g., GEP and GPS). The data protection agreement applied for this study does not cover posting data in public databases. Data will be held at the IVG and mediStatistica. The development of this study protocol was guided by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement and the SPIRIT-PRO Extension, where applicable (63-65). The results of the project will help to identify possible shortcomings in the care of older people with PFF and detect people with special needs of care. The findings of the study will be disseminated through scientific journals and public information.

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Authors contributions

SA, MR, and AI drafted the manuscript. SA, MR, GM, FH, AS, MB, JB, KJ, AF, BH, VG, WA, LT, DC, RH, ST, PF, CGGS, JW, CJR participated in the design and preparation of the study. BH and VG provided statistical analysis support. GM, FH, AS, MB, JB, KJ, AF, BH, VG, WA, LT, DC, RH, ST, PF, CGGS, JW, CJR critically revised the manuscript's drafts. All authors approved the final version of the manuscript.

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Competing interests statement

The authors declare that they have no competing interests.

Data sharing statement

Data are subject to national data protection laws and later on only available upon formal request.

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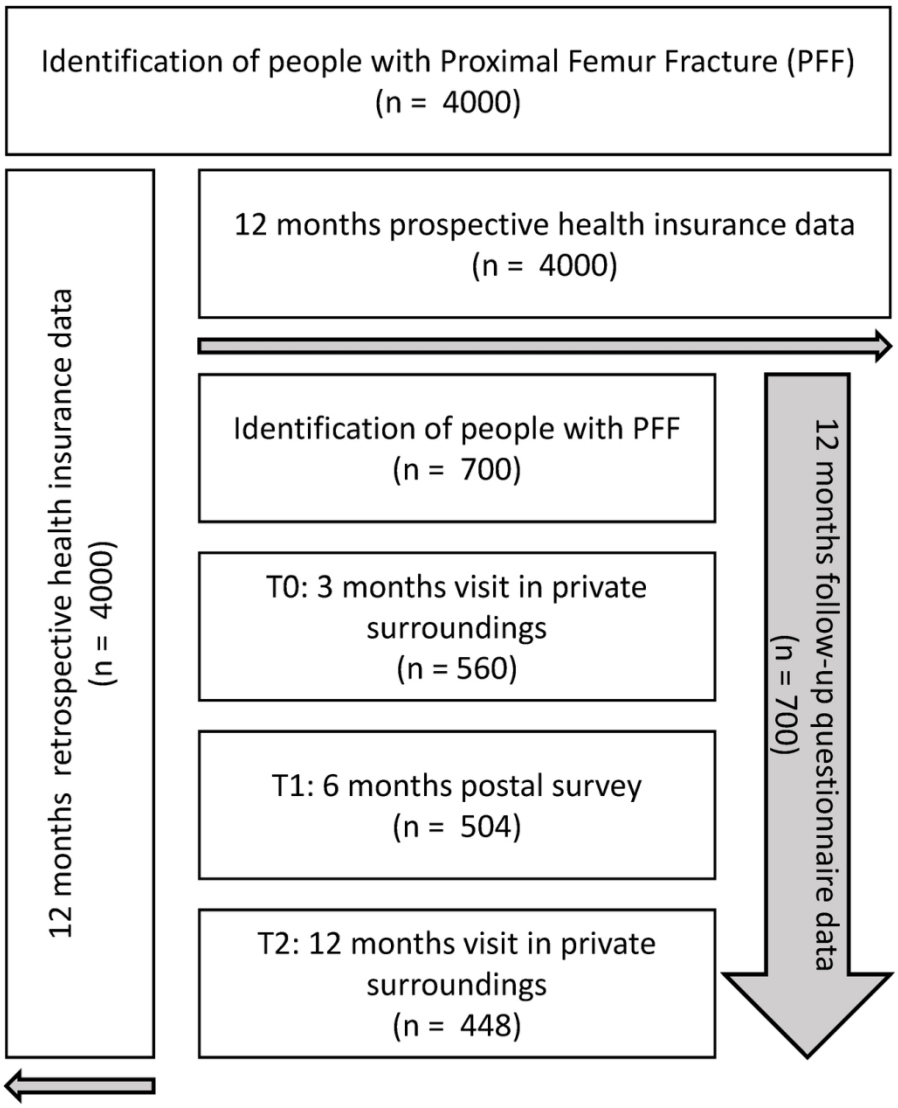

Figure 1 Study design

127x147mm (300 x 300 DPI)

Appendix A

OPS-Codes for:

- closed reduction and osteosynthesis with intramedullary nail, plate or dynamic hip screw:
  5-790.0e, 5-790.3e, 5-790.3f, 5-790.4e, 5-790.4f, 5-790.5e, 5-790.5f, 5-790.7e, 5-790.7f, 5-790.8e, 5-790.8f
- open reduction of a simple fracture on the proximal femur and osteosynthesis with intramedullary nail, plate or dynamic hip screw:
  5-793.2e, 5-793.2f, 5-793.4e, 5-793.4f, 5-793.5e, 5-793.5f, 5-793.ae, 5-793.af, 5-793.be, 5-793.bf
- open reduction of a multifragmentary fracture on the proximal femur and osteosynthesis with intramedullary nail, plate or dynamic hip screw:
  5-794.1e, 5-794.1f, 5-794.3f, 5-794.3e, 5-794.4f, 5-794.4e, 5-794.ae, 5-794.af, 5-794.be, 5-794.bf and,
- implantation of hip endoprosthesis:
  5-820

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Appendix B

Inclusion and exclusion criteria of the study population

Inclusion criteria:

- 60 years or older
- Resident in North Rhine-Westphalia
- Continuously insured with the AOK Rheinland/Hamburg at least 12 months prior to PFF
- Surgically treated PFF identified using ICD-10 codes S72.0, S72.1 and S72.2, and OPS-Codes (for OPS-Codes see Appendix A)

Exclusion criteria:

- Lack of German language skills
- People with e.g. dementia or reduced state of health who are no longer able to personally participate in the interview and for whom no eligible caregiving relative (person of trust) or legal guardian can be found to perform a proxy interview

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STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6-7, 27-28
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	no
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-14
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-14
Bias	9	Describe any efforts to address potential sources of bias	15-17
Study size	10	Explain how the study size was arrived at	15
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	16-17
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	16-17
		(*b*) Describe any methods used to examine subgroups and interactions	16-17
		(*c*) Explain how missing data were addressed	No
		(*d*) If applicable, explain how loss to follow-up was addressed	No
		(*e*) Describe any sensitivity analyses	No
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7, 15, Study Design Mono-Image
		(b) Give reasons for non-participation at each stage	No
		(c) Consider use of a flow diagram	7, Study Design Mono-Image

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Descriptive data		14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	No
			(b) Indicate number of participants with missing data for each variable of interest	No
			(c) Summarise follow-up time (eg, average and total amount)	No
Outcome data		15*	Report numbers of outcome events or summary measures over time	No
Main results	16		(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	No
			(*b*) Report category boundaries when continuous variables were categorized	No
			(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	No
Other analyses	17		Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	No
Discussion				
Key results	18		Summarise key results with reference to study objectives	No
Limitations	19		Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	No
Interpretation	20		Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	No
Generalisability	21		Discuss the generalisability (external validity) of the study results	No
Other information				
Funding	22		Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	26

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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