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Patient trajectories and their impact on mobility, social participation and quality of life in patients with vertigo/dizziness/balance disorders and osteoarthritis (MobilE-TRA): study protocol of an observational, practice-based cohort study

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ABSTRACT

Introduction Mobility limitations have a multitude of different negative consequences on elderly patients including decreasing opportunities for social participation, increasing the risk for morbidity and mortality. However, current healthcare has several shortcomings regarding mobility sustainment of older adults, namely a narrow focus on the underlying pathology, fragmentation of care across services and health professions and deficiencies in personalising care based on patients' needs and experiences. A tailored healthcare strategy targeted at mobility of older adults is still missing.

Objective The objective is to develop multiprofessional care pathways targeted at mobility sustainment and social participation in patients with vertigo/dizziness/balance disorders (VDB) and osteoarthritis (OA) .

Methods Data regarding quality of life, mobility limitation, pain, stiffness and physical function is collected in a longitudinal observational study between 2017 and 2019. General practitioners (GPs) recruit their patients with VDB or OA. Patients who visited their GP in the last quarter will be identified in the practice software based on VDB and OA-related International Classification of Diseases 10th Revision. Study material will be sent from the practice to patients by mail. Six months and 12 months after baseline, all patients will receive a mail directly from the study team containing the follow-up questionnaire. GPs fill out questionnaires regarding patient diagnostics, therapy and referrals.

Ethics and dissemination The study was approved by the ethical committee of the Ludwig-Maximilians-Universität München and of the Technische Universität Dresden. Results will be published in scientific, peer-reviewed journals and at national and international conferences. Results will be disseminated via newsletters, the project website and a regional conference for representatives of local and national authorities.

Strengths and limitations of this study

- This observational, practice-based prospective cohort study focuses on patients with vertigo/dizziness/balance disorders and/or osteoarthritis, both health conditions with high burden of disability in older adults.
- The study will contribute to identifying determinants of patient trajectories, special concerns in care of specific age groups and significant combinations with comorbidities.
- The study reflects the patients' perspective and treatment trajectories including diagnostic procedures, comorbidities, diagnostic and therapeutic procedures used, tentative and final diagnoses and referrals based on general practitioners' (GPs) information.
- All eligible patients who recently consulted a GP during office hours will be searched in the patient database and contacted for study participation.
- Only those who are able and interested in filling out questionnaires and who are able to go to the physician participate in the study.

INTRODUCTION

With a prevalence of up to 50%, vertigo, dizziness and balance disorders (VDB) are frequent complaints of those patients aged 60 and older. The causes of VDB are often multifactorial. Distinct treatable vestibular disease entities, dizziness caused by medication, cardiovascular disease or diabetes may align with symptoms of the ageing of vestibular, proprioceptive or somatosensory systems. By increasing postural instability, VDB are

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among the most obvious and prevalent causes for falls in aged adults[1]; they limit mobility and activities of daily life[2] and restrict social participation.[2 3]

Hip and knee osteoarthritis (OA) is ranked as the 11th overall out of 291 contributors to global disability.[4] The risk for OA increases with older age. In Germany, nearly half (40.4%, 95% CI 37.4 to 43.6) of those aged 60–69 are diagnosed as having OA.[5] Persons with OA have a specific increased risk for cardiovascular and dementia associated mortality, with low levels of physical activity arguably contributing to this excess mortality.[6] Several evidence-based recommendations and guidelines are available for the management of OA.[7] Frequently recommended non-surgical treatment options include patient education, exercise, weight loss and the use of assistive devices.

However, in Germany and internationally, appropriate care for patients with VDB and OA is a big challenge in all healthcare settings. Chronological age seems to be one major determinant of inappropriate care for both VDB[8] and OA.[9] We have recently shown from the perspective of a tertiary care centre that patients with VDB receive a large range of different unsuccessful diagnostic procedures and treatments prior to referral including extensive and expensive imaging.[10] In OA, the lack of standardised and coordinated approaches to pragmatic management[11] has been noted as well. Ultimately, OA regularly results in joint replacement at high economic costs, while benefits are not clear. Large regional variations of surgery rates[12 13] seem to indicate that to date there are no coordinated care pathways for OA in Germany. Information about the determinants and outcomes of patient trajectories will contribute to the identification of optimal care pathways and the development of targeted interventions. Managing the core causes for disability in old age promotes healthy ageing and a more efficient use of healthcare resources in Germany.

MobilE-Net is a network composed of three projects which aim to develop multiprofessional care pathways targeted at older adults to reduce the burden of disability and to promote healthy ageing, mobility and participation. The subproject MobilE-TRA investigates the status quo of care from the patient perspective with special regard to gateways, decisive transitions and decision interfaces. Patient-relevant participation outcomes will be modelled depending on main potential transition points. Treatment trajectories for patients with VDB and OA include diagnostic procedures, comorbidities, diagnostic and therapeutic procedures used, tentative and final diagnoses and referral practice.

METHODS

Study design

MobilE-TRA is an observational, practice-based prospective cohort study among general practitioner (GP) practices and their patients with VDB or OA. Its longitudinal design with data collection between 2017 and 2019 captures the trajectories and changes to functioning and quality of life as well as resource utilisation over time.

Participants and recruitment

GPs in two German cities, Munich and Dresden, and surrounding areas, recruit their patients presenting with VDB or OA. A recruitment strategy for hard-to-reach individuals will be applied, where eligible patients will be searched in the patient database to increase the number of contacted patients.[14] GPs will check the list of eligible patients before sending the paper-based study material out via mail. Patient information on study contents is done by means of the accompanying letter. After signing the informed consent form, patients are contacted by a researcher of the university team for follow-up. This researcher is not involved in data analysis.

GPs

GP practices will be invited via mail from a network of 262 GP practices associated with the Institute of Primary Care and Family Practice of the Ludwig-Maximilians Universität München (LMU)—as teaching and research partners and about 100 GP practices associated with the Department of General Practice of the University Hospital Carl Gustav Carus of the Technische Universität Dresden.

Patients

Participating practices will identify patients who presented with VDB or OA. Following an established procedure for data collection in GP practices,[14] eligible patients will be identified by searching the practice database. Patients are eligible if in the last quarter they visited the GP for an episode of VDB, or symptomatic hip or knee OA, having statutory health insurance, sufficient command of German language and being 65 years and older. Relevant diagnoses according to the ICD-10 are listed in table 1.

The patient receives the patient information, informed consent and baseline questionnaire along with a postage prepaid return envelope from the GP via mail. In case of consent, the patient fills out these forms and sends them back to the study centre, which is the team at the LMU Institute for Medical Information Processing, Biometrics and Epidemiology. The study is conducted in accordance with the Declaration of Helsinki[15] and was approved by the Ethical Committees of the LMU and Technische Universität Dresden.

For the follow-up surveys (after 6 and 12 months), a cover letter with instructions and the questionnaires will be sent via mail from the study team to the patient's address, with a postage prepaid return envelope.

Patient and public involvement

The final questionnaire was pretested in patients at the University Hospital, LMU Munich, before starting the actual data collection. Patients indicated the time it took to complete the questionnaire and reported any problems in filling out the questionnaire, for example, with the order of the questions or misunderstandings in the instructions.

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Table 1 Overview of research outcomes and instruments

Outcome	Instrument	No. of items	Patient with VBD	Patient with OA
Generic quality of life	EuroQol-5D-5L	6	x	x
Mobility limitation	HAQ-DI	44	x	x
Patient satisfaction	PACIC short form	11	x	x
Healthcare utilisation, medication	FIMA	73	x	x
Depression	PHQ-9	9	x	x
Sociodemographic information		16	x	x
Disease-specific measures				
Quality of life	WOMAC	17		x
Self-perceived level of handicap	DHI	25	x	
Activities and participation	VAP	20	x	

Disease-specific scales will be printed on coloured paper.
DHI, Dizziness Handicap Inventory; EuroQol-5D-5L, EuroQol Five-Dimensional Five-Level Questionnaire; HAQ-DI, Health Assessment Questionnaire Disability Index; OA, osteoarthritis; PACIC, Patient Assessment of Chronic Illness Care; PHQ-9, Patient Health Questionnaire—Nine questions; VAP, Vestibular Activities and Participation; VBD, vertigo/dizziness balance disorders; WOMAC, Western Ontario and McMaster Universities.

Results of the main study will be disseminated to study participants via the project website.

Study schedule

Outcome measures are applied at baseline at participant level (a continuous inclusion of participants until required sample size is reached) as well as at follow-up 6 month after baseline and 12 months after baseline.

Instruments and outcomes

General practitioners

The GPs are handed out the standardised Questionnaire of Chronic Illness Care in Primary Care.[16] It includes items on the number of patients treated per week, sociodemographic characteristics and GPs professional experience, the share of different patient groups in the practice, structural data of the practice, number of partners and employees in a practice, technical possibilities in the practice, implemented quality management systems and propensity for training.

GPs are also asked to complete a self-developed baseline questionnaire, including information, which might have an influence on diagnostic and referral behaviour.

After patients sent back questionnaires, physicians will complete this questionnaire on comorbidities, diagnostic and therapeutic procedures used, tentative and final diagnoses and referral practice or deliver the respective data out of their practice software.

Patients

Patients receive a self-developed questionnaire including sociodemographic data for example, age, gender, education, health insurance, living situation and difficulties in filling out the questionnaire.

The primary outcomes of the study measured by validated instruments are generic quality of life, mobility limitation, pain, stiffness and physical function in persons with hip and/or knee osteoarthritis and vertigo-specific physical and psychosocial functioning.

1. Generic quality of life is measured through the EuroQol Five-Dimensional Five-Level Questionnaire (EQ-5D-5L) by EuroQol Group.[17] The EQ-5D showed adequate sensitivity to change in a recent randomised trial in unselected patients with vestibular vertigo and dizziness in primary care.[18 19] For summary valuation, patients' report on the visual analogue scale and, as soon as available, a German value set for utilities based on EQ-5D-5L will be used.
2. Mobility limitation will be measured using the Health Assessment Questionnaire Disability Index.[20 21] The patients report the amount of difficulty they have in performing activities of daily living.
3. Pain stiffness and physical function in persons with hip and/or knee osteoarthritis is assessed using the German version of the Western Ontario and McMaster Universities Osteoarthritis Index.[22 23]
4. Patients with vertigo, dizziness and balance disorders will be asked to fill out the Dizziness Handicap Inventory (DHI)[24] and the Vestibular Activities and Participation questionnaire.[25] The instruments evaluate the effect of the disease on activity limitation, participation restrictions and experienced difficulties.

Secondary outcomes are patient satisfaction with healthcare and healthcare utilisation.

1. The Patient Assessment of Chronic Illness Care will be used as a measure for patient satisfaction.[26]
2. Healthcare resource utilisation and medication will be assessed using a validated questionnaire for unit costs for outpatient medical care, inpatient care, informal and formal nursing care and pharmaceuticals (FIMA).[27 28]
3. Depression is assessed using the Patient Health Questionnaire.[29]

An overview of research outcomes, instruments and the number of items is illustrated in table 2.

For non-responder patients to follow-up, a non-responder questionnaire will be provided to explore the reasons for withdrawal and to obtain a crude estimate on health status based on a small set of questions.

Sample size

Based on the recommendations for the minimally important differences of quality of life instruments to be 50% of the SD, we assumed 10.0 points on the Dizziness Handicap Inventory (DHI) as a clinically relevant difference. Assuming an SD of 20,[30] a sample size of 48 would allow estimating the mean DHI with a

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Table 2 ICD-10 codes of included patients

ICD-10 code	Title
H81	Disorders of vestibular function
H82	Vertiginous syndromes in diseases classified elsewhere
R42	Dizziness and giddiness
A88.1	Epidemic vertigo
E53.8	Deficiency of other specified B group vitamins
F45.8	Other somatoform disorders
G11.8	Other hereditary ataxias
G43.1	Migraine with aura (classical migraine)
G45.0	Vertebro-basilar artery syndrome
G62	Other polyneuropathies
G63	Polyneuropathy in diseases classified elsewhere
H55	Nystagmus and other irregular eye movements
H83.0–2	Other diseases of inner ear
I95.1	Orthostatic hypotension
N95.1	Menopausal and female climacteric states
R26 without R26.1	Abnormalities of gait and mobility (without Paralytic gait)
M16	Coxarthrosis (arthrosis of hip)
M17	Gonarthrosis (arthrosis of knee)

ICD-10, International classification of diseases, 10th Revision.

power of 0.8 while simultaneously adjusting for four CIs (alpha=0.0125).

We assume the loss to follow-up between data collection waves to be 28%.[31] This means that 100 participants for the baseline data collection will allow for up to three follow-up waves. Considering the design effect with 12 patients on average per cluster (GP practice), and an ICC of 0.017,[32] the sample size required is 118. Assuming a similar effect size in patients with OA, the total sample size required is 236, this means we will have to include at least 20 practices. At an estimated response rate of 25% among practices,[33] this means that 80 practices have to be contacted for the inclusion of a total of 236 patients with VDB and/or OA.

Statistical and health economic methods

First, to examine current treatment and referral behaviour of the primary healthcare providers, frequency and distribution of procedures, treatment, medication and referral will be analysed descriptively.

Second, to examine the differences of quality of life, mobility limitation, participation and satisfaction, trajectories will be examined graphically as a function of age stratified by sex.

Differences will be compared using χ^2 tests for categorical variables and analysis of variance for metric variables which are log transformed if necessary. Mixed-effects regression models will be used with age, gender, sociodemographic variables and comorbidity as independent variables to analyse the determinants of different trajectories of quality of life, mobility limitation, participation and satisfaction. This method is appropriate to investigate longitudinal data with more than one wave of data.[34]

Lastly, to examine healthcare resource utilisation of current practice, cost utility analysis will be used. Measurement of costs will focus on cost of care and will employ recent German measurement standards.[28] Economic assessment will be conducted from a healthcare perspective.[35 36] Primary endpoint of the economic evaluation is cost per quality-adjusted life year (QALY) at 12 months after inclusion. The incremental cost-effectiveness ratio will be calculated including probabilistic analysis using bootstrapping techniques. To model different trajectories, we will develop a state-transition (Markov) model. This model will characterise the process of treatment through all observable stages and also include both cost and QALY endpoints. Monte-Carlo simulation will be used for probabilistic analysis.[37]

DISCUSSION

This study aims to investigate the trajectories of healthcare delivery using vertigo, dizziness, balance disorders and joint diseases as a case in point and investigates determinants of healthcare utilisation and outcomes. Chronological age seems to be one major determinant of inappropriate care for both VDB and OA which makes this research particularly relevant.

While there is much variation in the management of VDB and OA in the challenging context of multimorbidity and polypharmacy in elderly patients in primary care, it seems reasonable to assume that there is no 'one-size-fits-all' strategy for optimal outcomes of these complex health conditions in aged adults. This project builds on the idea that care should be stratified based on distinct care pathways for aged adults with VDB or OA. Following Andersen and Newman's Behavioral Model of Healthcare,[38] we assume that such pathways are determined by disease-related factors, predisposition and enabling factors. This research will contribute in identifying these determinants, special concerns in care of specific age groups and significant combinations with comorbidities.

A potential limitation is that the study includes only patients who recently consulted a GP during office hours. Although most elderly patients in Germany go to the GP regularly, patients with limited mobility have limited possibility of healthcare utilisation. Thus, those patients who avoid going to a GP are not covered with this study, leading to an underestimation of mobility limitations as only those who are able and interested in filling questionnaires and who are able to go to doctors participate in the study.

The recruitment strategy with a search in the patient database will make the recruitment more efficient. Instead

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of physicians inviting each patient face to face during office hours and handing out an envelope containing a personalised cover letter, study information and informed consent form, the questionnaire and a return envelope will be sent via mail. The aim is to (1) reach every patient eligible for the study and (2) reduce GPs' effort of informing each patient about the study.[39] The recruitment bears the risk that fewer patients participate in the study compared with when the GPs invite the patients personally during office hours. The feasibility of the recruitment strategy and barriers will be reported.

While the implementation of care pathways in Germany is still at its beginning, there are good practice examples of successful integration.[40] Using results of MobilE-TRA to develop clinical pathways for patients with VDB and OA can make a significant difference to the practice in primary care. The identification of determinants of VDB and OA will be used to develop individualised treatment strategies to overcome inappropriate care.

ETHICS AND DISSEMINATION

The study was approved by the ethical committee of the Ludwig-Maximilians-Universität München and of the Technische Universität Dresden. Personal data will be pseudonymised before sending the study material out via mail.

Results will be published in scientific, peer-reviewed journals and at national and international conferences. Results will be disseminated via newsletters, the project website and a regional conference for representatives of local and national authorities. The data set will be available for project researchers on request.

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Contributors EG is the principal investigator. She conceived and supervised the project. RK coordinated the study. EG, DK, UM, RL, LSu, JS and MM contributed to the conception of the cohort and design of the project. LSa, JS, AB and KV are responsible for the accusation of the data recruitment. DK is responsible for the study's quality assessment and is, together with EG and UM, in charge of the overall study management. RK and EG drafted the manuscript. All authors approved and critically revised the final manuscript.

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Patient consent Obtained.

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