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Behavioural and patient-individual determinants of quality of life, functioning and physical activity in older adults (MobilE-TRA 2): study protocol of an observational cohort study in a tertiary care setting

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ABSTRACT

Introduction Vertigo, dizziness and balance problems (VDB) as well as osteoarthritis (OA) are among the health conditions with the greatest impact on mobility and social participation in older adults. Patients with VDB and OA were shown to benefit from specialised care such as vestibular rehabilitation therapy or joint replacement. However, these effects are not permanent and seem to disappear over time. One important reason might be a decreasing adherence to therapy recommendations. Findings from behavioural economics (BE) can help to shed light on individual effects on adherence behaviour and long-term outcomes of VDB and OA.

Objective Based on insights from BE concepts (ie, self-efficacy, intention, and time and risk preferences), MobilE-TRA 2 investigates the determinants of functioning and health-related quality of life (HRQoL) 3 and 12 months after discharge from total hip replacement (THR)/total knee replacement (TKR) in patients with OA and after interdisciplinary evaluation for VDB.

Methods and analysis MobilE-TRA 2 is a longitudinal observational study with data collection in two specialised tertiary care centres at the university hospital in Munich, Germany between 2020 and 2023. Patients aged 60 and older presenting for their first THR/TKR or interdisciplinary evaluation of VDB at Ludwig Maximilians University (LMU) hospital will be recruited for study participation. Three and twelve months after baseline assessment, all patients will receive a follow-up questionnaire. Mixed-effect regression models will be used to examine BE concepts as determinants of adherence, HRQoL and functioning.

Ethics and dissemination The study was approved by the ethics committee at the medical faculty of the LMU Munich under the number 20-727. Results will be published in scientific, peer-reviewed journals and at national and international conferences. Findings will also 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 prospective cohort study will provide comprehensive data of behavioural and patient-individual determinants of quality of life, functioning and physical activity in older adults at multiple time points.
- This study uses validated and well-established outcome measures.
- We investigate patients with vertigo, dizziness and balance problems or with osteoarthritis because these health conditions might have major impact on mobility and social participation in older adults.
- Data originate from one university hospital in Germany, so generalisability of the results is limited to this setting.

INTRODUCTION

Following economic modelling, adherence to therapy recommendations and other health behaviours, such as physical activity or a healthy diet, can be viewed as investments in one's own health.[1] However, despite long-term advantages of these investments, individuals tend to deviate from these behaviours, even after educational efforts to provide information regarding their positive effects. Behavioural economics (BE) is a field of research that helps to explain such harmful deviations.[2 3] Corresponding studies reveal that departures appear systematically and therefore can be predicted and explained using specific concepts, such as individual risk and time preferences.[4]

In the context of specialised hospital care, BE can help explaining patient-relevant outcomes after treatment, but also non-adherence to therapy recommendations. MobilE-TRA 2 uses insights from BE to shed light on individual effects on outcomes in patients with vertigo, dizziness and balance problems (VDB) as well as osteoarthritis (OA). These health conditions were chosen as they are among the health conditions with the greatest impact on mobility and social participation in older adults.[5] The current project focuses on the investigation of the determinants of quality of life, functioning and physical activity, after a definite diagnosis has been made, and after therapy and rehabilitation have been initiated. Furthermore, adherence to recommendations may play a prominent role as a process variable, which could also be influenced by self-efficacy and risk or time preferences of patients.

With a prevalence of up to 50 %, VDB are frequent problems of patients aged 60 and older. The causes of VDB are often multifactorial. Distinct treatable vestibular disease entities, dizziness caused by medication, cardiovascular diseases or diabetes may align with symptoms of the ageing of vestibular, proprioceptive or somatosensory systems. By increasing postural instability, VDB are among the most apparent and prevalent causes for falls in aged adults.[6] Furthermore, they significantly limit mobility and activities of daily life[5] and restrict social participation.[5 7] It is well established that aged adults with VDB benefit from vestibular rehabilitation therapy, regardless of the underlying pathology. However, it has been noted that old age is an independent predictor for unfavourable long-term outcomes, even after evidence-based and interdisciplinary treatment.[8]

With respect to VDB, only a limited number of BE concepts have been investigated to date. Patients showing resilience and high self-efficacy were less likely to develop secondary, chronic forms of functional vertigo.[9] Likewise, persons with high general self-efficacy reported more confronting, active behaviour to address their visual height intolerance.[10]

Likewise, OA is a major cause of mobility restrictions in older adults.[11] Persons with OA have an increased risk for cardiovascular and dementia associated mortality, with low levels of physical activity contributing to this excess mortality.[12] Several evidence-based recommendations and guidelines are available for the management of OA.[13] Specifically, after joint replacement, physical therapy, home exercises and increased physical activity are effective methods to reduce limitations of patients' functioning and mobility.[14 15] However, these effects are not permanent and seem to disappear over time. One major aspect contributing to this decline is non-adherence to physical activity recommendations,[16] which concerns up to 50% of OA patients and might be one decisive factor jeopardising positive surgery outcomes.[17] This may lead to reduced mobility and low physical functioning levels after joint replacement and increase the likelihood for subsequent revision.[18] Besides non-adherence to physical activity recommendations, there might be several other factors, which play a role in determining long-term outcomes after major treatment decisions, for example, after total hip or knee replacement (THR/TKR), but their role has yet to be acknowledged and understood.

In general, attitudes and motivation of patients are among the determinants for therapeutic success after THR/TKR.[19 20] Physical, social and socioeconomic factors, but also psychological aspects including self-efficacy, intentions, or expectancies for the future, serve as potential barriers to better outcomes.[21–25] Regarding BE, stronger orientation to the present appears to be associated with less healthy behaviour.[4 26 27] However, it is unclear if increased risk tolerance promotes or inhibits adherence to recommended exercise.[4 27]

In summary, too little attention has been paid to the role of BE concepts for long-term outcomes of OA and VDB. In fact, these factors may need to be considered not only in the preoperative phase, but also during discharge and rehabilitation planning and aftercare. Corresponding knowledge can be used to refine care pathways and to inform healthcare practice, potentially identifying persons at higher risk for adverse outcomes and tailoring specific interventions to improve adherence.

MobilE-TRA 2 is part of the second phase of MobilE-Net (Enabling participation by enabling MOBILity in older adults—Evidence-based health care research Network). MobilE-Net 2 is 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. Based on insights from BE, the second phase of the subproject MobilE-TRA 2 investigates the determinants of functioning and HRQoL for patients with OA at 3 and 12 months after discharge from THR/TKR and for patients with VDB at 3 and 12 months after interdisciplinary evidence-based evaluation. In addition, adherence to recommendations will be considered as a major process variable. Results are of particular importance for the other projects of MobilE-Net to explain unwanted variations in outcomes of an implementation process. We expect to deliver insights that can directly be applied in ambulatory care and in discharge and rehabilitation planning.

Specifically, we want

1. to examine BE concepts as determinants of adherence,
2. to examine BE concepts as determinants of HRQoL and functioning, and
3. to investigate the moderation effect of BE concepts on associations between physical activity and individual factors such as body mass index (BMI) or pain.

METHODS AND ANALYSIS

Study design

MobilE-TRA 2 is a prospective observational cohort study among patients with OA after THR/TKR and patients with VDB after interdisciplinary evidence-based evaluation

in two specialised tertiary care centres at the university hospital in Munich, Germany. The patient recruitment will take place from November 2020 until March 2022 and the data collection will end in March 2023 with the last patient completing the twelve months follow-up. The longitudinal design of the study captures changes in relevant outcomes. The study is monocentric to avoid variations in case ascertainment as well as surgical and medical treatment standards.

Participants and recruitment

Patient recruitment for MobilE-TRA 2 will take place at the Department of Orthopaedics, Physical Medicine and Rehabilitation (OPMR) and the German Centre for Vertigo and Balance Disorders (DSGZ) at the Ludwig Maximilians University (LMU) hospital in Munich. About 300 patients per year are admitted for first THR/TKR surgery at the Department OPMR. The DSGZ treats over 3000 ambulatory patients per year. Patients at OPMR and DSGZ obtain a rigorous clinical workup in line with current guidelines.[13 28] Typically, in the German system, patients after THR/TKR will undergo 3 weeks of postacute inpatient musculoskeletal rehabilitation and will be discharged from rehabilitation with a recommendation for physical therapy and physical activity. Patients with VDB will receive a recommendation for further measures in line with the recommendations of the Bárány Society[29] to be initiated by their primary care physician, potentially including physical therapy, physical activity or medication.

Patients aged 60 and older presenting at the participating centres for first THR/TKR or first interdisciplinary evaluation of VDB at the LMU hospital will be recruited for study participation. Patients with terminal disease, cognitive impairment, insufficient command of the German language or physical problems preventing participation, such as sensory impairments (bad sight or hearing) or a very low energy level, will be excluded. Patients will be recruited from both departments during their first consultations, that is, prior to surgery for patients with OA and during the first visit at the DSGZ for patients with VDB. Additionally, OA inpatients are recruited at the hospital 1 day ahead of their surgery. The recruitment is performed by trained members of the study team.

Patients participating in the MobilE-TRA 2 study will receive the patient information, the informed consent documents and the baseline questionnaire from the tertiary care centre. The patients in the study do not receive an incentive for study participation. In case of consent, they fill out these forms and hand them back to the study centre. Patients can also choose to complete the questionnaire at home and send it back to the respective study centre. The data collection in this study will be done with the help of pseudonymised identification keys during study conduct. For further information, refer to the section ethics and dissemination of this study protocol.

For the follow-up surveys after 3 and 12 months, a cover letter with instructions and the questionnaires will be sent via postal mail from the study teams to the patients' addresses. If no questionnaire is sent back within a month after the original follow-up invitation, one reminder will be sent. If the participant does not respond to the reminder, the data will be considered missing for the first follow-up. In the second follow-up, 1 month after an unanswered reminder, 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.

The recruitment of the study is taking place during the SARS-CoV-2 pandemic. This emergency forced hospitals to take measures to prevent a patient overload and to grant back-up capacities for patients in need of intensive care, for example, by cancelling all routine operations that are not immediately indispensable. This may lead to a potential preselection of the study participants based on their constitution and the severity of the underlying disease. These challenges will be addressed by a careful documentation of the recruitment process and the specifications in force.

Patient and public involvement

Before starting the actual data collection, the questionnaires were pretested on a total of 11 patients at both the OPMR and the DSGZ at the LMU hospital in Munich from October to November 2020, using a think-out-loud approach. Patients did not indicate any major problems, such as ambiguous instructions, when filling out the questionnaire. The results of this pretest then were then used to revise and finalise the questionnaires. Results of the main study will be disseminated to study participants via the project website.

Measures

The primary outcomes of the study are generic quality of life, OA-specific physical functioning in patients with OA and vertigo-specific physical and psychosocial functioning in patients with VDB after 3 and 12 months, measured using validated instruments. Generic quality of life is measured through the EuroQol Five-Dimensional Five-Level Questionnaire (EQ-5D-5L) of the EuroQol Group.[30] For summary valuation, patients' report on the visual analogue scale and the German value set for utilities based on EQ-5D-5L[31] will be used.

OA-specific physical functioning in persons with hip and/or knee OA is assessed using the German version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).[32 33] The WOMAC is an OA-specific tridimensional patient relevant outcome measure with 24 questions (5 on pain, 2 on stiffness and 17 on physical functioning). The main focus of the WOMAC is on the domain mobility that is addressed by 15 of the 24 questions.[34] This study applies the Likert scaled format with 5 response categories (0=none, 1=mild, 2=moderate, 3=severe, 4=extreme). The sum of the assigned values

results in the score of each scale. The WOMAC has been proven valid, reliable and responsive[32] and is arguably the most frequently used OA-specific patient relevant outcome measure.

Patients with VDB will be asked to fill out the German version of Dizziness Handicap Inventory (DHI),[35] which assesses disability caused by dizziness and unsteadiness on everyday activities, including activity limitation, participation restrictions, and experienced difficulties.

Adherence behaviour to therapy recommendations, physical activity, pain and satisfaction is used as secondary outcome measure. Adherence behaviour to therapy recommendations is addressed with three items dealing with adherence to disease-specific exercises and physical activity (sporting activities and general regular exercise)[16] and one item dealing with weight control. OA specific pain is assessed using the pain scale of the WOMAC.[36] Pain and satisfaction in patients with OA were further assessed by single-item measures following Rolfson *et al* (2016).[37] The pain question asks: 'During the past 4 weeks, how would you describe the pain you usually have in your affected hip/knee?'. Response options are none, very mild, mild, moderate and severe. The satisfaction question asks: 'How satisfied are you with the results of your joint replacement that you received 3 months (12 months) ago?', with the response options very dissatisfied, dissatisfied, neutral, satisfied and very satisfied.

Physical activity for patients with OA or VDB is measured using the self-administered Global Physical Activity Questionnaire (GPAQ).[38 39] The WHO developed the GPAQ for physical activity surveillance. Fifteen questions collect information in the three domains activity at work, travel to and from places, and recreational activities. In addition, one single question asks for sedentary behaviour. The weekly energy expenditure in Metabolic Equivalents is estimated using the frequencies and durations of moderate and vigorous physical activity in each domain in a usual week. The GPAQ is validated in Germany and many other countries[40] and has been applied to various populations including patients with OA.[41]

Concepts of BE are used as exposure. Risk attitudes are measured via two questions including an 11-point Likert scale, where individuals can state their attitude to risk in general and in the health domain from (0) 'not at all ready to take risks' to (10) 'very likely to take risks'.[42] Self-efficacy is rated using the validated Allgemeine Selbstwirksamkeit Kurzskala questionnaire, where individuals are asked to answer three questions on general self-efficacy.[43] Additionally, a further question focuses on self-efficacy concerning physical activity supplemented by an item addressing intention to carry out physical activities.[44]

Time preferences are measured by using three distinct instruments. First, a questionnaire instrument with six items is applied creating a series of binary choices between hypothetical amounts of money now or in the closer future and alternative amounts in the further future. From these choices, individual discount rates can be derived.[45] Second, a qualitative item based on Borghans and Golsteyn (2006)[46] asks respondents to indicate their present-future tradeoff on a 5-point Likert scale. Third, respondents' self-assessed willingness to wait has to be stated on an 11-point Likert scale.[47]

In order to consider potential confounding, information on age, sex, education, occupation, marital status, living conditions, alcohol consumption and smoking behaviour is collected in the questionnaire. We further gathered information about comorbidities of the heart, lung, liver and kidneys as well as neurological diseases, high blood pressure, inflammatory joint diseases and further diseases specifically indicated by the participants. Depression will be assessed using the Patient Health Questionnaire.[48]The exact diagnosis of VDB will be obtained from the patient documentation at the DSGZ. In patients with OA, weight and height are measured routinely as a part of the premedical examination prior to the surgery at the OPMR and are used to calculate the BMI.

German translations were not available for the concepts of BE, the pain and satisfaction in patients with OA, and the adherence behaviour to therapy recommendations. These items thus were independently translated by at least two members of the study team. Discrepancies between the translations were discussed and resolved between the translators. The translated versions then were examined by the respective expert within the study team for each item in order to ensure that the translation did not change the construct of interest.

An overview of research outcomes and instruments used, including the number of items and corresponding references, is shown in table 1.

Sample size

Sample size calculation for THR/TKR is based on a minimally important difference (MID) of 8 for TKR and 9 for THR and a SD of 18 of the EQ-5D-5L.[49] Thus, 37 THR and 47 TKR patients are needed to estimate the mean with a power of 0.8 (alpha=0.05). Assuming a loss to follow-up of 20% between baseline and follow-ups, we need to include 131 (58+73) patients at baseline. Attrition rate is reasonable, based on our previous experiences with primary care patients where we found that 88% of patients of this age group had responded to the first postal follow-up. MID for the EQ-5D-5L are not available for VDB, so based on previous work,[50] we assume 10.0 points on the DHI[35] as a clinically relevant difference for patients with VDB. Assuming an SD of 25, a sample size of 52 will allow estimating the mean with a power of 0.8 (alpha=0.05). Assuming a loss to follow-up of 20%, we need to include 81 patients at baseline. For patients with VDB, different underlying pathologies will have to be considered. Thus, we plan to sample 81 patients from each of the four main somatic aetiologies of VDB, namely Benign Paroxysmal Positional Vertigo, Menière's disease, vestibular migraine, and functional vertigo, yielding a target sample size of 324.

Table 1 Research outcomes and instruments used, including the number of items

	Instrument, items	Baseline		Follow-ups	
		Patients with THR/TKR	Patients with VDB	Patients with THR/TKR	Patients with VDB
Primary outcome measures					
HRQoL	EQ-5D-5L,[30] 5 items and VAS	x	x	x	x
Specific functioning (OA)	WOMAC functioning scale,[32 33] 17 items	x		x	
Dizziness-specific functioning (VDB)	DHI,[35] 25 items		x		x
Secondary outcome measures					
Pain, satisfaction (OA)	As recommended by Rolfson *et al*,[37] 1 item each	x		x	
OA-specific pain	WOMAC pain scale,[32 33] 5 items	x		x	
Physical activity (OA and VDB)	Global Physical Activity Questionnaire (GPAQ)[38]	x	x	x	x
Adherence behaviour	3 items on exercises and physical activity,[16] 1 item on weight control			x	x
Exposures					
Risk attitude	2 items: general and health specific risk attitude[42]	x	x		
Self-efficacy (general)	3 items[43]	x	x		
Self-efficacy (physical activity)	1 item[44]	x	x		
Intention (physical activity)	1 item[44]	x	x		
Time preferences	8 items[45–47]	x	x		
Confounding variables					
Age, sex, education, occupation, marital status, living conditions, alcohol consumption, smoking behaviour, and comorbidities		x	x	x	x
BMI, diagnosis of VDB	Assessed at the OPMR /DSGZ	x	x		
Depression	PHQ-9[48]	x	x	x	x

BMI, body mass index; DHI, Dizziness Handicap Inventory; DSGZ, German Centre for Vertigo and Balance Disorders; EQ-5D-5L, EuroQol Five-Dimensional Five-Level Questionnaire; HRQoL, health-related quality of life; OA, osteoarthritis; OPMR, Department of Orthopaedics, Physical Medicine and Rehabilitation; THR/TKR, total hip or knee replacement; VAS, visual analogue scale; VDB, vertigo, dizziness and balance problems; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Data analysis

In a first step, BE concepts, HRQoL and functioning will be analysed descriptively. Differences will be compared using χ^2 tests for categorical variables and analysis of variance for metric variables, which are log transformed if necessary.

Second, mixed-effect regression models will be used in the sample with patients with OA and VDB to examine BE concepts as determinants of adherence, HRQoL and functioning. This method is appropriate to investigate longitudinal data with more than one wave of data.[51] Third, to investigate the impact of BE and psychological concepts as confounders for the association between physical activity and other factors, we will conduct stratified analyses and incorporate interaction terms in the regression models.

ETHICS AND DISSEMINATION

The study was approved by the ethics committee at the medical faculty of the Ludwig Maximilian University Munich under the number 20-727. Patients are supplied

with sufficient information about their participation in the study and are only included if written informed consent is present. Participants will not be exposed to any medical risk due to study participation. The study is conducted in accordance with the Declaration of Helsinki. Data collection in this study will be done with the help of pseudonymised identification keys during study conduct. All links between the pseudonymised keys and person identifying information such as name or address will be destroyed after study completion. Conclusion about the actual patient will then no longer be possible and data will be de facto anonymised. Data will be double pseudonymised before being forwarded for data analysis to project partners only.

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, LS, MW and AP are the principal investigators. They conceived and supervised the project. BK coordinated the study. EG, LS, MW, AP and DK contributed to the conception of the cohort and design of the project. DK, BK and EG are responsible for the study's quality assessment. SF is responsible for the data management at the OPMR and preliminary analysis of the osteoarthritis data. LS and SP are responsible for secondary data management, preliminary analysis and preparation and contribute expertise on behavioural economics. BK, EG, LS, MW SP, SF and AP drafted the manuscript. All authors approved and critically revised the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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