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Development of an interprofessional diagnostic toolkit to enhance outside walking gait-related participation of people after stroke in Germany: study protocol of an ongoing multi-methods study

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ABSTRACT

Introduction Persons after stroke experience limitations in activities of daily living even in the chronic phase. Many patients who had a stroke report mobility limitations with loss of social roles such as reduced gait-related participation. International best-practice recommendations for patients who had a stroke include interprofessional diagnostics as a core element for goal setting and intervention planning to improve social participation. Interprofessional diagnostics has not yet been implemented in Germany.

Methods and analysis The aim is to develop an interprofessional diagnostic toolkit. This will be done in a multi-step process: first, an integrative review is conducted to synthesise the literature. Second, the experiences regarding diagnostics and walking outside is captured in focus groups with persons after stroke, relatives and health professionals. Third, a toolkit for the interprofessional diagnostic process of gait-related-participation will be developed based on the results of the previous steps in a future workshop. Fourth, the results of each work package will be integrated into the iterative development process for evaluation and implementation. All steps will be performed in accordance with the respective reporting guidelines.

Ethics and dissemination This study has been approved by the ethics committee at the Ludwig Maximilians University (LMU), Germany and is overseen by LMU-Medical Institutional Review Board. Written informed consent will be obtained from all participants. Results will be disseminated through knowledge exchange with stakeholders and in peer-reviewed journal publications, scientific conferences, formal and informal reports. Stakeholders, patients and providers will be involved in most steps of the development from the beginning, which will facilitate later implementation at a larger scale.

Trial registration number German Register Clinical Trials/Deutsches Register Klinischer Studien DRKS00032389.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Multi-methods design for methodological triangulation to obtain a more adequate and comprehensive picture of the concepts of interprofessional diagnostic and the concept of gait-related participation.
⇒ Orientation towards participatory research principles.
⇒ The study does not investigate whether improved interprofessional diagnosis of walking abilities outside the home leads to an improvement in gait-related participation.

INTRODUCTION

Worldwide, 33 million people experience a stroke every year.[1] The number of cases is anticipated to double by 2030.[2] 6.5 million people affected patients die annually.[3] 26% of the survivors have significant disabilities and 50% are restricted in their mobility.[4] About 3 months post-stroke, 20% of persons after stroke (PaS) remain dependent on a wheelchair and approximately 70% encounter walking difficulties.[5] Even among those discharged from the hospital as able to walk, showing no obvious walking difficulties, only one-third will leave the house in their daily lives.[6] This reluctance may largely stem from the fear of falling, reported in 32–83% of PaS between 6 months to over 4 years post-stroke.[7] This leads to limitations in gait-related-participation, that is, activities that may be important to an individual's quality of life,[8] such as taking part in social life, exercise or other recreational activities.[9] Outside walking gait-related participation is a complex multidimensional construct and an identity-constructing behaviour,[10]

restrictions in gait-related participation may partly result from stroke-related consequences, as well as deficits in health services, such as access, time constraint and information sharing.

National guidelines, such as the Rehabilitation of Mobility after Stroke, are based on target criteria including walking ability, distance, speed and balance. These recommendations refer to chronic patients who had a stroke but tend to overlook the complexities of outside walking. Also, the Canadian Stroke Best Practice Guidelines recommend comprehensive diagnostic and goal setting, regularly updating shared documentation and coordinating information transfer through a designated team member.[11] A systematic review of stroke guidelines conclude that it would be highly beneficial to consider comorbidity and include patients and health professionals with lived experience in the development of future guidelines.[12]

In Germany, diagnostics, intervention planning and prescription of assistive products in the outpatient setting are predominantly provided by general practitioners (GP) who often face time constraints.[13] Physiotherapists, who are predominantly involved in the therapy of PaS, might not yet sufficiently incorporate evidence-based practice.[14] A solution for caring for PaS could involve allowing direct access to health professionals like physiotherapists or work in interprofessional teams, as practiced, that is, in Canada or Great Britain.[15 16]

Such a collaboration can impact organisations, professionals and patients; facilitators, barriers and outcomes on organisation-level, team-level and individual level interrelate and should be considered for intervention development.[17] Scientific studies on interprofessional collaboration have identified facilitators for successful collaboration, namely supportive, inclusive relationships and practices and an understanding of the concept,[18] recognition of other professionals' skills, co-location and tools for improved communication.[19] Identified barriers include a lack of resources and understanding of the concept[18]; deficiencies in time/training, clear roles, fears about professional identity and poor communication.[19] For the German outpatient setting, neither structures nor processes have been implemented to ensure interprofessional diagnostic collaboration.

For a potential implementation of such interprofessional diagnostics, a toolkit could be developed. Toolkits are considered complex interventions[20] as knowledge translation strategies for integrating evidence into clinical care.[21] A toolkit should contain resources that accelerate science-practice transfer, focusing on a specific intervention or target group and can contain documents that can be used individually or collectively.[22] The development of toolkits should be based on conceptual frameworks and on the assessment of contextual barriers.[22] To evaluate the effectiveness of a newly developed toolkit, the desired change must be clearly stated, such as a change in patients clinical outcome, change in clinician behaviour only or in addition to patient clinical outcomes.[21]

This protocol describes a research programme to develop an interprofessional intervention as a first step towards improving outside walking gait-related participation in the form of a toolkit. This diagnostic toolkit will be initially developed as a printed manual, which can later, in a subsequent study, be converted into a digital application. The objectives of the multi-methods study are (1) to synthesise the literature, (2) to explore the experiences of the different groups (PaS, relatives and health professionals) regarding the gait-related-participation diagnostic process, (3) to develop an interprofessional diagnostic toolkit and (4) to formulate implementation strategies for the German healthcare context.

METHODS AND ANALYSIS

The multi-methods study is a subproject of the larger PARTICIPATE project based at Rosenheim University of Applied Sciences.[23] Members of the project team have professional expertise in therapy and nursing science, nursing pedagogics and research, public health and work experience as physiotherapists. The development of the intervention adheres to participatory research principles[24] and is guided by the Intervention Mapping Framework,[25 26] which includes six steps:

1. Understand and describe the health problem of a group of individuals, the behavioural and environmental causes and determinants and assess available resources.
2. Describe the behavioural and environmental outcomes, set goals for changes in behavioural determinants and environmental causes and determine the objectives of the intervention programme.
3. Identify theory-based and evidence-based behaviour change methods that influence the determinants and translate them into practical applications that fit the intervention context.
4. Combine the intervention components into a coherent programme that uses contextual approaches.
5. Develop implementation strategies to facilitate the adoption, implementation and maintenance of the programme.
6. Plan a process and outcome evaluation to assess programme implementation and effectiveness or efficacy.

The proposed study focuses mainly on the steps 1–5.

Aim

The aim of the multi-method study is to develop an interprofessional diagnostic toolkit for gait-related participation of PaS with systematic consideration of PaS, relatives, GP, neurologists, therapists, experts in the provision of assistive products, representatives of health insurances and the local community. The aims of successive phases are outlined as follows (for detailed descriptions, see Methods section):

1. Phase 1: Synthesis of the scientific literature in an integrative review for the development of the toolkit.

2. Phase 2: Exploration of the current care situation with regard to gait-related diagnostic from the perspective of the actors involved and further toolkit development through focus groups.
3. Phase 3: Exploration of stroke aftercare from different perspectives, identifying facilitators for implementing the toolkit and gaining agreement to establish interprofessional collaboration in a future workshop.
4. Phase 4: Development of the toolkit and the evaluation concept: The development of the toolkit will take place in consecutive phases. Results from each work package will be integrated into the iterative development process and will structure the following phase of data collection and analysis. The desired change is in clinician behaviour regarding the use of evidence-based recommendations and to support effective interprofessional collaboration.

Data collection

This protocol reports an ongoing study. Data collection for Phase 1 and Phase 2 is mostly completed.

Phase 1

We conducted an integrative review (IR) to synthesise the scientific knowledge about the interprofessional diagnostic of gait-related participation among people after stroke in the outpatient setting. An IR is a methodology that provides a synthesis of knowledge and applicability of results from significant studies to practice.[27 28] Furthermore, IRs enable the synthesis of empirical and theoretical findings to generate conclusions for research and policy.[27 28] That includes searching of databases, hand and backward searches. The aim of the IR is to define the concept of outside walking gait-related outpatient interprofessional diagnostics and to formulate practice guidelines for the development of the toolkit. Data collection is based on a consensus-based search protocol[29] (online supplemental file 1) and according to the Peer Review Strategy for Electronic Search Strategies.[30] The sensitive iterative literature research includes databases such as Cochrane Library, MEDLINE, CINAHL, Psyindex, and PEDro and is completed by search of grey literature and backward search. The development of the search string follows a building block approach and ECLIPSE-Mnemonic (E=Expectation, C=Client Group, L=Location, I=Impact, P=Professionals, SE=Service), which is suitable for research questions in the field of health policy and management.[31] The IR has been carried out and will be published in a scientific journal.

Phase 2

Based on the results of the IR, we developed a guide for conducting focus groups. These sessions aimed to explore the experiences of the different groups (PaS, relatives and health professionals) regarding the diagnostic process and outside walking gait-related participation to gain an in-depth understanding. The researchers with experience in public health (CP), co-moderated workshops and had clinical experience as physiotherapists within client-centred communication group settings with patients and/or relatives (CP and MF). Five focus groups were conducted at two outpatient rehabilitation centres in Bavaria. Prior to the main sessions, three pretests took place (PaS; N=5, relatives; N=6 and health professionals; N=5) to validate the group-specific semi-structured discussion guide, assess inputs/stimuli and determine group composition criteria. Questions in the guides for the three groups were similar, each had a different focus. While discussions in the PaS group centred on their experience of going outside, the focus in the group of healthcare professionals was on examining interprofessional collaboration. In the relatives' group both sets of topics were explored. After some adaptations and modifications of the guide (online supplemental file 2) and group member settings, we conducted two more semi-structured focus group discussions. These were carried out in separate groups: one mixed group with PaS and relatives (N=5) and a group of healthcare professionals (N=5). The mixed group included both PaS and relatives, due to insufficient participants for separate groups. Various moderation methods appropriate for participatory research with vulnerable groups were included, making it easier for participants to express their interests and questions. During the interviews, attention was paid to reflexivity and field notes were documented. The focus group interviews were recorded in audio and video formats and subsequently transcribed according to Dresing and Pehl.[32]

Phase 3

A future workshop will be carried out as a form of participatory research.[24] This method was chosen to achieve new knowledge through democratic collaboration. A future workshop is a method for promoting the participation of citizens and vulnerable groups. The future workshop consists of three typical main phases: (1) problem identification (criticism phase), (2) brainstorming (fantasy phase) and (3) development of project outlines with concrete action plans in the near and long-term, involving responsible stakeholders (realisation phase).[33] Two researchers (CP and MF) will moderate the future workshop, supported by the research team in conception and realisation. Field notes will be taken. The results of the future workshop will be documented through photos of the materials contributions, for example, stimuli, personas, results fixed on flip charts and protocols. This approach prevents an interpretative or analytical stage from being interposed. The future workshop will be also audio-recorded and video-recorded and transcribed according to Dresing and Pehl.[32]

Eligibility and recruitment

The context is the outpatient setting in Germany. Sampling and recruitment were applied according to team-based preliminary considerations as defined by inclusion and exclusion criteria. Table 1 displays the eligibility criteria

Table 1 Eligibility criteria for participants of interviews, focus groups and future workshop

Eligibility criteria for participants		
	Inclusion criteria besides signature of informed consent	**Exclusion criteria**
Phase 2 focus groups		
PaS	► Age: 18 and older. ► Receiving outpatient therapy. ► Emotional and physical stability for participation. ► Sufficient German language skills.	► Severe cognitive or motor consequences of stroke. ► Severe concomitant disease. ► Severe aphasia.
Relatives	► Patient's consent for participation of relative. ► Emotional and physical stability for participation. ► Sufficient German language skills.	
Health professionals	► Occupational and physical therapists, employees of rehabilitation management/integration service, orthopaedic technicians/mechanics, general practitioners and neurologists (professional experience minimum 2 years). ► Sufficient German language skills.	
Phase 3 future workshop		
PaS	► Age: 18 and older. ► Receiving outpatient therapy. ► Emotional and physical stability for participation. ► Sufficient German language skills.	► Severe cognitive or motor consequences of stroke. ► Severe concomitant disease. ► Severe aphasia.
Relatives	► Patient's consent for participation of relative. ► Emotional and physical stability for participation. ► Sufficient German language skills.	
Health professionals	► Occupational and physical therapists, rehabilitation management/integration specialists, orthopaedic technicians/mechanics, general practitioners and neurologists (professional experience (minimum 2 years). ► Representative of health insurances. ► Representative of local community. ► Sufficient German language skills.	

PaS, persons after stroke.

for participants in interviews, focus groups and the future workshop. Access and recruitment of participants were achieved through gatekeepers and snowball systems. Rehabilitation facilities and self-help groups were also involved. Other potential participants were recruited via the researchers' professional networks and through the members of an existing research-practice network within the larger PARTICIPATE project. This network consists of institutions and facilities in the fields of care, rehabilitation, social work and citizen representatives. A meeting is held once a year and members are kept up to date on the activities of the research focus via newsletters.

In Phase 2, participants for the focus groups were invited by letter, email and telephone. They received written information detailing the study procedure and informed consent requirements.

Further inclusion criteria were physical and psycho-emotional stability for participation in a focus group discussion, as well as sufficient ability to concentrate for the duration of the sessions (approximately 2 hours). Exclusion criteria encompassed severe cognitive consequences of the stroke, concomitant diseases such as psychiatric diagnosis or addictions. The determination of limitations and eligibility regarding cognitive functions and psycho-emotional resilience was based on therapists' judgement. The presence of aphasia was not an exclusion criterion per se. Instead, the potential participation of people with aphasia was checked with assessments, subjective evaluation of communicative abilities by a speech therapist and in a preliminary conversation with a member of the research group. Patients with doubts about their ability to give consent were excluded. Relatives and health professionals were recruited concurrently with PaS. In the case of relatives, the patient's consent had to be obtained. Five to a maximum of seven participants per group participated in the focus groups in order to give all participants sufficient opportunity to take part in the discussion. The participants did not receive an expense allowance or reimbursement for their travel expenses.

The sampling and recruitment process for the future workshop (Phase 3) is similar to the focus groups. Participants of the focus groups were invited to take part in the future workshop, as were stakeholders working at health insurances and the local community representatives. The researchers will approach them directly by email or telephone. We intend to recruit approximately 20 people, ensuring a heterogeneous composition (PaS, relatives, health professionals) to participate in the future workshop. The participants will not receive financial incentives, however, their travel expenses will be reimbursed.

Data analysis

Phase 1

For the IR we applied Covidence systematic review software.[34] Titles and abstracts were screened by CP, in case of uncertainty were double-checked by MF. Full texts were screened independently by CP and MF according to the eligibility criteria. In case of uncertainty, a joint decision was made by the research team (CP, MF, DL). The Mixed Methods Appraisal Tool (MMAT) V.2018,[35] was used to critically appraise the quality of the selected studies in the proposed review. MMAT is intended to be used as a checklist for appraising studies included in systematic mixed studies reviews. Ratings for each MMAT criteria will be displayed in a table to provide an overview of the quality of included studies, when the results will be reported. Data analysis was carried out descriptive-numerically, and with summarised content analysis according to Mayring.[36]

Phase 2

Data will be analysed by means of structuring content analysis (primary method). The qualitative content analysis with deductive–inductive category formation will be carried out based on Mayring's structuring content analysis.[36] The deductive category formation is based on two frameworks to include both interprofessional diagnostics and the aspect of walking outside the home: For the interprofessional diagnostics we applied the Collaboration Framework.[37] This model distinguishes three determinants: interactional determinants/interpersonal relationships, organisational determinants and systemic determinants (external factors).[37] For walking outside the home, we used the model of physical activity of people with disabilities.[9] This model is based on the theory of planned behaviour and the International Classification of Functioning, Disability and Health.

Inductive category formation will be carried out using subsumption.[38] The structuring content analysis and inductive category supplementation will be conducted with MAXQDA.[39] Consensual coding (MF and DL) according to Rädiker and Kuckartz will be performed for 50% of the data.[40] The results of the various focus groups will be first analysed separately and then compared, identifying similarities/differences and relationships. A protocol of the results will be sent to the participants with the possibility to comment on it.

Phase 3

Data (written and visual materials) from the future workshop will be analysed iteratively by means of content-structuring content analysis (primary method) employing content categories. Consensual coding will be conducted with an additional team member for 50% of the data material. The qualitative content analysis with deductive-inductive category formation will be carried out based on Mayring's structuring content analysis.[36] The deductive category formation will be guided by the Context and Implementation of Complex Interventions framework (ICF). It comprises the dimensions of context, implementation and setting[41] interventions. For further evaluation of the systematised data, a typifying structuring will take place.[36] Data synthesis will be discussed and consented to in team meetings.

Phase 4

Results of Phase 1–3 will be assessed for overlapping, complementing or contradictory content (CP and MF). Validity and plausibility will be reflected within the research group. The findings will be summarised in a preliminary iterative logical model.[42]

Based on the logical model, the toolkit will be developed in the form of a manual. It will be based on health promotion theories such as person-centredness, empowerment and socio-spatial orientation. The toolkit will include recommendations for different levels of interprofessional collaboration. Examples of content include information on ICF-based documentation, goal setting process or patient-reported outcomes measures and materials for all professionals involved in clinical practice such as assessment forms, checklists, etc. The development of the toolkit is an iterative process in which the members of the research team reflect on the current state of development in the form of standardised team meetings with the involvement of experts (PaS). The main criterion is the potential for application within the specific regional structures of outpatient therapy. The resulting toolkit should be seen as a first step that will later be implemented in a digital application.

DISCUSSION

The aim of the multi-method study is to develop an interprofessional diagnostic toolkit for outside walking gait-related participation of PaS with systematic consideration of PaS, relatives, GPs, neurologists, therapists, experts in the provision of assistive products, representatives of health insurances and local community. We will take these aspects into account for the discussion. The designed toolkit could be a promising tool to improve the ability of people to walk outside after a stroke in the outpatient setting and to enable them to participate better. Subsequent studies will be required to evaluate the acceptance and feasibility of the toolkit, as well as changes in interprofessional collaboration.

Ethics

This study has been approved by the Ethics committee at the Ludwig-Maximilians-University (LMU). The study is registered on the German register of clinical studies (DRKS00032389). All participants will be required to provide written informed consent. Findings will be disseminated through knowledge exchange with stakeholders and in peer-reviewed journal publications, scientific conferences, formal and informal reports. All study participants were/will be informed in written and (additionally) in oral form by a researcher. All participants have signed/will sign the informed consent (easy/layman language for PaS/relatives). In case of legal guardianship of a PaS the legal guardian was/will be informed and can give informed consent (in addition). The written report for study participants will be given via letter and a semi-annual information letter for members of the practice-research network.

Strengths and limitations

The multi-methods design employs methodological triangulation to obtain a more adequate and comprehensive picture of the concepts of interprofessional diagnostic, and gait-related participation. It is based on participatory research principles. However, some limitations have to be addressed. In the IR, abstracts have only been assessed by a single person, though additional team members could be included, in case of questions. The focus groups did not recruit enough participants for separated PaS/relative groups. Therefore, the results of the mixed group have to be interpreted with this in mind. The future workshop, as well as the focus groups before, include participants in the setting of Bavaria. While we think the results can be transferable to other regions, this is a limitation to be considered.

Moreover, with the multi-methods design, we will be able to report the results to political stakeholders, such as regional politicians, payers, professional policy representatives and seek a partnership-based cooperation after the end of the project.

The dissemination strategy will also include international peer-reviewed journal publications, scientific conferences, formal and informal reports and discussions with those involved in care at symposia and specialist conferences.

Patient and public involvement statement

In terms of a participatory research approach, qualitative research methods will be used to explore and influence social reality in a spirit of partnership.[43] The development of the research questions, the design and all study materials are conducted participatory. Co-researcher (JL) is the founder and member of the management board of 'Schlaganfall-Ring-Schleswig-Holstein', a self-help-organisation,[44] with whom there is a long-standing relationship of trust. JL will not receive an expense allowance. The perspective of PaS, relatives, health professionals and stakeholders from health insurance services will be directly integrated in the development of the toolkit. We will invite representatives from the community to participate, including their expertise with regard to structural improvements in the region.

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Competing interests None declared.

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