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Development of a smart walker for clinical settings: a protocol of an exploratory mixed-methods study

Nicole Strutz ,[1,2] Thorsten Meyer-Feil,[3] René Schwesig,[2] Stephan Schulze,[2] Helen Gissendanner[3]

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[1]Munich Campus for Health and Engineering, Munich University of Applied Sciences, Munich, Germany
[2]Department of Orthopaedic and Trauma Surgery, Martin-Luther-Universität Halle-Wittenberg Medizinische Fakultät, Halle (Saale), Germany
[3]Institute for Rehabilitation Medicine, Martin-Luther-Universität Halle-Wittenberg, Halle (Saale), Germany

Correspondence to
Professor Nicole Strutz;
nicole.strutz@hm.edu

ABSTRACT

Introduction Mobilisation and mobility in clinical settings are essential to the recovery process after surgery and trauma-related hospital admission. In addition to personal support from physiotherapists and nursing staff, aids such as walkers are applied. Walkers equipped with smart features have the potential to benefit geriatric patients by facilitating routine clinical workflows and, where appropriate, by providing health professionals with information on gait patterns and vital parameters.
The overarching goal of this project is to develop an innovative smart walker for clinical use, guided by three objectives: (a) Identify the feature requirements of the smart walker from the perspectives of patients and health professionals, (b) Co-design the smart walker using a user-centred approach involving older patients, health professionals and clinical engineers and (c) Pilot-test the smart walker in real time with older patients admitted to German clinics.

Methods and analysis We will employ a three-phased exploratory sequential mixed-methods approach in this project. Phase I explores potentially useful characteristics of a smart walker via a scoping literature review (part 1 of phase I) and a qualitative interview and observational study, including questionnaires on sociodemographic data and technology readiness, involving four to six patients and four to eight nurses and physiotherapists (part 2 of phase I). Phase II focuses on developing and validating a smart walker through a user experience design, with at least three iterative test cycles involving a minimum of three asymptomatic participants and three to seven potential users in each cycle. Phase III comprises a pilot study conducted at a University Hospital in Germany involving at least twelve patients. Data integration takes a data-building approach, combining qualitative and quantitative results in the final analysis to generate a comprehensive understanding and to create and refine insights into the feature needs and use of a smart walker by patients.

Ethics and dissemination The study was approved by the Ethics Committee of University Medicine Halle, Germany (Approval No. 2025-032; date of approval: 03/04/2025). Study results will be disseminated through peer-reviewed journals and conferences.

PROSPERO registration number The study protocol was registered at the Open Science Framework Platform (OSF, register number: 10.17605/OSF.IO/CTPF4).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Users will be actively involved in the development process, contributing their experiences, needs and preferences regarding a smart walker. Due to their iterative participation at every stage of the study, we aim for a higher probability of feasibility, acceptability and appropriateness in clinical settings.
⇒ Due to our research focus on technological development within user-centred iterative cycles over the course of a 2 year project, we will not adopt a rigorous qualitative sampling strategy aimed at generating transferable conclusions about mobility needs.
⇒ The integration of multiple data sources, along with the combined utilisation of qualitative and quantitative data, facilitates a comprehensive understanding of desirable components of a smart walker.

INTRODUCTION

Mobility is a critical prerequisite for maintaining functional ability[1] and is essential for independent living and active social participation. Both advancing age and acute or chronic illnesses can substantially impair mobility, often through multifactorial mechanisms. These include age-related or disease-related declines in sensory perception, motor control, sensorimotor integration and alterations in motor activity, processing speed, movement amplitudes and postural stability.[2] Psychosocial factors, such as mobility-related fears stemming from fall risk, further influence mobility outcomes.

Even brief periods of reduced mobility—such as those resulting from accidents or surgical procedures—can precipitate rapid functional decline, particularly in older adults in clinical settings.[3] This decline may trigger a cascade of health complications, including metabolic disorders and physiological impairments.[4] In acute clinical settings, early mobilisation and activity promotion are vital interventions to mitigate these risks and support recovery.

Beyond individual functionality, targeted mobilisation strategies can positively impact the entire care continuum, including reducing hospital length of stay.[5 6] Implementing early, frequent and tailored programmes—aligned with the patient's specific health status and functional level—is crucial for effective mobility enhancement.

However, routine clinical practice faces significant challenges. Limited personnel and time resources constrain the implementation of mobilisation and activity promotion measures. The ongoing shortage of skilled healthcare workers is expected to exacerbate these limitations. Additional barriers include surgical complications, multimorbidity-related needs, organisational obstacles and technical difficulties in delivering care. Moreover, patients often refrain from independently engaging in mobilisation activities due to fears (eg, falls), pain, confusion or delirium, disorientation or perceived reduced resilience.[7 8]

To address these challenges, it is imperative to develop and deploy early, appropriately frequent intervention programmes tailored to individual health problems and functional capacities. Technological innovations, such as smart assistive devices, hold promise in this context. For instance, a motorised walker equipped with needs-adapted functionalities—such as orientation support within hospital environments and assistance in increasing movement range—could enhance patient confidence during mobilisation. Such devices could serve as a means to improve safety, foster self-motivation and streamline the care process in everyday hospital settings.

Smart walkers with a range of advanced functions are currently under development and being tested in laboratory settings and with asymptomatic and/or young adults, as demonstrated, for example, in several publications.[9–11] One reason why smart rollators have seen little commercial use to date may be that their development has largely taken place under laboratory conditions. Results obtained in such overly controlled environments may not translate to clinical use, as such strict control is neither feasible nor intended in the clinical setting. In particular, functions for the complex assessment of gait patterns and the generation of targeted feedback have not yet been studied with end users in the current literature.[12–15]

This study aims to develop a smart walker that can be used by patients in an acute geriatric ward at a hospital. Smart walkers are discussed in literature, but the focus here is on the developers' perspective[10 16–19] and the perspective of potential users is hardly represented.[20]

Study objectives

To address existing research and development gaps to improve mobility in clinical settings, the study aims to:

1. Identify the requirements for a smart walker based on a scoping review of literature from 2015 to 2024.
2. Determine the feature needs and functionalities for a smart walker within an acute care setting from the perspective of patients and professional caregivers, ensuring direct integration into technical development.
3. Conduct testing of the developed smart walker and further refine it through iterative development and evaluation cycles.
4. Provide a smart walker in the form of a demonstrator and define potential outcome variables for a follow-up project.

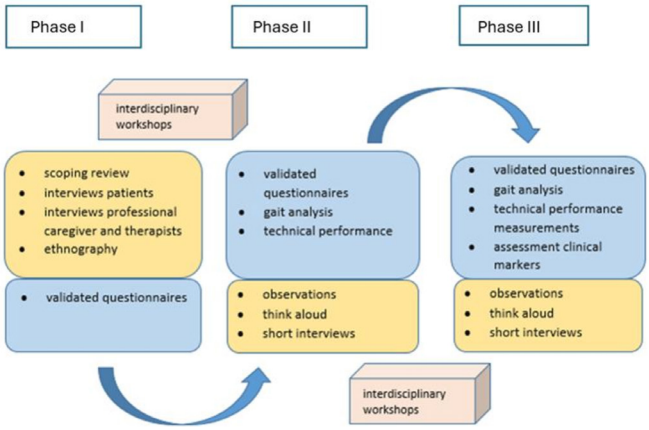

Figure 1 Mixed-methods approach in convergent design.

METHODS AND ANALYSIS

With a duration of 2 years (January 2025 to October 2026) this mixed-methods study will be conducted by the Department of Orthopaedic and Trauma Surgery and the Institute of Rehabilitation Medicine, Martin-Luther-University Halle-Wittenberg, Germany. The study protocol was registered at the Open Science Framework Platform (OSF, register number: 10.17605/OSF.IO/CTPF4) on 12 January 2025.

To address the four study objectives, the development project SmartRoll is carried out by a multidisciplinary team of scientific and technical professionals in a mixed-methods study with a sequential exploratory approach. The study is structured in three consecutive phases (figure 1). In each phase, a convergent design will be used to gain in-depth insights of potential users' perspectives as well as the necessary understanding about the context and potential outcomes regarding mobility for which the smart walker is being developed:

- Phase I has two parts: in part 1 we carry out a scoping review to answer objective 1. In part 2, we comprise data from observations, interviews, informal conversations and a quantitative survey to answer objective 2. All information gathered in this phase will be integrated to produce the first version of the smart walker.
- In phase II, the first version of the smart walker will be tested in at least three iterative cycles to achieve objective 3. All data gathered in these iterative cycles will be used to further develop the smart walker, resulting in a demonstrator by the end of this phase.
- In phase III, final pilot tests with a demonstrator of the smart walker at technological readiness level (TRL) 5 will be conducted to achieve objective 4.

Phase I: needs analysis

To determine the technological functionalities and feature needs of the smart walker from the perspective of patients and professional caregivers, a requirement analysis will be conducted in two parallel approaches:

Phase I, part 1: a scoping review

At the time of submission of the study protocol, a scoping review on the current state of research had been completed, and a related publication had been submitted to an international journal. We followed the Joanna Briggs Institute (JBI) guideline for scoping research and reported in accordance with the Preferred Items for Systematic Reviews and Meta-Analyses statement for reporting scoping.[21]

We followed the JBI guidelines for scoping reviews and reported in accordance with Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR), and registered the protocol at OSF (10.17605/OSF.IO/CTPF4) on 12 January 2025. Our search strategy was developed in consultation with the library, using key concepts such as (list all key concepts). The strategy was adapted for five databases: PubMed, SSCI, CINAHL, IEEE Xplore and the Cochrane Library. Citations were exported to Rayyan management software (Rayyan Systems, Cambridge, MA 02142, USA)[22] for deduplication and screening. Three authors independently screened titles, abstracts and full texts using predefined inclusion and exclusion criteria. We excluded reviews, articles that described smart walking aids with two wheels or fewer, and non-smart walkers. Data were extracted from each study by multiple authors independently using a predefined extraction framework. Any disagreements were resolved through discussion with the principal investigator. Consistent with scoping review methodology, the methodological quality of included studies was not appraised.

Results of the literature review will be an overview of current research landscape, including identified areas of application, previous smart walker developments and their documented outcomes. These insights will help avoid unnecessary redundancies and allow the integration of successful functionalities from the outset.

Phase I, part 2: user-centred assessment

In the second part of phase I, we will conduct a user-centred assessment[23] that involves ethnographic approaches like observations, qualitative interviewing and quantitative surveying to describe study participants and determine technology readiness. Patients and health professionals will be participants in this phase.

Recruiting, sampling and sample

Approval from the hospital management and the staff council has been obtained to recruit participants in an acute geriatric ward at the University Hospital Halle (Saale). Health professionals who provide care at the university hospital will be identified by the research team as potential interviewees and invited to participate in direct interviews and/or an offer to be accompanied during their daily work. To identify potential patient-side participants, the research team, together with health professionals of the geriatrics ward at the university hospital, will identify potential interview partners. Hospital staff, by virtue of their long-standing practical experience in inpatient patient care, are qualified to assess the suitability of prospective study participants—including their physical and psychological status. Recruitment of patients with information about the study will be conducted by members of the research team.

The sampling strategy will be guided by theoretical considerations, initially based on the scoping review results and expert opinions. After preliminary data collection, a criterion-based sampling strategy is carried out to ensure a broad spectrum of perspectives.

Inclusion criteria for professional caregivers (nurses, physiotherapists and occupational therapists) will be German- or English-speaking individuals who are aged 18 years or older. Given that trainees in both academic and non-academic pathways toward nursing, as well as toward occupational therapy and physiotherapy, are already eligible, health professionals may be enrolled directly on completion of their respective training. Exclusion criteria will be individuals with markedly limited hearing, language or speech abilities. Due to the setting and the insights to be gained from observations on the ward, participants in the ethnographic approaches may overlap with those in the interviews.

Inclusion criteria for patients will be German-speaking or English-speaking individuals who can walk at least 20 m independently and are therefore considered ambulatory, and who are capable of giving informed consent, ie, not under compulsory legal guardianship. Exclusion criteria include impaired cognition. Exclusion criteria will be as follows: individuals with cognitive impairment (DemtTect ≤8 points, assessed routinely during the inpatient stay[24]), individuals in the end-of-life phase as perceived by caregivers or by the participants themselves, individuals with limb amputation, individuals with insufficient functional capacity (≥NYHA III), individuals following spinal surgery, and individuals with markedly limited hearing, language or speech abilities. Participants will give informed written consent. Because the study population is highly heterogeneous in terms of age, care needs and degree of disability, we aim to ensure maximum variations in the selection of patient participants to capture the full spectrum of experiences and perspectives.

Four to eight health professionals from a geriatric ward of a university hospital and four to six patients will participate in the first phase of the project.

Four to six patients will be interviewed using a semi-structured interview guide in which questions are asked about mobility and problems and needs when walking.

Data collection

To ensure a comprehensive understanding of user needs, multiple data sources will be collected:

- Ethnographic approach with observations and informal conversations with care providers: to understand how mobility and patient mobilisation are embedded in everyday clinical workflows, health professionals (eg, nurses, physiotherapists, occupational therapists) will be observed in their daily work. Following established ethnographic methodology,[25 26] observations will be conducted openly and flexibly without a pre-defined observation guide to allow for a responsive exploration of everyday care practices and interactions in situ. The approach is explicitly exploratory, with an initial phase of only a few days of observations and informal conversations, which may be adapted and expanded as insights emerge. The focus will be on identifying when and where mobility support is provided, how patient movement is facilitated, and in which situations a walker is already used or could potentially be used. Additionally, observations aim to capture implicit and habitual practices related to patient mobility that are often taken for granted and not explicitly verbalised by health professionals but are crucial for understanding real-world needs. Observations may be supplemented by informal conversations or ethnographic interviews, which allow professional caregivers to reflect on their experiences, describe challenges and elaborate on observed situations in more detail. These interactions will help contextualise the observed practices and uncover additional insights that may not emerge in structured interviews alone. Observations and informal conversation will result in field notes and observations protocols used for analysis.
- Semi-Structured Interviews: patients and health professionals will participate in semi-structured face-to-face interviews to explore their perspectives on mobility challenges and needs, potential use cases for a smart walker, and factors that could facilitate or hinder its adoption in hospital settings. The interviews will be recorded and are expected to last 30 to 40 min. The interview guides were developed by a team of sociologists and rehabilitation and health scientists. The researchers are qualified and highly experienced in qualitative research. A pre-test has been conducted. No revision was required. Below are exemplary primary and secondary research questions that informed the development of the interview guide for older patients.

  Primary questions: (a) What mobility limitations are experienced? (b) To what extent can a walker, with its various functions, contribute to increased mobility, dexterity and orientation? Secondary questions: a.1 What problems related to mobility, walking and movement (especially in small settings) are experienced? a.2 Which assistive devices are (so far) used, and how do they contribute to mobility and movement? a.3 What is currently missing for patients in terms of support for mobility and mobilisation? b.1 Which functions/assistive devices do patients think could help improve their mobility? b.2 What factors could support the use of a smart walker in the clinical setting from the patient perspective? b.3 What obstacles do patients see in the potential adoption of a smart walker in the clinical setting? b.4 What additional factors influence the acceptance of implementation and use of a smart walker?
- Sociodemographic and validated questionnaires: sociodemographic data will be collected using a questionnaire to contextualise qualitative findings and gain additional insights into participant characteristics and technology-related attitudes. Furthermore, validated instruments, such as technology readiness questionnaire 'Technology Commitment',[27] will help frame the qualitative findings and provide a broader understanding of potential user needs and barriers. The technology readiness questionnaire 'Technology Commitment' is, as Neyer *et al*[27] stated '[…] based on a model of technology readiness, which identifies three distinct facets as determinants of individually different readiness to use technology: Technology acceptance, technology competence and technology control convictions. Readiness to use technology is intended to predict the successful use of new technologies, especially in old age'. The total questionnaire and its subscales—Technology Acceptance and Technology Competence—demonstrate good reliability (Cronbach's α=0.84). The subscales likewise show acceptable reliability (α=0.74) and exhibit good validity in two validation studies with regard to technology use (β=0.31 and 0.40, $p<0.001$) and Openness to Experience (β=0.29 and 0.11, $p<0.01$).[27]

Data analysis plan

Raw qualitative data will be managed using the software MAXQDA. Interviews will be transcribed by trained investigators, and an additional investigator will conduct a data audit to ensure accuracy. A combination of rapid techniques[28] and thematic analysis[29] will be employed to balance the need for quick iterative insights with a systematic, in-depth analysis of user needs.

Rapid techniques will be used to extract key findings quickly from protocols or audio recordings[30] and make them immediately available to technical developers, ensuring that insights from observations, interviews and informal conversations can directly inform the design process. This approach allows for an agile development cycle, where feature needs and requirements can be continuously refined based on emerging findings. Unlike conventional methods and in accordance with Vindrola-Padros and Johnson,[28] the rapid technique eliminates the transcription production phase. The research team will listen to the audio interviews within days of each conducted interview and immediately identify and extract core statements. The core statements pertaining

to mobility and smart walkers will be annotated with supporting quotes from the interviews. The first three interviews analysed with the rapid technique will be coded by two researchers and checked for concordance. In the presence of heterogeneity among the core statements, they will be discussed to develop a shared understanding of the relevant statements. The first three interviews will subsequently be re-coded.

Thematic analysis will be conducted to identify recurring patterns and underlying themes in the verbatim transcribed data. This more comprehensive analysis, carried out by two experienced researchers, will provide a structured, methodological rigour understanding of user needs, mobility challenges and potential barriers or facilitators for the smart walker's use in clinical settings.

Additionally, data from the validated and sociodemographic questionnaires will be analysed descriptively to contextualise the qualitative findings and identify aspects of technology acceptance and sociodemographic influences on mobility support needs.

By integrating qualitative and quantitative elements, this phase aims to provide a comprehensive understanding of the needs, expectations and potential barriers related to smart walker usage in hospitals.

Merging and utilisation of results

The findings of the needs analysis will be discussed in workshops with project partners and possible other experts to meet needs observed and mentioned in the interviews with technical solutions. The integration of perspectives from all participants across different disciplines aims to develop solutions for identified needs and problems that are feasible, appropriate and acceptable.

Depending on the amount of new information gathered in the user needs assessment, it may be feasible to conduct one or two workshops with six to twelve participants each. Key discussion points and insights will be recorded on moderation cards and flip charts, while the entire discussion will be audio-recorded for documentation purposes. All participants will receive a report summarising the results of the outcome production and technical solution development.

At the end of phase I, a first version of the smart walker in line with patient and therapist needs will be developed. The initial and iterative developed versions comprise two components: first, a foundational framework consisting of a market-standard four-wheeled walker with two handbrakes; second, an integrated hardware-software architecture designed to equip the walker with functions such as navigation, assistive propulsion, or an emergency stop or others. The addition of these features and the associated hardware and software render the walker 'smart'.

Phase II: iterative testing

Following the feature needs analysis, the second phase of the project focuses on the iterative testing and refinement of the smart walker. Over the course of at least three iterative test cycles, the device will be tested under real-world conditions to assess usability, functionality and potential improvements. Participants will be observed during use, encouraged to provide real-time feedback, and various parameters will be measured to evaluate both the walker's performance and potential outcome variables related to users' gait patterns.

Recruiting, sampling and sample

The testing phase will begin with internal trials conducted by project team members and their colleagues, asymptomatic persons for first tests, to identify initial usability issues and technical adjustments in a controlled setting. The project team comprises health scientists with primary qualifications as registered nurses or physiotherapists, as well as engineers and sport scientists. A portion of the team possesses extensive experience in the outpatient and inpatient care and therapy of geriatric patients. The term 'asymptomatic' is used instead of 'healthy' here, as the emphasis is on the symptom-free status of the test subjects. Subsequently, participants from the target population—hospitalised patients with varying levels of mobility—will be recruited from the geriatric ward. Involving patients as study subjects is indispensable, as the iteratively developed walker must address the abilities and needs of the target group. The inclusion and exclusion criteria correspond to those for older patients, as described in phase 1.

Each iteration cycle includes tests with at least three asymptomatic persons and three to seven potential users; patients from the university hospital. This approach ensures a broad representation of different clinical conditions, mobility impairments and user needs, allowing for a more comprehensive evaluation of the smart walker's functionality.

Data collection

During the tests, multiple data sources will be gathered to assess both the technical performance of the smart walker and the user experience (UX):

- Observations of participants' interactions with the walker, focusing on usability issues, comfort and ease of navigation.
- Think-aloud and concurrent feedback, where participants are encouraged to share their thoughts and immediate impressions while using the device.
- Technical performance measurements, including accuracy of distance tracking, obstacle detection and sensor responsiveness.
- Gait parameter assessments, such as step length, walking speed and cadence, which may serve as outcome variables in further research.
- Sociodemographic data collection to analyse potential influences of age, mobility level and clinical background.
- Short post-test interviews to gather qualitative feedback on perceived usability, safety and potential improvements.

In each walker testing session, at least three team members will be present, with roles clarified and assigned

in advance. Two team members will be primarily responsible for observing the session and monitoring potential risks and are tasked with intervening in case of emergency. The third team member will focus on observing the use of the walker's functions and will also facilitate the think-aloud technique by asking the user relevant questions. Gait parameters are assessed using specialised instruments worn by participants during the tests. Each testing session will last a maximum of 20 min, and observations will be conducted only during this time frame. Sociodemographic information and post-test interviews will be conducted after the actual test.

Data analysis plan

The collected data will be analysed using a mixed-methods approach:

- Qualitative data (eg, observations, think-aloud protocols and interview responses) will be analysed using thematic analysis, identifying recurring usability issues, barriers, user needs and patient experiences.
- Technical and gait-related quantitative data will be analysed using descriptive statistics and comparative analysis across test iterations to assess improvements in measurement accuracy and walker performance.
- An iterative feedback loop will ensure that findings from each test cycle directly inform subsequent modifications, leading to continuous refinements of the smart walker's design.

This iterative process allows for an agile and user-centred development approach, ensuring that the final smart walker aligns with real-world clinical needs and effectively enhances mobility in hospital settings.

Merging and utilisation of results

Findings from each testing circle will be discussed with project partners and four to six health professionals from the hospital in workshops to ensure a further development of the smart walker according to observed and mentioned needs from patients and included perspectives on those needs by care givers in a setting well known for them. For documenting the course of the discussion, key results will be recorded on moderation cards, and the conversation will be recorded. A summary report of the results will be provided to all participants, the technical included, afterward. The results of the workshops will be directly integrated into the technological further development of the smart walker. Furthermore, researchers will stay in contact with technological experts to discuss possible solutions for addressed results in the workshops.

Phase III: pilot testing and demonstrator deployment

After the iterative testing phase, a refined version of the smart walker will be available as a demonstrator for pilot testing with hospital patients. This phase aims to collect further UX data and to identify potential outcome variables that could be used to assess the impact of the smart walker on mobility and mobilisation in a future follow-up study.

Recruiting, sampling and sample

A criteria-based sampling will be used based on the collected UXs and the experiences within the project team, which may influence the potential increase in the number of participants. Patients will be selected based on factors such as mobility impairments, rehabilitation needs, varying levels of prior experience with walking aids and other criteria that will be identified during the research process. At least twelve hospital patients with diverse mobility challenges will be recruited. These processes ensure that the demonstrator is tested under real-world clinical conditions, capturing diverse feedback on usability and functionality.

Data collection

The pilot study will take place exclusively in a clinical setting, specifically in a geriatric trauma ward at a university hospital. One smart walker is being used in the pilot test. The accompanied use by the participants will take place on 1 day and will include mobility in the participants' everyday ward routine (eg, getting out of bed, going to the toilet, moving around within the ward). The test subjects will be accompanied by the study staff. Feedback will be collected in the context of a short interview.

Pilot testing will focus on both qualitative and quantitative aspects:

- Technical performance evaluations, assessing the walker's usability, stability and integration into clinical routines.
- Assessment of potential outcome variables, including gait parameters (eg, walking speed, step variability), mobility indicators (eg, distance walked, time to complete a mobility task), and potential clinical markers (eg, perceived effort, confidence in walking).
- UX data, gathered through observations, concurrent feedback and short post-use interviews with patients.
- Health professionals' perspectives, collected through structured feedback sessions to understand facilitators and barriers to integrating the walker into patient care.

Data analysis

Quantitative gait and mobility data will be explored through descriptive statistics to determine variability, trends and suitability as outcome measures. Identified outcome variables will be assessed for their validity and feasibility in measuring mobility improvements, forming the basis for a future clinical trial. Qualitative data (user feedback, interviews and observations) will be analysed using thematic analysis, focusing on recurring usability themes and areas for further improvement.

Merging and utilisation of results

In the third part of the study, at least one more workshop is planned, where results and observations from the tests will be discussed. One workshop will involve four to six participating professional caregivers. Results will be recorded on moderation cards and provided to

participants in the form of a protocol. For documentation purposes, the discussions will be recorded. The results of the discussion aim to contribute particularly to understanding how feasible, appropriate and acceptable the developed smart walker is in the clinical daily routine, as well as understanding what has to be considered for implementation and development for a higher Technology Readiness Level (TRL).

Results of phase III

This pilot phase ensures that the demonstrator is thoroughly tested in clinical practice while establishing a foundation for future evidence-based evaluation of the smart walker's effectiveness. The result of the third phase is a developed demonstrator of the smart walker with TRL 5 for use in the hospital.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The study was approved by the Ethics Committee of University Medicine Halle, Germany (Approval No. 2025-032; date of approval: 03/04/2025) and is in line with the Declaration of Helsinki. All personal information from the interviews, short questionnaires and patient records will be stored separately from personally identifiable data (such as your gender and name from the consent form). The study data from interviews, short questionnaires and patient files will be stored digitally on a project-specific server. The server is located in the university's IT system and is subject to strict IT and data protection standards. Only project staff have access to the project-specific server. Audio recordings of interviews and their transcripts will be stored in encrypted form until the end of the project.

The protocol outlines an iterative user-centred process for technological development. This study protocol may serve as a useful guide for planning similar studies and projects that aim to develop and test technological devices in clinical settings.

Findings will be disseminated in international peer-reviewed journals and conferences. For reporting our research, different guidelines and statements will be applied for different purposes: for mixed methods research, we will use the 'Mixed Methods Reporting in Rehabilitation and Health Sciences'. For results from qualitative research, we will use the 'Consolidated criteria for reporting qualitative research', and for results of the scoping review, we will follow the PRISMA-ScR. The 'Strengthening the Reporting of Observational Studies in Epidemiology' statement will be applied to report quantitative data.

Contributors HG, NSt and SS conceptualised the study. The manuscript was written by HG and NSt. SS provided ongoing feedback and critically revised the manuscript. TM-F and RS critically reviewed the study design and manuscript for important intellectual content. The corresponding author, NSt, is the guarantor. All authors have reviewed the drafts and approved the final version.

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ORCID iD

Nicole Strutz https://orcid.org/0000-0002-4780-2188

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