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Challenges and Strategies in Recruiting Patients for a Trial on Patient-Centered Navigation in Age-Associated Diseases

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Abstract

Patient navigation initiatives aim to improve the coordination of healthcare by reducing the barriers patients encounter when seeking access to appropriate services. These types of interventions are currently being tested both within Germany and internationally. A common obstacle in such research, as with most clinical trials, is developing recruitment methods that successfully enroll enough participants from the target groups. The results presented here aim to share insights and experiences regarding a common challenge in healthcare research: identifying factors that influence patient participation and refusal in studies testing new interventions, and how these factors can guide study design. This study, part of a mixed-methods feasibility evaluation involving randomized and cohort components, systematically recorded the recruitment process for a patient-focused navigation program. Between June 2021 and September 2022, individuals with lung cancer or stroke were recruited from inpatient wards and specialized outpatient clinics across urban and rural regions of Germany. Data were collected on why some patients were excluded or not approached, as well as the reasons patients declined participation. Quantitative findings were analyzed descriptively, and thematic analysis was applied to interviews with recruitment staff to capture their perspectives. Among screened individuals, eligibility rates ranged from 74% to 76.5% for stroke patients and 91% to 93% for those with lung cancer. Of those eligible, recruitment efforts reached 44% to 46.9% of inpatients and 73% of outpatients. Factors preventing patients from approaching were primarily linked to organizational or situational constraints. Common reasons patients refused involvement included feelings of being overwhelmed (noted in stroke patients) and perceiving the study as irrelevant (noted in lung cancer patients). The lessons learned and recruitment challenges encountered during this feasibility study provide valuable insights for refining patient enrollment strategies in future trials focusing on age-related health conditions.

Keywords: Navigation program, Age-related illnesses, Participant recruitment, Process evaluation

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Introduction

Developing an effective patient recruitment strategy is essential for the success and planning of clinical studies, as failing to enroll the required number of participants can compromise the trial's validity and reduce the reliability of outcome measures [1, 2]. However, achieving target sample sizes remains one of the most

significant hurdles in trial design and execution. A systematic review from the UK, examining recruitment outcomes in over 100 multicenter clinical trials, found that fewer than one-third of the trials met their planned enrollment goals [3–5]. The difficulties in recruitment stem from a range of factors, including organizational challenges, study design issues, and patient-related barriers [6]. Despite numerous investigations, systematic reviews have yet to identify definitive strategies for improving recruitment rates [3]. Some factors shown to enhance recruitment include clear and effective communication—such as combining face-to-face interactions with written materials, providing concise and jargon-free information, and having skilled communicators deliver study details—along with employing open trial designs and sending follow-up reminders via phone or SMS after initial invitations [3, 7]. Previous research also highlights concerns about selection bias and underrepresentation, particularly among patients with barriers like severe cognitive impairments post-stroke [8, 9] or language difficulties [10, 11].

When planning recruitment for healthcare interventions, multiple considerations arise, such as: (a) identifying the most comprehensive care settings to access the target population (for example, inpatient units, rehabilitation centers, or outpatient clinics); (b) determining the ideal timing within the patient care pathway to approach individuals and offer the intervention under study. Notably, the setting or time that allows broad patient contact may not align with the period when patients are most receptive or in need of the intervention [7]. Additionally, (c) the choice of recruiter and method of patient contact are critical. While using internal staff is advantageous due to their familiarity with the site and ease of access, it can also alleviate data privacy concerns. However, adding recruitment responsibilities to already busy healthcare workers can cause workload strain and deprioritize study recruitment [12–14]. Finally, (d) understanding patients' motivations or hesitations toward participating is vital. Prior studies indicate that perceived personal benefit or the desire to contribute to scientific knowledge can encourage participation [7]. Conversely, the required time commitment and feelings of being overwhelmed by their health status at enrollment may deter patients from joining studies [7, 14, 15].

For an effective recruitment strategy, it is crucial to consider and balance all the aforementioned factors while also accounting for the project's available financial and human resources. This paper outlines the recruitment process employed in a study evaluating the feasibility of a patient navigation intervention for individuals with stroke and lung cancer. Patient navigators are tasked with assisting patients in managing and coordinating their care, which is particularly important given the complexity and fragmentation of the German healthcare system. Older patients or those lacking social support may especially benefit from such navigational assistance [16]. Recruitment for the CoreNAVI study involved actively approaching patients in inpatient and specialized outpatient settings by dedicated study staff. As part of the feasibility evaluation, a concurrent process evaluation was conducted to determine whether the recruitment strategy was suitable and effective for enrolling the intended patient population or if alternative approaches should be considered. This process was carefully documented to identify who was reachable within these care settings and the reasons behind patients not enrolling, including organizational, contextual, and individual factors. The results presented here aim to share insights and experiences regarding a common challenge in healthcare research: identifying factors that influence patient participation and refusal in studies testing new interventions, and how these factors can guide study design.

Materials and Methods

Study design

The data discussed in this paper derive from a mixed-methods feasibility study designed to evaluate a patient-oriented navigation program for patients with age-related diseases, specifically stroke and lung cancer [17]. The study incorporated two-arm randomized controlled trials (RCTs) alongside parallel cohort studies, qualitative interviews, and secondary analyses of health insurance data. The primary objective was to assess the feasibility of the navigation program in terms of acceptance, demand, and practicality, as well as to explore preliminary efficacy outcomes. Here, we focus on the process evaluation conducted alongside the screening and recruitment phases to assess the effectiveness of the recruitment strategy. This evaluation employed multiple methods, including comprehensive documentation of the recruitment process, assessments of reasons for refusal, and qualitative interviews with recruitment personnel. Further details on the study design are available in the published protocol by Gödde *et al*. [17]. The study was

registered in the German Clinical Trials Register (DRKS-ID: DRKS00025476) on June 4, 2021.

Recruitment strategy

Patients diagnosed with acute stroke or lung cancer, along with their caregivers, were proactively invited to participate in the feasibility study testing the patient navigation program. All eligible individuals were offered enrollment in a two-arm RCT: the intervention group received personalized navigation support for one year. In contrast, the control group was provided with a brochure detailing regional support services. Those who declined participation in the RCT were invited to join a parallel cohort study where no randomization or navigation intervention was involved. Across all study arms, participants completed baseline assessments using questionnaires at enrollment and three follow-ups at four, seven, and thirteen months post-enrollment. The intervention group also responded to additional questions related to their experience with the navigation service during follow-up. Ethical approval for the study was obtained from the Ethics Committees of Charité–Universitätsmedizin Berlin (EA2/249/20) and Medizinische Hochschule Brandenburg–Theodor Fontane (Z-01–20210517).

The inclusion criteria required patients to have a diagnosis of acute stroke or transient ischemic attack (TIA), or lung cancer, be aged 18 years or older, and reside within a designated catchment area—either the metropolitan region of Berlin or the rural German state of Brandenburg. Exclusion criteria included living in a nursing home at the time of enrollment, inability to speak German, and having dementia at the time of enrollment. Eligible patients were initially screened by the trial coordination team or in collaboration with medical staff at the recruitment sites and reported daily to the project's recruitment team.

For recruitment, eligible patients or their caregivers were proactively approached in person by the study's recruitment staff, which included nurses and social workers. The recruitment took place in inpatient settings—specifically, two stroke units in Berlin and one in rural Brandenburg for stroke patients, as well as in a specialized outpatient clinic for lung cancer patients in Berlin. These locations were selected to ensure comprehensive access to the target population **(Table 1)**. Stroke patients were contacted soon after their stroke event, while lung cancer patients were approached during their outpatient treatment phase. Potential participants received both verbal and written explanations about the CoreNAVI study directly at the recruitment sites. Recruitment primarily occurred onsite; however, if patients or caregivers needed additional time or consultation, a follow-up appointment was arranged, or permission was secured for future contact. Written informed consent was obtained upon enrollment. Participants were provided with detailed information about the study procedures, either in person (for the cohort study) or by mail after randomization (for the RCT).

Due to access limitations such as those caused by the COVID-19 pandemic, some stroke patients who could not be reached in person from March 2022 onward were contacted via postal mail. Additionally, informational materials were distributed through rehabilitation centers, self-help groups, and other support services, including contact details for the study coordination team for interested patients.

Table 1. Description of the selected sites for recruiting participants with stroke and lung cancer for the CoreNAVI study

Setting	Location	Recruiter	Estimated number of participants	Recruitment period
Inpatient stroke units	Berlin	Project study assistant	365 participants (215 in RCT, 150 in cohort)	June 2021–July 2022
Inpatient stroke unit	Brandenburg	Project study assistant	319 participants (244 in RCT, 75 in cohort)	January 2022–September 2022
Outpatient specialized lung cancer clinic	Berlin	Project study assistant	168 participants (98 in RCT, 70 in cohort)	August 2021–July 2022
Inpatient lung cancer hospital unit	Brandenburg	In-house staff	22 participants (17 in RCT, 5 in cohort)	April 2022 –September 2022

Estimated participant numbers are based on hospital records from previous years, assuming that 60-70% of patients screened will be eligible for recruitment, and 30-50% of these will enroll in the RCT. For the cohort study, an additional 30% participation is expected from those who decline the RCT.

Screening documentation

Throughout the recruitment period, recruiters meticulously recorded the screening and recruitment activities. Every patient who presented at recruitment sites was logged daily, regardless of whether they met the inclusion criteria. Recorded details included age, sex, comorbidities (for the Berlin stroke cohort), and stroke severity using the modified Rankin Scale (mRS) — a standardized tool measuring post-stroke disability from 0 (no symptoms) to 6 (death). Enrollment status was also documented, with participants defined as those who provided written informed consent for either the randomized controlled trial (RCT) or the cohort study. Reasons for non-participation were systematically noted, encompassing predefined exclusion criteria such as residency in a nursing home, living outside Berlin or Brandenburg, language barriers, or cognitive impairments that prevented consent. Additional reasons for exclusion included refusal to participate, patients not approached or not found, involvement in other trials, discharge or transfer, among others. Multiple reasons could be recorded for a single patient. Once recruitment concluded, all screening data were anonymized.

Refuser assessment

This assessment aimed to understand why eligible patients who were approached declined participation. A standardized questionnaire or checklist was used, listing common reasons such as perceiving the study as irrelevant, feeling overwhelmed, prior negative experiences with research, or concerns about data privacy. Basic demographic information, such as age and gender, was also collected. Patients either completed the questionnaire themselves or with assistance from study staff. If patients verbalized reasons during conversations with recruiters, these were also recorded on the checklist. All data were collected anonymously without linking to patient identities.

Analysis process

Recruiters entered all screening and refusal data into Microsoft Excel databases during the recruitment phase. Frequencies and percentages from the refusal assessments were calculated using Excel. At the same time, descriptive statistics (including participation rates, exclusion reasons, non-approach reasons, demographic characteristics, comorbidities, and disease severity) were analyzed using IBM SPSS version 27. Recruitment flowcharts showing reasons for non-participation were generated. For stroke patients in Berlin, mean age with standard deviation, as well as absolute and relative frequencies of sex, disease severity (mRS), and selected comorbidities, were computed.

Qualitative interviews with recruiters

To evaluate the recruitment strategy and capture the perspectives of recruiters, qualitative interviews were conducted periodically with the recruitment team. Eight face-to-face interviews were conducted between September 2021 and October 2022, involving four recruiters (three female and one male) based in Berlin and Brandenburg. The same recruiters were interviewed both during and after recruitment to track evolving experiences and potential process adaptations. Post-recruitment interviews focused on identifying facilitators and barriers related to recruitment settings and timing. Recruiters were professionals with backgrounds in nursing or social work, and they had experience in recruitment. Interviews were conducted by an experienced qualitative researcher holding a Master's degree in communication sciences and public health. Since all participants were project staff familiar with each other, interviews were conducted in a collegial atmosphere. Sessions lasted 30 to 80 minutes, were audio recorded, and transcribed verbatim. The interview guide, informed by literature review and team expertise, centered on two key questions: (1) Are the selected recruitment settings appropriate for engaging potential participants? Why or why not? (2) Is the timing of the patient approach appropriate? Why or why not? Thematic analysis was selected as the method for analyzing the qualitative data [18-20]. The analysis focused on four main themes: (1) recruitment settings, (2) timing of patient approach, (3) recruitment challenges, and (4) reasons patients declined participation. Consequently, the interview data were categorized deductively into setting, timing, challenges, and refusal of participation. Relevant text excerpts were coded according to these categories. To maintain rigor and

reliability, the coding process was regularly reviewed in discussion with the principal investigator (CH).

It is important to note that quantitative and qualitative findings are analyzed and reported separately in the results section.

Results and Discussion

Screening and recruitment analysis

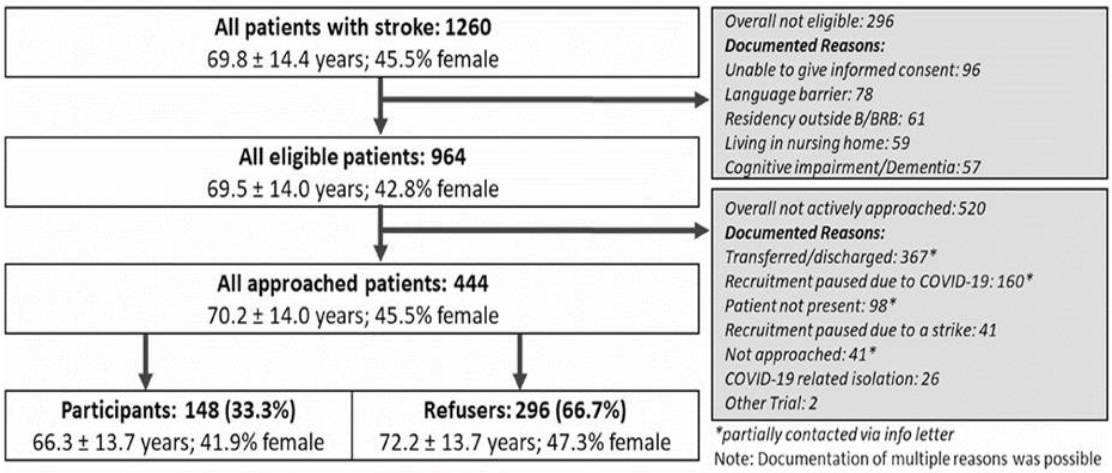
This section presents detailed results from the screening and recruitment documentation, organized by patient groups for stroke and lung cancer.

Stroke

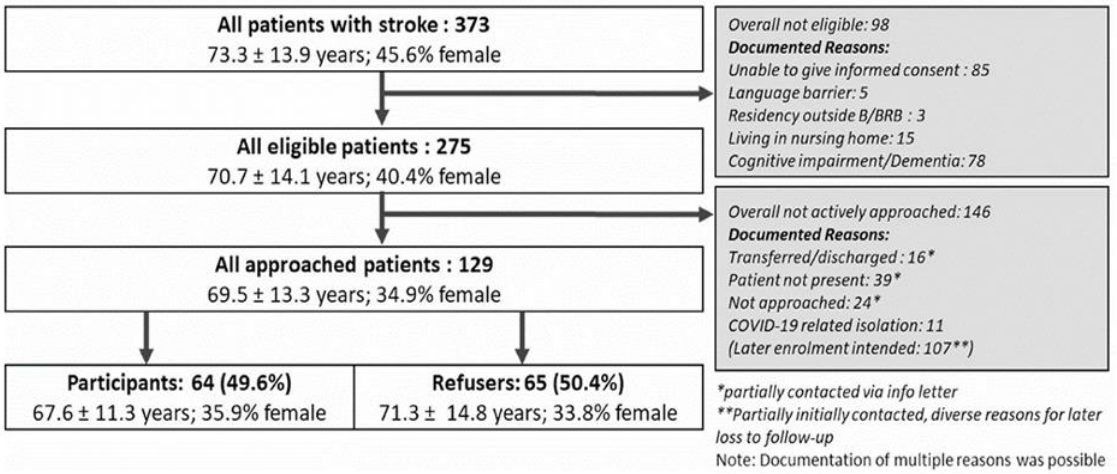
During recruitment, a total of 1,633 stroke patients were screened at participating sites (1,260 in Berlin and 373 in Brandenburg) **(Figure 1)**. Among these, 76.5% (964/1,260) in Berlin and 74.0% (275/373) in Brandenburg were deemed eligible for the study. The predominant reason for ineligibility was an inability to provide informed consent, primarily due to stroke-related cognitive impairments. In Berlin (an urban area), language barriers (insufficient German proficiency to understand study information) were also a common exclusion cause, whereas this was rarely noted in the more rural Brandenburg region.

Of the eligible stroke patients, 46.1% (444/964) in Berlin and 46.9% (129/275) in Brandenburg were actively approached for recruitment across any study arm. The main factor preventing patient approach in Berlin was early hospital discharge or transfer to non-recruiting departments. COVID-19 also hindered in-person contact in Berlin—due to restrictions and patient isolation—but these patients were subsequently contacted by mail. In both Brandenburg and Berlin, a key reason for not approaching patients was their absence from the room during recruitment efforts, often due to medical procedures. COVID-19-related barriers were less significant in Brandenburg, likely because recruitment began after major pandemic restrictions had eased.

Ultimately, 33.3% (148/444) of approached patients in Berlin and 49.6% (64/129) in Brandenburg consented to participate. Of those enrolled, 178 provided written consent for the RCT, and 34 joined the cohort study. Compared to the overall screened stroke population, participants were slightly younger (Berlin: mean age 66.3 years [SD 13.7] vs. 69.8 years [14.4]; Brandenburg: 67.6 years [11.3] vs. 73.3 years [13.9]) and less frequently female (Berlin: 41.9% vs. 45.5%; Brandenburg: 35.9% vs. 45.6%). For stroke inpatients in Berlin, additional comparisons between participants and refusers on comorbidities and stroke severity (measured by mRS) showed that participants generally had milder strokes (lower mRS scores) than both the overall screened population and refusers **(Table 2)**.



a) Location: Berlin



b) Location: Brandenburg

Figure 1. Flowcharts illustrating the recruitment process for stroke patients in inpatient settings within the metropolitan area of Berlin (a) and the rural region of Brandenburg (b). The charts include the patients' mean age with standard deviation (in years) and the proportion of female patients. Note that some patients were recorded with multiple reasons for exclusion. Abbreviations: B = Berlin; BRB = Brandenburg.

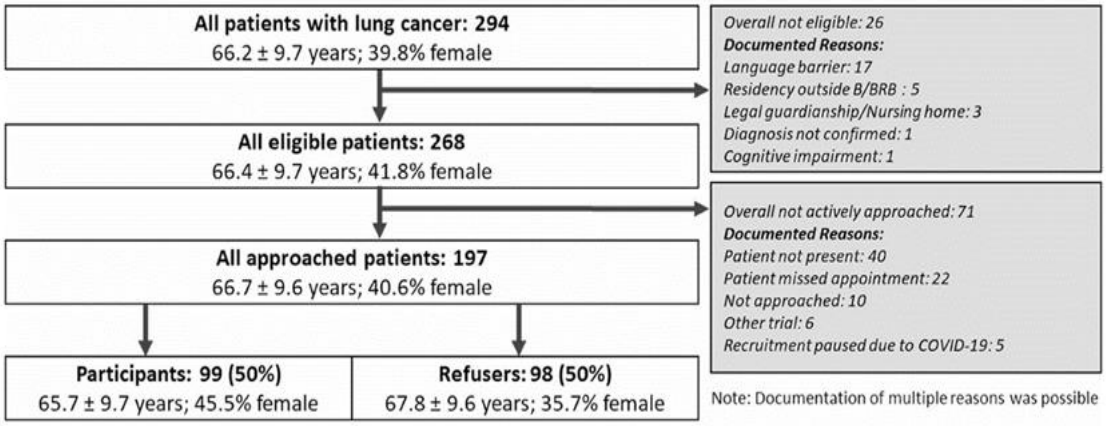
Table 2. Analysis showing the frequency of selected comorbid conditions and stroke severity, measured by the modified Rankin Scale (mRS), among stroke patients screened and enrolled in inpatient settings in Berlin. Cases with missing data were excluded, and percentages are calculated based on the number of valid observations

	All patients with stroke (n = 1260)	**All eligible patients (n = 964)**	**All approached patients (n = 444)**	**Participants (n = 148)**	**Refusers (n = 296)**
No. of comorbidities below Mean (95% CI)	1.73 (1.65; 1.81)	1.75 (1.66; 1.83)	1.96 (1.82; 2.1)	1.91 (1.7; 2.13)	1.98 (1.8; 2.14)
Hypertension	68.3% (761/1114)	69.0% (589/854)	71.2% (297/417)	68.0% (100/147)	73.0% (197/270)
Atrial fibrillation	25.8% (287/1113)	24.3% (207/851)	22.7% (94/415)	18.4% (27/147)	25.0% (67/268)
Coronary heart disease	17.1% (190/1109)	18.1% (154/852)	16.2% (67/414)	13.6% (20/147)	17.6% (47/267)
Diabetes	24.1% (268/1114)	22.7% (194/853)	23.6% (98/416)	19.7% (29/147)	25.7% (69/269)
Lipometabolic disorder	34.4 % (381/1107)	36.5% (310/850)	45.2% (188/416)	51.0% (75/147)	42.0% (113/269)
Former stroke	21.1 % (234/1108)	20.6% (175/850)	22.7% (94/414)	17.0% (25/147)	25.8% (69/267)
Former TIA	5.7% (63/1110)	6.4% (54/850)	7.2% (30/414)	4.8% (7/147)	8.6% (23/267)
Active smoker	23.7% (263/1108)	24.8% (210/847)	28.3% (117/413)	29.9% (44/147)	27.4% (73/269)
mRS	2.0 (0;4)	2.0 (0;3)	2.0 (0.25; 3)	1.0 (0;3)	2.5 (1; 4)
			Median (25; 75%)		

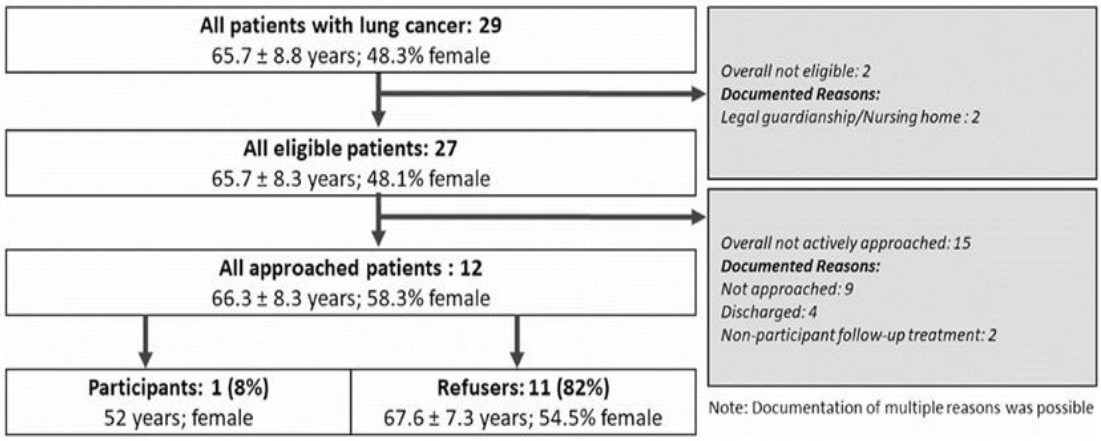
Lung cancer

A total of 323 lung cancer patients were screened, with 294 from Berlin and 29 from Brandenburg **(Figure 2)**. Among these, 91% of Berlin patients (268/294) and 93% of Brandenburg patients (27/29) met the eligibility criteria for study participation. The primary reason for exclusion in Berlin was the patients' inability to provide informed consent due to language barriers, while in Brandenburg, two patients were excluded because they were nursing home residents or had legal guardianship at the time of recruitment. Of the eligible patients, 73.5% (197/268) in Berlin's inpatient setting and 44% (12/27) in Brandenburg's outpatient setting were approached for recruitment. Notably, the 44% approach rate in Brandenburg aligns closely with the 46% approach rate for stroke patients in inpatient settings. Discharge before recruitment was the primary factor limiting patient approach in inpatient settings; however, lung cancer

patients in outpatient care often returned multiple times, thereby increasing recruitment opportunities (the median number of visits per patient during recruitment was 5, with an interquartile range of 2 to 9 visits). Among those approached, 50% (99/197) of Berlin patients consented to participate in the study (either the RCT or the cohort), with one participant recruited from Brandenburg. Of the consenting patients, 68 provided written consent for the randomized controlled trial, while 32 joined the cohort study. The average age of participants in Berlin (65.7 ± 9.7 years) was similar to that of the total screened lung cancer population in Berlin (66.2 ± 9.7 years).



a) Location: Berlin



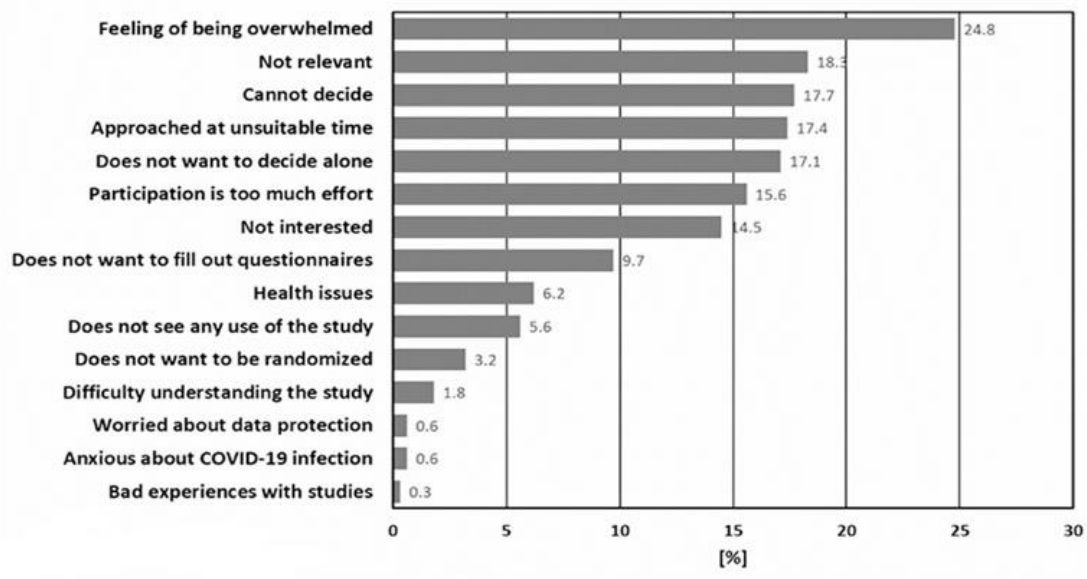
b) Location: Brandenburg

Figure 2. Flow diagrams depicting the recruitment process of lung cancer patients in a specialized outpatient clinic in metropolitan Berlin (a) and an inpatient facility in rural Brandenburg (b). The charts display the average age with standard deviation (in years) and the proportion of female patients. It should be noted that some patients had multiple documented reasons for exclusion. Abbreviations: B = Berlin; BRB = Brandenburg.

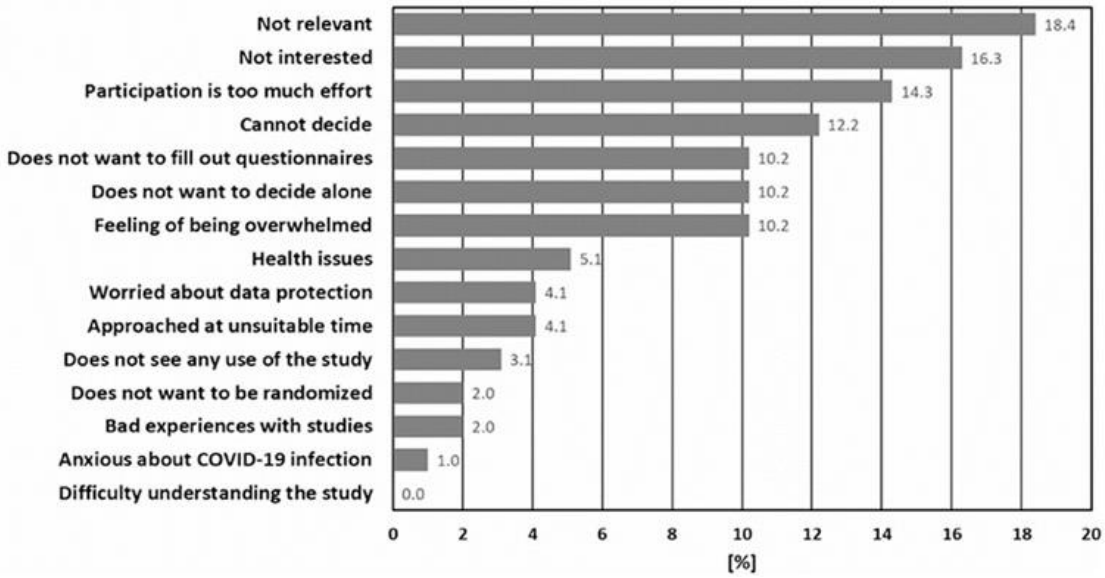
Reasons for declining study participation

Among stroke patients who were approached for recruitment, the most commonly recorded reason for refusal was feeling overwhelmed, reported by 24.8% (84 out of 339) of patients. Other prominent reasons included perceiving the study as irrelevant (18.3%, 62/339) and recruitment contact occurring at an inconvenient time (17.4%, 59/339) **(Figure 3a)**. For lung cancer patients, the main reasons for declining participation were viewing the study as irrelevant (18.4%, 18/98) and general disinterest (16.3%, 16/98). Additionally, 14.3% (14/98) felt that participation would require too much effort **(Figure 3b)**. Across both patient groups, indecision and reluctance to make a decision alone were frequently cited reasons. Notably, concerns about contracting COVID-19

during the study were minimal and rarely influenced refusal decisions **(Figures 3a and 3b)**.



a) Disease: Storke



b) Disease: Lung Cancer

Figure 3. Reasons documented by recruiters for refusal to participate in the study among patients approached with stroke (a) and lung cancer (b). A total of 339 stroke patients (271 in Berlin, 68 in Brandenburg) and 98 lung cancer patients (86 in Berlin, 12 in Brandenburg) were analyzed. Percentages represent the proportion of respondents endorsing each reason. Multiple reasons could be selected.

Qualitative interview findings with recruiters

Based on thematic analysis, findings are organized into categories including setting, timing, challenges, and reasons for refusal.

Recruiters noted differences in recruitment suitability between settings for patients with stroke and lung cancer. Stroke patients were approached early in the stroke unit shortly after the acute event. Recruiters perceived that many patients experienced mental overload and impaired

cognitive function, which were major factors preventing study inclusion or leading to refusal.

"Most often, I think it's simply being overwhelmed. Poor timing, too many documents. Many people say it's just too much at that moment." (Study nurse_01_01).

"With stroke patients, it's often difficult when they are constrained. They may be unable to speak or concentrate and can't follow even two sentences." (Study nurse_01_02).

Another frequent reason for refusal was that some patients felt adequately supported by family and social networks, perceiving no added benefit from the study's support.

"Many patients feel very well cared for already. They have other support and feel well taken care of." (Study nurse_01_02).

Barriers to approaching stroke patients included ward organization and hospital routines. The busy daily schedule, in which patients were often undergoing examinations or treatment, made patients unavailable. Additionally, COVID-19 led to frequent patient transfers and faster discharges from the stroke unit.

"On the wards, there's always the difficulty that when patients go for examinations, they're gone for hours. Mobile patients often aren't in their rooms in the afternoon, but instead wander around the grounds. Sometimes it's tough to find patients and conduct recruitment interviews calmly." (Study nurse_01_01).

"During high COVID-19 periods, many patients were transferred frequently or discharged quickly. Recruitment was especially challenging in inpatient settings because we simply didn't see many patients." (Study nurse_01_02).

In contrast, recruiters found the outpatient clinic setting for lung cancer to be less challenging. One advantage was that many patients spent several hours onsite for treatment, providing ample opportunity for recruiters to approach them. Additionally, patients attended regular treatment sessions, so if they missed being approached during one visit, there was usually another chance at their next appointment. Consequently, a large proportion of lung cancer outpatients could be contacted regarding study participation.

"As for the lung tumor outpatient clinic, the challenges are quite minimal because these patients return regularly. When they're in the therapy phase, they come at least once a week, so approaching them is straightforward and uncomplicated." (Study nurse_01_02).

However, the outpatient clinic's busy atmosphere posed difficulties. Patients were often informed about the study during chemotherapy sessions, which were frequently interrupted by nursing staff attending to their duties.

"Sometimes I feel rushed, but I want to conduct the procedure thoroughly. It's just too hectic to do it properly. I am often interrupted by nurses and doctors, which is understandable, but it means having to start over multiple times. It's quite uncomfortable to be interrupted five or six times with patients." (Study nurse_02_02).

Similar to stroke patients, lung cancer patients commonly cited the perceived effort and paperwork involved in participation as reasons to decline, alongside feeling sufficiently supported by their networks.

"Many patients say it's too much paperwork and effort. The majority feel they don't need additional support or already have a supportive network." (Study nurse_02_01).

Overall, qualitative insights suggest that recruiters viewed the acute stroke setting as far more challenging than the lung cancer outpatient environment. They recommended considering rehabilitation clinics as additional recruitment sites for stroke patients, allowing engagement later in their disease trajectory beyond the acute phase.

"I found it interesting to observe the difference between tumor patients and acute stroke patients. Stroke patients are often shocked by the suddenness of the event, making them harder to approach than patients with a life-limiting diagnosis like lung cancer, who are somewhat more prepared. For acute patients—whether stroke or heart attack—the surprise factor is significant. Perhaps it's better to wait until after the acute phase to approach them when they have a clearer understanding of their condition. That's my impression." (Study nurse_01_03).

This paper presents insights and challenges encountered during the recruitment of patients for the CoreNAVI feasibility study, which evaluated a patient navigation program for patients with stroke and lung cancer [17]. We provided detailed data on screening and recruitment, revealing final enrollment rates ranging from 8% among approached lung cancer patients in rural Brandenburg to 50% among approached lung cancer patients in Berlin and stroke patients in Brandenburg. Enrollment rates varied considerably depending on the recruitment setting. Organizational and contextual factors were identified as primary reasons for not reaching or approaching patients at recruitment sites. Additionally, patients frequently declined participation due to feeling overwhelmed

(particularly stroke patients) or perceiving the study as irrelevant at the time of approach (notably among lung cancer patients). These factors were further explored through thematic analysis of recruiter interviews. Overall, the observed eligibility rate (60–70%) and recruitment rate (30–50%) were consistent with initial expectations. However, only 36% of the initially projected participants ultimately consented to participate, with variation across settings, diseases, and study arms. This shortfall was primarily due to a substantial number of eligible patients who were not actively approached, as well as organizational and staffing issues that resulted in shorter recruitment periods at some sites.

As noted in previous reviews, achieving target sample sizes for randomized controlled trials (and other observational studies) is a frequent challenge often unmet [3–5]. Our study similarly fell short of its enrollment target, which had been based on prior assumptions about the number of patients that would participate. We identified overestimation of eligible patients available for the direct approach as a key factor limiting recruitment, consistent with findings from prior meta-analyses of recruitment barriers and facilitators [6].

We further suggest that trial planning should better incorporate "real-life" factors and unforeseen events that affect recruitment. These include organizational issues, contextual challenges, and constraints related to the recruiter. Recruitment typically occurs within clinical environments where patient care and diagnostics take precedence, often limiting access to potential participants, particularly when recruitment staff are external to the organization. Additional organizational barriers included the turnover of contact persons at recruitment sites and the complexity of university hospital settings, which involved competing studies and rotating personnel. Contextual disruptions, such as labor strikes and the COVID-19 pandemic, also interrupted recruitment. Recruiter-related challenges included delays in hiring due to personnel shortages and unplanned sick leave, resulting in delayed starts and shortened recruitment windows at specific sites. Consequently, we recommend that future studies realistically factor in these unpredictable but common disruptions to better estimate achievable sample sizes.

Our findings also underscore the need for trade-offs in designing recruitment strategies. For example, stroke patients were recruited shortly after their acute event in specialized stroke units, which treat about 77% of stroke patients in Germany [21]. While this setting enabled broad reach, qualitative interviews and refusal data suggest that approaching patients so soon after stroke may be too early, as many feel overwhelmed and are less receptive to study participation and its complex procedures. These results align with prior research on recruitment challenges across diseases [7, 12]. Moreover, these patients may not yet perceive the need for additional support before returning home and experiencing the changes of post-stroke life.

Conversely, lung cancer patients were recruited in specialized outpatient clinics, where regular appointments facilitated access to many eligible patients. However, recruitment timing may have been too late for some, as indicated by refusals citing a lack of perceived relevance, likely reflecting patients already advanced in their integrated care pathway.

Another important consideration during study planning is whether recruitment should be carried out by in-house staff or external project personnel. In our study, recruitment was mainly conducted by project-employed study nurses who were not part of the participating clinical departments. This arrangement had the advantage that recruitment was their primary focus, allowing them to dedicate their efforts fully without juggling other responsibilities. However, being external also posed significant challenges, such as limited access to patient data, reduced time spent at recruitment sites, less familiarity with the department's organizational structure and staff, and restricted access to essential infrastructure, including computers and printers. Successfully integrating external recruiters often requires embedding them into the clinical team and developing efficient workflows, which can prolong the initial recruitment phase before optimal performance is achieved.

Conversely, using in-house personnel for recruitment can present difficulties as they must balance recruitment tasks with their regular clinical duties. These recruitment duties are time-intensive, involving providing oral and written information to patients and caregivers, addressing their questions, assisting with consent forms, and completing baseline assessments. Consistent with previous research on stroke patient recruitment [12], we conclude that dedicated in-house staff whose primary responsibility is recruitment would be ideal for this purpose. However, appointing full-time recruiters at each site can also be challenging, especially when they are limited to a single location.

It is also crucial to weigh the goal of meeting target sample sizes against recruiting a representative patient population from the outset [22]. Our data showed that enrolled patients were generally younger and had milder stroke severity. This bias toward less severe cases in stroke recruitment has been reported elsewhere, likely due to many severely affected patients being unable to provide informed consent [8, 9]. Additionally, our study excluded patients with complete language barriers, as resources did not permit the provision of translation services during recruitment or the navigation intervention. This exclusion highlights a significant issue: the complexity of the German healthcare system and its personalized care organization may hinder patients with migration backgrounds and language barriers from fully accessing healthcare resources [23]. Such barriers could potentially be mitigated through effective navigation support. We attempted to address the exclusion of patients with cognitive or language difficulties by allowing caregiver participation (with patient consent or legal guardianship). However, few caregivers participated, possibly because recruitment took place during COVID-19 restrictions, which limited visitor access.

This study has limitations. Recruitment occurred amid ongoing COVID-19 hospital access restrictions, which varied in intensity. Additionally, qualitative findings on reasons for participation or refusal may reflect recruiters' perceptions rather than patients' actual views. While patient interviews were part of the overall feasibility study, they primarily focused on experiences with the navigation intervention rather than recruitment. Furthermore, the recruitment documentation was maintained as a working database by the recruiting staff, which may have led to slight inconsistencies. For example, the category 'Later enrolment intended' at the Brandenburg site encompassed diverse reasons such as ongoing diagnostics or lost follow-up contacts. These limitations should be taken into account when interpreting the comparability and generalizability of the results.

Conclusion

Based on our experience recruiting patients for a navigation intervention study, we highlight several key lessons. First, actively approaching potential participants proved effective. Still, this approach should be expanded to include multiple access points along the patient care continuum, such as rehabilitation centers or outpatient clinics, to ensure a broader reach. This approach would help engage patients at moments when they are most in need and receptive to support, which can vary across individuals and different age-related disease pathways. Second, enrollment procedures should be designed to minimize barriers and encourage participation, including involving caregivers to avoid excluding those most severely affected. Strategies might include creating concise, patient-friendly study materials (potentially using easy-to-understand language) and offering shorter baseline assessments. Lastly, planning for recruitment must more thoroughly anticipate real-world disruptions—organizational, contextual, or related to recruitment staff—that can impact success. Taking these factors into account is especially important given ongoing challenges in the German healthcare system, such as staffing shortages and shorter hospital stays, which may influence future recruitment efforts.

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