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Barriers and facilitators to conducting randomised controlled trials within routine care of neurorehabilitation centres: a qualitative study

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Abstract

Background Randomised controlled trials (RCTs) are considered the gold standard for generating clinical evidence. The focus on high internal validity in RCTs challenges the external validity and generalisability of findings, potentially hindering their application in routine care. In neurorehabilitation, limited literature addresses conducting RCTs feasibly and efficiently. We investigated barriers and facilitators to conducting RCTs within routine care of neurorehabilitation centres from the perspective of stakeholders in neurorehabilitation in Germany and Austria.

Methods We conducted semi-structured interviews with stakeholders in neurorehabilitation from four centres in Germany and Austria, informed by the Theoretical Domains Framework (TDF) and the Capability, Opportunity, Motivation and Behaviour model (COM-B). Employing a hybrid approach, the interview analysis integrated both deductive, theory-driven analysis based on the TDF domains and COM-B model and inductive, reflexive thematic analysis.

Results Twelve stakeholders (4 physicians, 4 therapy managers, 4 therapists; 5 females, 7 males; with research experience spanning 0–40 years) were interviewed. Key barriers to conducting RCTs in neurological rehabilitation centres include limited financial, human, and time resources, high clinical workloads, and a lack of interest of some therapists. Ineffective leadership, perceived lack of research expertise, and communication issues were also significant barriers. Social influence factors such as lack of employer support and inadequate training access further contributed to the challenges. Additionally, barriers included insufficient research infrastructure, limited space, internal power struggles, and rigid cost bearer specifications. Key facilitators included physicians' and therapists' motivation to advance the field, contribute to knowledge, and to prioritise patient health. Support from supervisors, joint decision-making, and efficient organisation were crucial facilitators. Flexible therapy planning, mutual support, and interdisciplinary collaboration also played important roles.

Conclusion Our results suggest that increasing professional development and understanding, along with providing adequate financial, human, time, and spatial resources to support research endeavours, implementing effective

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communication strategies to enhance interdisciplinary collaboration and coordination among team members may contribute to increased motivation and facilitate RCTs within the setting of neurorehabilitation centres.

Trial registration This study was prospectively registered with the German Clinical Trials Register (08.04.2021 DRKSID DRKS00024982).

Keywords Feasibility, Randomised Controlled Trial, Delivery of Health Care, Barriers and facilitators, Interview

Background

Medical guidelines rely on a wide range of evidence, from high-quality meta-analyses of randomised controlled trials (RCTs) to expert opinion [1, 2]. High-quality evidence offers clear guidance for clinical decision-making, prioritising reliable and applicable data over individual experience [1]. Rehabilitation teams favour evidence-based interventions, referring to services and treatments with a solid research foundation demonstrating their effectiveness [3]. RCTs are typically employed to assess the effectiveness of these new interventions [4]. Despite their prominent position in the evidence hierarchy, the limitations of RCTs should not be overlooked [5]. The emphasis RCTs place on achieving high internal validity presents challenges to the external validity and generalisability of findings, which in turn limits the widespread dissemination of results into routine care [6, 7]. Additionally, recruiting patients for RCTs can be difficult due to factors such as clinicians' challenges in adhering to study protocols as compared to clinical care, perceived lack of clinical equipoise, local clinical arrangements, trial publicity, and overall management [8]. Moreover, the responsibility for conducting RCTs often falls on already overburdened health professionals, adding further strain. It entails additional tasks such as recruitment assistance and specific documentation requirements, introducing complexities for provider organisations. These issues are particularly pronounced when conducting traditional RCTs in rehabilitation centres, where the need for uniform and controlled conditions to establish efficacy further complicates the process. This situation is similar when conducting RCTs in primary care settings, both of which are critical for building evidence relevant to the environments where most clinical decisions occur [9]. In these settings, research indicates that physicians often perceive RCTs as overly intellectual or confronting for patients, with recruitment hindered by practice policy or culture [9]. Consequently, untested interventions may enter clinical practice, posing risks to patients, clinicians, and the healthcare system [1].

Despite their value, the high cost, complexity, and slow pace of RCTs result in many unanswered clinical questions. As a result, practitioners advocate for increased effectiveness studies in real-life settings and theory-based implementation of effective interventions [10] to facilitate the translation of research findings into

routine clinical practice [10]. A systematic review found that participation in an active multi-component knowledge translation intervention led to improvements in evidence-based knowledge and practice behaviours among physiotherapists, compared to passive dissemination strategies [12]. Additionally, there is a growing demand for more Phase IV trials to gather information on intervention effectiveness and adverse effects during widespread use [11]. While Phase I trials assess the safety and tolerability of a new treatment, typically involving 20 to 80 patients across various dose levels, Phase II trials evaluate the treatment's efficacy to justify further investigation in a large-scale Phase III trial, usually involving several hundred patients [13]. In contrast, the primary objective of Phase IV trials is to monitor the safety and effectiveness of a treatment among a larger population over an extended period. These trials offer greater flexibility, allowing data collection from participants who meet less stringent eligibility criteria than those in Phase III trials, based on the intervention's approved indications and contraindications. Importantly, Phase IV studies aim to identify potential latent and rare safety concerns while focusing on effectiveness rather than strict efficacy, reflecting real-world usage with less intensive monitoring and compliance [14]. Phase IV trials play a crucial role in bridging research findings with routine clinical practice [11], while various factors—such as knowledge brokering, knowledge-sharing platforms, stakeholder engagement, institutional culture, and capacity development initiatives—impact the dissemination of knowledge [15].

Integrating even well-supported RCTs into routine rehabilitation service systems presents a multifaceted challenge for organisations and individuals involved particularly in the field of neurorehabilitation. Although there is guidance from the United Kingdom's Medical Research Council on developing complex interventions [16], there is limited literature on conducting RCTs effectively to ensure feasibility and time-efficiency [17]. Despite its high relevance, no studies have investigated the feasibility of RCTs in the clinical routine of rehabilitation centres. Therefore, the aim of this study was to investigate barriers and facilitators to conducting RCTs within routine care of neurorehabilitation centres from the perspective of stakeholders in neurorehabilitation in Germany and Austria.

Methods

This qualitative study employed a design centred on a hybrid approach [18], integrating both deductive analysis based on the Theoretical Domains Framework (TDF) [19, 20] and Capability, Opportunity, Motivation – Behaviour COM-B model [21] and inductive, reflexive thematic analysis (TA) [22, 23]. The identified codes were aligned with the components of the COM-B model and connected to the domains of the TDF as described in the Behaviour Change Wheel [24]. The TDF comprises 13 key determinants from 35 different theoretical models of behaviour and includes knowledge, behavioural regulation, memory, attention, and decision processes, skills, goals, motivation/intentions, professional role and identity, beliefs about consequences, beliefs about capabilities, optimism/pessimism, emotions, social influences, environmental context, and resources [19, 20]. The COM-model proposes a system in which behaviour results from an interaction of capability, motivation and opportunity and in which behaviour in turn impacts on these three components [24]. The study was based on the paradigm of pragmatism according to Susan Haack [25] to facilitate an in-depth exploration of the research question. A pragmatic approach allows for the selection of appropriate research methods from a diverse range of qualitative and quantitative options. This pluralism is a key strength of pragmatism, providing an inclusive framework that promotes interdisciplinary collaboration and cooperative research [26]. The research question was formulated using the SPIDER (Phenomenon of Interest Design Evaluation Research type) scheme [Additional file 1] [27] while adherence to transparent reporting standards was ensured through compliance with the Standards for Reporting Qualitative Research (SRQR) [28] [Additional file 2].

Ethics approval was obtained from the research ethics committee of the Medical University of Innsbruck, Austria (EC No. 1038/2021) on 1st April 2021. All participants provided their written informed consent prior to study participation. This study was prospectively registered with the German Clinical Trials Register (08.04.2021; DRKS-ID: DRKS00024982).

Reflexivity of the researchers

The authors' perspectives shaped this research by providing a diverse range of expertise and insights relevant to the study's focus. The first author (IH), a physiotherapist specialised in neurological rehabilitation offered valuable insights into the structures and processes of rehabilitation facilities in German and Austrian contexts. IH highlighted that practical experience in conducting rehabilitation studies is often limited and noted that research responsibility largely falls to physicians in most clinics. The second author (NE), a female dance

therapist, emphasised the importance of patient-centred approaches and interprofessional collaboration, advocating for the inclusion of diverse perspectives in the research process. The third author (CB), a male neurologist with extensive clinical experience and training in Public Health and Management in Healthcare influenced the study through his critical thinking and insights as medical director in a rehabilitation centre. His general attitude towards facilitating RCTs and supporting knowledge development among therapists contributed to the broader context of the research. GD, the penultimate author, a female scientist with a PhD in physiotherapy, brings her experience in teaching qualitative research and clinical training in neurology to the study. As an expert in implementation science, she is knowledgeable about the various barriers and facilitators affecting the implementation of novel interventions in healthcare settings. Lastly, BS, a neurological physiotherapist with a PhD, contributes expertise in neurorehabilitation and qualitative research, emphasising that the use of evidence-based practice and the conduct of studies vary among healthcare professionals, influenced by personal interest and job position. All researchers acknowledge the challenges of insider research, recognising potential influence from pre-existing beliefs or interview direction [29]. Addressing these challenges throughout the research process was deemed crucial to enhance the credibility of the results [29].

Sampling

We employed purposeful sampling to select four neurological rehabilitation centres, consisting of two from Germany and two from Austria. We aimed to reach saturation, typically around 12 participants [30], by including one physician, one therapy manager, and one therapist from each of the four centres, proficient in both spoken and written German. The therapists comprised individuals from the disciplines of physiotherapy and occupational therapy. There was personal contact with at least one person from the respective rehabilitation centre. Purposive sampling involved selecting 4 physicians from a group of 40, 4 therapists from a total of 88, all of whom are employed in the neurology department, as well as 4 therapy managers, with one manager from each rehabilitation centre. For the sake of clarity and coherence, individuals belonging to physiotherapy and occupational therapy are referred to as therapists throughout the subsequent manuscript.

Data collection

Demographic and professional data (age, sex, profession, educational level, professional experience, research experience, and area of research) were collected from all participants. Individual semi-structured telephone

interviews with a duration of 30 to 45 min based on an interview guide were used for data collection [31]. Interviews were recorded using the computer's audio recording programme.

The interviews were based on the categories of the COM-B model [24], the TDF domains [19, 20], and the researchers' expertise [32]. Participants were guided thematically towards the research subject, with interview guides developed from the models and any questions clarified during the process. Topics covered included the relevance of RCTs in rehabilitation settings, participants' competencies and experiences in research or standardised assessments, individual strengths and weaknesses, the role of their professional group, perceptions of others in the team, teamwork dynamics, barriers and facilitators in their facility, and study preferences. To enhance credibility, ad-hoc questions were posed to confirm alignment between researcher and interviewee constructs [31]. To accommodate diverse requirements, three interview guides were developed with similar structures but with customised thematic focus tailored to the specific professional group being interviewed [Additional file 3]. A pilot test was conducted with a physiotherapist [31], resulting in modifications in the wording of six questions and the inclusion of an additional question on communication. Transcription followed the content-semantic transcription system of Dresing and Pehl [33].

Data analysis

Descriptive statistics were used to analyse demographic and professional data. Frequencies are reported for counted and nominal data (sex, profession, educational level, and area of research). For continuous variables (age, professional experience, and research experience) the mean (95% confidence interval [CI]) is provided if the data exhibit a normal distribution. Otherwise, they are presented using the median (25th – 75th percentiles).

Qualitative data analysis of the interview transcripts was supported by MAXQDA qualitative analysis software (VERBI Software, Berlin, 2020). Before commencing the coding process, coders underwent training tailored to the specific research objectives. We utilised a hybrid TA approach [18], combining deductive methods based on the TDF and COM-B model [21] with inductive, reflexive TA [22, 23].

After establishing deductive components, we organised inductively generated codes. Reflexive TA facilitated systematic identification and understanding of patterns of meaning in the data [22, 23]. For the inductive approach, we iteratively explored the data without preconceived categories, deriving new themes. We performed pilot testing on a data subset to identify and correct any discrepancies in coding, refining the coding framework. Inductive codes were matched to appropriate

deductive components, and if any codes did not align, the model was expanded accordingly. Two researchers (IH, NE) immersed themselves in the data, independently generating inductive codes. Collaborative reflexivity, involving an additional researcher (BS), guided the process. Through continuous revisiting and collaboration among all researchers (IH, NE, CE, GD, BS), a hierarchical organisation of themes was established, capturing nuances beyond the original frameworks. Themes underwent rigorous review for accuracy and coherence with the research question, involving peer scrutiny. Selected quotes were used to illustrate each theme, and findings were presented in the research report. Member checks were implemented to enhance credibility and trustworthiness. After each content block in the interview, the interviewer summarised the content and asked clarifying questions to ensure understanding and ensure completion. A final summary was also provided at the interviews' end with all information documented in the field notes and transcripts. Follow-up questions led to only minor additions and transcripts were not returned to participants for feedback.

Results

Twelve semi-structured interviews were conducted with stakeholders from four rehabilitation centres in Germany and Austria from April to June 2021. Due to the COVID-19 pandemic, seven telephone interviews and five video call interviews (conducted via Microsoft Teams) were carried out.

All physicians were male, with a mean age of 60 years (95% CI 52–67), with research experience ranging from 5 to 40 years. Among the therapy managers, two were male and two were female, with a mean age of 46 years (95% CI 36–56), and three reported research experience of 1–11 years. Among the therapists, three of four were female, with a mean age of 30 years (95% CI 21–39), with all reporting approximately 1 year of research experience. In two centres, the respective therapy manager stated that they also worked as a therapist. Table 1 shows the demographic and professional characteristics of the sample (see Additional Table 1 for participant characteristics at the individual level).

Both Germany and Austria have universal healthcare systems primarily funded by social health insurance. In Germany, this involves a mix of statutory and private insurance, with most people covered under statutory insurance, financed by income-based contributions. Austria's system is similar, with mandatory insurance funded by both employers and employees. Both countries offer extensive services, including primary, specialist, and hospital care. However, academic training for therapists differs: in Austria, a Bachelor's degree from a university of applied sciences is typically required to become a

Table 1 Demographic and professional characteristics of the participants

	Physicians, n = 4	Therapy managers, n = 4	Therapists, n = 4
Sex, men : women ¹	4:0	2:2	1:3
Age, years ²	60 (52–67)	46 (36–56)	30 (21–39)
Educational level¹			
Diploma	-	1	-
Bachelor	-	-	3
Master	-	2	1
Doctorate			
Doctorate	4	1	-
Professional experience, years²	31.5 (27.7–35.3)	22 (15.5–28.5)	7.9 (1.6–14.2)
Research experience, yes : no¹	4:0	3:1	4:0
Research experience, years³	19 (7–35)	2 (1–11)	1 (1–1)
Area of research¹			
Neurorehabilitation	3	3	4
Physical medicine	1	-	-
No experience	-	1	-

¹Frequency; ²mean (95% confidence interval); ³median (25th – 75th percentiles)

physiotherapist or occupational therapist, while in Germany, training can occur at various institutions with no Bachelor's degree required.

Centres 2–4 provide inpatient care, while Centre 1 is the only centre to offer additional outpatient services. All centres are public institutions. Centre 1 is a German rehabilitation facility offering inpatient and outpatient treatment for patients with cardiological, orthopaedic, and neurological disorders. In Centre 1, there are a total of 11 physicians and 16 therapists working in the department of neurology, and one therapy manager. Centre 2 focuses on orthopaedics, neurology, and oncology with both inpatient and outpatient rehabilitation services, each having its own interdisciplinary team. In Centre 2, there are 12 physicians and 35 therapists specialised in neurology, and one therapy manager. Centre 3 is a phase B rehabilitation facility in Austria with 16 physicians and 20 therapists working in the department of neurology, and one therapy manager. Centre 3 is unique in offering acute care for patients with neurological diseases. A key distinction between Centre 3 and the other centres is that the therapy planning and timing are determined by the therapists themselves. Centre 4 is an Austrian rehabilitation facility specialising in the treatment of people with traumatological and neurological injuries resulting from work-related accidents. It has 1 physician and 8 therapists specialised in neurology, and one therapy manager.

From our data analysis, we uncovered 112 codes. All barriers and facilitators could be identified within the TDF. Eight out of the 12 TDF domains were considered crucial for understanding the barriers and facilitators of conducting RCTs, combining goals and motivation/intentions into a single domain. Table 2 presents these domains alongside a domain descriptor of the purpose of this study. 'High frequency' refers to cases where 80% or more of participants described six or more barriers and/

or facilitators related to the TDF domain. Meanwhile, 'high perceived relevance' pertains to TDF domains that participants considered very important in influencing the behaviour of interest (conducting RCTs). The identified domains are outlined below and a coding tree containing the COM-B components, TDF domains, codes, and illustrative quotations is presented in Additional file 4.

Memory, attention, and decision processes

Barriers: Therapists expressed limited involvement in decision-making for initiating and conducting RCTs: '... the decision to proceed lies with the primary investigators or physicians. Thus, we have no direct influence on that aspect.' (ID11, therapist).

Facilitators Therapists highlighted facilitators such as attentiveness to relevant aspects of RCTs and joint decision-making based on available resources and priorities rather than individual preferences. By collectively determining study topics relevant to the clinic, the research agenda can maximise its impact. Additionally, suggestions were made for promoting individual autonomy in study participation decisions and implementing a strength-based task distribution.

Skills

Barriers Participants identified a lack of research expertise as a key barrier to conducting RCTs in their rehabilitation centre. Other barriers included insufficient staff training and professional development, as well as feelings of professional devaluation. They noted that technical and computer skills were also lacking, which hindered their efforts.

Facilitators: Participants recognised that procedural knowledge is beneficial for initiating and executing RCTs: 'We possess extensive experience with the equipment,

Table 2 TDF domains with high frequency and/or relevance to understanding barriers and facilitators to conducting RCTs in neurorehabilitation centres

TDF domain	Domain description	High frequency of occurrence in data set	High perceived relevance
Knowledge	Awareness of RCTs' existence		
Behavioural regulation	NRC staff's attempts to influence RCT conduct		
Memory, attention, and decision processes	The capacity to remember, focus selectively, and decide on RCTs		✓
Skills	A practiced skill or acquired ability related to RCTs		✓
Goals and motivation / intentions	Desired outcomes and the actions to achieve them	✓	✓
Professional role and identity	NRC staff's professional behaviours and traits	✓	
Beliefs about consequences	Expectations about NRCs' RCT outcomes.	✓	✓
Beliefs about capabilities	NRC staff's perceptions or confidence in their ability to accomplish RCTs		✓
Optimism / pessimism	Positive outlook on RCTs		
Pessimism	Negative outlook on RCTs		
Emotion	Feelings about conducting RCTs		
Social influences	Interpersonal dynamics driving NRC staff to conduct RCTs		✓
Environmental context and resources	Environmental influences on NRC staff's skills, independence, social competence, and adaptability	✓	✓

NRC, neurorehabilitation centre; RCT, randomised controlled trial; TDF, theoretical domains framework

as well as with various other aspects of our work. As the ones who implement these practices daily in our professional lives, this hands-on experience is our greatest asset.' (ID2, therapist).

Goals and motivation / intentions

Barriers: Diverging priorities, often driven by pressing clinical obligations, and a lack of interest in pursuing RCTs, particularly among therapists, were identified as barriers. Therapists reported to prioritise hands-on clinical practice. Physicians noted that any sense of competition could reduce patient referrals from colleagues and, consequently, reducing the patient pool available for studies. Lack of commitment was also cited by physicians: 'Engaging in such [research] tasks demands significant energy and time commitment. One must be willing to invest both resources to succeed.' (ID8, physician).

Facilitators: All stakeholders recognised the ability to contribute to knowledge and the intention to benefit patients as significant facilitators: 'It is of no use to us if the patient does not benefit from it.' (ID12, physician). Some saw intrinsic motivation as a key driver for pursuing RCTs, supporting evidence-based practice in clinical care. Therapists emphasised the importance of grounding therapy in solid evidence, and engaging in research was viewed as part of lifelong learning.

Professional role and identity

Barriers One barrier identified for physicians was related to the role of a resident physician, where the focus is on the medical practice. Therapists identified as data collectors for both clinical purposes and studies and considered

themselves committed implementers of interventions. However, they primarily saw themselves as health practitioners rather than study conductors.

Facilitators: In general, participants viewed research as part of their professional role. Roles included study principal investigator and contact point: 'It is helpful that the medical director typically oversees the acquisition of study funding, either through newly established channels or via existing contacts.' (ID6, therapy manager). Therapy managers and therapists saw physicians as clinical administrators and considered therapy managers as clinical routine organisers, coordinators, and internal networkers/communicators, all of which related to both clinical healthcare practice and conducting RCTs. Facilitators included those with specialised expertise such as statistics, research assistants, or designated research teams. It was unanimously stated that it is '... crucial to establish a clear distribution of roles, ensuring that each individual understands their specific responsibilities, boundaries, and interfaces within the project.' (ID10, therapist).

Beliefs about consequences

Participants identified several potential consequences affecting the conduct of RCTs in their rehabilitation centre, with a mix of barriers and facilitators perceived.

Barriers On the one hand, some participants expressed concerns that RCTs might create time constraints for patient treatment, lead to disengagement from research if studies were not seen as integral to their work, and result in incomplete studies due to therapist frustration

or resource constraints, yielding potentially meaningless results.

Facilitators: On the other hand, several potential benefits were recognised. Participants noted that RCTs could lead to cost savings and operational efficiency, ultimately improving outcomes: 'By identifying the most effective therapies, we can optimise our time and resources, ultimately leading to faster patient recovery, shorter hospital stays, and enhanced independence during rehabilitation.' (ID3, therapist). Some participants anticipated that RCTs might increase job attractiveness and boost staff skills and progress. Physicians also noted that pursuing studies could enhance both personal and institutional reputations, benefiting the team scientifically: 'And the advantage, the BIG advantage is that the entire team benefits in a way, because one approaches things with, let's say, a very scientific and critical perspective.' (ID1, physician).

Beliefs about capabilities

Participants had contrasting views on their capabilities and identified several barriers and facilitators in the implementation of RCTs in their setting.

Barriers: Some participants pointed out significant shortcomings in RCT implementation, indicating that progress was not as smooth as expected and highlighting a perceived lack of readiness and capability in some areas: 'At times, I find myself surprised by the occasional hiccups and challenges we encounter, realising that things aren't progressing as smoothly as expected.' (ID4, therapy manager).

Facilitators In contrast, physicians perceived their organisational skills as excellent, aiding any RCT. Participants highlighted their versatile abilities and agile learning, which allowed them to adapt to various tasks, including statistical analysis. Physicians stressed the importance of careful planning and readiness to start RCTs on schedule. Additionally, critical self-assessment and the ability to translate theory into practice were recognised as facilitators. Physicians also noted motivational and leadership skills, as along with ideating as supportive of RCTs.

Social influence

Although only a few codes related to social influence were derived, they were deemed relevant in that they provided profound insights.

Barriers: All stakeholder groups identified a lack of employer support as a key barrier. One therapy manager stated: 'The biggest obstacle is that the basic conditions are not suitable. There is neither time, money, nor a vision for it from the employer.' (ID7, therapy manager). Ineffective leadership was identified as another major barrier, leading to confusion and ineffective collaboration.

Therapists noted their dependency on physicians due to the system's structure, as certain tasks can only be performed by them.

Facilitators In contrast, support from superiors was seen as a significant facilitator. A therapist expressed a desire for collaborative idea generation across departments, emphasising the importance of including speech therapists, occupational therapists, neuropsychologists, and others to explore common interests. This inclusive approach would allow responsibilities to be shared, preventing any single person from bearing the entire burden of the task.

Environmental context and resources

Numerous statements regarding the environmental context and resources revealed differing perspectives.

Barriers: Major barriers identified included insufficient research infrastructure, lack of space, internal power struggles, and rigid cost specifications. Participants noted that staff often engage in research outside official working hours. Also mentioned were inadequate computers and space for therapists. According to one physician, '... it's not uncommon in large hospitals or clinics for individuals to encounter obstacles due to internal power struggles or other factors. Such factors impede research endeavours.' (ID12, physician). Study tasks frequently diverged from clinical routines as they are not integrated into regular plans. The most significant barriers included a lack of financial, human, and time resources. A therapy manager cited ineffective communication as hindering the pursuit of RCTs: 'For me, communication comes FIRST before even initiating [studies]. I need to get EVERYONE on board in terms of communication, because otherwise it won't work. If only one party is opposed to it, implementing anything becomes impossible.' (ID4, therapy manager). Strict clinical organisation would limit flexibility for studies, making them seem burdensome. Additionally, participants noted a lack of shared spaces and expressed a desire for them. They highlighted the importance of having surplus resources, dedicated research rooms, a team with extensive expertise, mutual support, interdisciplinary collaboration, and integrating research into regular hours rather than personal time.

Facilitators: In contrast, facilitators for RCTs included sufficient time resources, inter-institutional collaboration, and higher education for therapists. Participants also valued free access to articles, networking, and knowledge sharing. Both effective organisation and a 'flexible therapy planning system were seen as key facilitators, enabling the integration of research into clinical routines: 'The research design should seamlessly integrate with clinical practice.' (ID10, therapist). Finally,

assessing and adjusting resources was mentioned as a facilitator in creating a structured approach.

Synthesis

Therapists, therapy managers, and physicians have differing perspectives on research activities in clinical settings. Therapists prefer hands-on treatment over research due to its complexity and time demands, facing challenges from resource constraints that hinder integration with clinical routines. They identify a need for further training to ensure research benefits patients and advocate for collaboration with other departments. Therapy managers highlight organisational challenges and inadequate support for incorporating research, emphasizing the need for structured leadership to facilitate research activities. Physicians, as key decision-makers, drive studies and advocate for evidence-based practices, though they face challenges in patient selection and resource limitations. All groups stress the importance of institutional support, including dedicated time and resources, to effectively conduct research while managing clinical responsibilities. Figure 1 visualises the key barriers and facilitators identified in the study.

Discussion

This study explored the barriers and facilitators to conducting RCTs within routine care of neurorehabilitation centres, as perceived by stakeholders in Germany and Austria.

Key barriers identified include a significant lack of financial, human, and time resources, alongside high clinical workloads, insufficient research infrastructure, limited space, and rigid cost bearer specifications. Additionally, a portion of therapists exhibited a lack of interest. Ineffective leadership, perceived lack of research expertise, communication issues, and internal power struggles were also identified as significant barriers. Inadequate access to training and social influence factors such as lack of employer support further contributed to the challenges. Key facilitators included physicians' and select therapists' motivation to conduct RCTs to advance the field, contribute to knowledge, and, as a priority, benefit patients' health. Support from superiors, joint decision-making based on available resources, and efficient organisation were identified as crucial facilitators. A flexible therapy planning system, mutual support, and interdisciplinary collaboration also played important roles in facilitating RCTs.

There is a notable lack of literature on the barriers and facilitators of conducting RCTs, especially regarding their practical implementation in real-life settings. Thus, we compare our findings with the most relevant studies available. Our results align with a qualitative study on the willingness to conduct clinical trials in inpatient physiotherapy, which emphasises integrating research projects with routine therapeutic activities and highlights the value of such studies for patient rehabilitation [34]. Both studies identified time as a critical barrier and a prerequisite for the successful implementation of RCTs,

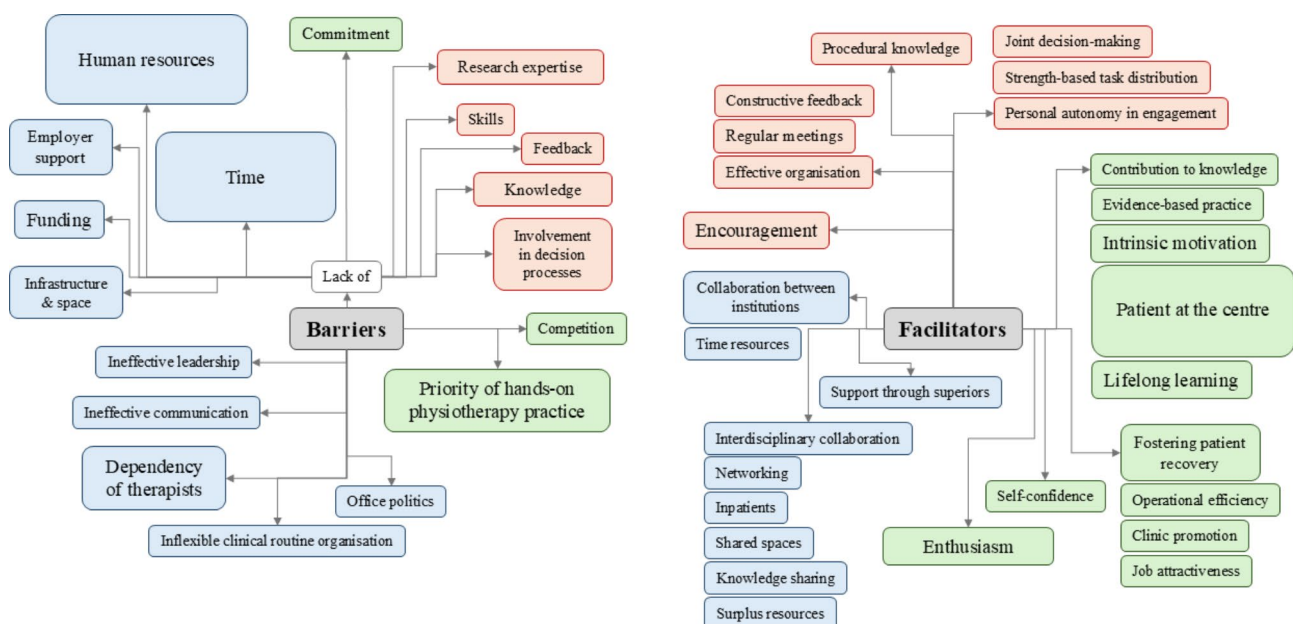


Fig. 1 Visualisation of identified barriers and facilitators. The figure illustrates the identified codes categorised into barriers and facilitators. Red-coloured boxes correspond to the capability category of the COM-B framework, blue boxes represent opportunities, and green boxes denote motivational factors. The size of each box is proportional to the relative importance of each aspect, with larger boxes indicating a higher frequency of coding and greater perceived importance. *Abbreviations:* COM-B Capability, Opportunity, Motivation and Behaviour model

underscoring the need for adequate time to establish a communication structure that prevents tension between patient care and research efforts [34].

Additionally, a comprehensive qualitative study in the United States explored similar themes in implementing evidence-based interventions within an RCT comparing SafeCare to usual caregiver services within county-based and community-based child welfare agencies [3]. Identified barriers included increased effort and time demands, traditional views on healthcare services, a lack of shared vision among leaders, and insufficient planning, preparation, guidance, and experience among staff. Further barriers stemmed from the lack of integration of evidence-based interventions into contracts and procedures. Facilitators included perceived enhanced competitiveness among healthcare providers, support from leadership, proactive communication, and an innovative organisational culture [3]. Our study's findings are consistent with all the identified barriers and facilitators from these evaluations.

A qualitative study which examined the barriers and enablers to implementing a pragmatic RCT across Indigenous Health Services and private healthcare practice settings in Australia [35], revealed challenges similar to those in our study. Key barriers included inadequate research infrastructure, excessive administrative demands, insufficiently trained staff, and potential financial impacts. The implementation of the pragmatic RCT was aided by strong relationship building among core investigators and service providers. Facilitators identified included high motivation among health providers, increased professional satisfaction, enhanced collaboration, improved research capacity, and opportunities for better patient care [35]. Additionally, our findings resonate with a qualitative study conducted in Canada focused on regional health authorities, hospitals, and primary care practices that excel in knowledge translation [36]. This study, which included in-depth interviews with senior managers and knowledge brokers, identified limited resources, time constraints, and resistance to change as significant barriers. In contrast, facilitators included decision-makers' genuine interest in resource investment and fostering a culture of knowledge translation. Priorities for advancement identified by this study included establishing technical infrastructures for research utilisation and connecting with external researchers to bolster evidence-informed decision-making [36].

Despite our research being based in high-income countries, our findings align with a scoping review of six studies investigating barriers and facilitators of critical care research in low and lower-middle-income countries [37]. Both studies identified barriers such as limited funding, poor institutional investment, inadequate access to mentors, lack of training in research methods, and insufficient

research support. Facilitators common to both studies included developing mentorship networks, streamlining regulatory processes, and implementing centralised institutional research agendas [37]. Despite the varying populations, settings, and countries examined in these studies, the barriers and facilitators identified were remarkably similar across all studies, including ours. Consistent with findings from a systematic review and other studies [38–40], this study identified several pertinent TDF domains for conducting RCTs in neurorehabilitation centres, including 'memory, attention, and decision processes', 'skills', 'goals and motivation/intentions', 'professional role and identity', 'beliefs about consequences', 'beliefs about capabilities', 'social influences', and 'environmental context and resources' [19, 20]. Notably, the domain of environmental context and resources revealed significant barriers and facilitators reported by physicians, therapy managers, and therapists. While prior studies indicated low willingness among healthcare providers [38], our findings showed more facilitators than barriers in the goals and intentions and beliefs about capabilities domains, suggesting a positive outlook and some confidence in abilities among professionals. Also evidenced by the results of a recent study [40], this alignment between skills and tasks fosters motivation and a sense of control. The participants' emphasis on facilitators indicates a strategic problem-solving approach and effective use of available resources.

The dominance of facilitators within the environmental context and resources domain suggests a supportive organisational culture that encourages innovation and enhances professional performance. However, participants expressed a desire for personal autonomy in research engagement, preferring the freedom to choose tasks that align with their strengths. Also stressed were the importance of integrating research into working hours, having free access to scientific articles, and establishing dedicated research positions or teams. Additionally, specialised training, adequate human resources, funding, and time were highlighted as essential needs. Consistent with earlier research [35, 36], participants sought a culture that fosters readiness, collaboration, innovation, and efficient decision-making to minimise obstacles and enhance research productivity.

The use of theoretical frameworks in the design and evaluation of 'interventions' has gained significant attention from implementation researchers [41–43]. Guidance from the United Kingdom's Medical Research Council suggests that when psychological theory informs the iterative processes involved in designing a complex intervention, the likelihood of innovation success increases [44]. The COM-B model and TDF are frameworks designed to theoretically understand behaviours, enabling effective targeting of processes for change [42]. Reflecting on our

study, the data analysis process was complex, lengthy, and iterative. However, the categories and domains from the TDF and COM-B model facilitated this process rather than hindered it, as their descriptors are clear and distinct. Using these deductive descriptors to organise the codes sparked several interesting discussions within the research team, all of which were resolved by consensus.

Overall, our findings reflect a strong commitment to advancing evidence-based practice in therapy, with participants motivated to conduct RCTs to contribute to knowledge, and, ultimately, improve patient health, emphasising the need for research designs that seamlessly integrate into clinical routines.

Implications

Given the multitude of barriers and facilitators identified through our analysis, along with the RCT facilitation preferences of individual stakeholders, the question arises: What could be a suitable approach for implementing RCTs in healthcare institutions overall, or specifically in neurorehabilitation centres? Michie and West [24] conceptualised the components of the COM-B model, including capabilities and opportunities as gates that must be open for an individual to be motivated to engage in a desired behaviour. The frequency of these gates being open is determined by the extent of available capabilities and opportunities, which play a crucial role in shaping an individual's motivation [45]. People with higher competence and a supportive environment have been found to be more motivated to participate in the target behaviour [45]. By considering the interplay of capability, opportunity, and motivation, tailored strategies may promote desired behaviours and address said challenges effectively [46]. In alignment with previous studies [24], our results suggest that increasing professional development and understanding (i.e., addressing capabilities), along with providing adequate financial, human, time, and spatial resources to support research endeavours, implementing effective communication strategies to enhance interdisciplinary collaboration and coordination among team members (i.e., addressing opportunities) may contribute to increased motivation and facilitate RCTs within the setting of neurorehabilitation centres.

Limitations

The COVID-19 pandemic impacted interview conditions, necessitating the use of telephone or video calls for all twelve interviews. Technical challenges and audio quality issues occasionally arose, leading to some data loss during transcription. Additionally, replicating the same interview atmosphere as face-to-face interactions proved challenging [31]. Moreover, while participants were encouraged to schedule telephone interviews at their convenience, some conducted them from their staff

room or in-between treating patients. This environment may have hindered participants' willingness to disclose certain information. Our study gathered perspectives from physicians, therapy managers, physiotherapists and occupational therapists, but did not include nurses, speech therapists, or psychologists. Although barriers and facilitators may overlap across these groups, our findings cannot be generalised to them.

While we identified numerous codes from the interview data, many of which were reported by various participants, we acknowledge that our study has limitations due to the small number of physicians, therapy managers, and therapists involved, as well as the exclusive focus on two countries. Specifically, our sample included only 4 out of 40 physicians (10%) and 4 out of 88 therapists (4.5%), which may not accurately reflect the broader population of therapists and physicians in the field of neurology. However, we did include all four available therapy managers, making that aspect of the sample representative. The topics and statements collected were quite consistent, suggesting that we likely identified relevant barriers and facilitators for conducting RCTs in neurorehabilitation centres. Moreover, the findings tend to highlight barriers and facilitators related to research in general rather than focusing specifically on RCTs. Many participants, especially therapists, reported limited research experience. To address questions about specific research types, it might have been beneficial to include individuals with more extensive research experience in the sample. Despite these limitations, we achieved saturation and provided a detailed examination of four specific centres, illuminating their internal structures and processes.

Conclusions

Key barriers to conducting RCTs in neurological rehabilitation centres, as perceived by stakeholders in Germany and Austria, include limited financial, human, and time resources, compounded by heavy clinical workloads. Ineffective leadership, perceived lack of research expertise, and communication issues were also significant barriers. Inadequate training access and lack of employer support further contributed to the challenges. Additionally, barriers included insufficient research infrastructure, 'office politics', and rigid cost bearer specifications. Key facilitators included physicians' and therapists' motivation to advance the field, contribute to knowledge, and prioritise patient health. Support from superiors, interdisciplinary collaboration, joint decision-making, and efficient organisation were crucial facilitators. Increasing professional development, providing adequate resources, and implementing effective communication strategies may contribute to higher motivation and facilitate RCTs.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12874-024-02386-0>.

Additional file 1 – SPIDER scheme.

Additional table 1. Demographic and professional characteristics of the individual participants.

Additional file 2 – Standards for Reporting Qualitative Research (SRQR).

Additional file 3 – Interview guides for physicians, therapy managers and therapists.

Additional file 4 – Coding tree with illustrative quotes.

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Author contributions

All authors (I.H., N.E., G.D., C.B., and B.S.) conceived the study, collected and coded data (I.H.), double-coded data (N.E.), contributed to analysis (G.D. and C.B.), and interpreted findings. B.S. oversaw data collection and contributed to analysis. All authors reviewed and approved the final manuscript.

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Data availability

All data generated or analysed during this study are included in this published article and its supplementary information files.

Declarations

Ethics approval and consent to participate

Ethics approval was obtained from the research ethics committee of the Medical University of Innsbruck, Austria (EC No. 1038/2021) on 1st April 2021. All participants provided their written informed consent prior to participating in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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References

- Howard-Jones AR, Webb SA. Embedding clinical trials within routine health-care delivery: challenges and opportunities. *J Paediatr Child Health*. 2021;57(4):474–6.
- Winstein CJ, Stein J, Arena R, Bates B, Cherney LR, Cramer SC, Deruyter F, Eng JJ, Fisher B, Harvey RL, et al. Guidelines for adult Stroke Rehabilitation and Recovery: a Guideline for Healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2016;47(6):e98–169.
- Jaramillo ET, Willging CE, Saldana L, Self-Brown S, Weeks EA, Whitaker DJ. Barriers and facilitators to implementing evidence-based interventions in the context of a randomized clinical trial in the United States: a qualitative study. *BMC Health Serv Res*. 2023;23(1):88.
- Tiffany F, Laure P, Andrea CT, Sharon ES, Peter J, Merrick Z, Lisa ML, Mark S, Laura CR, David AH. Protocol for a scoping review of post-trial extensions of randomised controlled trials using individually linked administrative and registry data. *BMJ Open*. 2017;7(2):e013770.
- Tomlin G, Borgetto B. Research pyramid: a New evidence-based practice model for Occupational Therapy. *Am J Occup Therapy*. 2011;65(2):189–96.
- Borgetto B, Born S, Bünemann-Geißler D, DÜchting M, Kahrs AM, Kasper N, Menzel M, Netzband A, Reichel K, Reßler W et al. Die Forschungspyramide - Diskussionsbeitrag zur Evidenz-basierten Praxis in der Physiotherapie. *physioscience* 2007, 3(01):27–34.
- Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, et al. How we Design Feasibility studies. *Am J Prev Med*. 2009;36(5):452–7.
- Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to recruitment in randomized controlled trials. *Trials*. 2012;13(1):218.
- Foster JM, Sawyer SM, Smith L, Reddel HK, Usherwood T. Barriers and facilitators to patient recruitment to a cluster randomized controlled trial in primary care: lessons for future trials. *BMC Med Res Methodol*. 2015;15(1):18.
- Deenik J, Czosnek L, Teasdale SB, Stubbs B, Firth J, Schuch FB, Tenback DE, van Harten PN, Tak E, Lederman O, et al. From impact factors to real impact: translating evidence on lifestyle interventions into routine mental health care. *Transl Behav Med*. 2020;10(4):1070–3.
- Hill TP. Conducting Phase IV clinical studies: a moral imperative? *Ecanccermed-icalscience*. 2012;6:276. <https://doi.org/10.3332/ecancer.2012.276>. eCollection 2012.
- Menon A, Korner-Bitensky N, Kastner M, McKibbin KA, Straus S. Strategies for rehabilitation professionals to move evidence-based knowledge into practice: a systematic review. *J Rehabil Med*. 2009;41(13):1024–32.
- Torres-Saavedra PA, Winter KA. An overview of phase 2 clinical trial designs. *Int J Radiat Oncol Biol Phys*. 2022;112(1):22–9.
- Henry BM, Lippi G, Nasser A, Ostrowski P. Characteristics of phase IV clinical trials in Oncology: an analysis using the ClinicalTrials.gov Registry Data. *Curr Oncol*. 2023;30(6):5932–45.
- Chapman E, Pantoja T, Kuchenmüller T, Sharma T, Terry RF. Assessing the impact of knowledge communication and dissemination strategies targeted at health policy-makers and managers: an overview of systematic reviews. *Health Res Policy Syst*. 2021;19(1):140.
- O’Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, Yardley L, Hodinott P. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ open*. 2019;9(8):e029954.
- Farrell B, Kenyon S, Shakur H. Managing clinical trials. *Trials*. 2010;11(1):78.
- Swain J. A Hybrid Approach to Thematic Analysis in Qualitative Research: Using a Practical Example. In: London; 2018.
- Cane J, O’Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci*. 2012;7(1):37.
- Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care*. 2005;14(1):26.
- Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis: striving to meet the trustworthiness Criteria. *Int J Qualitative Methods*. 2017;16(1):1609406917733847.
- Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Res Psychol*. 2006;3:77–101.
- Braun V, Clarke V. Thematic analysis: a practical guide. London, Thousand Oaks, New Delhi, Singapore: SAGE Publications Ltd; 2021.
- Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6(1):42.
- Haack S. Evidence and Inquiry: towards Reconstruction in Epistemology. Volume 19. Wiley-Blackwell; 1993.
- Kaushik V, Walsh CA. Pragmatism as a Research Paradigm and Its Implications for Social Work Research. In: *Social Sciences*. vol. 8; 2019.
- Cooke A, Smith D, Booth A. Beyond PICO: the SPIDER Tool for qualitative evidence synthesis. *Qual Health Res*. 2012;22(10):1435–43.

28. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med* 2014, 89(9).
29. Fleming J. Recognizing and resolving the challenges of being an insider researcher in work-integrated learning. *Int J Work-Integrated Learn*. 2018;19(3):311–20.
30. Guest G, Bunce A, Johnson L. How many interviews are Enough? An experiment with data saturation and variability. *Field Methods*. 2006;18(1):59–82.
31. Döring N, Bortz J. *Forschungsmethoden und evaluation in den Sozial- Und Humanwissenschaften*. 5 ed. Berlin, Heidelberg: Springer; 2016.
32. Gläser J, Laudel G. *Experteninterviews und qualitative Inhaltsanalyse als Instrumente rekonstruierender Untersuchungen*, 4. Auflage edn: Wiesbaden: VS Verlag; 2010.
33. Dresing T, Pehl T. *Praxisbuch Interview, Transkription & Analyse. Anleitungen Und Regelsysteme für qualitativ Forschende*. 8 ed. Marburg; 2018.
34. Nilsagård Y, Westerdahl E, Forsberg A. Engagement in performing clinical physiotherapy research: perspectives from leaders and physiotherapists. *Physiotherapy Res Int*. 2019;24(2):e1767.
35. Liu H, Massi L, Eades AM, Howard K, Peiris D, Redfern J, Usherwood T, Cass A, Patel A, Jan S, et al. Implementing Kanyini GAP, a pragmatic randomised controlled trial in Australia: findings from a qualitative study. *Trials*. 2015;16:425.
36. Ellen ME, Léon G, Bouchard G, Ouimet M, Grimshaw JM, Lavis JN. Barriers, facilitators and views about next steps to implementing supports for evidence-informed decision-making in health systems: a qualitative study. *Implement Sci*. 2014;9(1):179.
37. Tirupakuzhi Vijayaraghavan BK, Gupta E, Ramakrishnan N, Beane A, Haniffa R, Lone N, de Keizer N, Adhikari NKJ. Barriers and facilitators to the conduct of critical care research in low and lower-middle income countries: a scoping review. *PLoS ONE*. 2022;17(5):e0266836.
38. Evrard P, Péteïn C, Beuscart JB, Spinewine A. Barriers and enablers for deprescribing benzodiazepine receptor agonists in older adults: a systematic review of qualitative and quantitative studies using the theoretical domains framework. *Implement Sci*. 2022;17(1):41.
39. van Dijk H, Köke AJA, Elbers S, Mollema J, Smeets R, Wittink H. Physiotherapists using the Biopsychosocial Model for Chronic Pain: barriers and Facilitators-A scoping review. *Int J Environ Res Public Health* 2023, 20(2).
40. McLellan JM, O'Carroll RE, Cheyne H, Dombrowski SU. Investigating midwives' barriers and facilitators to multiple health promotion practice behaviours: a qualitative study using the theoretical domains framework. *Implement Sci*. 2019;14(1):64.
41. The Improved Clinical Effectiveness through Behavioural, Research G. Designing theoretically-informed implementation interventions. *Implement Sci*. 2006;1(1):4.
42. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Qual Saf Health Care*. 2005;14(1):26–33.
43. Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. *J Clin Epidemiol*. 2005;58(2):107–12.
44. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, Tyrer P. Framework for design and evaluation of complex interventions to improve health. *BMJ*. 2000;321(7262):694–6.
45. West R, Michie S. A brief introduction to the COM-B Model of behaviour and the PRIME Theory of motivation. *Qeios* 2020.
46. West R, Brown J. *Theory of addiction*. John Wiley & Sons, Ltd; 2013.

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