The Stay-At-Work (SAW) Trial:

Developing and Evaluating a Co-designed, Person-Centred, Cross-Sectoral Vocational Rehabilitation Intervention for Individuals with Chronic Low Back Pain

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List of papers

This thesis is based on the following four articles that will be referred to in Roman numerals throughout the thesis:

Paper I:
Frydenlund G, O´Neill S, Mortensen OS, Søndergaard J, Hansen A.
Mapping Vocational Rehabilitation Interventions for People with Chronic Low Back Pain: A Scoping Review.
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Paper II:
Frydenlund G, Hansen A, O´Neill S, Søndergaard J, Mortensen OS.
System Responsiveness and Health Literacy in Return-to-Work Challenges for Individuals with Chronic Low Back Pain: A Qualitative Study.
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Paper III:
Frydenlund G, Mortensen OS, O´Neill S, Søndergaard J, Hansen A.
Co-developing a vocational rehabilitation intervention for individuals with chronic low back pain across a regional spine centre and three municipalities in Denmark: a three-stage intervention development study guided by the Medical Research Counsil framework
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Paper IV:
Frydenlund G, O´Neill S, Mortensen OS, Søndergaard J, Hansen A.
Evaluating the Feasibility of the Stay-At-Work Cross-Sectoral Vocational Rehabilitation Intervention for Individuals with Chronic Low Back Pain: A Feasibility Study informed by Process Evaluation
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Summary (English)

Introduction

Chronic low back pain (CLBP) is a leading cause of disability and a major contributor to reduced work participation. Despite the availability of evidence-based multiprofessional interventions, individuals with CLBP frequently experience fragmented vocational rehabilitation (VR) pathways characterised by inconsistent communication, limited coordination, and unclear roles across healthcare and employment services. Navigating such complex systems requires not only individual capacities to access, understand, and apply information, but also health and welfare systems that are responsive to varying health literacy needs. However, few VR interventions explicitly address these challenges at a cross-sectoral level. There is therefore a need to develop and test person-centred, interdisciplinary, cross-sectoral VR interventions that are theoretically informed and co-designed with relevant stakeholders to enhance feasibility, acceptability, and contextual fit.

Aim

The overall aim of this PhD project was to develop, test, and evaluate the feasibility of the Stay-At-Work (SAW) intervention, a co-designed, person-centred, interdisciplinary, cross-sectoral VR intervention for individuals on, or at risk of, sick leave due to CLBP. The project examined the feasibility within existing Danish healthcare and employment service structures and the suitability of the intervention for future effectiveness evaluation.

Design and methods

The project comprised four interrelated studies. *Study I* was a scoping review mapping multiprofessional VR interventions for CLBP, including the professional groups involved, intervention components, outcome measures on work status, and reported stakeholder involvement. *Study II* was a qualitative interview and focus group study exploring experiences of return-to-work pathways, analysed using reflexive thematic analysis and interpreted through a health literacy perspective. *Study III* involved co-design of the SAW intervention and development of a program theory, informed by *Studies I* and *II* and guided by the Medical Research Council framework, INDEX principles, and Hawkins et al.'s co-

production and prototyping framework. *Study IV* was a three-month, single-arm multi-method feasibility study informed by a theory-informed process evaluation guided by Moore et al.'s framework. Feasibility was assessed using predefined progression criteria addressing recruitment, retention, data completeness, fidelity, acceptability, and mechanisms of impact. Preliminary changes in clinical and work-related outcomes were examined descriptively to assess whether the selected measures appeared suitable for future evaluation.

Results

The scoping review revealed substantial heterogeneity in VR interventions and highlighted limited use of dynamic measures of work participation, sparse description of collaborative processes, and rare reporting of PPI or stakeholder involvement. *The qualitative study* identified four overarching themes: psychological vulnerability; seeking diagnostic and return-to-work clarity; lack of recognition and flexible support; and absence of professionals' consensus in return-to-work planning. Interpreted through a health literacy perspective, the findings illustrated how fragmented systems amplify individual health literacy demands and contribute to incoherent rehabilitation pathways. *Study III* resulted in the specification of eight SAW intervention activities and a program theory comprising four mechanisms: strengthening cross-sectoral understanding and collaboration; aligning around functional capacity and work ability; addressing psychological vulnerability; and enhancing coordination of care and rehabilitation efforts. In *Study IV*, recruitment, retention, and data collection exceeded feasibility thresholds. The SAW intervention was overall assessed as feasible, with minor modifications required before further effectiveness evaluation, primarily related to timing, variable uptake, and documentation. Most core components were mainly delivered as intended, whereas physiotherapist participation in employer meetings was not feasible. Furthermore, the process evaluation indicated that three of the four hypothesised mechanisms of impact were activated during implementation. Descriptive outcome patterns also suggested that the selected measures were appropriate for future evaluation.

Conclusion

This PhD project demonstrates that a complex, cross-sectoral VR intervention can be systematically developed and feasibility-tested through a transparent, theory-informed, and co-designed process. The SAW intervention is feasible within the Danish healthcare and employment

context. It provides a robust foundation for subsequent effectiveness and implementation research, although selected components require refinement prior to further testing.

Summary (Danish)

Introduktion
Kroniske lænderygsmerter (CLBP) er en af de hyppigste årsager til funktionsnedsættelse og udgør en væsentlig årsag til reduceret arbejdsdeltagelse. På trods af tilgængeligheden af evidensbaserede, multiprofessionelle interventioner oplever personer med CLBP ofte fragmenterede forløb i den erhvervsrettede rehabilitering (VR), kendetegnet ved inkonsistent kommunikation, begrænset koordination og uklare roller på tværs af sundheds- og beskæftigelsessektoren. Navigation i sådanne komplekse systemer forudsætter ikke alene individuelle kompetencer til at tilgå, forstå og anvende information, men også sundheds- og velfærdssystemer, der er lydhøre over for forskellige niveauer af sundhedskompetence. Imidlertid adresserer få VR-interventioner eksplicit disse udfordringer på tværs af sektorer. Der er derfor behov for at udvikle og afprøve personcentrerede, tværprofessionel og tværsektorielle VR-interventioner, der er teoretisk funderede og samskabt med relevante interessenter for at styrke gennemførlighed, acceptabilitet og kontekstuel tilpasning.

Formål
Det overordnede formål med dette ph.d.-projekt var at udvikle, afprøve og evaluere gennemførligheden af Stay-At-Work (SAW)-interventionen, en samskabt, personcentreret, tværprofessionel og tværsektoriel VR-intervention for personer, der er sygemeldt eller i risiko for sygemelding på grund af CLBP. Projektet undersøgte gennemførligheden inden for eksisterende dansk sundheds- og beskæftigelsesstruktur samt interventionens egnethed til efterfølgende effektorienteret evaluering.

Design og metoder
Projektet omfattede fire indbyrdes forbundne studier. *Studie I* var et scoping review, der kortlagde multiprofessionelle VR-interventioner for CLBP, herunder involverede faggrupper, interventionskomponenter, effektmål for arbejdsstatus og rapporteret brug af interessentinddragelse. *Studie II* var et kvalitativt interview- og fokusgruppestudie, der udforskede erfaringer med tilbagevenden til arbejde efter sygemelding, analyseret ved refleksiv tematisk analyse og fortolket gennem et sundhedskompetence perspektiv. *Studie III* omfattede samskabelse af SAW-

interventionen og udvikling af en programteori, informeret af *Studie I* og *II* og styret af Medical Research Council's framework, INDEX-principperne samt Hawkins et al.'s co-production- og prototyping-framework. *Studie IV* var et tre-måneders, single-arm multi-method gennemførlighedsstudie informeret af en procesevaluering guided af Moore et al.'s framework. Gennemførlighed blev vurderet ud fra prædefinerede progressionkriterier vedrørende rekruttering, fastholdelse, datakomplethed, fidelity, acceptabilitet og mekanismer for effekt. Foreløbige ændringer i kliniske og arbejdsrelaterede outcomes blev undersøgt deskriptivt med henblik på at vurdere, om de valgte måleinstrumenter fremstod egnede til fremtidig evaluering.

Resultater

Scoping reviewet viste betydelig heterogenitet i VR-interventioner og pegede på begrænset anvendelse af dynamiske mål for arbejdsdeltagelse, sparsom beskrivelse af samarbejdsprocesser samt sjælden rapportering af patient- og interessentinddragelse. *Det kvalitative studie* identificerede fire overordnede temaer: psykologisk sårbarhed; søgen efter diagnostisk klarhed og plan for tilbagevenden til arbejde; manglende anerkendelse og fleksibel støtte; samt fravær af professionel konsensus i planlægning af tilbagevenden til arbejde. Fortolket gennem et sundhedskompetenceperspektiv illustrerede fundene, hvordan fragmenterede systemer øger individuelle sundhedskompetencekrav og bidrager til usammenhængende rehabiliteringsforløb. *Studie III* resulterede i specifikation af otte SAW-aktiviteter og en programteori bestående af fire mekanismer: styrkelse af tværsektoriel forståelse og samarbejde; fælles fokus på funktionsevne og arbejdsevne; adressering af psykologisk sårbarhed; samt styrket koordination af rehabiliteringindsatser. I *Studie IV* oversteg rekruttering, fastholdelse og datakomplethed gennemførlighedstærsklerne. SAW-interventionen blev samlet set vurderet som gennemførlig, med behov for mindre justeringer før videre effektafprøvning, primært relateret til timing, varierende anvendelse og dokumentation. De fleste kernekomponenter blev leveret overvejende som planlagt, mens fysioterapeuters deltagelse i møder på arbejdspladsen ikke viste sig gennemførlig. Procesevalueringen indikerede endvidere, at tre af de fire hypotetiserede virkningsmekanismer blev aktiveret under implementeringen. De deskriptive outcome-mønstre indikerede ligeledes, at de valgte måleinstrumenter var egnede til fremtidig evaluering.

Konklusion

Dette ph.d.-projekt demonstrerer, at en kompleks, tværsektoriel VR-intervention kan udvikles og gennemførlighedsafprøves systematisk gennem en transparent, teoribaseret og samskabt proces. SAW-interventionen er gennemførlig i en dansk sundheds- og beskæftigelseskontekst og udgør et solidt grundlag for efterfølgende effekt- og implementeringsforskning, om end udvalgte komponenter kræver yderligere justering før videre afprøvning.

List of contents

List of abbreviations

CLBP	Chronic low back pain
GP	General practitioner
HL	Health literacy
ICF	International Classification of Functioning, Disability and Health
INDEX	Identify, Network, Develop, Evaluate, and eXecute
LBP	Low back pain
MRC	Medical Research Council
PPI	Patient and public involvement
RTW	Return to work
SAW	Stay-At-Work
VR	Vocational rehabilitation
WORQ	Work Rehabilitation Questionnaire

List of Definitions

Vocational rehabilitation (VR):
"*A multi-professional evidence-based approach that is provided in different settings, services, and activities to working-age individuals with health-related impairments, limitations, or restrictions with work functioning, and whose primary aim is to optimise work participation*" [1].

Co-design:
"A collaborative and inclusive design approach that actively involves diverse stakeholders in the design process to address a specific problem, ensuring that varying degrees of participation throughout different stages lead to innovative and relevant solutions that meet the needs and expectations of all participants." [2].

Health Literacy (HL):

"*People's knowledge, motivation, and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention, and health promotion to maintain or improve quality of life during the life course*" [3].

List of Tables

List of figures

01 Introduction

The overall aim of this PhD project was to develop, test, and evaluate the feasibility of the *Stay-At-Work (SAW)* intervention, a co-designed, person-centred, interdisciplinary, cross-sectoral vocational rehabilitation (VR) intervention for individuals on, or at risk of, sick leave due to chronic low back pain (CLBP).

The research process was guided primarily by the Medical Research Council's (MRC) framework for developing and evaluating complex interventions [4], complemented by the Identify, Network, Develop, Evaluate, and eXecute (INDEX) principles to strengthen methodological rigour [5], and organised according to Hawkins et al.'s co-production and prototyping framework [6]. This framework offers a three-stage narrative comprising evidence review and stakeholder consultation, co-production, and prototyping.

Within this framework, the PhD project focuses on the development and feasibility evaluation of the SAW intervention. The four articles address complementary aspects of this focus, progressing from an examination of existing VR interventions (*Paper I*) and exploring individuals' experiences of return-to-work (RTW) processes (*Paper II*) to the co-design of the SAW intervention (*Paper III*) and its real-world feasibility testing informed by process evaluation (*Paper IV*). Collectively, the articles aim to inform whether the intervention is sufficiently robust and acceptable to warrant evaluation of effectiveness in a future large-scale study.

02 Background

This chapter provides the conceptual and empirical foundation for the PhD thesis. It outlines the societal and individual impact of LBP, current understandings of LBP, situates it within the International Classification of Functioning, Disability and Health (ICF), and describes evidence-based approaches to the management of LBP. The chapter then introduces VR as a concept and organisational practice and outlines key coordination challenges in contemporary VR for individuals with CLBP. Finally, the MRC framework for developing and evaluating complex interventions is described, leading to the overall rationale for this PhD project.

02.01 The impact of low back pain on individuals and society

For most individuals, LBP is transient and self-limiting. However, for a substantial subgroup, recurrent or persistent symptoms lead to long-term functional limitations [7]. CLBP therefore constitutes a major and enduring burden for individuals, healthcare systems, and societies. At the population level, LBP is consistently identified as the single largest contributor to non-fatal disability worldwide, reflecting its high prevalence and cumulative impact on everyday functioning [7]. Global estimates suggest that 600 million people are affected at any given time, and that the number is expected to rise markedly in the coming decades due to population growth and ageing [8].

In high-income welfare states, CLBP is closely associated with extensive healthcare utilisation, reduced work participation, and reliance on social welfare systems [9–12]. In Denmark, LBP accounts for approximately 13% of all sick leave days among individuals aged 16-64 and represents the leading cause of early retirement, responsible for 38% of new cases [9]. Consequently, the societal burden is driven primarily by indirect costs related to long-term sickness absence and premature labour market exit, with total annual costs to Danish society estimated at approximately 34 billion DKK (≈4.5 billion euros) in 2021 [13].

At the individual level, CLBP is associated with persistent pain, reduced physical functioning, psychological distress, and impaired quality of life [7]. Among people of working age, these consequences often manifest as uncertainty regarding work ability, increased vulnerability during RTW processes, and an elevated risk of labour market marginalisation [14–16]. Together, these individual and societal impacts underscore the need for interventions that extend beyond symptom management and explicitly support coordinated and work-oriented rehabilitation approaches.

02.02 Low back pain

LBP is a broad clinical term referring to pain or discomfort localised between the lower rib margins and the gluteal folds, with or without associated leg pain [17]. LBP is not a distinct disease entity but a symptom complex arising from interacting biological, psychological, and social factors [7]. In most cases, LBP is classified as non-specific, indicating that no clear pathoanatomical cause can be identified despite appropriate clinical assessment [18].

LBP is commonly categorised by symptom duration as acute (<6 weeks), subacute (6–12 weeks), or chronic (>12 weeks), with chronic pain defined as persisting beyond the expected time for tissue healing [19,20]. However, increasing evidence suggests that LBP is better understood as a recurrent and fluctuating condition rather than a linear transition from acute to chronic states, with episodic symptom trajectories that may cumulatively affect functioning over time [21–23]. In this thesis, the term CLBP is used pragmatically to describe persistent or recurrent LBP, consistent with contemporary understandings of fluctuating symptom trajectories rather than duration alone [21–23].

Beyond pain intensity, LBP is frequently associated with reduced physical functioning, limitations in daily and work-related activities, restrictions in social and occupational participation, and diminished quality of life [7,24]. Psychosocial factors, including fear-avoidance beliefs and low recovery expectations, play an important role in shaping symptom experience and are recognised predictors of delayed RTW, particularly among individuals with unstable labour market attachment [14,25,26]. Consequently, LBP is widely recognised as a complex condition best understood within a biopsychosocial framework, as operationalised in ICF, where pain, functioning, and participation emerge from dynamic

interactions between health-related and contextual factors [27–29]. This perspective underpins the need for assessment and intervention approaches that extend beyond symptom-based classification.

02.03 The International Classification of Functioning, Disability and Health (ICF) as a framework for functioning and work participation

The ICF provides a biopsychosocial framework for understanding health and disability that aligns closely with contemporary conceptualisations of CLBP [30]. Rather than centring on diagnosis, the ICF conceptualises functioning as the dynamic interaction between a health condition and personal and environmental factors, thereby offering a structured approach to understanding how pain influences everyday life.

The framework distinguishes between body functions and structures, activities, and participation, while explicitly accounting for contextual factors that may facilitate or hinder functioning (Figure 1) [30]. Individuals with CLBP often prioritise pain and seek structural or biomedical explanations for their symptoms (e.g., through requests for diagnostic imaging), corresponding to the ICF's body functions and structures domain [31,32]. However, work ability and everyday functioning are shaped not only by pain, but also by personal factors, such as coping strategies, and environmental factors, such as employer support and opportunities for work accommodations. These factors influence both activity limitations (e.g. walking, lifting) and participation restrictions, including work participation.

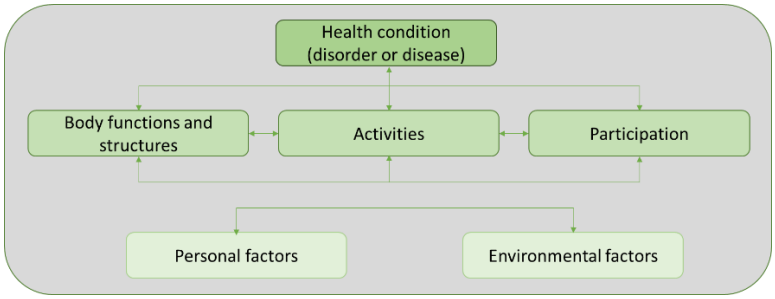

Figure 1. The ICF model.
Conceptual illustration of the dynamic interactions between health condition, body functions and structures, activities, participation, and contextual factors (personal and environmental) [30].

By shifting attention from symptom-focused assessment to a functional perspective, the ICF is particularly relevant in CLBP, where pain intensity alone provides limited insight into work ability and rehabilitation needs. Framing rehabilitation goals in terms of functioning, activity, and participation further supports communication and coordination across stakeholders involved in VR [1,33]. As such, the ICF provides a coherent conceptual foundation for cross-sectoral approaches to support sustainable work participation among individuals with CLBP.

02.04 Evidence-based care for low back pain

Clinical guidelines for the management of CLBP consistently recommend a multiprofessional, non-surgical, biopsychosocial approach that prioritises education, physical activity, and active rehabilitation strategies [34–36]. The recent WHO guideline further emphasises that care should be person-centred, function-oriented, and delivered through coordinated, non-pharmacological interventions, with attention to contextual and psychosocial factors that influence everyday functioning and participation [36]. In addition, the importance of maintaining active and working, with early and supported RTW strategies, is regarded as a central component of effective LBP management [37].

Multiprofessional interventions delivered within healthcare settings are therefore widely endorsed. However, guidelines provide limited direction regarding the specific professional composition, modes of collaboration, or organisational structures required to support work participation [34–36]. Evidence from systematic reviews shows substantial variation in the effects of multiprofessional interventions on RTW outcomes, with some studies indicating improved work participation compared with usual care, physical or no interventions. In contrast, others demonstrate limited or no added benefit relative to existing approaches [24,38–43]. Rather than reflecting contradictory evidence per se, these divergent findings appear to be driven by marked variation in intervention content, intensity, and delivery, as well as variation in how work status is defined and measured, which complicates comparison across studies [24,44].

Together, this body of evidence suggests that while multiprofessional care for CLBP is well supported at a conceptual level, substantial challenges remain in translating evidence-based principles into coherent, work-oriented rehabilitation pathways in routine practice [24,28,44,45].

Several reviews emphasise that the main challenges in the field are not primarily related to a lack of effective treatment components, but to difficulties in translating evidence-based principles into coherent and sustainable rehabilitation pathways in routine practice [28,45,46]. This includes challenges related to implementation, coordination across sectors, and adaptation to local organisational and policy contexts. This underscores the need for systematic, theory-informed approaches to the development and evaluation of work-oriented rehabilitation models integrating health and occupational perspectives for individuals with CLBP in real-world practice.

02.05 Vocational rehabilitation: concept and organisation

In this thesis, VR is understood as a multi-professional, evidence-based approach delivered across different settings, services, and activities to support working-age individuals with health-related impairments that affect work functioning, with the overarching aim of optimising work participation, as conceptualised by Escorpizo et al. [1].

RTW processes are shaped by national welfare and healthcare systems, making cross-national differences central to understanding rehabilitation pathways [44,47]. Across Europe, substantial variation exists in how work reintegration is organised, including employer responsibility for workplace accommodations, the role of employment services, and the distribution of economic incentives [47]. In Denmark, as in several Northern European welfare systems, employers have relatively limited direct financial responsibility for RTW compared with countries such as the Netherlands or Germany, where obligations during sickness absence are more extensive [47,48]. Consequently, RTW is organised mainly through public employment and healthcare services, resulting in a system-driven approach to VR that has implications for the design and transferability of VR interventions.

In Denmark, individuals with CLBP typically navigate parallel systems involving healthcare services, employers, municipal employment services, and possibly private health insurance companies. In the Danish context, municipal employment services usually become involved in sickness absence cases after the first month, whereas employers retain the legal right to terminate employment during periods of sick leave [48]. This structure places substantial responsibility on individuals to

coordinate between stakeholders at a time of physical and psychosocial vulnerability.

Access to specialised LBP care follows a gatekeeper model, with general practitioners (GPs), chiropractors, and medical specialists in hospitals and private practice responsible for referrals. Individuals with persistent LBP are typically referred to regional spine centres if there is insufficient improvement in pain, function, or workability after 6-8 weeks of primary care management. Spine Centres provide diagnostic assessments, evaluate surgical indications, and issue recommendations for conservative management, including referrals to publicly funded municipal rehabilitation services [49]. Municipal rehabilitation commonly focuses on exercise, education, and functional restoration, while employment-related follow-up is managed separately within the municipal employment service system [50,51]. Although this division reflects clear sectoral responsibilities, it also contributes to fragmented RTW pathways and underscores the need for improved coordination across healthcare and employment services.

02.06 Coordination challenges in vocational rehabilitation

VR pathways for individuals with chronic pain, including CLBP, are often characterised by fragmented support and insufficient coordination between stakeholders, which has been identified as a key barrier to RTW [16,52–56]. These coordination challenges are commonly rooted in differing professional paradigms, misaligned organisational goals, and legislative boundaries, hindering the development of timely and individualised RTW plans [53,57].

Although interdisciplinary collaboration, characterised by shared goals, joint planning, and coordinated communication, has been associated with more coherent rehabilitation pathways and, in some contexts, more efficient RTW processes [58,59], many VR interventions provide limited detail on how such collaboration is operationalised [44]. This lack of transparency constrains the interpretation, transferability, and implementation of evidence-based VR approaches.

Navigating VR pathways places substantial demands on individuals with CLBP. From an RTW perspective, individuals are required to interpret clinical information, communicate with healthcare professionals,

employers, and employment services, and articulate personal needs and work-related considerations across sectors. These demands can be understood in relation to different dimensions of health literacy (HL), including *functional abilities* to access and understand information, *interactive skills* to engage with professionals and apply information in context, and *critical capacities* to appraise information, question recommendations, and act strategically within complex systems [3,60]. These dimensions have been widely applied in chronic disease management [61–63] but remain underexplored in LBP-related VR and RTW processes [64].

Pain, emotional distress, and uncertainty related to work ability may further challenge these competences, particularly in prolonged RTW trajectories [14,65]. Contemporary HL research emphasises that HL extends beyond individual capabilities to include system responsiveness. That is when healthcare and rehabilitation systems recognise, accommodate, and support varying HL needs through clear communication and navigation support [66]. In fragmented, multi-sectoral RTW processes, insufficient system responsiveness may amplify individual HL demands and contribute to experiences of incoherence and inequity.

Together, these challenges highlight the need for coordinated, person-centred, interdisciplinary, and cross-sectoral VR interventions.

02.07 Medical Research Council's framework for developing and evaluating complex interventions

A person-centred, interdisciplinary, and cross-sectoral VR intervention constitutes a complex intervention according to the MRC framework, as it involves multiple interacting components, requires specialised expertise, and is implemented across multiple settings. To address such complexity, the MRC framework provides structured guidance for the development and evaluation of complex interventions and is widely applied within health sciences [4,67].

The updated MRC framework (2021), building on earlier versions from 2000 and 2006, outlines four interconnected research phases: development, feasibility, evaluation, and implementation. It identifies six core elements that should be considered iteratively throughout the research process [4]. These core elements are illustrated in Figure 2.

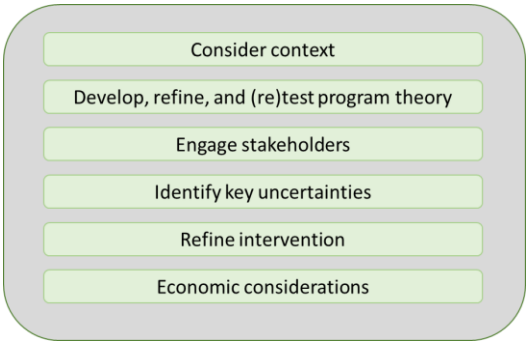

Figure 2. Core elements in the Medical Research Council's framework for developing and evaluating.

Rather than prescribing specific methods, the MRC framework serves as an overarching methodological guide, emphasising the importance of theory-informed development, attention to context, and early stakeholder involvement. Engaging relevant stakeholders, such as end-users, professionals delivering care, decision-makers responsible for implementation, and contextual experts who provide key insights, is highlighted as essential for understanding implementation conditions and enhancing feasibility, acceptability, and potential impact in real-world settings [4].

02.08 Rationale for this PhD thesis

Although multiprofessional, biopsychosocial care for CLBP is strongly supported by clinical guidelines and systematic reviews [24,34–36,38–41], considerable uncertainty remains regarding how VR should be organised to effectively support RTW. Existing VR interventions are heterogeneous, often poorly described, and frequently lack explicit operationalisation of cross-sectoral collaboration, limiting transparency, transferability, and implementation [24,44].

Qualitative research further shows that individuals with CLBP commonly experience fragmented support, misaligned stakeholder expectations, and a substantial coordination burden during RTW processes [16,52–56]. These challenges are particularly pronounced in welfare-based systems such as Denmark, where responsibility for RTW is distributed across healthcare, rehabilitation, and employment services [50,51].

Together, these gaps indicate a need for a systematically developed, theory-informed, and context-sensitive VR intervention that explicitly targets cross-sectoral coordination, perceived coherence, and work functioning [28,45,46]. Guided by contemporary frameworks for complex interventions and co-design [4–6], this PhD project addresses these needs through sequential research phases, progressing from evidence synthesis and qualitative exploration to intervention development and feasibility testing informed by process evaluation. This approach provides a robust foundation for assessing whether a co-designed, cross-sectoral VR intervention for individuals with CLBP is sufficiently feasible and acceptable to warrant effectiveness evaluation in a future large-scale study.

03 Aims, objectives, and research phases

The overall aim of this PhD project was to develop, test, and evaluate the feasibility of the SAW intervention, a co-designed, person-centred, interdisciplinary, cross-sectoral VR intervention for individuals on, or at risk of, sick leave due to CLBP. The project examined the feasibility of implementing the SAW intervention within existing health and employment service structures and its suitability for future effectiveness evaluation.

The SAW intervention was developed to support coordinated, person-centred VR across healthcare and employment services, with the long-term aim of supporting sustainable work participation and a particular focus on vocational functioning and perceived coherence in rehabilitation pathways.

03.01 Research phases

The development and evaluation of the SAW intervention were informed by established frameworks for complex intervention research. The MRC framework for developing and evaluating complex interventions was chosen as the overarching framework, as it provides a well-recognised, structured approach to intervention development, feasibility testing, evaluation, and implementation [4]. Importantly, the MRC framework explicitly recommends applying phase-specific frameworks tailored to the aims and methodological demands of each research stage [4,5].

In the development phase, the INDEX principles were applied to guide dynamic and iterative intervention development, as recommended by the MRC framework when designing new interventions, in contrast to ADAPT guidance, which is more appropriate for adapting existing interventions [4,5,68]. The INDEX principles were selected to strengthen transparency and methodological rigour, with particular emphasis on stakeholder partnership, contextualisation, program theory, and ongoing refinement [5]. Specifically, a partnership approach was adopted to

ensure sustained stakeholder involvement across research phases, and a theory- and evidence-informed approach was applied to explicate theory- and evidence-informed assumptions about how the intervention was expected to work [5].

In the feasibility phase, the study was informed by Moore et al.'s framework for process evaluation, in line with the updated MRC guidance, which emphasises feasibility testing and process evaluation prior to large-scale effectiveness evaluation [4,69]. This framework supported systematic assessment of implementation, mechanisms of impact, and contextual influences under real-world conditions.

Together, these frameworks supported a coherent, phase-specific methodological approach that emphasised stakeholder involvement, theory- and evidence-informed decision-making, contextual sensitivity, and iterative refinement to enhance the relevance, feasibility, and potential impact of the SAW intervention [4,5,69].

The PhD project was organised into three interrelated research phases, corresponding to the stages described in Hawkins et al.'s co-production and prototyping framework [6]. Phase 1 comprised an evidence review (*Paper I*) and stakeholder consultation (*Paper II*), which informed Phase 2, which focused on the co-design of the intervention (*Paper III*). Phase 3 involved prototyping and feasibility testing of the developed SAW intervention (*Paper IV*).

Hawkins et al.'s three-stage framework was selected because it is explicitly developed within the MRC framework, aligns closely with the INDEX principles, and supports an iterative yet clearly structured intervention development process [4–6]. The framework enables integration of evidence review, stakeholder consultation, co-design, and prototyping without imposing additional preparatory co-design stages. In contrast, several co-design frameworks in public health describe four or five sequential stages, often including an initial co-design phase prior to needs identification [2]. Given the scope and design of this PhD project, where needs identification was grounded in empirical evidence and stakeholder consultation rather than early co-design activities, Hawkins et al.'s framework provided a more appropriate and pragmatic structure.

Figure 3 provides an overview of the three research phases, illustrating how the MRC framework [4], the INDEX principles [5], the Hawkins et al.'s co-production framework [6], and Moore et al.'s framework for process evaluation collectively guided the development and feasibility evaluation of the SAW intervention.

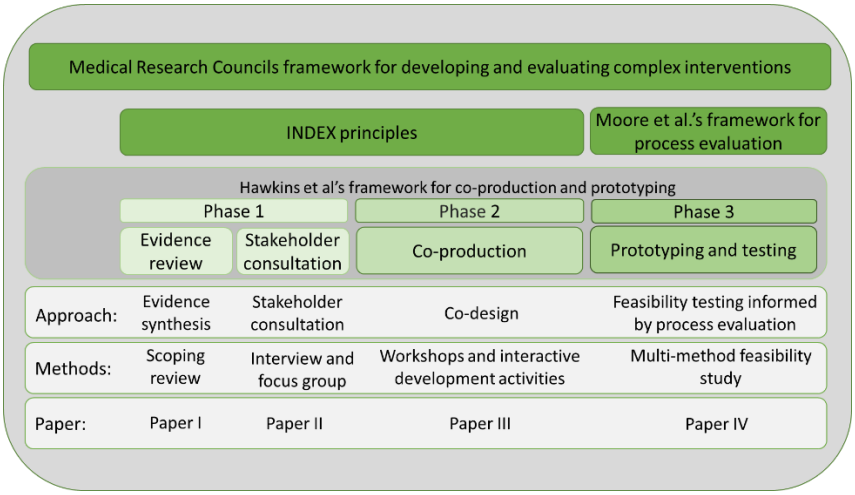

Figure 3. Methodological frameworks guiding the research phases of this PhD project.

03.02 Objectives

Specific objectives were as follows:

Paper I

To map VR interventions delivered within the healthcare sector for individuals with CLBP. It explored: 1) which professional groups were involved and how they collaborate, 2) the setting, 3) the duration, intensity, and components of interventions, 4) how and when work status was assessed, and 5) whether Patient or Public Involvement (PPI) or other forms of stakeholder involvement were reported.

Paper II

To explore how individuals on long-term sick leave (exceeding 30 days) due to CLBP in Denmark experience and navigate RTW processes, to identify their suggestions for improving coherence in RTW processes, and to analyse these findings through an HL perspective.

Paper III

To co-develop the SAW intervention, a person-centred, interdisciplinary, cross-sectoral VR program for individuals on, or at risk of, sick leave due to CLBP, and to advance methodological understanding of how evidence, qualitative insights, stakeholder input, and program theory can be systematically integrated and operationalised into concrete intervention components.

Paper IV

To evaluate the feasibility of implementing the SAW intervention in routine cross-sectoral VR for individuals with CLBP under real-world conditions, informed by a process evaluation.

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04 Philosophical and methodological positioning

This PhD project is grounded in a *constructivist epistemological position*, which assumes that reality is multiple and context-dependent, and that knowledge is co-constructed through individuals' experiences, values, and social interactions [70]. Within constructivism, the researcher is viewed as an active participant in the knowledge production process. Prior knowledge, assumptions, and theoretical commitments cannot be bracketed out; instead, they must be handled reflexively and transparently [70].

This philosophical position had concrete implications for the empirical and developmental phases of the PhD project. In *Study II*, the constructivist understanding of knowledge as co-constructed through interaction supported the use of focus groups to explore how participants' accounts of RTW processes were shaped and elaborated through dialogue. In *Study III*, the emphasis on context-dependent knowledge informed the inclusion of stakeholders across sectors and municipalities and the organisation of workshop groups to ensure both interprofessional and cross-municipal perspectives. In *Study IV*, the same context-sensitive orientation informed the use of setting-specific professional focus groups when evaluating, while the feasibility aim required a more pragmatic orientation, including predefined fidelity indicators and progression criteria to support decisions about further evaluation [71,72]. Thus, the project combined constructivist attention to situated knowledge production with pragmatic tools for assessing whether the intervention could be delivered and evaluated in practice.

04.01 My role as a researcher

I seek to be transparent about my professional background and prior experiences to enable readers to assess the confirmability of the PhD project [70].

I am a physiotherapist with a Master's degree in Public Health. Early in my career, I worked for five years in a municipal rehabilitation centre and briefly in a hospital setting, primarily treating older adults and individuals with multimorbidity, including chronic pain. These experiences have shaped my preunderstanding of organisational and structural constraints as potential barriers to coherent rehabilitation trajectories across sectors in the Danish healthcare and social systems.

More than a decade of teaching physiotherapy students at a university college has further strengthened my theoretical understanding of chronic pain management and rehabilitation.

To familiarise myself with local procedures and clinical approaches, I observed clinical assessments and treatments at the Spine Centre of Southern Denmark at the beginning of the PhD program. However, I have not treated patients with LBP during the PhD project. This relative distance from direct clinical practice positioned me as an *outsider* during interviews and focus groups (*Paper II*), the co-design process (*Paper III*), and the process evaluation in the feasibility study (*Paper IV*), supporting a reflective and analytical stance in data generation and interpretation.

From a constructivist perspective, this preunderstanding was not bracketed out but actively engaged as an analytic resource, while continuously reflected upon throughout data collection and analysis [70]. Reflexive considerations regarding how my role and pre-understandings may have influenced data generation, facilitation, analysis, and interpretation are further elaborated in the methodological chapters of *Studies II–IV*.

05 Ethical considerations

Addressing ethical considerations in both qualitative and quantitative research is a fundamental component of good research practice [73–75]. To ensure compliance with data protection regulations, the study was registered in the Research Registry of the Region of Southern Denmark (journal no. 23/44927). All processing of personal data was conducted in accordance with the General Data Protection Regulation (GDPR) [76] and the Danish Data Protection Act (Act No. 289 of 8 March 2023) [77].

In practice, this meant that all sensitive personal data, including audio recordings and corresponding transcripts from interviews and focus groups, interview notes, process logs, patient records, and self-reported data collected across *Papers II–IV*, were handled with strict confidentiality. Data were stored on a secure, password-protected server approved by the Region of Southern Denmark, with access restricted to authorised members of the research team. To further protect participant confidentiality, individuals participating in *Papers II and IV* were assigned unique identification numbers, ensuring pseudonymisation of the data.

Papers II and III–IV were reported separately to the Regional Committee on Health Research Ethics. Both projects were deemed exempt from ethical review, in accordance with Section 14(1) of the Danish Act on Research Ethics Review (journal no. S-20232000–111 and S-20242000–37) [78].

Overall, this PhD project adhered to the ethical principles outlined in the Declaration of Helsinki [79] and the Danish Code of Conduct for Research Integrity [80].

In studies involving research participants (*Papers II and IV*), written informed consent was obtained prior to participation. Participants received written and oral information about the study. They were informed that participation was voluntary, confidential, and that consent could be withdrawn at any time without consequences for current or future

access to healthcare services. Where applicable, written consent was also obtained for audio recording of interviews, focus groups, and workshop discussions (*Papers III and IV*).

06 Stakeholder involvement and the use of co-design

Stakeholder involvement and co-design were central methodological strategies throughout this PhD project. Rather than being confined to a single development phase, stakeholder engagement was deliberately embedded throughout the research process to address contextual complexity, enhance feasibility, and ensure that the SAW intervention was grounded in real-world practice [4,5].

The terminology used to describe stakeholder involvement in intervention research remains inconsistent. Concepts such as *co-design*, *co-creation*, *co-production*, and *co-development* are frequently applied interchangeably, and no single, widely accepted definition has emerged [2,81]. A recent systematic review of co-design concepts and frameworks in public health research found that nearly half of the included studies did not provide an explicit definition, and that more than twenty distinct definitions were in use [2]. This reflects an evolving field in which conceptual clarity is still developing.

In *Papers III and IV*, the term *co-development* was used pragmatically to describe collaboration with stakeholders throughout the intervention development process. In the present thesis, stakeholder involvement is analytically framed using the concept of *co-design*, as defined by Vargas in her recent systematic review, which outlines that co-design actively involves different stakeholders involved in varying degrees throughout the different research phases to find relevant solutions that meet the needs and expectations of all participants [2].

To maintain conceptual continuity with the submitted and published articles while ensuring terminological transparency, this thesis distinguishes between *co-creation* as an overarching concept encompassing approaches such as co-design and co-production, a *co-design group* responsible for intervention development, and a *co-production group* responsible for implementation and evaluation activities. This distinction

follows earlier conceptual work by Vargas et al. [82] and reflects differences in roles and responsibilities across research phases.

The overall research process was structured according to Hawkins et al.'s three-stage framework, comprising evidence review and stakeholder consultation, co-production, and prototyping and testing [6]. These phase labels are retained throughout the thesis to preserve coherence with the submitted studies and to reflect the iterative nature of intervention development. Within Hawkins' co-production stage, the collaborative development activities are analytically framed as a co-design process, consistent with emerging definitions in the public health literature [2].

06.01 Stakeholder involvement in this PhD thesis

Stakeholder involvement was informed by the National Institute for Health Research's guidance on inclusive involvement [83] and operationalised using Smits et al.'s Involvement Matrix [84,85]. This framework supported explicit consideration of stakeholder roles, levels of influence, and timing of involvement across research phases (Figure 4).

During the initial stakeholder consultation (*Paper II*), individuals with lived experience of CLBP participated as "*co-thinkers*" in interviews and focus groups to inform problem identification and needs assessment.

In the co-production phase (*Paper III*), a multi-stakeholder co-design group was established, comprising clinicians from a specialised spine centre and municipal rehabilitation centres, professionals and managers from employment services, representatives from general practice, employer and employee organisations, and two individuals living with CLBP. Most participated as "*partners*"; however, clinicians from the spine centre only wished to participate as "advisors," according to Smits et al. 's involvement roles [84,85].

Rehabilitation centres and employment services from three Danish municipalities (Kolding, Middelfart, and Aabenraa) participated as active partners throughout the project. Local management representatives were involved at key decision points to ensure alignment with organisational priorities and implementation conditions. The author group functioned as "*decision makers*" in their role as the steering committee. They retained final decision-making authority to maintain role clarity and methodological progression where consensus could not be reached [5].

The Involvement Matrix						
			Role in the research project			
			Co-thinker Is asked to give opinion	Advisor Gives (un)solicted advise	Partner Works as an equal partner	Decision-maker Takes initiative, (final) decision
Stage of research project	Preparation	Preparetion	Participants in interviews and focus groups			Steering committee
		Research question identification				Steering committee
		Research design development		Spine Centre clinicians	Municipalities, GP consultants, Patient partners, Representatives of employer and employees	Steering committee
	Execution	Project management		Spine Centre clinicians	Municipalities	Steering committee
		Participant recruitment				Steering committee
		Data collection	Municipalities, Spine Center clinicians			Steering committee
	Evaluation	Data analysis & interpretation	Municipalities, Spine Center clinicians			Steering committee

Figure 4. Stakeholder roles across project phases.
Adapted from Smits et al.'s Involvement Matrix [84,85] and Paper III (Appendix C). © Center of Excellence for Rehabilitation Medicine Utrecht, used with permission

All participants from the qualitative interviews and focus groups were invited to join the co-design group to prioritise PPI and support research conducted *with*, rather than *to, about, or for* patients and members of the public [86]. However, participation from this group was limited. Barriers were primarily related to participants' ongoing efforts to RTW, limited flexibility to attend daytime workshops, and pain-related functional limitations. As a result, PPI within the co-design group was more restricted than initially intended.

The subsequent co-production group consisted of clinicians, municipal professionals and managers (*Paper IV*).

07 Methods study I

This chapter presents the primary methodological considerations of *Study I* and describes in more detail the eligibility criteria, the classification of team collaboration, and the extraction of data on PPI and stakeholder involvement, as these are particularly relevant to this PhD thesis.

Study I, a scoping review, aimed to map VR interventions for individuals with CLBP delivered within healthcare settings, focusing on professional composition and collaboration, intervention characteristics, assessment of work status, and reporting of PPI or stakeholder involvement.

A scoping review design was chosen to map the characteristics, components, and organisation of VR interventions, as this approach is suited to capturing the breadth and variation of complex interventions rather than evaluating effectiveness [87]. During the review process, the planned research question regarding conclusions on work status was removed due to substantial heterogeneity and inconsistent reporting of outcomes across studies. The review followed established methodological guidance for scoping reviews by drawing on the Joanna Briggs Institute methodology [88], and was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review (PRISMA-ScR) checklist [89]. To ensure transparency and reduce the risk of selective outcome reporting in the scoping review, a protocol was published on the Open Science Framework prior to data collection [90]. Study selection and data extraction were managed using Covidence® software [91]. Detailed methods are reported in the published manuscript for *paper I* (Appendix A) [44].

07.01 Eligibility criteria

Studies were eligible if they included working-age individuals with CLBP who were on sick leave or assessed as being at risk of sick leave, and examined vocational rehabilitation interventions operationalised according to Escorpizo et al.'s definition of VR [1] (see Definitions, page 18). Only studies of interventions initiated within the healthcare setting were included to ensure a relatively coherent organisational context and to

inform the development of a healthcare-initiated VR intervention in subsequent phases of the PhD project. Interventions initiated in welfare, labour market, or workplace settings were therefore excluded. The review was restricted to European experimental and observational studies published in peer-reviewed journals, preprints, or reports from 2013 onwards and written in English or a Scandinavian language. The review further focused on individuals with CLBP to ensure clinical and contextual relevance for the PhD project's target population and to support subsequent intervention development. While challenges related to multiprofessional and cross-sectoral coordination may not be diagnosis-specific, this delimitation was considered appropriate given the project's condition-specific focus.

Studies were excluded if more than 50% of participants had been on sick leave for more than 12 months to ensure comparability across studies, as prolonged sick leave has been associated with a reduced likelihood of RTW, and this may influence intervention intensity and duration [27]. Studies primarily including musculoskeletal conditions other than CLBP or focusing on surgical interventions were also excluded. In addition, qualitative studies were excluded, as the purpose of the scoping review was to map intervention characteristics, components, and outcome measures across VR interventions, which are typically reported in observational and experimental study designs. While qualitative studies may provide important insights into experiences and implementation processes, these did not align with the primary aim of systematically mapping intervention structures and evaluation approaches. These aspects were instead addressed in subsequent phases of the PhD project.

07.02 Classification of team collaboration

A key analytical focus of the scoping review was the nature of team collaboration within VR interventions. Drawing on established conceptual distinctions, interventions were categorised as multidisciplinary, interdisciplinary, or transdisciplinary [58]. When the type of collaboration was not explicitly stated, classification was based on the roles, interaction patterns, and degree of coordination across disciplines described in the article, its protocol, or previous publications of the intervention.

Multidisciplinary collaboration was characterised by the involvement of multiple professional groups delivering parallel interventions with limited interaction or joint decision-making. In contrast, interdisciplinary collaboration was defined by active coordination among professionals,

including shared goal-setting, integrated planning, and regular communication to align expertise around the individual's rehabilitation process. Transdisciplinary collaboration represented a more integrated model, in which professional boundaries were less distinct, and roles could overlap or be flexibly shared, allowing for adaptive responses but requiring substantial cross-disciplinary competence [58].

07.03 Data extraction of Stakeholder or Patient and Public Involvement

Although not specified as objectives in the scoping review protocol, data on stakeholder involvement or PPI in the development or evaluation of the interventions were extracted to provide contextual insight into how these interventions were developed and evaluated.

08 Results study I

This chapter summarises the included studies, key findings, and outlines how findings from *Study I* informed the co-production phase.

08.01 Overview of the included studies

Of the 3,169 screened records, 26 articles were included (Figure 5).

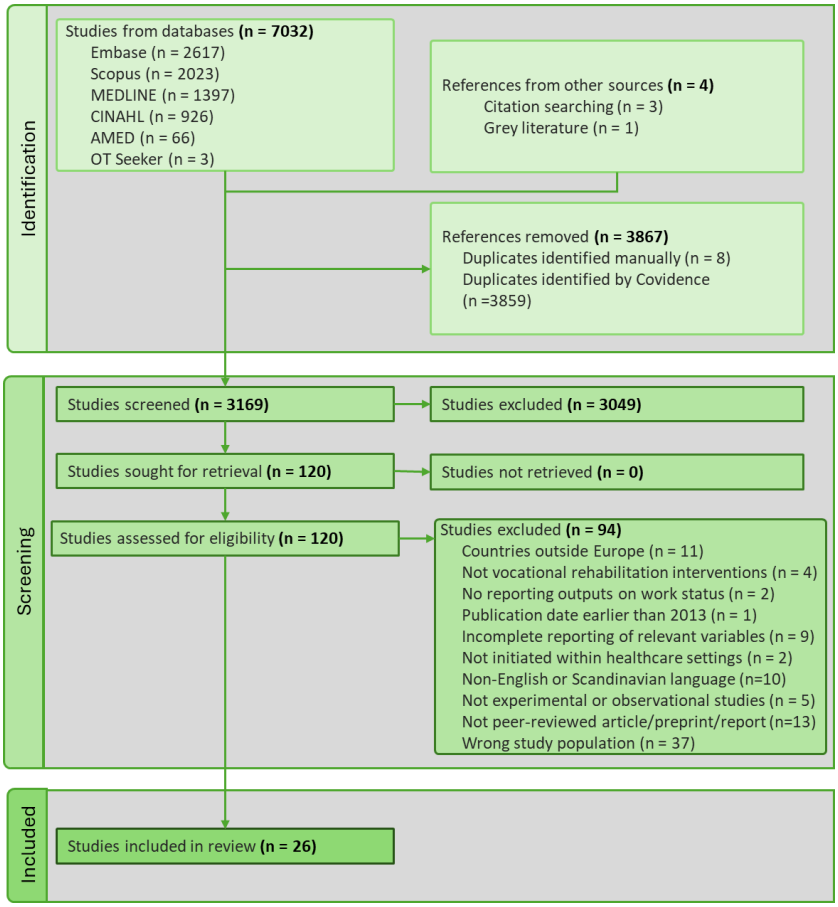

Figure 5 PRISMA Flow chart of article identification and screening process of the scoping review.
Reproduced from paper I [44].

The twenty-six included articles [92–117] were based on 21 separate studies from seven European countries (Table 1). Sample sizes varied substantially, although most studies included between 100 and 500 participants. Study populations comprised working-age adults, with mean ages ranging from 39.1 to 53.3 years. Both men and women were represented in all studies, with most samples showing a relatively balanced gender distribution, with a maximum of 60% of one gender [92,94–96,98–100,103–107,110–117]. Across studies, reported pain intensity generally reflected moderate to high symptom levels. This indicates that the interventions targeted individuals with clinically meaningful CLBP rather than mild LBP.

Table 1. Study characteristics of included studies in the scoping review. *Based on data reported in Paper I* [44]

Country	**Study: 1st author, (Yr of publication),**	**Sample size**
Denmark	Fisker (2022), [92]	n=770
Denmark	Hansen (2019), [93]	n=305
Denmark	Jensen, C. (2013), [94] Jensen, O. (2013), [95] Momsen (2014), [96] Pedersen (2018), [97]	[94]: n=471 [95]: n=325 [96]: n=282 [97]: n=464
Denmark	Langagergaard (2021), [98] Pedersen (2022), [99]	n=476
Denmark	Lindholdt (2017), [100]	n=160
Denmark	Rolving (2022), [101]	n=136
Finland	Rantonen (2018), [102]	n=176
France	Caby (2016), [103]	n=44
France	Cougot (2015), [104]	n=217
France	Nguyen (2017), [105]	n=88
France	Ronzi (2017), [106]	n=159
Germany	Hampel (2015), [107]	n=84
Germany	Hampel (2019), [108]	n=583
Germany	Streibelt (2014), [109]	n=102
Norway	Harris (2017), [110]	n=214
Norway	Myhre (2014), [111] Marchand (2015), [112]	n=405
Norway	Reme (2016), [113]	n=413
Norway	Werner (2019), [114]	n=433
Switzerland	Ibrahim (2019), [115]	n=201
Switzerland	Steiner (2013), [116]	n=45
United Kingdom	Wynne-Jones (2018), [117]	n=338

Reporting of sick leave duration at baseline varied substantially across studies and was therefore not summarised in Table 1. Studies reported sick leave using heterogeneous formats (e.g., mean or median duration, proportions above specific thresholds, or inclusion criteria), limiting meaningful comparison across studies.

08.02 Main findings

The included studies differed substantially in intervention duration, intensity, component composition, professional involvement, and approaches to measuring work status, limiting comparability across studies and highlighting the need for more transparent intervention development and reporting [44].

Hospital outpatient programs were the most common setting [92–103,106,111,112,114–116]. The interventions ranged from 1 week to 3 months [92,93,98,99,101,102,110,113,114] or continuing to the participant RTW or another plan was designed [94–97,100]. Furthermore, the interventions ranged from 0-5 hours per week with 1-2 components [102,106,108] to 5-6 hours daily, 5 days a week, with 5-7 components [103,106,115,116], reflecting the heterogeneity of VR practices for individuals with CLBP. The complete mapping of intervention characteristics and outcome measures is presented in *Paper I* [44].

08.03 Type of collaboration

Despite broad professional representation, explicit descriptions of how team-member collaboration was organised were provided in only one study [92], while a further seven studies reported sufficient detail to allow classification. Interdisciplinary collaboration was the most commonly identified model (six studies) [92,94–100,110,115], whereas multidisciplinary [117] and transdisciplinary [101] approaches were each identified in one study. However, for the majority of interventions (13 studies), descriptions of professional roles and interactions were insufficient to determine the nature of team collaboration [93,102–109,111–114,116].

Overall, these findings indicate that although VR interventions for individuals with CLBP often involve multiple professional disciplines, reporting on how collaboration is structured remains limited [44].

08.04 Assessment of work status

Overall, the findings demonstrate substantial variation in how and when work status is assessed across VR interventions for individuals with CLBP, including both measurement approaches and follow-up timing [44].

Follow-up periods ranged from 5 weeks [103] to 5 years post-intervention [97], with most studies assessing work status at six months [92,93,101,107,108,110,113,115] or one year [92,94–98,100,101,105–113,117].

Most studies focused on overall sick leave duration [92,94,96,97,99,103,105–107,109,111] or work status at a predefined follow-up point [92,95,96,99,103–105,109,115,116]. In contrast, dynamic RTW assessments, such as sequence analysis capable of capturing the fluctuating nature of CLBP, were rarely applied [97,100]. In total, 19 different approaches to reporting work status were identified. Definitions of RTW also varied across studies, including reporting RTW or sick leave as full-time return only [92–96,98,99,107,108,111,112], reporting changes in the degree of sick leave [110,113–115], or not specifying how RTW or sick leave were defined [97,100–106,109,116,117]. This complicated comparison of work status outcomes across interventions.

08.05 Stakeholder and Patient and public involvement in intervention development

Reporting on stakeholder involvement and PPI was sparse and inconsistent. One study described active involvement of both patients and healthcare professionals across all phases of intervention development [117], while another reported involvement of healthcare professionals in the development of educational materials, without patient participation [101]. This pattern points to a potential gap in the VR literature.

08.06 How *Study I* informed the co-production phase

Study I contributed to the co-production phase (*Study III*) by mapping how VR interventions for individuals with CLBP are organised within healthcare settings. The findings revealed substantial heterogeneity in

intervention characteristics and a lack of standardised approaches. As no dominant model was identified, the co-design process prioritised strengthening cross-sectoral collaboration rather than replicating specific intervention components.

Interdisciplinary collaboration was most commonly identified, but descriptions of collaboration across professional groups were often limited. This informed the decision to prioritise and operationalise interdisciplinary collaboration through a participant-centred coordination meeting (Activity 6), where stakeholders jointly align goals and plans with the participant, rather than relying on a case-management approach.

The review also identified minimal reporting of stakeholder involvement, which informed the decision to apply a co-production approach and actively involve stakeholders in shaping intervention components during the workshops.

Variation in outcome measures and reliance on single follow-up points informed the inclusion of more dynamic measures of work participation in *Study IV*. This was operationalised through weekly self-reported sick leave collected through SMS prompts. Although intervention outcomes may be relevant for informing intervention design, they were not synthesised in *study I* because heterogeneous definitions, measurement methods, and follow-up periods limited meaningful comparison within the scope of the scoping review.

Together with *Study II*, *Study I* provided a complementary evidence base that was translated into key design decisions during the co-production phase.

09 Methods study II

This chapter outlines the primary methodological considerations of *Study II* (Appendix B) [65], with emphasis on the prioritisation of lived experience in RTW trajectories, participant characteristics, data collection, and the analytical process. Particular attention is given to data management, reflexive thematic analysis, and the application of HL as an interpretive framework.

We explored stakeholder experience through a qualitative study, which aimed to explore how individuals with CLBP and prolonged sickness absence (>30 days) in Denmark experience and navigate RTW processes, and to identify their perspectives on how coherence within these processes could be strengthened. This was analysed through an HL perspective.

09.01 Prioritisation of lived experience in RTW trajectories

In line with Hawkins et al.'s co-production framework [6], stakeholder consultation prior to the co-production phase may involve multiple groups; however, not all perspectives need to be addressed at the same stage of a development process or within a single study [5]. In this study, stakeholder consultation was deliberately limited to individuals with lived experience of sickness absence due to CLBP, as the intervention was intended to be grounded in the experiences and needs of those directly navigating RTW pathways. These perspectives were less prominent in the subsequent co-design group, which included only two patient partners.

09.02 Participants

Eligible criteria:

- Working age
- Current or recent sick absence due to CLBP over a long enough period to have been in contact with the municipal employment service
- Danish language proficiency

Although participants were recruited using convenience sampling, the final sample of 17 participants comprised a heterogeneous group in terms of age, duration of LBP, employment status, and occupational background (Table 2). This variation was considered appropriate for the exploratory and experience-oriented aim of the study [73,118]. Although women were overrepresented in the sample, the breadth of clinical and vocational characteristics provided a rich and diverse foundation for generating accounts of navigating RTW processes.

Table 2. Characteristics of the participants in the interviews and focus groups. *Based on data reported in Paper II* [65].

Characteristics	N=17 Count (%)
Sex [Female]	12 (70.6)
Age group	
20-29	1 (5.9)
30-39	3 (17.6)
40-49	2 (11.8)
50-59	6 (35.3)
60-62	5 (29.4)
Duration of back pain	
<6 months	4 (23.5)
6-12 months	3 (17.6)
1-5 years	4 (23.5)
>5 years	6 (35.3)
Employment status	
Sick leave during termination	2 (11.8)
Full-time sick leave	7 (41.2)
Part-time sick leave	4 (23.5)
Resumed work	2 (11.8)
Resumed work after unemployment	2 (11.8)
Occupational group	
White collar	5 (29.4)
Blue Collar	3 (17.6)
Health care	3 (17.6)
Education	3 (17.6)
Service	3 (17.6)

09.03 Data collection

Data were generated through 3 semi-structured individual interviews and 4 focus groups, each with 2-5 participants. Focus groups were used to support interaction between participants and to elicit both shared and divergent experiences, consistent with a constructivist approach in which meaning is co-constructed through dialogue. In particular, the focus group format enabled participants to reflect collectively on inconsistencies, negotiations, and tensions in RTW processes across sectors, thereby providing insight into how coherence was experienced and discussed in situ, beyond individual accounts [70,118]. Individual interviews were initially conducted as pilot interviews to refine the interview guide [73].

The interview guide was developed by an interprofessional research team with clinical and research expertise in general practice, rehabilitation, and occupational medicine. It was structured around three overarching topics: facilitators and barriers for RTW, challenges in navigating multiple stakeholders, and suggestions for improving RTW processes (Appendix B1). During data collection, the guide was used flexibly to support an exploratory approach, with open-ended questions, prompts, and follow-up questions applied to deepen participants' reflections.

09.04 Data management and analytical process

Data were analysed by broadly following the phases of Braun and Clarke's reflexive thematic analysis, progressing iteratively from familiarisation with the dataset to coding, theme development, theme review, and interpretation prior to write-up [119–121]. We applied an inductive approach to theme construction, followed by a theoretically informed interpretive phase. This approach aligns with a constructivist epistemological position and supports an exploratory analysis of participants' experiences [70]. Interpretive Description [122] was considered but not applied, as translation into practice-oriented solutions was deferred to the subsequent co-design phase.

Audio recordings were transcribed verbatim by a secretary present during data collection. Transcripts were validated against recordings by the first author (GF), read repeatedly for familiarisation, and supplemented with initial notes. Data were managed and coded using NVivo 14.

Transcripts were not returned to participants, as the analysis aimed to move beyond individual accounts and generate interpretive insights [122].

GF conducted inductive coding using both semantic and latent codes, with occasional double-coding to capture multiple meanings. GF and AH then independently developed preliminary themes, which were refined through iterative dialogue into a set of candidate themes reflecting patterns across the dataset.

Themes were subsequently reviewed against coded extracts and the full dataset, marking a shift from description to interpretation. At this stage, HL was introduced as a sensitising framework and applied exclusively in the interpretive phase, not during initial coding, to support a theoretically informed understanding of how participants navigated RTW processes in relation to individual capacities and system-level demands [3,66]. This use of HL during theme development, rather than coding, is consistent with reflexive thematic analysis to deepen interpretation [120].

This analytic progression is illustrated by participants describing conflicting guidance across sectors, for example: *"One is pulling in the opposite direction of the other… my physiotherapist says, you need to be ready... the municipality (Sickness benefit office)…wants me to get back to work."* This was initially coded as being caught between professionals and challenges in cross-sectoral communication. These codes informed themes on system fragmentation and inconsistent guidance. In the interpretive phase, applying an HL perspective enabled further understanding of how such fragmentation places demands on participants to coordinate their own RTW trajectories, reflecting a misalignment between system complexity and individual capacity. Through this interactive process, themes were further refined and defined, supported by illustrative quotes to ensure transparency and demonstrate the link between data and interpretation.

Reflexivity was integral to the analysis. GF's background in health education and counselling supported close engagement with participants' experiences but required ongoing awareness of potential pre-understandings. This was evident in the development of initial themes, where GF's interpretations primarily reflected lived experiences, while AH's clinically informed perspective emphasised system-level aspects. These perspectives were actively contrasted and integrated through iterative

discussions, resulting in themes capturing both individual and structural dimensions of RTW processes.

Analytic decisions were continuously discussed within the research team to challenge interpretations, broaden perspectives, and strengthen credibility rather than to achieve consensus [120].

To enhance methodological transparency and reporting quality, the study was conducted and reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist [123] (Appendix B2). Further methodological details are provided in the published manuscript (Appendix B) [65].

10 Results study II

The present chapter presents the qualitative findings most relevant to the subsequent development phase of this PhD project and elaborates on their interpretation through an HL perspective. In addition, it describes how findings from *Study II* informed the initial co-production phase of the intervention development.

The analysis generated four overarching themes, as shown in Figure 6.

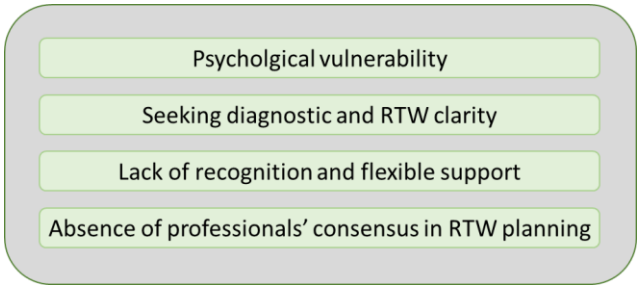

Figure 6. Main themes from the qualitative study.
Based on data from Paper II [65].

The first theme, *psychological vulnerability*, captures how participants' emotional well-being was challenged during periods of sickness absence. Pain, uncertainty about prognosis, and social isolation contributed to heightened emotional strain, which in turn affected participants' capacity to manage everyday demands and engage constructively in RTW processes. Participants described a lack of attention to psychological challenges within spine care and expressed a need for structured support to address emotional distress alongside physical rehabilitation.

The second theme, *seeking diagnostic and RTW clarity*, highlights participants' strong desire for clear explanations regarding diagnosis, prognosis, and expected recovery trajectories. Diagnostic uncertainty complicated planning and communication with employers and municipal stakeholders. Diagnostic imaging was often perceived as a means of

legitimising symptoms and structuring RTW expectations, although its usefulness depended on how the information was explained and interpreted. For some, imaging results facilitated engagement in rehabilitation and RTW planning, whereas for others, the results were experienced as confusing or difficult to translate into concrete guidance for recovery and RTW.

The third theme, *lack of recognition and flexible support from stakeholders*, underscored the importance of being recognised and taken seriously by key stakeholders during the RTW process. Participants described how mistrust from employers, municipal caseworkers, and, at times, healthcare professionals constituted a significant barrier. Repeatedly having to justify their condition was experienced as exhausting and undermined their ability to focus on recovery and RTW planning.

Participants differed in their need for support when communicating with stakeholders. Some emphasised the value of having a healthcare professional present at meetings with employers or caseworkers to help articulate limitations, legitimise their situation, and reduce the burden of self-advocacy during vulnerable periods. This was especially pronounced among those without supportive employers or colleagues. Others found written clinical documentation sufficient and reported being able to interpret and apply this information in RTW negotiations independently. This variation indicates differing capacities to engage with and act upon health information in RTW-related interactions.

The fourth theme, *absence of professionals' consensus in RTW planning*, concerns participants' experiences of fragmented systems and inconsistent guidance across sectors. Participants frequently encountered contradictory advice regarding treatment, activity levels, and RTW readiness and were left to coordinate information between stakeholders while managing pain and emotional strain. Although preferences regarding the desired level of professional involvement varied from clear contact points to more active coordination, such as coordinated stakeholder meetings or cross-sector care coordinators, all participants called for clearer responsibilities, improved cross-sectoral communication, and more coherent RTW planning.

10.01 Results analysed through a health literacy perspective

An HL-informed analysis revealed a consistent pattern across themes [3,60,66]. Participants' accounts indicated that fragmented RTW systems became particularly burdensome when health information was not perceived as understandable, meaningful, or actionable. Variations in responses to diagnostic imaging and stakeholder communication suggested differences in functional, interactive, and critical HL. Together, these findings illustrate how individual HL capacities and system-level responsiveness interact to shape RTW trajectories in CLBP (Figure 7). A more detailed HL-informed interpretation of the qualitative findings is presented in *Paper II* [65].

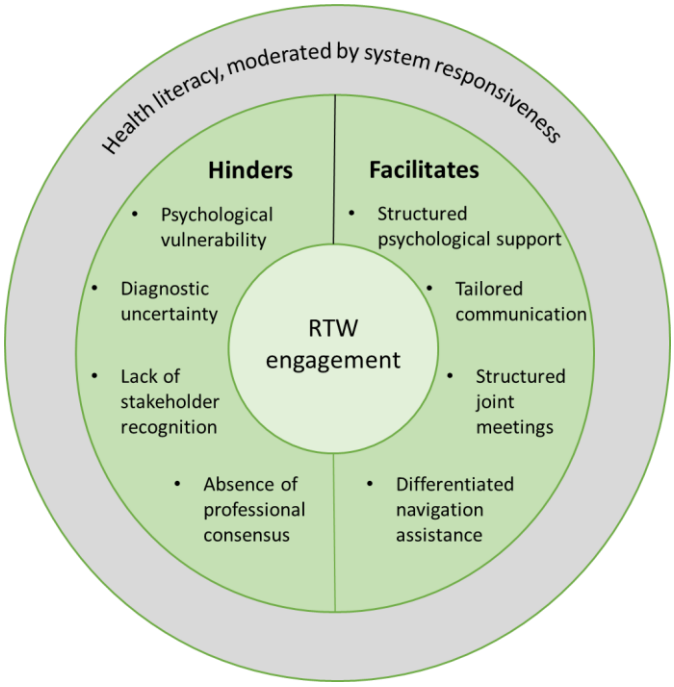

Figure 7. Health literacy in relation to return-to-work trajectories for individuals with chronic low back pain.
The conceptual model illustrates how four main themes hinder or facilitate RTW engagement among individuals with CLBP. These processes are shaped by individual HL levels and moderated by system responsiveness to HL. Reproduced from Paper II [65].

10.02 How Study II informed the co-production phase

Study II contributed to the initial co-production phase (*Study III*) by providing an empirically grounded understanding of participants' experiences of navigating RTW processes across sectors. The four themes identified in *Study II* were used to structure the first co-design workshop and to guide stakeholder discussions on challenges and potential improvements in existing rehabilitation pathways.

In the first workshop, the themes were presented alongside illustrative quotes to ensure a shared understanding of the identified challenges. Participants were then divided into interprofessional groups and worked systematically with each theme. For each theme, targeted discussion questions were developed to translate empirical findings into practice-oriented reflections. For example, challenges related to inconsistent guidance across sectors informed discussions on how to reduce conflicting messages and minimise mistrust among stakeholders, while findings on psychological vulnerability informed discussions on how to better integrate psychosocial considerations into RTW processes. Each group was asked to generate concrete suggestions for improving current practices. These discussions informed the initial identification of key areas for intervention development.

In this way, *Study II* not only identified challenges in RTW processes but also directly informed the content and direction of the co-production phase by structuring stakeholder dialogue and generating initial proposals for intervention components. The input generated in the first workshop was synthesised and carried forward to subsequent workshops, where it was further refined and prioritised as part of the iterative co-design process. Further details on how these proposals were developed into specific elements of the SAW intervention are described in *Study III* (Chapter 11).

11 Methods study III

This chapter reports the primary methodological considerations and describes the co-design process, as these aspects are particularly relevant to the present PhD thesis.

The aim of *Paper III* [124] (Appendix C) was to co-develop the SAW intervention while contributing methodological insight into how evidence, qualitative findings, stakeholder perspectives, and program theory can be systematically combined and translated into concrete intervention components within a cross-sectoral development process.

The MRC framework informed the overall structure of stakeholder involvement, contextual considerations, program theory development, iterative refinement, and feasibility considerations [4]. The INDEX principles complemented this by guiding concrete methodological choices during development [5]. A partnership approach was operationalised through an interprofessional co-design group involving stakeholders from healthcare, municipal rehabilitation, employment services, employer and employee representatives, and patient partners. A theory- and evidence-based approach integrated findings from *Studies I and II* with existing theoretical perspectives and program theory development. Furthermore, the iterative nature of the INDEX principles informed repeated feedback loops, refinement cycles, and collective decision-making processes across workshops and prototyping activities.

In line with MRC guidance, economic considerations were addressed during the co-design process [4]. We addressed it qualitatively rather than through formal cost analyses. Stakeholders were encouraged to propose intervention components, which were subsequently refined through collective assessment of resource implications, proportionality, and implementation feasibility within routine practice settings.

To support methodological transparency and transferability, the development process was documented using established reporting guidelines, including the Guidance for Reporting Intervention Development (GUIDED) checklist (Appendix C1) [125], the Template for Intervention

Description and Replication (TIDieR) checklist (Appendix C2) [126], and the Guidance for Reporting Involvement of Patients and the Public (GRIPP2—short form) (Appendix C3) [127].

The outcome of the co-design process was a structured intervention manual comprising eight activities and role-specific implementation guides, which informed subsequent prototyping and feasibility testing (*Paper IV*). Detailed descriptions of methods and activities are provided in *Paper III* [124] (Appendix C).

11.01 Co-design process

Stakeholders were purposively selected to ensure representation of key actors involved in cross-sectoral VR and to reflect perspectives relevant to both intervention development and subsequent feasibility testing. Selection was guided by relevance to the intervention context and representation across sectors.

Municipal stakeholders were recruited from three collaborating municipalities (Kolding, Middelfart, and Aabenraa), selected pragmatically based on willingness to participate and representing variation in organisational contexts. Local management appointed participants with experience in VR and cross-sectoral collaboration. Clinical representatives from the Spine Centre were selected by management based on roles in coordinating patient pathways. General practitioners were recruited through practice consultant roles to ensure insight into primary care interfaces. Employer and employee representatives were included to reflect occupations with increased risk of LBP, and patient representatives were recruited from *Study II* based on their lived experience of RTW processes.

Participants in the co-production group (*Study IV*) were selected from the same settings based on predefined criteria related to experience in service delivery to the intervention target group.

Overall, this sampling strategy ensured inclusion of relevant stakeholders across sectors and supports assessment of transferability to *Study IV*.

Intervention content was developed through an iterative co-design process informed by participatory research principles [128]. Individual and

group expectation meetings were conducted with the co-design group prior to the workshops to clarify roles and responsibilities, supporting psychological safety and shared ownership [4,6]. Two structured workshops were conducted, supplemented by written correspondence and interim feedback rounds. The process followed an action-oriented cycle of reflection, idea generation, testing, and refinement [5].

The first workshop focused on translating findings from *Study II* into preliminary intervention ideas. After an introductory presentation, participants were organised into interdisciplinary groups. Each theme was explored through structured group discussions followed by plenary sessions. Group discussions were documented through participant notes, while plenary discussions were audio-recorded with informed consent.

Data from Workshop 1 were synthesised through analytic condensation. The analytic process progressed iteratively from workshop discussions and notes to analytic summaries, thematic categorisation, and progressively refined intervention proposals. Audio recordings were not transcribed verbatim, as the analytic focus was on synthesising proposed intervention components and decision-making processes rather than detailed linguistic interaction; instead, the first author (GF) produced audio-informed analytic summaries based on repeated listening, which were subsequently compared with participant notes and field notes [73]. These summaries captured key perspectives and were used to generate preliminary improvement proposals organised by theme. The synthesis was discussed with a senior researcher (AH) to support reflexivity and subsequently circulated to the co-design group for validation.

The resulting proposals were recategorised into focused discussion areas for Workshop 2 to support operationalisation, for example, transforming broad themes such as cross-sectoral communication into concrete discussion domains (e.g., participant-centred coordination meetings, shared documentation, and interprofessional knowledge exchange). The second workshop was conducted using the World Café method, enabling iterative and cumulative dialogue across interdisciplinary stakeholder groups [129]. Participants rotated between thematic stations, where discussions built on prior input with support from designated facilitators. Notes were taken at each station, and plenary discussions were audio-recorded. Participants were asked to formulate 1–3 concrete intervention proposals within each thematic area and outline their practical implementation. This was followed by mono-professional

group discussions to identify relevant outcome measures for feasibility assessment, then a plenary synthesis. These discussions informed outcome selection and supported the linkage between intervention components, mechanisms, and anticipated outcomes.

Across workshops, data were progressively condensed and prioritised through iterative categorisation and comparison. Decisions regarding inclusion, modification, or exclusion of intervention components were guided by three criteria: 1) alignment with identified needs, 2) feasibility within organisational and legislative frameworks, and 3) consistency with clinical guidelines and the defined scope of the intervention. For example, proposals for fast-track referral to the Spine Centre were excluded as they fell outside the intervention's scope, which focused on the rehabilitation process from the point of Spine Centre contact onward. Similarly, the proposal for routine diagnostic imaging was rejected due to inconsistency with clinical guidelines [49], although the underlying need for diagnostic clarity was addressed through structured communication and shared documentation. Both decisions were made collectively within the co-design group during Workshop 2.

Where agreement could not be reached, the facilitator proposed a compromise solution balancing stakeholder perspectives, which was subsequently assessed collectively for feasibility. Following Workshop 2, stakeholder input from recordings and notes was synthesised into draft intervention components, which were refined through iterative feedback within the co-design group. Targeted feedback was obtained from stakeholder groups on relevant elements, and minor revisions were made accordingly.

Reflexivity was integral throughout the co-design process. GF facilitated the workshops and led the analytic synthesis of stakeholder input. This dual role required ongoing awareness of how categorisation, prioritisation, and reformulation of ideas could influence the resulting intervention. While GF's background in health education supported facilitation of inclusive and structured dialogue, limited recent clinical experience may have influenced interpretation of certain proposals. To mitigate this, analytic decisions were continuously discussed with co-authors, and stakeholder validation was incorporated through feedback loops to ensure that the final intervention remained grounded in collective input rather than individual assumptions.

12 Results study III

This chapter presents the intervention's overall structure and the underlying program theory including how stakeholder involvement informed key design decisions, the remaining uncertainties, the prototyping phase, and how the co-production phase links to the subsequent feasibility study.

12.01 The Stay-At-Work intervention

Figure 8 provides an overview of the SAW intervention structure, sequencing, and timing of the eight activities.

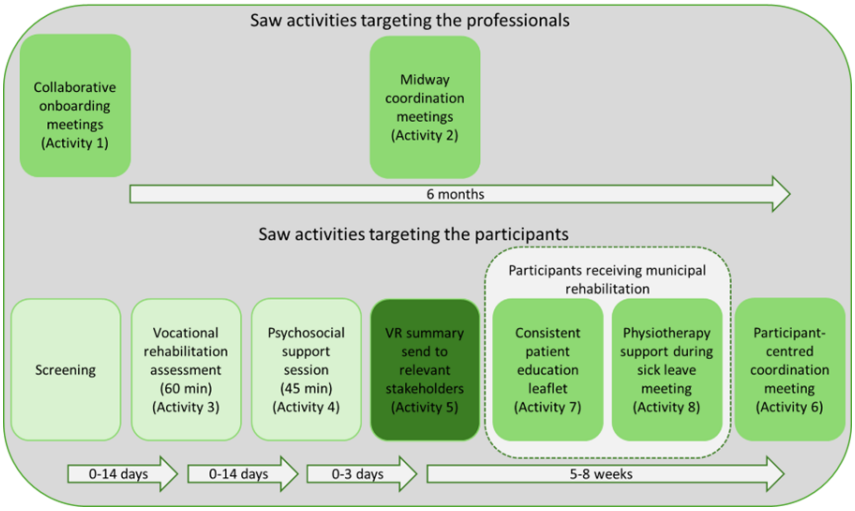

Figure 8. Overview of the Stay-At-Work intervention activities and their timing. *The six-month timeline represents the planned period for participant inclusion during the feasibility test. The bottom timelines show the participants' intervention process. Light green boxes = Activities delivered at the Spine Centre. Green boxes = Activities delivered within the municipality. Dark green box = Activity prepared at the Spine Centre and shared with municipal stakeholders and GPs to support subsequent coordination.*
Activities 7 and 8 are positioned before the participant-centred coordination meeting (Activity 6) to reflect the practical implementation. Municipal rehabilitation and related workplace-oriented activities may be initiated shortly after

referral, but only for a selected group of participants, whereas the coordination meeting took 5-8 weeks to coordinate. Reproduced from Paper IV (Appendix D).

Prior to the SAW intervention, the co-production group received an intervention manual describing each activity, including its rationale, procedures, materials, providers, setting, delivery, and economic compensation, as well as profession-specific step-by-step implementation guides to ensure clarity and consistency across settings. Spine Centre clinicians in the co-production group received structured training in the assessment, screening, and communication components of Activities 3–5 to support consistent delivery.

The SAW intervention comprised eight structured activities. Activities 1–2 were preparatory and targeted the co-production group, whereas Activities 3–8 were delivered to participants. A detailed description of all activities is provided in Table 3 and further elaborated in *Paper III* [124] (Appendix C).

Table 3. Detailed description of the Stay-At-Work intervention.

Activity 1: **What (Procedures):** ***Collaborative onboarding meetings*** to align professionals and managers across sectors, establish a shared understanding, and clarify roles and responsibilities related to the SAW intervention. **What (Materials):** Intervention manual outlining all activities; role-specific implementation guides; presentations from each professional group on roles, responsibilities, and relevant legislation; presentation on CLBP; introduction to the SAW intervention with opportunity for questions. **Who provided:** Physiotherapists, nurses, and the project manager from the Spine Centre, together with municipal management representatives, physiotherapists, and social workers. **How:** Face-to-face. **Where:** Municipal employment services in Kolding, Middelfart, and Aabenraa. **When and how much:** One meeting in each municipality of 2.5 hours prior to intervention start.
Activity 2: **What (Procedures):** ***Cross-sector coordination meetings*** to support ongoing collaboration and adjust the intervention as needed. **What (Materials):** Presentations and structured discussions. **Who provided:** Same as Activity 1. **How:** Face-to-face. **Where:** Same locations as Activity 1.

When and how much: One meeting in each municipality of 1.5 hours, conducted midway through the feasibility study.
Activity 3: **What (Procedures):** ***VR assessment*** to identify work-related limitations, set individualised rehabilitation goals, and evaluate the need for further municipal services. **What (Materials):** Standardised screening package including WORQ [130] and DASS-42 [131]; screening result sheets; the Spine Centre patient leaflet "Understand your pain in the lower back" [132]; and the Patient-Specific Functional Scale [133] for goal setting. **Who provided:** Physiotherapists at the Spine Centre (project manager supported screening procedures). **How:** Face-to-face; optional follow-up conducted face-to-face or by telephone. **Where:** The Spine Centre. **When and how much:** One session (45–60 minutes) scheduled within 14 days of the initial consultation. Optional follow-up if needed.
Activity 4: **What (Procedures):** ***Psychosocial screening and tailored support session***. Participants scoring moderate to extremely severe on any DASS-42 domain [131], or identified as psychologically vulnerable during Activity 3, were offered a session focusing on coping strategies and assessment of the need for GP follow-up. **What (Materials):** Standardised screening using DASS-42 [131]. **Who provided:** Nurses at the Spine Centre (project manager supported screening procedures). **How:** Face-to-face; optional follow-up conducted face-to-face or online. **Where:** The Spine Centre. **When and how much:** One session (45 minutes), preferably on the same day as Activity 3 or within 14 days; optional follow-up if needed.
Activity 5: **What (Procedures):** Preparation and dissemination of a ***shared VR summary*** outlining functional limitations, psychosocial findings, rehabilitation goals, referral status, and a request to initiate Activity 6. **What (Materials):** Standardised shared rehabilitation summary. **Who provided:** Physiotherapists at the Spine Centre (prepared the summary); administrative staff (distributed it to the participant, GP, municipal case worker, and relevant municipal services). **How:** Disseminated via secure electronic health record systems and email. **Where:** The Spine Centre. **When and how much:** Approximately 30 minutes; completed on the same day as Activity 3, with additional notes added if Activity 4 was conducted.
Activity 6: **What (Procedures):** ***Participant-centred coordination meeting*** to enhance cross-sector coordination of care and rehabilitation. Mandatory for participants on sick leave and optional for others. **What (Materials):** Shared VR summary from Activity 5. **Who provided:** Municipal case worker (organised the meeting) with participation from the participant, GP, municipal case worker, and, where relevant,

a municipal physiotherapist. **How:** Face-to-face or, where necessary, online. **Where:** The participant's GP clinic. **When and how much:** One session (30–45 minutes) conducted 5–8 weeks after the VR summary was received by the employment service.
Activity 7: **What (Procedures):** Provision and discussion of a ***standardised patient education leaflet*** for participants receiving municipal rehabilitation, ensuring consistent communication and shared understanding of CLBP management across sectors. **What (Materials):** Spine Centre patient leaflet "Understand your pain in the lower back" [132]. **Who provided:** Municipal physiotherapists. **How:** Face-to-face. **Where:** Municipal rehabilitation centres in Kolding, Middelfart, and Aabenraa. **When and how much:** Approximately 15 minutes during an early rehabilitation session.
Activity 8: **What (Procedures):** Optional ***Physiotherapy support during workplace sick leave meetings*** for participants on sick leave receiving municipal rehabilitation, aiming to facilitate dialogue and shared understanding regarding management of CLBP, the participant's current work-related functional limitations, and possible workplace accommodations. **What (Materials):** Information letter to employers. **Who provided:** Municipal physiotherapists. **How:** Online meeting. **Where:** Municipal rehabilitation centres and participants' workplaces. **When and how much:** Approximately 30 minutes, provided as needed during the rehabilitation period.

CLBP: chronic low back pain. DASS-42: Depression, Anxiety, and Stress Scale. GP: general practitioner. SAW-intervention: Stay-At-Work intervention. VR: Vocational rehabilitation. WORQ: work rehabilitation questionnaire.

12.02 Program theory and mechanism of impact

The program theory was developed iteratively across research phases 1–3 to articulate how the SAW intervention is expected to produce change through four core mechanisms (Figure 9) [4]. The systematic translation of evidence-based input into intervention activities and its linkage to hypothesised mechanisms is described below.

Strengthening interprofessional and cross-sectoral understanding and collaboration

Qualitative findings highlighted fragmented service pathways and inconsistent communication as key barriers to coherent VR [52,53,57,65]. These issues were echoed in the co-design process, where limited

awareness of sectoral mandates and the absence of a shared language hindered collaboration. These insights informed *Activities 1–2 and 5–7*, which aimed to establish a shared conceptual foundation, clarify roles, and support cross-sectoral collaboration.

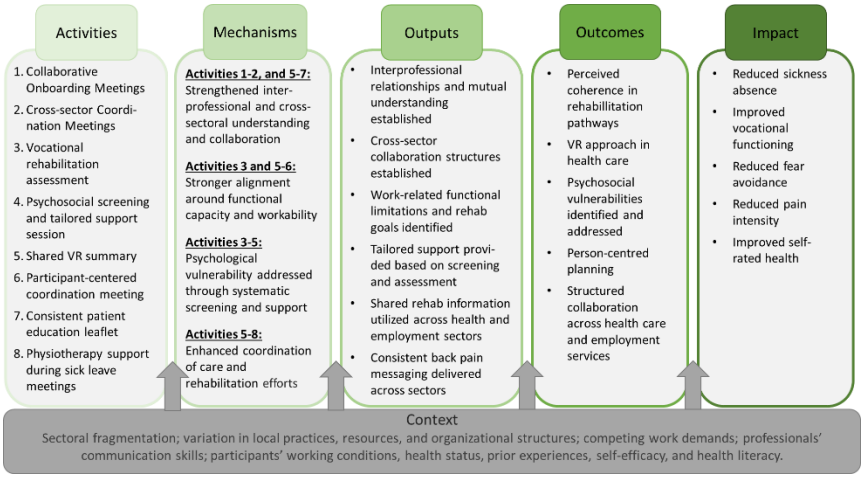

Figure 9. Logic model illustrating the program theory for the Stay-At-Work intervention.
VR: vocational rehabilitation. Reproduced from Paper III.

Stronger alignment around functional capacity and work ability

Unclear diagnostic communication and lack of professional consensus emerged as sources of uncertainty in RTW planning [65], while the scoping review identified substantial variation in work status assessment [44]. In response, stakeholders emphasised the need for structured VR assessments and shared documentation. This rationale underpinned *Activities 3 and 5-6*, including use of the Work Rehabilitation Questionnaire (WORQ) [130] to support systematic assessment, shared goal formulation, and coordinated planning across settings.

Addressing psychological vulnerability through systematic screening and support

Psychological distress and vulnerability were prominent among interviewed individuals on long-term sick leave [65] and recognised by co-design participants as a barrier to coordinated rehabilitation. These insights informed systematic screening using the Depression, Anxiety, and Stress Scale (DASS-42) [131] and the integration of tailored

psychosocial support and GP follow-up recommendations within the VR summary (*Activities 3–5*), enabling identification and communication of psychological vulnerability across sectors.

Enhancing coordination of rehabilitation and RTW efforts
Participants frequently described having to coordinate information across sectors, often encountering conflicting messages that delayed RTW [65]. Co-design participants reinforced the need for shared plans and standardised communication. Together with findings from the scoping review indicating interdisciplinary collaboration as a common organising principle in VR [44], these insights informed *Activities 5–8,* which aimed to strengthen coordination, consistency, and shared responsibility across services.

Across the four mechanisms, the SAW intervention linked specific intervention activities to hypothesised mechanisms of change expected to generate proximal outputs, including established interprofessional relationships and cross-sector collaboration structures; identification of work-related functional limitations and rehabilitation goals; tailored support based on screening results; and consistent messages used across healthcare and employment services.

These outputs were expected to generate outcomes at participant and system levels, most notably perceived coherence in rehabilitation pathways, alongside more structured collaboration and person-centred planning. Within the program theory, perceived coherence therefore functions as a key process indicator of activated mechanisms and a prerequisite for downstream impact, rather than an effectiveness endpoint.

In turn, improved coherence and alignment among stakeholders may facilitate more timely and coordinated decision-making in RTW processes, thereby reducing delays and uncertainties that can prolong sickness absence [16,52–56]. An enhanced VR approach in healthcare may also support more appropriate work-related adaptations, thereby contributing to improved vocational functioning.

However, impact cannot be assessed solely in terms of reduced sickness absence and vocational outcomes, as work participation is influenced by contextual and labour market factors beyond the reach of health interventions [47]. To address this, the co-design group identified additional relevant impact indicators, including self-rated health, fear

avoidance, and pain intensity, which are established outcomes in VR for individuals with CLBP [24,44].

12.03 How stakeholder involvement shaped the intervention

Stakeholder involvement was central to translating evidence and experiential knowledge into concrete, contextually feasible design decisions within the SAW intervention. Throughout the co-design process, stakeholders actively contributed to shaping intervention components, participant-facing materials, and recruitment strategies, facilitating shared ownership and alignment across sectors.

The co-design process functioned as a forum for negotiating tensions between participant preferences, clinical evidence, and system-level feasibility. For example, proposals to introduce a dedicated care coordinator were discussed but ultimately rejected, as stakeholders prioritised structured interdisciplinary collaboration and joint coordination meetings across sectors over adding a separate coordinating role. Similarly, several individuals in the qualitative study expressed a desire for early diagnostic imaging to obtain clarity and reassurance [28]. While acknowledging this need for certainty, the co-design group agreed that routine diagnostic imaging would conflict with clinical guidelines [21] and risk reinforcing maladaptive illness perceptions. Instead, stakeholders decided to integrate clear, shared rationales for diagnostic imaging decisions into the cross-sector VR summary, thereby supporting consistent communication across healthcare and employment services.

12.04 Key uncertainties.

We identified key uncertainties for the SAW intervention during the co-design process. The main uncertainties concerned the feasibility and acceptability of the participant-centred coordination meeting (*Activity 6*) and physiotherapist participation in employer meetings (*Activity 8*). For Activity 6, uncertainty is related to timing, participant acceptance, and alignment with RTW trajectories. Activity 8 challenged established sectoral boundaries, with acceptance from participants, physiotherapists, and employers remaining uncertain.

12.05 Proptotyping

The prototyping stage was conceptualised as part of the intervention development phase (*Study III*) and focused on testing deliverability and practical implementation under real-world conditions. This phase overlapped temporally with the early stages of the feasibility study and involved the same initial participants, reflecting a pragmatic and iterative approach to complex intervention development. While feasibility data collection commenced during this period, the purpose of prototyping was formative, supporting iterative refinement of intervention components rather than formal evaluation, consistent with the MRC framework [4]. Minor adjustments were made during this phase, including revised timelines for *Activity 6*, more explicit role definitions, and streamlined communication. Although feasibility data collection began during prototyping, data generated in this phase were used only to support formative refinement and were not analysed as feasibility outcomes in *Paper III*. Formal feasibility outcomes and evaluation data are reported separately in *Study IV*.

12.06 How Study III informed the feasibility study

Study III provided the foundation for *Study IV* by delivering a fully specified intervention, including an intervention manual, implementation guides, and an explicit program theory, enabling standardised delivery and evaluation across settings.

The prototyping phase, conducted within the early feasibility study, served a formative purpose by testing initial delivery and identifying minor practical challenges related to coordination, timing, and role clarification. As only minor, non-substantive adjustments were required, the intervention was refined iteratively within the ongoing feasibility study without necessitating a separate feasibility phase following prototyping.

The identified mechanisms of impact informed the design of the process evaluation, including the development of interview guides exploring whether intervention activities supported cross-sectoral collaboration, alignment around work ability, psychosocial support, and coordinated rehabilitation pathways. Likewise, the emphasis on work-related functioning and psychosocial vulnerability in *Study III* contributed to the inclusion of DASS-42 [131] as a screening tool and WORQ [130] as a combined screening and outcome measurement tool in *Study IV*. In

addition, outcomes identified during the co-design process informed the selection of outcome measures, ensuring coherence between development and evaluation.

13 Methods Study IV

This chapter reports the primary methodological considerations and describes more detailed inclusion criteria, fidelity, and feasibility criteria. Finally, I report how we assessed a key process indicator, participant perceived coherence in rehabilitation pathways, as a supplement to *Paper IV*.

The aim was to evaluate the feasibility of implementing the SAW intervention under real-world conditions, informed by process evaluation.

Study IV (Appendix D) was a three-month, single-arm, multi-method feasibility study rather than a pilot effectiveness study, in line with recommendations from the MRC framework and Moore et al.'s framework for process evaluation [4,69]. The study, therefore, focused on implementation processes, feasibility, fidelity, mechanisms of impact, contextual influences, preliminary clinical and work-related outcome patterns and the acceptability of data collection prior to decisions about further evaluation or scale-up [69].

Fidelity and feasibility were assessed using predefined criteria [134]. Data on self-reported sick leave were collected over a 12-week period to evaluate the acceptability and feasibility of repeated, time-sensitive data collection, reflecting the fluctuating nature of work participation among individuals with CLBP [21,44]. In addition, preliminary changes in clinical and work-related outcomes were examined descriptively to assess whether the selected measures appeared informative.

Qualitative data from participant interviews and professional focus groups were used to assess whether the SAW intervention operated as intended in relation to hypothesised mechanisms and context, thereby informing refinement decisions [69]. Reflexivity was integrated throughout the analysis process, as GF held a dual role as project lead, interviewer and moderator in the process evaluation. GF was not part of the clinical services delivering the intervention, and this outsider position was made explicit to participants and the co-production group to support openness about both positive and critical experiences. However,

participants and professionals may still have associated GF with the SAW project, and social desirability cannot be ruled out. To manage this influence, interviews were guided by structured interview guides for participants, the Spine Centre, and municipal settings, respectively (Appendix D1-D3). Analyses followed a deductive framework approach inspired by Ritchie and Spencer [135], guided by predefined analytical domains derived from the intervention's program theory and Moore et al.'s process evaluation domains [69]. Structured analytic summaries based on repeated listening to audio recordings were developed to support systematic comparison across predefined domains rather than detailed linguistic analysis [136]. Data were subsequently charted in a case-by-theme matrix across analytical domains and participant groups (Appendix D4), enabling comparison of patterns within and across cases [73]. Interpretations were discussed within the research team to challenge assumptions and support balanced interpretation.

Reporting adhered to the CONSORT 2010 extension for pilot and feasibility trials [137]. No formal economic evaluation was conducted as it was considered premature [4,138].

Detailed descriptions of the methodological considerations and the eight interrelated activities of the SAW interventions are provided in *Paper IV* (Appendix D).

13.01 Inclusion criteria

Eligibility criteria:

- 18–65 years
- Residence in Kolding, Middelfart, or Aabenraa municipality
- Current or imminent risk of sick leave due to CLBP, defined by meeting both the following criteria:
    - pain-related sick leave within three months or Work Ability Score ≤7 (0-10 scale), derived from the Work Ability Index [139]; and
    - unmet needs for workplace accommodations or self-reported likelihood of future absence if symptoms persist

Exclusion criteria:

- >1 year of sick leave
- Spinal pathology requiring surgery
- Pregnancy
- Severe psychiatric illness

- Insufficient Danish proficiency

13.02 Fidelity

Intervention fidelity was evaluated to determine the extent to which the SAW intervention was delivered as intended across activities and settings [69]. Fidelity indicators captured key aspects of delivery, such as whether activities were offered, conducted, timed, and documented according to protocol, but did not assess the quality or content of delivery, which was instead partly explored through the qualitative process evaluation. Each fidelity indicator was classified using an adapted three-level rating structure that distinguished between components delivered as intended, components requiring modification, and components not feasible in their current form [134]. The operationalisation and categorisation of fidelity indicators are provided in Appendix D5.

13.03 Feasibility criteria

Feasibility was assessed at both the activity and study levels, building on the fidelity assessment described above and informed by established progression frameworks for complex interventions [4,134]. Overall feasibility of the SAW intervention was determined by combining activity-level assessments with predefined criteria for recruitment and retention rates and for completeness of outcome data to assess whether the intervention was suitable for progression to further evaluation [4,67,69].

At the activity level, feasibility judgments were based on aggregated activity-specific fidelity indicators. Each intervention activity was evaluated according to predefined decision rules that distinguished between activities delivered as intended, activities requiring modification, and activities not feasible in their current form. Critical indicators were predefined as components considered essential for the intervention's core function, including offering activities, holding coordination meetings where applicable, and distributing the shared VR summary. We differentiated between core activities (*Activities 1, 2, 3, 5, and 6*) and supportive components (*Activities 4, 7, and 8*) to support a nuanced interpretation of feasibility across the intervention.

Detailed feasibility criteria, thresholds, and classification rules are reported in *Paper IV* (Appendix D).

13.04 Perceived coherence in rehabilitation pathways.

Perceived coherence was included in this PhD thesis, as a supplement to *Paper IV*, to assess whether the intervention was experienced as meaningful and navigable by participants, a central aspect of acceptability and thus feasibility [4,69]. Within the program theory, perceived coherence functioned as a key process indicator reflecting activation of intended mechanisms rather than intervention effectiveness [69]. The measure was therefore excluded from *Paper IV* to avoid conflating feasibility assessment with outcome evaluation in a small, non-comparative study.

Participant-reported perceived coherence in rehabilitation pathways was assessed in relation to 1) the coherence of activities received and 2) the coherence of information provided. Responses were rated on a 5-point Likert scale and reported descriptively as yes (to a very high/to some degree), neither, and no (not really/not at all). For feasibility assessment, only “yes” responses were considered indicative of acceptable perceived coherence, whereas “neither” and “no” responses were interpreted conservatively as not meeting the criterion. Progression thresholds inspired by Avery et al. [134] were applied as follows: ≥75% (“go”) indicating acceptable coherence, 40–74.9% (“amend”), and <40% (“stop”).

14 Results Study IV

This chapter presents the main findings from the feasibility evaluation informed by process evaluation of the SAW intervention, including a description of the participants, qualitative insights into mechanisms of impact and contextual influences, and participants' perceived coherence in rehabilitation pathways.

14.01 Main findings

Thirty participants were included in the SAW intervention, and 29 completed the 3-month follow-up (Figure 10).

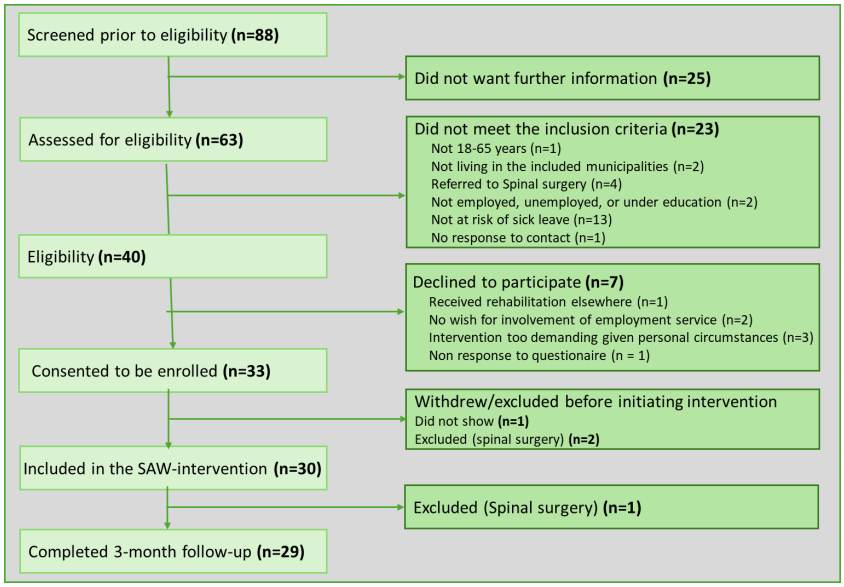

Figure 10. Flow chart for the Stay-At-Work-feasibility trial.
Reproduced from Paper IV.

Based on the predefined progression criteria, the SAW intervention was overall assessed as feasible with minor modifications. The feasibility evaluation demonstrated that the intervention could be implemented across healthcare and employment services under real-world

conditions, with recruitment (82.5%) and retention (96.7%) above predefined thresholds (Table 4). High adherence to data collection (86.7-100%) with no indication of response fatigue supports the feasibility and acceptability of repeated, time-sensitive sick leave outcome measurement in this population.

Table 4. Feasibility rating of the Stay-At-Work intervention.
Based on predefined criteria and data from Paper IV.

Feasibility indicators	Observed/ expected, n/N (%)	Feasibility
Activity 1: *Collaborative onboarding meetings*		✓
Activity 2: *Cross-sector coordination meetings*		✓
Activity 3: *Vocational rehabilitation assessment*		△
Activity 4: *Psychosocial screening and tailored support session*		△
Activity 5: *Shared VR summary*		✓
Activity 6: *Participant-centred coordination meeting*		△
Activity 7: *Consistent use of patient education leaflet*		△
Activity 8: *Physiotherapy support during sick leave meetings*		×
Recruitment rate	33/40 (82.5)	✓
Retention rate	29/30 (96.7)	✓
Completeness of weekly reporting of sick leave	26/30 (86.7)	✓
Completeness of baseline data	29/30 (96.7)	✓
Completeness of follow-up data	29/29 (100)	✓

Activity and study-level feasibility were classified as feasible (✓), feasible with modification (△), or not feasible (×) based on predefined progression criteria and critical indicators. Detailed thresholds and fidelity indicators are reported in Paper IV (Appendix D).

Furthermore, at the activity level, most components were delivered acceptably or required minor refinements before further evaluation (Table 4). Core activities targeting cross-sectoral onboarding and coordination meetings (*Activities 1-2*) and shared VR summary (*Activity 5*) met the predefined feasibility criteria. Several activities (*3, 4, 6, and 7*) were classified as feasible with modifications, while one supportive component (*Activity 8*) was not feasible in its current form. Importantly, no critical intervention components were classified as not feasible. Based on these findings, Activities 3, 4, 6, 7, and 8 require revision before the intervention can be considered feasible for further evaluation. The required revisions primarily concerned the following:

- Increased staffing capacity at the Spine Centre is needed to ensure timely delivery of Activity 3 within 14 days, during periods of absence.
- The purpose and communication of written materials in Activity 3 and the shared VR summary to participants in Activity 5 should be reconsidered or clarified.
- The role, delivery procedure, and intended added value of Activity 4 should be clarified to ensure consistent offering and better alignment with participants' needs and expectations.
- A more sustainable communication strategy than direct email contact between the Spine Centre and municipal caseworkers is needed for scale-up.
- Activity 6 should be reconsidered with regard to target group (universal versus targeted delivery for participants with particular coordination needs).
- A clearer strategy is needed to ensure timely delivery of Activity 6 within 5–8 weeks.
- More systematic registration in Activities 3 and 7 is needed to document whether the patient education leaflet was delivered and discussed with participants.
- Activity 8 should be substantially redesigned or discontinued.

In addition to these activity-level revisions, changes in clinical and work-related outcomes suggested that the selected measures were informative for future evaluation. Across the 3-month follow-up, most outcomes changed descriptively in a direction consistent with improvement, including lower LBP pain and leg pain intensity, higher work ability, lower physical, psychological, and cognitive functioning limitations, and higher self-rated health, whereas no adverse trend was observed for sick leave days. Outcome data are reported descriptively in *Paper IV* (Appendix D), as these analyses were not intended to estimate intervention effectiveness.

Detailed descriptions of the results are reported in *Paper IV* (Appendix D).

14.02 Participants

The participant group was predominantly female (73.3%), with a median age of 52 years, and most were in ordinary employment at the time of inclusion (72.4%). Overall, participants reported moderate levels of pain and reduced work ability, while symptoms of depression, anxiety, and stress were generally within the normal to mild range (80.0%, 83.3%, and 66.7%, respectively). At inclusion, 27.6% of participants were on sick leave due to back or leg pain, whereas 72.4% were at risk of taking sick leave, which is relevant when interpreting the variability in the uptake of coordination-oriented components.

14.03 Mechanisms of impact and contextual influences

Qualitative findings from the process evaluation indicated that three of the four hypothesised mechanisms of impact were activated during implementation of the SAW intervention. Across sectors, professionals reported increased insight into one another's roles, mandates, and responsibilities following the onboarding and coordination activities (*Activities 1, 2, and 6*), and that this contributed to strengthened interprofessional understanding and more consistent communication with participants and across settings.

Alignment around work-related functional capacity and work ability also emerged as an activated mechanism. Both participants and professionals described that the systematic use of the WORQ [130] and structured goal setting [133] during Activities 3 (*VR assessment at the Spine Centre*) and 5 (*VR summary shared with stakeholders*) shifted the dialogue from symptom intensity towards functional implications for work in both primary and secondary sectors. This shift was described as facilitating more concrete and work-oriented planning across healthcare and employment services.

Enhanced coordination of care and rehabilitation efforts was reflected in accounts from both participants and professionals. They reported that shared tools, including the VR summary (*Activity 5*) and the patient education leaflet (*Activities 3 and 7*), provided a common informational basis and reduced the need for repeated explanations across sectors. However, several physiotherapists emphasised that it was consistency

in terminology and explanations, rather than the leaflet itself, that they perceived as central to creating a coherent rehabilitation narrative.

Both participants and professionals reported that the participant-centred coordination meeting (*Activity 6*) improved alignment of plans and clarification of responsibilities. At the same time, they reported that meetings held outside the intended timeframe were less well aligned with the participants' rehabilitation trajectories. This pattern addresses the key uncertainty identified during the co-production phase (*Paper III*) by demonstrating that the timing of the meeting is critical for achieving adequate alignment with participants' RTW trajectories.

Participants' engagement with written materials varied (*Activities 3, 5, and 7*), with some expressing uncertainty regarding their purpose and use, indicating that this mechanism was not consistently activated across participants.

The psychosocial support component (*Activity 4*) was generally delivered as intended; however, participants reported mixed experiences of this activity, suggesting variability in how its intensity and role were perceived within the intervention.

Contextual factors influenced the delivery and uptake of several components. Participants described the relevance of coordination meetings (*Activity 6*) as dependent on their work situation and perceived need for employment service involvement, while professionals reported that organisational factors, such as GP availability and staff turnover, affected the timing of meetings. Participants reported limited perceived relevance or concerns about stigma as reasons to decline Activity 8 (*support during sick leave meeting*), whereas physiotherapists described role ambiguity as a barrier to offering the activity. This pattern addresses the key uncertainty identified during the co-production phase (*Paper III*) by demonstrating the limited acceptability and feasibility of physiotherapist participation in employer meetings under current contextual conditions.

Taken together, these qualitative findings illustrate how contextual conditions shaped the activation of hypothesised mechanisms during implementation and complement the feasibility assessment by elucidating how intervention components were experienced in practice.

14.04 Perceived coherence in rehabilitation pathways

Participants' (n = 30) perceived coherence in rehabilitation pathways in the SAW intervention exceeded the predefined 'go' threshold. Twenty-eight participants (93.3%) responded yes regarding coherence across activities, two (6.7%) responded neither, and none (0%) responded no. For coherence across information received, 25 participants (83.3%) responded yes, two (6.7%) responded neither, and three (10.0%) responded no. These findings indicate activation of the program theory's key process indicator, perceived coherence in rehabilitation pathways, thereby supporting the plausibility of the intervention's underlying mechanisms.

15 Discussion

15.01 Summary of main findings

Based on findings from a scoping review and stakeholder consultation, we developed the SAW intervention, a person-centred, interdisciplinary, cross-sectoral VR intervention for individuals on, or at risk of, sick leave due to CLBP through a co-design process. Subsequently, the SAW intervention was tested and evaluated in a feasibility study.

The process evaluation demonstrated that the SAW intervention could be implemented across healthcare and employment services under real-world conditions, but minor modifications are needed to be addressed before future large-scale effectiveness evaluation.

Study I demonstrated that comparability is difficult due to substantial variation in the measured components of the interventions. Furthermore, the study highlighted a lack of reporting on the type of collaboration and on whether PPI and stakeholder involvement were utilised during the development phase, as well as the scarcity of dynamic methods used to capture multiple transitions in work status over time. These methods are considered a more accurate representation of CLBP's fluctuating nature.

Study II showed that RTW processes for individuals with CLBP are characterised by psychological strain, diagnostic ambiguity, and fragmented professional support. These factors limited participants' capacity to navigate RTW demands, particularly when health information was difficult to understand or apply. Interpreted through an HL perspective, the findings highlight how individual HL capacities and system responsiveness jointly shape engagement in RTW processes and contribute to unequal experiences of coherence and support.

Study III demonstrated that the SAW intervention could be systematically developed through a structured, multi-stakeholder co-design process grounded in empirical evidence and program theory. The intervention comprises eight coordinated activities underpinned by four core mechanisms targeting cross-sectoral understanding, alignment around work ability, recognition of psychological vulnerability, and coordinated

rehabilitation planning. Stakeholder involvement was central in translating qualitative findings and evidence into contextually feasible and implementable design decisions that balanced participant needs, clinical appropriateness, and organisational constraints.

Study IV showed that the applied feasibility and progression criteria enabled a nuanced assessment of deliverability, implementation processes, and mechanism activation across intervention components. The findings delineated core elements feasible and acceptable, components requiring modification, and contextual conditions influencing uptake, thereby providing an empirically grounded basis for refining the intervention prior to further testing.

15.02 Interpretation of findings and comparison with previous research

This section integrates and interprets findings across the four studies and situates them within the existing literature, with particular attention to mechanisms of impact, stakeholder involvement, system-level coherence, and contextual conditions shaping RTW pathways for individuals with CLBP.

Perceived coherence as a key process indicator in return-to-work pathways

Previous research has consistently shown that fragmented support and insufficient coordination between stakeholders constitute major barriers to RTW for individuals with chronic pain or CLBP receiving VR [16,52–56]. These challenges are often attributed to differing professional paradigms, organisational objectives, and sectoral boundaries [53,57].

Findings from the qualitative study [65] corroborate this literature. Participants described a lack of consensus among the professionals involved in their RTW processes regarding symptoms, treatment, activity levels, and RTW readiness, often receiving conflicting advice across sectors. Many reported being left with the responsibility of coordinating their own RTW trajectory. While preferences varied, ranging from coordinated stakeholder meetings or a designated coordinator to self-coordination, participants consistently emphasised the need for more precise role delineation and improved cross-sectoral communication to achieve more coherent RTW planning.

In response, the SAW intervention was deliberately designed to support coordinated VR across healthcare and employment services, with a particular focus on perceived coherence in rehabilitation pathways. In the feasibility study, a large majority of participants reported experiencing coherence across both intervention activities (93%) and the information received (83%). These findings suggest that the SAW intervention aligns with its underlying program theory by addressing known coordination challenges in routine practice. In this way, the findings provide nuanced insight into how broadly endorsed recommendations for multiprofessional VR can be operationalised in real-world settings, thereby helping to bridge the gap between evidence-based principles and the practical organisation of cross-sectoral rehabilitation pathways [24,28,44,45]. However, as causality was not examined, it cannot be determined whether the intervention itself produced the perceived coherence.

According to the program theory, coherence was expected to be facilitated through cross-sectoral preparation, shared documentation, and coordinated communication practices. One plausible mechanism relates to the use of consistent language and shared explanatory frameworks across sectors, aligned with an ICF-informed understanding of functioning that emphasises activity and participation rather than diagnosis alone [30]. In particular, the systematic use of a shared educational leaflet across the Spine Centre and municipal rehabilitation services (*Activity 7*) may have contributed to more uniform explanations of symptoms and activity recommendations. The rationale for using the same educational leaflet across the Spine Centre and municipal rehabilitation services was to support consistent explanations and a shared vocabulary in cross-sector RTW communication. The leaflet was intended to function as a common reference point, promoting alignment in explanations of symptoms, activity recommendations, and recovery expectations. While patient information leaflets are primarily studied as tools to improve patient knowledge and understanding [140], the use of shared educational materials across sectors has received limited empirical attention. This design choice was therefore informed by communication theory. Van Riel's concept of "common starting points" [141] highlights how shared communicative references can reduce interpretive variation across organisational contexts, a principle considered transferable to cross-sectoral rehabilitation pathways.

During the process evaluation, physiotherapists described that drawing on the leaflet's core messages, rather than delivering the material itself, supported a shared language and more transparent communication across settings. This may be especially relevant for individuals with limited functional, interactive, or critical HL, who may have difficulty reconciling divergent messages from multiple stakeholders [3,60]. Nevertheless, participants' engagement with the leaflet outside consultations varied, often due to uncertainty about its purpose.

This pattern is consistent with findings from a Finnish study examining patients' and practitioners' perceptions of an evidence-based LBP booklet designed to reduce inappropriate imaging [142]. In that study, patients and clinicians emphasised different benefits. Approximately half of the patients reported improved understanding of LBP, whereas all clinicians reported that the booklet supported patient communication, and most indicated that it facilitated adherence to imaging guidelines. Taken together, these findings suggest that educational materials may function primarily as implementation tools that support professional consistency and guideline-concordant communication. In the context of cross-sectoral rehabilitation, such tools may therefore contribute more strongly to system-level coherence across healthcare and municipal services than to individual-level self-management.

Co-design and stakeholder involvement as a driver of feasibility

Our findings demonstrate that it is possible to co-design a complex, person-centred, cross-sectoral VR intervention that is feasible and acceptable under real-world conditions when recommended development frameworks are applied transparently and combined with meaningful stakeholder involvement throughout the research phases. Importantly, stakeholder involvement in the co-design process extended beyond consultative roles. Individuals with CLBP and professionals contributed actively to shaping intervention components, negotiating tensions between evidence-based recommendations and experiential needs, and identifying solutions that were both clinically appropriate and organisationally realistic. In terms of Smits et al.'s Involvement Matrix [84,85], this corresponds primarily to *co-thinker* and *partner* roles rather than the more limited "listener" role.

This pattern is consistent with findings from other development and feasibility studies of complex rehabilitation interventions. Feasibility has similarly been demonstrated in interventions developed through structured, MRC-guided processes with early involvement of multiple stakeholder groups, such as VR for individuals with chronic inflammatory arthritis [143,144], for individuals with inflammatory arthritis and substantial disease impact [145,146], and a multiprofessional intervention for chronic pain management in municipal healthcare [147]. Across these studies, stakeholder involvement was characterised by shared influence during development rather than post hoc consultation, and feasibility was assessed as acceptable under routine conditions.

In contrast, an earlier feasibility study of individuals with CLBP in secondary care was deemed unfeasible, primarily due to recruitment and acceptability challenges [148]. Although the study was guided by the MRC framework, stakeholder involvement was limited to the "*co-thinkers*" role in the Involvement Matrix [84,85], and the involvement occurred after key design decisions had already been made. This suggests that applying the MRC framework alone may be insufficient if stakeholder involvement is introduced late or remains consultative, underscoring the importance of early and substantive stakeholder engagement during key design decisions.

Overall, these findings contribute to the growing body of evidence indicating that early stakeholder involvement, when engaged as more than "co-thinkers", combined with the transparent application of complex intervention frameworks, functions as a critical driver of feasibility, particularly for interventions targeting cross-sectoral coordination in real-world rehabilitation settings. Rather than merely supporting acceptability, co-design appears to shape intervention content, delivery, and alignment with organisational realities, thereby enhancing the likelihood of successful implementation.

Taken together, these findings extend existing literature by illustrating how co-design can function not only as a means of enhancing acceptability but as a structured mechanism for integrating evidence, experiential knowledge, and contextual constraints into operational intervention components, contingent on active facilitation, clear structures, and explicit decision-making criteria [2,5]. This resource-intensive process places specific demands on the researcher. Beyond analytical expertise, co-design requires competencies in relationship-building,

stakeholder engagement, and facilitation of collective dialogue, shifting the researcher's role from knowledge provider to process facilitator who enables stakeholders to contribute, negotiate, and co-create solutions across professional boundaries [83].

When participant preferences conflict with evidence

In the qualitative study, participants expressed a strong need for clear explanations regarding diagnosis, prognosis, and the expected RTW process. Diagnostic imaging was frequently perceived as a means of legitimising symptoms and providing structure to RTW planning. However, participants' ability to understand, appraise, and act upon imaging-related information varied substantially. For some, diagnostic imaging facilitated active engagement in rehabilitation, whereas for others it led to confusion, uncertainty, or a more passive approach to RTW. This variation highlights differences in functional, interactive, and critical HL, underscoring the need for communication strategies responsive to these differences [3,60,66].

These findings align with recent qualitative studies showing that individuals with LBP often view diagnostic imaging as essential, particularly following unsuccessful conservative management [31,32]. Responses to diagnostic imaging information range from relief and validation to increased anxiety or misinterpretation, underscoring that imaging does not uniformly support rehabilitation [31].

Participants expressed a preference for diagnostic imaging, which contrasts with clinical guidelines, which discourage routine diagnostic imaging for CLBP due to the high prevalence of non-specific findings with limited clinical utility for guiding treatment or RTW decisions [149]. During the co-production phase, this tension between participant preferences and evidence-based recommendations was explicitly addressed. While acknowledging participants' need for certainty, the co-design group agreed not to contravene clinical guidelines. Instead, it was decided that the clinical rationale for imaging decisions, whether imaging was performed or not, should be clearly articulated and documented in the shared VR summary (*Activity 5*). This approach aimed to support consistent, cross-sectoral communication by enabling GPs, physiotherapists, and municipal caseworkers to convey a shared and transparent message to participants.

Participants' preferences for diagnostic imaging should also be understood in light of the broader RTW context in which multiple stakeholders operate with different mandates and information needs [53,57]. Individuals with chronic pain frequently encounter stigma and disbelief from professionals, which negatively affects RTW outcomes [53,56,150]. In this context, medical documentation and diagnostic labels may become salient reference points in interactions with municipal caseworkers, particularly for conditions with less visible symptoms and therefore harder to translate into concrete work-related restrictions [151]. Moreover, a qualitative study showed that even knowledgeable, guideline-oriented primary care clinicians may feel pressured to accommodate patients' requests for imaging, especially when they fear negative consequences for the therapeutic relationship or encounter highly insistent patients [152]. Together, this broader structural role of diagnosis may help explain why participants in the qualitative study expressed a strong desire for diagnostic certainty despite clinical guidelines discouraging routine imaging and suggests that such preferences are co-produced within cross-sectoral systems rather than reflecting individual beliefs alone.

Building on this understanding of diagnostic preferences as shaped within cross-sectoral contexts, findings from the feasibility study provide preliminary support for the SAW intervention's strategy of prioritising aligned, guideline-consistent communication rather than accommodating all expressed preferences. Although causality cannot be established, participants reported high levels of perceived coherence in the information provided across SAW intervention activities. This suggests that aligning communication across sectors, rather than providing imaging on demand, may contribute to perceived coherence. As indicated in longitudinal qualitative research, patients' beliefs about the value of diagnostic imaging may also evolve over time through ongoing experiences and reinterpretation [32].

From an HL perspective, these findings contribute important insight into how system-level responsiveness can mitigate HL-related challenges in RTW pathways [3,60,66]. Rather than framing conflicting preferences as non-adherence or misunderstanding at the individual level, the SAW intervention illustrates how coherent, guideline-consistent communication across sectors may support individuals with varying HL capacities. For the development and implementation of future VR interventions for individuals with CLBP, this underscores the importance of designing communication strategies that explicitly acknowledge uncertainty,

provide clear rationales for clinical decisions, and ensure alignment across stakeholders, thereby supporting informed engagement without compromising evidence-based practice.

Employer involvement in RTW: contextual and feasibility constraints

In *Study II*, a subgroup of participants expressed a wish for professional support during meetings with their employer. This need was particularly pronounced among participants who described psychological vulnerability, uncertainty regarding their work ability, or mistrust in the employer relationship, and who found it challenging to articulate work-related limitations and accommodation needs on their own. Although not all participants shared this preference, it informed the decision during the co-production phase to include an activity that aimed to support employer dialogue through physiotherapist participation (*Activity 8*).

However, physiotherapist participation in employer meetings (*Activity 8*) was identified during the co-production phase process as a key uncertainty, given that it challenged established sectoral boundaries and relied on acceptance from participants, physiotherapists, and employers. During the feasibility study, no participants accepted this activity. This finding does not necessarily indicate an absence of need but rather highlights important contextual constraints. First, only a minority of participants were on sick leave at baseline, limiting the relevance of employer-focused activities in this sample. Second, qualitative findings from the process evaluation revealed that participants who declined the activity either perceived it as unnecessary because of adequate workplace support or expressed concerns about potential stigma or negative consequences of disclosing health-related information to their employer. This suggests that even when a need for support exists, anticipated risks may outweigh perceived benefits.

These findings are consistent with Danish qualitative studies reporting reluctance among individuals with musculoskeletal conditions to reveal health problems at work [153–155], often driven by concerns about stigma, being perceived differently from other colleagues, or risking financial consequences [154]. Such concerns may limit early disclosure of work-related difficulties and constrain opportunities for timely workplace accommodation. In the Danish context, this reluctance must be

understood in light of the Health Information Act [156], which restricts employers' access to employees' health information, and the flexicurity labour market model, which combines relatively weak employment protection with strong social security [48]. While these structures are designed to prevent discrimination, they may also unintentionally discourage open dialogue about health-related work limitations.

At the same time, previous qualitative research has documented ambivalent expectations regarding employer involvement. Some individuals with chronic pain report a desire for greater understanding and support from employers and colleagues [54,55,154], and describe a lack of employer recognition as a significant barrier to RTW [52,54]. Conversely, studies also indicate that employers often expect employees to initiate dialogue about work-related challenges [155] and that some employers express willingness to engage more [55]. Together, this body of literature points to a mismatch between employee concerns, employer expectations, and the institutional frameworks governing disclosure and responsibility.

Taken together, the lack of uptake of Activity 8 should not be interpreted solely as a failure of intervention design, but rather as an indication of structural and contextual barriers to employer involvement in VR pathways. Facilitating employer engagement requires more than the availability of professional support; it depends on broader cultural norms, legal frameworks, power asymmetries, and perceptions of risk associated with disclosure. From an occupational health systems perspective, employer involvement can be viewed as part of a broader ecosystem in which working conditions, organisational practices, and rehabilitation efforts interact to shape work participation [157]. Future VR interventions may therefore benefit from multi-level, context-sensitive strategies that address not only individual support needs but also organisational and societal conditions that influence employer engagement.

15.03 Methodological discussion

This section presents a methodological discussion across the four studies, focusing on key considerations in the co-design and process evaluation of a complex intervention, the measurement of work participation and work-related functional capacity, and the transferability and context dependency of the findings.

Co-design as a methodology strategy

In line with the MRC framework for developing and evaluating complex interventions and the INDEX principles, stakeholder involvement across research phases was considered essential to enhance the feasibility, acceptability, and contextual fit of the SAW intervention [4,5]. This is particularly relevant for cross-sectoral VR interventions for individuals with CLBP, where fragmented support and insufficient coordination between stakeholders are consistently reported as major barriers to RTW [16,52–56]. As professional paradigms and organisational boundaries shape coordination challenges [53,57], involving stakeholders across sectors was deemed necessary to inform intervention design.

The choice of frameworks and specific INDEX approaches [5] shaped both the focus and structure of the development process. Emphasising stakeholder involvement and an evidence-informed approach directed attention towards cross-sectoral coordination, organisational interfaces, and perceived coherence in rehabilitation pathways, aligning with the overall aim of the SAW intervention. This orientation influenced the selection of focus groups in *Study II*, prioritising collective exploration of cross-sectoral experiences over individual interviews. Furthermore, it influenced the prioritisation of interprofessional dialogue in the co-design process and the focus on barriers and facilitators across sectors. Alternative approaches within INDEX [5], such as theory-driven and implementation-oriented frameworks like the Theoretical Domains Framework [158], would likely have shifted attention towards behavioural determinants influencing how professionals adopted and delivered intervention components. This may have increased focus on training needs, professional roles, and implementation support across sectors, potentially resulting in a different intervention emphasis. Thus, the applied methodological choices did not merely guide the process but actively shaped the nature and scope of the intervention developed.

In this project, stakeholders included clinicians from the Spine Centre, professionals and managers from municipal rehabilitation and employment services, GPs, employer and employee representatives, patient partners, and individuals with CLBP who participated in qualitative interviews and focus groups, thereby operationalising the selected approach to stakeholder involvement in the co-design process. To support meaningful engagement and shared ownership, we applied Smits et al.'s Involvement Matrix [84,85] as a reflective tool to clarify roles, decision-

making influence, and levels of participation prior to the co-design workshops [159].

A key methodological consideration was the distinction between broad stakeholder involvement and the more specific concept of PPI, which emphasises conducting research *with* or *by* patients rather than *for* them [86]. While patient involvement was a core priority, it was anticipated that patient partners would be numerically underrepresented in a multi-stakeholder co-design group. To address this, individuals with lived experience of long-term sick leave due to CLBP were engaged early through qualitative interviews and focus groups, ensuring that the intervention development was grounded in participant perspectives before entering the co-production phase.

Despite inviting all interview and focus group participants to join the co-design activities, sustained participation from individuals with lived experience proved challenging, with only two patient partners joining the co-design group. Practical and contextual factors constrained patient partner involvement. Workshops were scheduled during working hours to accommodate professionals, which limited participation among individuals who had returned to work, as they often reported little opportunity to take additional time off. Further, the length of the workshops limited participation from individuals on full-time sick leave experiencing pain-related limitations. Together, these experiences illustrate a methodological tension in co-design research: strong normative support for PPI [160] does not automatically translate into equitable participation. Co-design formats may inadvertently exclude individuals at critical points in the RTW trajectory, underscoring the need for more flexible and context-sensitive approaches to stakeholder engagement.

This challenge resonates with the scoping review, which found that PPI is rarely reported in the development of VR interventions for CLBP, suggesting that limited patient involvement remains common in this field [44].

Choosing a relevant evaluation design

In this PhD project, feasibility was evaluated through a feasibility study informed by process evaluation, guided by Moore et al.'s framework for complex interventions [69]. This reflects a deliberate prioritisation of understanding *how* and *under what conditions* the SAW intervention could

be delivered and function in routine practice, rather than prematurely assessing effectiveness. In early-phase evaluation of complex, cross-sectoral interventions, insights into mechanisms of impact and contextual influences are often more informative than outcome estimates alone, as they help determine whether an intervention has been implemented as intended and whether its underlying assumptions are plausible [4,69].

By focusing on implementation processes, fidelity, mechanisms of impact, and contextual constraints, the evaluation reduces the risk of type III errors, in which an intervention is judged ineffective due to inadequate implementation rather than a lack of effect [161]. This was particularly relevant given the SAW intervention's reliance on coordinated delivery across healthcare and employment services, where organisational and contextual factors are expected to shape both delivery and activation of mechanisms under real-world conditions. Consequently, outcome data were collected primarily to assess the feasibility, acceptability, and completeness of repeated measurements, and secondarily to explore descriptively whether the selected measures appeared informative for future evaluation, not to estimate intervention effectiveness. While this precludes conclusions about effectiveness, it provides a robust basis for determining whether the intervention is sufficiently well-defined, implementable, and theoretically plausible to justify further testing.

An alternative design could have prioritised pre–post changes in quantitative outcomes as the primary indicator of feasibility or early promise. Such an approach might have provided earlier descriptive signals of potential effect but would offer more limited insight into how the intervention was implemented, how it interacted with organisational contexts, and whether its underlying mechanisms were activated. The present design, therefore, reflects a deliberate trade-off, privileging an explanatory insight into implementation and mechanisms over early effect estimation [4,69].

Measuring work participation and work-related functional capacity

The scoping review showed that VR studies of individuals with CLBP most commonly assess work status at a single follow-up point, typically using measures of sick leave duration or RTW status [92,94–

97,99,103–107,109,111,115,116]. Only a few studies captured repeated transitions in and out of work over time [97,100], despite RTW trajectories often being fluctuating and non-linear. This highlights an important methodological gap and supports the use of more dynamic approaches to measuring work participation [44].

In the feasibility study, we therefore examined the acceptability of weekly self-reported sick leave prompted by SMS reminders. Although Danish register-based data, such as the DREAM database, are widely used to capture sickness-benefit period [162], they only record benefits after 30 consecutive days of sick leave and do not provide daily absence data or condition-specific information. More detailed registers, such as the Danish Register of Work Absence, capture absence on a daily basis but do not cover the entire Danish workforce, as they include the public sector and a sample of private enterprises [163]. Consequently, register data alone are insufficient to capture short-term, recurrent, and fluctuating absences related to CLBP across a population working in both the public and private sectors. The high response rate over 12 weeks indicates that weekly self-reporting is feasible and acceptable in the short term, although feasibility over longer follow-up periods remains uncertain.

In line with Escorpizo et al.'s definition of VR [1], work participation was considered the overarching long-term impact of the SAW intervention. The additional impact indicators included in the program theory, such as vocational functioning, self-rated health, pain intensity, and fear avoidance, should therefore not be interpreted as competing end-points, but as intermediate or complementary outcomes that may support, precede, or modify pathways towards sustainable RTW. Their relevance may vary between participants depending on work status, symptom burden, psychosocial vulnerability, and rehabilitation needs, consistent with an ICF-informed understanding of rehabilitation as context-dependent and individually variable [30]. This reflects the person-centred and individually tailored nature of the intervention, while maintaining work participation as the primary long-term goal.

Work participation alone, however, provides an incomplete picture of rehabilitation progress, as work status is strongly influenced by contextual and labour market factors beyond the reach of health interventions [47]. Moreover, in CLBP, changes in pain intensity do not necessarily correspond to changes in functional capacity or activity performance.

Individuals may learn to manage symptoms, adapt activities, and increase tolerance for work-related demands even in the presence of ongoing pain. From an ICF perspective [30], such changes reflect improvements at the level of functioning and activity that may precede, or occur independently of, changes in participation. This distinction is supported by rehabilitation studies showing improvements in work-related functional capacity without parallel improvements in employment outcomes [164].

Accordingly, the SAW intervention combined measurement of work participation with assessment of work-related functional capacity using WORQ [130,165]. Although rarely applied in VR interventions for LBP, WORQ has demonstrated validity and reliability in a LBP population tested in the Spine Centre [165,166]. Findings from the process evaluation further suggest that WORQ functioned not only as a measurement tool but also as a clinically meaningful framework that shifted the dialogue from symptom intensity to functional implications for work, thereby supporting more concrete, work-oriented planning across sectors. Together, these findings underline the value of combining dynamic measures of work status with assessments of work-related functioning when evaluating complex VR interventions.

Transferability, generalisability, and context dependency

The findings of this PhD project are closely embedded in the Danish welfare, healthcare, and employment context, characterised by publicly funded healthcare, municipally organised VR, and a flexicurity-based labour market model [48,49]. Consequently, the findings from *Papers II–IV* should not be interpreted as directly generalisable to settings with fundamentally different institutional, legislative, or organisational structures.

This PhD project was grounded in a constructivist epistemological framework, with a pragmatic methodological orientation in selected phases [71,72]. From this perspective, the focus was to generate an in-depth understanding of how and why interventions function through underlying mechanisms and contextual conditions, rather than to produce findings intended for direct replication across settings [71,72,167].

Accordingly, the relevance of the present findings lies not in their statistical generalisability, but in their potential transferability, that is, the

extent to which the identified mechanisms and theoretical insights may be meaningfully applied in other contexts with comparable organisational and institutional features. Consistent with guidance for complex interventions, the SAW intervention was developed and tested within existing service structures to enhance contextual relevance and ecological validity [4,168]. Transferability to other settings, therefore, depends on careful consideration of contextual similarities and differences, and on whether the identified mechanisms, such as perceived coherence in rehabilitation pathways, are theoretically plausible within alternative systems of care and employment. From this perspective, the study contributes methodological and conceptual insights that may inform the development of VR interventions both within and beyond the Danish context, while underscoring the importance of contextual adaptation rather than direct implementation [4,168].

15.04 Strengths and limitations

Studies I–IV each have strengths and limitations described in the respective papers. The strengths and limitations of the overall PhD project are outlined below.

A major strength of this PhD project is the systematic co-design of the SAW intervention with representation from key stakeholders across healthcare and employment services. This ensured that the intervention was shaped to reflect organisational structures, legislative boundaries, and professional paradigms, contributing to high contextual relevance, acceptability, and feasibility in real-world settings [4,5,67]. The cross-sectoral development and testing further enhance the ecological validity of the findings [168].

The project is additionally strengthened by the transparent and consistent application of established methodological frameworks and internationally recognised reporting guidelines across all research phases, supporting rigour, transparency, and reproducibility, including the MRC framework, INDEX principles, and Hawkins et al.'s co-production and prototyping framework [4–6]. Together with a feasibility study informed by a theory-informed process- and mechanism-oriented evaluation approach [69], this supported a coherent progression from problem identification to feasibility testing and strengthened alignment between empirical findings, program theory, and intervention design.

This PhD project also has several limitations. First, patient-partner representation in the co-design group was limited. Participation from individuals with lived experience of CLBP proved challenging, primarily due to restricted flexibility during daytime workshops related to ongoing RTW trajectories or pain-related functional limitations. This may have constrained the extent to which the intervention was informed by individuals with CLBP's perspectives, potentially affecting its acceptability [4,5]. However, their experiences and needs were explored in depth through interviews and focus groups in the initial qualitative study, and the feasibility study indicated that the intervention was acceptable with only minor modifications required prior to further testing.

A second limitation concerns the relatively short 12-week follow-up in the feasibility study. Although weekly self-reported sick leave prompted by SMS reminders was feasible and acceptable within this timeframe, it remains uncertain whether such data collection can be sustained over more extended periods. Longer follow-up is required in future effectiveness studies, as RTW trajectories among individuals with CLBP often extend over several months [169]. Similar sustained engagement has been reported in an LBP study using weekly SMS monitoring over 12 months, although feasibility and work participation were not the primary focus [170].

A third limitation relates to the use of self-reported measures to assess work-related functional capacity. Previous research indicates that self-reported ratings may underestimate physical performance capacity and overestimate occupational physical activity compared with objective measures, suggesting reduced precision for quantifying physical intensity or performance [171,172]. However, objective performance-based assessments are resource-intensive, require specialised equipment, and assess participants outside their everyday work context [173,174]. Importantly, a randomised study comparing objective functional capacity evaluations with functional interviews in VR found no differences in rehabilitation recommendations, RTW outcomes, or functional work levels [171]. Moreover, none of the studies included in the scoping review applied objective performance tests [44]. In this context, the use of self-reported measures represents a pragmatic and methodologically defensible choice aligned with prevailing practice in VR research.

An additional methodological consideration relates to the heterogeneous reporting of baseline sick leave duration across studies in *Paper I*. As baseline sick leave duration is recognised as an important factor influencing RTW outcomes [27], inconsistent reporting formats limited the possibility for comparison across interventions and highlight a broader challenge in synthesising VR research.

In addition, the restriction to healthcare-initiated VR interventions and to studies focusing on CLBP should be considered when interpreting the overall project. While these methodological delimitations supported a focused analysis within a relatively coherent organisational and clinical context, they may have influenced the development process by limiting the range of cross-sectoral and cross-diagnostic approaches considered. This should be taken into account when interpreting how *Study I* informed the design of the SAW intervention.

The data collection approach and composition of the research team in *Study II* warrant consideration. The use of focus groups supported exploration of shared experiences and cross-sectoral challenges but may have limited insight into more sensitive individual or family-related circumstances [73,118]. As such factors are known to influence RTW processes [25,95], their potential underrepresentation may have affected the comprehensiveness of identified needs. In addition, the research team's healthcare background may have introduced a health-oriented perspective. While this aligned with the aim of developing a healthcare-initiated VR intervention, it may have limited attention to workplace and employment-related aspects during *Study II*. Together, these factors may have influenced the identification and prioritisation of needs in the development of the SAW intervention (*Study III*).

A further limitation is that the effectiveness of the SAW intervention could not be assessed, as the feasibility study employed a single-arm design without a comparison group. Consequently, no conclusions can be drawn about the intervention's effects on work or health outcomes. However, this reflects a deliberate methodological decision rather than a design flaw. At the feasibility stage, the primary focus is on deliverability, acceptability, and understanding how an intervention functions under real-world conditions. In line with guidance for complex interventions, the process evaluation therefore prioritised implementation processes, mechanisms of impact, and contextual influences to inform refinement and future evaluation [4,69].

An additional limitation relates to the scope of the SAW intervention. The intervention was designed primarily to strengthen coordination and coherence across healthcare and employment services, rather than to optimise the content, intensity, or quality of rehabilitation components delivered within each sector. Accordingly, the intervention relied on existing services to address broader rehabilitation needs, and usual rehabilitation practices were therefore not systematically assessed. This reflects the methodological orientation of the development process: the selected INDEX approaches emphasised stakeholder involvement and evidence-informed development, directing attention towards cross-sectoral coherence, stakeholder alignment, and contextual fit [5]. A more implementation-focused approach within the INDEX principles could have placed greater emphasis on adoption, implementation quality, and maintenance within each organisational setting [5]. Consequently, the feasibility assessment prioritised delivery, fidelity to planned activities, and activation of cross-sectoral mechanisms over quality, intensity, and variation in usual rehabilitation practices within each sector. Variation in local practices and rehabilitation delivery may therefore have influenced both implementation and participant outcomes and should be considered when interpreting the findings and planning future evaluations. However, improved cross-sectoral coordination and shared understanding can indirectly influence the quality and appropriateness of rehabilitation delivery. Enhanced alignment around work-related functional capacity and clearer communication between stakeholders may support more timely, targeted, and contextually appropriate rehabilitation decisions. These potential indirect effects were not formally assessed in the present study and should be explored in future evaluations.

Relatedly, no formal economic evaluation was conducted during the development or feasibility studies, despite recommendations to consider economic aspects across intervention stages [4,138]. This can be viewed as a limitation; however, economic analyses are most informative once effectiveness data are available and costs can be interpreted in relation to demonstrated outcomes. In the absence of such data, an economic evaluation would likely have limited value for decisions regarding progression to large-scale testing [4,138].

Finally, the researcher's close involvement across all phases of the project introduces a potential risk of researcher bias [175]. I moderated focus groups and conducted qualitative analyses, facilitated the co-design process, and conducted participant screening and follow-up interviews

in the feasibility study. While this continuity supported coherence across phases, it may also have influenced data generation, categorisation, prioritisation, and interpretation. This risk was addressed through reflexive positioning within each qualitative sub-study, including explicit consideration of my role as interviewer, facilitator, project lead, and analyst. In addition, analytic procedures were made transparent through detailed descriptions of coding, theme development, analytic condensation, use of case-by-theme matrices, stakeholder validation, and critical research team discussions and interpretations [119,120]. For example, in Study II, GF's initial interpretations primarily reflected participants' lived experiences, whereas AH's clinically informed perspective emphasised system-level aspects. Actively contrasting these perspectives supported the development of themes capturing both individual and structural dimensions of RTW processes. Nevertheless, the potential influence of researcher proximity cannot be eliminated and should be considered when interpreting the findings.

16 Conclusion

This PhD thesis demonstrates how a complex, person-centred, interdisciplinary, cross-sectoral VR intervention for individuals on, or at risk of, sick leave due to CLBP can be systematically developed and feasibility-tested. This was achieved through a transparent, theory-informed, and co-designed process based on evidence review and stakeholder consultation and guided by established frameworks for complex intervention development and evaluation. The SAW intervention was developed in close collaboration with individuals with CLBP and key stakeholders across healthcare and employment services, as well as employer and employee representatives, ensuring alignment with participants' needs, clinical guidelines, and organisational realities.

The project shows that the SAW intervention is feasible to implement within Danish healthcare and employment services under real-world conditions, and that core components supporting coordinated, person-centred, and coherent RTW pathways can be delivered largely as intended. However, selected components require refinement prior to further testing. Recruitment, retention, and data collection exceeded feasibility thresholds, key mechanisms related to cross-sectoral coordination and perceived coherence in rehabilitation pathways were activated, and most clinical and work-related outcomes changed descriptively in a direction consistent with improvement.

Overall, this thesis provides a robust foundation for subsequent effectiveness-oriented evaluation and contributes methodological and conceptual insight into the development and early evaluation of complex VR interventions in real-world, cross-sectoral contexts.

17 Perspectives

Beyond the specific findings of the SAW intervention, this PhD project contributes to the broader field of VR by demonstrating how program theory–informed and co-designed approaches can bridge the gap between evidence-based recommendations and real-world practice. These insights have implications for the future development, evaluation, and implementation of complex, cross-sectoral VR interventions.

17.01 Implications for future research

A logical next step is to refine the SAW intervention in collaboration with the co-design group based on the feasibility findings and subsequently evaluate its effectiveness in a larger-scale study. In line with the MRC framework, such an evaluation should include an economic component to assess whether potential benefits justify the required resources and to inform decisions about implementation [4,138].

In future effectiveness and implementation studies, questions of long-term normalisation and sustainability will become increasingly important. In this context, it may be relevant to draw on Normalisation Process Theory, which examines how complex interventions are embedded, sustained, and routinised in everyday practice through mechanisms such as coherence, cognitive participation, collective action, and reflexive monitoring [176]. Such an approach could complement effectiveness evaluation by providing insight into how the SAW intervention is taken up and integrated across healthcare and employment services. Alternatively, realist evaluation could be applied to further refine the program theory by examining how, why, and for whom the intervention works across different contexts [177].

Future research should also examine the feasibility and acceptability of weekly self-reported sick-leave data collection over longer follow-up periods (e.g., 6–12 months), as RTW trajectories for individuals with CLBP often unfold over extended timeframes [44,169]. This approach may provide a more nuanced understanding of fluctuating work participation than register-based data alone.

Finally, future research should examine how HL can be embedded at the system level within cross-sectoral VR interventions, for example, by designing communication practices and navigation support that promote consistent and coherent messages across sectors, rather than relying on individual-level HL screening.

17.02 Implication for practice

Even though causality cannot be inferred, the findings of this PhD project point to several implications for the organisation and delivery of VR for individuals with CLBP.

For clinical practice, the findings suggest:

- Following clinical guidelines, including avoiding routine diagnostic imaging, while explicitly addressing individuals' need for clear explanations regarding diagnosis, prognosis, and the rationale for clinical decisions.
- Adapting communication strategies to individuals' HL capacities and, where relevant, offering structured psychosocial and navigational support.
- Considering systematic assessment of work-related functional capacity (e.g., WORQ [130,165]) as a clinically meaningful framework that may shift dialogue from symptom intensity toward functional implications for work and support more concrete, work-oriented planning across sectors.

At the organisational level, the findings suggest:

- Considering cross-sectoral educational leaflets or other "common starting points" as shared communicative references that may reduce variation in how CLBP management is communicated.
- Offering structured coordination activities to support coherent and person-centred RTW pathways and contribute to HL-responsive practice across healthcare and employment services.

- Prioritising shared documentation tools (e.g., VR summaries) and agreed communication practices to align language, expectations, and responsibilities across sectors.

At the system level, the findings suggest:

- Paying attention to how institutional conditions shape the feasibility of cross-sectoral collaboration and role clarity across healthcare and employment services.
- Drawing on transparent, program theory–informed and co-designed development approaches with early and sustained stakeholder involvement when designing interdisciplinary, cross-sectoral initiatives, as such approaches may enhance contextual fit, acceptability, and feasibility.
- Taking into account contextual constraints related to employers' limited formal responsibility for RTW in Denmark when designing cross-sectoral VR interventions.

In particular, the findings further illustrate how institutional conditions shape the feasibility of employer involvement in VR. In a labour market characterised by relatively weak employment protection and limited formal employer responsibility for RTW [47], individuals with chronic pain may fear stigma or job loss when disclosing health-related limitations [154]. As long as responsibility for RTW primarily rests with municipal services and the individual rather than with employers, such structural conditions may constrain open dialogue and employer engagement. Future VR initiatives should therefore consider how these system-level arrangements influence disclosure practices and the feasibility of employer-focused components.

Beyond the immediate clinical, organisational, and system-level implications, the findings are also relevant in light of ongoing reforms in the Danish healthcare system, which emphasise improved coordination and more coherent cross-sectoral care pathways [178]. This PhD project provides empirically grounded insights into mechanisms, practices, and organisational conditions that may be important to consider when designing and implementing coordinated VR initiatives within such reform contexts.

18 References

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19 List of appendices

Appendix A: Paper I: Mapping Vocational Rehabilitation Interventions for People with Chronic Low Back Pain: A Scoping Review

Appendix B: Paper II: System Responsiveness and Health Literacy in Return-to-Work Challenges for Individuals with Chronic Low Back Pain: A Qualitative Study
Appendix B1: Supplemental material Paper II: Interviewguide
Appendix B2: Supplemental material Paper II: COREX checklist

Appendix C: Paper III: Co-developing a vocational rehabilitation intervention for individuals with chronic low back pain across a regional spine centre and three municipalities in Denmark: a three-stage intervention development study guided by the Medical Research Counsil framework
Appendix C1: Supplemental material Paper III: GUIDED Checklist
Appendix C2: Supplemental material Paper III: TIDieR Checklist
Appendix C3: Supplemental material Paper III: GRIPP2 SF Checklist

Appendix D: Paper IV: Evaluating the Feasibility of the Stay-At-Work Cross-Sectoral Vocational Rehabilitation Intervention for Individuals with Chronic Low Back Pain: A Feasibility Study Informed by Process Evaluation
Appendix D1: Supplemental material Paper IV: Structured interview guide - Participant
Appendix D2: Supplemental material Paper IV: Semistructured focus group interview guide – Spine Centre
Appendix D3: Supplemental material Paper IV: Semistructured focus group interview guide – Municipal
Appendix D4: Supplemental material Paper IV: Framework for the case-by-theme matrix
Appendix D5: Supplemental material Paper IV: Operationalisation and categorisation of fidelity indicators