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WORK-ON: Vocational rehabilitation for people with chronic inflammatory arthritis - protocol for a randomised controlled trial

Short running title: Protocol for WORK-ON RCT

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ABSTRACT

Introduction

Among people with chronic inflammatory arthritis (IA) up to 40% lose their job in the first few years after diagnosis of this condition and are hence at high risk of being permanently excluded from the labour market. Therefore, we developed a new context-specific vocational rehabilitation (VR) for people with IA. This six-month VR (WORK-ON) includes: 1) an initial assessment and goalsetting by a coordinating occupational therapist, who supports cooperation and coordination between relevant partners and navigation across primary and secondary care, 2) four group sessions with peers and 3) individual sessions with a social worker, nurse or physiotherapist. Tthe objective of this trial is to test the overall efficacy of WORK-ON as an add-on to usual care and compare it with usual care provided to a control group.

Methods and analysis

A randomised controlled trial has been planned. Patients with IA, aged at least 18 years and experiencing job insecurity will be randomised to one of two groups: 1) the intervention group receiving WORK-ON VR as an add-on to usual care and 2) the control group receiving usual care. The primary outcome is the difference in work ability 12 months after baseline, which will be measured using the Work Ability Index single item. The key secondary outcome measures are absenteeism, presenteeism, overall work impairment, activity impairment, and job loss measured at baseline and at 6, 12, 18- and 30-month follow-up. Secondary outcomes measures are quality of life, mental well-being, fatigue, sleep, physical activity, occupational balance, and pain, which will be measured at baseline and at 6- and 12-month follow-up.

Ethics and dissemination

The Regional Committees on Health Research Ethics in Southern Denmark waived the requirement for a formal approval (Journal number S-20232000–3). The participants will provide informed consent prior to participating in the trial.

Trial registration number

NCT06299917

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The WORK-ON intervention was thoroughly developed and feasibility tested using the Medical Research Council's framework for development and testing of complex interventions.
- The WORK-ON intervention is preventive and targets patients with inflammatory arthritis who consider they are at risk of losing their job.
- The WORK-ON intervention may be followed by a cost-effectiveness analysis.
- There may be a risk of exclusion of patients with a lower social status.

KEYWORDS

Axial spondyloarthritis, psoriatic arthritis, rheumatoid arthritis, complex interventions, Medical Research Council, job loss, sick leave, work ability, presenteeism, work rehabilitation.

INTRODUCTION

Worldwide, the prevalence of rheumatoid arthritis (RA) is 0.21% (1), of psoriatic arthritis (PsA) 0.13% (2) and of axial spondyloarthritis (axSpA) 0.3–1.4% (3). In this study, we refer to these diagnoses together as chronic inflammatory arthritis (IA). Despite major advances in the pharmacological treatment, people with IA still have unmet needs (4). Many experience pain, fatigue, sleep problems, psychological distress, physical limitations and problems with participation in everyday activities, including paid work (5, 6).

Up to 40% lose their job in the first few years after IA is diagnosed (7, 8). Thus, this cohort needs to be offered support early for enabling them to retain their jobs as they will find it difficult to resume work after long-term absence due to sickness (9, 10). In 2013, people in Denmark with RA were absent from work for 5.6 more days than those without RA (11). This corresponds to more than 50,000 days of sickness absence per year and a productivity loss of DKK67.3 million (approximately EUR9 million) (11).

Being able to work is of great importance to individuals' identity and quality of life, including for people with IA (12, 13). People with IA struggle to find a balance between their disease, paid work and other aspects of everyday life (13, 14). A systematic review on job loss prevention interventions among people with IA found that strategies such as job accommodation, job coaching, physical exercise and ergonomic and vocational counselling may have an effect on job loss, work ability and sickness absence (6). Given that vocational rehabilitation (VR) depends on the context and that countries have different social security systems, the review pointed to the need for context-specific VR tailored for people with IA (6).

Therefore, we developed a VR called 'WORK-ON' for people with IA, who considered they were at risk of losing their job within the following two years (15). The development of WORK-ON was based on the Medical Research Council's updated framework for

developing and evaluating complex interventions (16). The development process involved relevant stakeholders, including patient research partners (PRPs) and various professionals from the hospital and municipalities. As part of the development, we created a logic model to help explain the associations between the resources and outcomes of the intervention.

In 2022–2023, we tested the feasibility of the WORK-ON intervention for 19 participants (17). Using the results from this study, as well as qualitative evaluations with patients and rehabilitation clinicians (to be published later), we have slightly adjusted the initial version of WORK-ON (15). The adjusted WORK-ON includes an additional group session, an increased focus on the reduction of sickness absence, the management of fatigue and the involvement of the participants' employers. Therefore, the aim of the present study is to test the efficacy of the adjusted WORK-ON intervention as an add-on to usual care and compare it with usual care in a randomised controlled trial (RCT).

METHODS AND ANALYSIS

This study protocol was developed in accordance with the Usual Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guideline (18, 19). The trial is planned as an RCT with a two-group parallel design.

Study hypothesis

Building on the findings from our feasibility study, we hypothesise that WORK-ON will be effective in increasing work ability at 6-, 12-, 18- and 30-month follow-up. The primary outcome is the difference between the two groups in work ability at 12 months, which will be measured using the Work Ability Index (WAI) single item. The key secondary outcomes are decreases in sickness absence and job loss at 12-, 18- and 30-month follow-up. For secondary outcomes, we expect an

improvement in quality of life, fatigue, mental well-being, physical activity level and pain measured at 6 and 12 months after baseline. Further, the association between work hours per week, compensatory schemes, work ability and job loss at 12-, 18- and 30-month follow-up will be investigated.

Study setting

The WORK-ON RCT will be conducted at the Danish Hospital for Rheumatic Diseases (DHR), which is a specialised hospital for rheumatic diseases and rehabilitation. The hospital has a large outpatient department and offers inpatient rehabilitation for patients with rheumatic diseases from all five regions in Denmark.

Patient and public involvement

Four PRPs, all diagnosed with IA, have been involved in the development and the feasibility test of WORK-ON (15). In the WORK-ON RCT, these four PRPs will be involved in all aspects of the study. They will continue to assist in tasks such as reading and providing feedback on documents provided to participants that contain information on the study and lay descriptions of the RCT for funding applications. Furthermore, before initiating the RCT study, the PRPs will read and try to fill the questionnaires to ensure that all the questions are appropriate, relevant and easily understandable. The PRPs will also be involved in discussions about recruitment and in interpretation and dissemination of the results and will be offered co-authorship on publications deriving from the trial. The involvement of PRPs will be reported in accordance with the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) guidelines (20).

Inclusion criteria

- Aged 18–65 years.
- Diagnosed with RA, PsA or axSpA by a rheumatologist.
- Undertakes paid work (full- or part-time work or studying).
- Able to read and understand Danish.
- Answers 'unlikely' or 'not certain' to question #6 from the WAI questionnaire: 'Do you believe, according to your present state of health, that you will be able to do your current job two years from now?' (21).
- Willing to participate in an RCT of the modified WORK-ON VR.

Exclusion criteria

- Adjustment or change in pharmacological anti-rheumatic treatment has been planned.
- Presence of morbidities other than IA that may explain reduced work ability.
- Under examination for comorbidities that influence work ability.
- Major surgery was conducted within the past six months, or a surgery has been planned.
- Unable to understand or speak Danish at a sufficient level to participate.
- Has cognitive or psychological impairments that may affect participation.
- Involved in another rehabilitation program (apart from physiotherapy).
- Participated in the WORK-ON feasibility study.
- Retirement application process is ongoing or plans to retire within the next five years.
- Has taken long-term sick leave (>4 weeks).

Randomisation and blinding

Participants will be allocated 1:1 to either the WORK-ON VR (the intervention group) or usual care (the control group) stratified by diagnosis. Typically, block randomisation is used to secure a balanced randomisation to the two groups and to ensure that the randomisation is unpredictable. An algorithm calculates the balance within and between blocks (22). Block randomisation and data collection will be performed using the Research Electronic Data Capture (REDCap) hosted by the Open Patient data Explorative Network (OPEN) (23). OPEN is a safe storage and analysis environment in the Region of Southern Denmark. REDCap is a secure web application to be used for randomisation and for building and managing online surveys. Given the nature of the intervention, neither the rehabilitation clinicians nor the participants can be blinded. The statistical analyses will be performed blinded to group allocation.

Adverse events

All participants will continue receiving usual care regardless of the group to which they are allocated, and any unintended events will be registered in the medical journal at the DHR throughout the trial period. This journal will be read after the participant completes the intervention. No health or safety risks associated with participation in the WORK-ON feasibility test have been identified. Therefore, we consider that the risk of adverse events is low.

Recruitment

Before each outpatient consultation at the DHR, all patients with IA need to complete questionnaires, which are collected in the national rheumatology quality database, DANBIO (24). Patients can complete these either using a touchscreen in the hospital's waiting area or on their own mobile phone, tablet or computer at home. An initial screening for eligible patients will be

performed using DANBIO. For patients with a diagnosis of RA, axSpA or PsA and age ≥ 18, the regular questionnaires at the current visit will be followed by a question regarding whether they are in paid work/studying. If they reply 'yes', they will be asked question #6 from the WAI questionnaire (21): 'Do you believe, according to your present state of health, that you will be able to do your current job two years from now?' If a patient answers 'unlikely' or 'not certain', a pop-up text with brief information about WORK-ON will be displayed on the screen. If the patients indicate that they are interested to hear more about the trial, they will be prompted to insert their phone number and email address. Rheumatologists and nurses in the outpatient clinic will also be requested to identify their patients who are eligible to participate in the WORK-ON RCT. Then, interested patients will be contacted on phone within the following week by a project member in order to offer more information about the study. Patients who are still interested in participating in the study will be screened for eligibility by a project member in accordance with the remaining inclusion and exclusion criteria. Those who meet all the eligibility criteria will be sent the participant information via email to allow them time for consideration before they give their written consent. Then, patients who confirm their willingness to participate in this study will be requested to provide their written consent, which will be collected through REDCap (see Figure 1).

[*Figure 1 near here: Flowchart of the study*]

Control group (usual care)

Usual care will comprise planned outpatient consultations every 3 to 12 months, depending on the patient's needs, provided alternately by a rheumatologist and rheumatology nurses. In addition, the participants will have access to support from the rheumatology nurses via a telephone helpline. The planned consultations will include a review of blood tests; joint examinations; a review of

completed questionnaires in DANBIO (24); a review of the side effects of, and adherence to, the pharmacological treatment; and an evaluation of whether pharmacological adjustment is necessary. The nurses will occasionally provide limited patient education on the management of the disease, medications and symptoms, which will be tailored to the specific patient. Further, the participants in the control group will be offered pamphlets for their employer and colleagues, titled 'Dear employer – I have arthritis' and 'Dear colleague – I have been diagnosed with arthritis'. The pamphlets were developed at the Danish Centre for Expertise in Rheumatology at the DHR in 2023 and describe some of the challenges people with IA may face at work (25).

The intervention group

WORK-ON is offered as an add-on to usual care. The six-month VR will include consultations with a coordinating occupational therapist (OT), group sessions and need-based individual consultations with different rehabilitation clinicians (15) (see Figure 2). WORK-ON was developed using the following theories and approaches: self-management (26), occupational balance (27), shared decision-making (28), and Focused Acceptance and Commitment Therapy (FACT) (29). All rehabilitation clinicians at the DHR use a biopsychosocial approach in their work (30) and are trained in FACT and motivational interviewing (31). The VR consists of three parts, which are explained next.

[*Figure 2 near here: The WORK-ON* intervention]

Coordinating occupational therapist:

Consultations with the coordinating OT, who will perform an initial two-hour physical consultation at the DHR with an initial assessment and goal setting process, are mandatory. The coordinating OT

has experience with the rehabilitation of patients with IA and the challenges they face in the labour market. The two-hour consultation will start with a structured interview guided by the Work Experience Survey for Patients with Rheumatic Conditions, which is a survey targeting problems at work (54). Guided by this Survey, a detailed assessment will be performed of the participants' work barriers, activity limitations, roles and tasks in relation to their work and at home, values in life and balance in activities in everyday life, including work. Goal setting and prioritisation of activities will be performed using the Canadian Occupational Performance Measure, which the OTs are trained to use (55). Furthermore, the participants' wish regarding involvement of relatives will be clarified.

The participants will be able to contact the coordinating OT through a phone call or an email at agreed-upon hours (also outside the participants' normal working hours). The coordinating OT will support the participants to identify and establish contact with relevant partners and to navigate offers in the municipality (i.e. the municipal jobcentre or health centre). Furthermore, the participant will be encouraged to involve their employer, and the coordinating OT will participate in meetings between the participant and their employer, if the participant agrees. The coordinating OT will also assess whether a workplace assessment or specific aids are required. In Denmark, an OT at the municipal jobcentre performs workplace assessments, and the coordinating OT will help establish contact. The OT will also support participants to apply for specific aids. These participants will also be offered the pamphlets given to the control group, titled 'Dear employer – I have arthritis' and 'Dear colleague – I have been diagnosed with arthritis', which they can give to their employer and colleagues for easing dialogue about IA and the challenges they experience at work. In addition, each participant's need for individual offers (e.g. individual support from a physiotherapist, nurse or social worker) will be evaluated together by the participant and the OT.

The day before each meeting with the coordinating OT, the booking system will remind the participant through a text message: 'Dear … I look forward to seeing you tomorrow at … to …'.

The coordinating OT will provide individual support in relation to the agreed-upon goals, and personal challenges at home and at work that limit their work ability, by using principles in FACT and supporting the patients' self-management ability. The individual support can encompass concerns, issues with bad conscience, negative thoughts and balance in activities in everyday life to be able to maintain work. The coordinating OT will also assess and guide in relation to the need for hand exercises, small aids and bandages, and guidance on ergonomic positions in relation to work, pain and sleep.

A final follow-up consultation (for a maximum of two hours, including documentation) with the participant and relevant partners (e.g. social workers, consultants from the municipality jobcentre, employers or relatives) will be planned to evaluate goals and progress during the intervention period and to discuss future needs for rehabilitation or self-management support.

During the six-month intervention period, the coordinating OT and the participant will agree on when, where and how (physical, telephone or online) the consultations will take place. The coordinating OT and the participant can use up to 10 hours throughout the six months, including for the initial assessment and goalsetting and the final follow-up consultation, individual support including the initial assessment and follow-up.

Twelve months after baseline, the coordinating OT will invite the participant for a follow-up consultation via phone (for maximum 45 minutes, including documentation) to discuss the participant's challenges and goals and will enquire about any further difficulties in relation to work.

Group sessions:

Four two-hour group sessions will be held to provide self-management support and to give the participants the opportunity to meet with peers in the same situation and exchange experiences. This part is mandatory. The coordinating OT who has conducted the initial assessment and goalsetting with 7–10 participants will host the subsequent group sessions together with a social worker, a nurse or a physiotherapist to secure coherence. The first three group sessions will be held at one-week intervals after the participants have completed the initial assessment and goalsetting consultation. The fourth group session will be held by the end of the six-month VR and before the final follow-up consultation with the coordinating OT. The group sessions will encompass:

1. *Legislative offers.* The first session will focus on legislative offers and will be held by a social worker and the coordinating OT. The focus will be on the general legislative offers for patients with IA, such as various opportunities for support and compensatory schemes, offers in the municipal jobcentre and possibilities for a flexi-job. A flexi-job is an offer individuals can apply for in Denmark. The municipality pays a subsidy to the employer for citizens who have decreased work ability and are only able to work for less than half the usual time (in Denmark, a full-time job is for 37 hours/week). Furthermore, they will discuss the participants' values in relation to work and everyday life, guided by the Bulls Eye's Exercise that helps prioritise values as part of the FACT approach (32).
2. *Acceptance of the disease in relation to work.* The second session will be held by the coordinating OT and a rheumatology nurse with experience in rheumatology rehabilitation. They will focus on identifying ways to deal with lack of understanding from the employer or colleagues at the workplace, providing information and understanding about the disease, including fatigue management, and sharing experiences with other participants.

3. *Self-management strategies.* An experienced rheumatology physiotherapist and the coordinating OT will hold the third session. The focus will be on managing fatigue, managing energy and balancing work as part of everyday life; pain management; physical activity; and energy-saving techniques.
4. *Follow-up.* A rheumatology nurse and the coordinating OT will hold the fourth session. The focus will be on how the participants have achieved their goals, follow-up on the Bulls Eye's Exercise, ways to retain new habits, and follow-up on the second session regarding acceptance of the disease in relation to work.

Individual consultations:

If needed, the patient will be offered up to eight consultations (each lasting 60 minutes, including documentation) with relevant rehabilitation clinicians to achieve their goals. This part is optional and will involve the following:

- *Social worker:* Discussion on specific legislative offers of relevance for the individual participant and/or the need for job change.
- *Rheumatology nurse*: Provision of information about the disease, comorbidities, treatment, side effects of, adherence to, and concerns about the pharmacological treatment, as well as about ways to manage pain, fatigue and sleep problems.
- *Rheumatology physiotherapist:* Provision of information about individually tailored physical activity and exercise; discussions about motivation for, and barriers to, exercise and where and how to exercise or be physically active; and examination of the feet and guidance regarding foot health and footwear.

Outcomes and data collection

Sociodemographic and disease-related information will be collected at baseline. The primary outcome measure, work ability measured by the WAI single item, will be measured at baseline, 6 and 12 months after baseline through a questionnaire, and 18 and 30 months after baseline through a phone call.

Key secondary outcome measures will be measured at baseline and 6, 12, 18 and 30 months after baseline and consist of the questionnaire for Work Productivity and Impairment: General Health (WPAI:GH) (33), WAI questions 2 and 6 and number of work hours per week. In addition, the number of days and hours of sickness absence will be collected through text messages with a one-month interval after baseline during the six-month WORK-ON intervention period. Job loss will be measured at 12, 18 and 30 months after baseline.

The secondary outcome measures comprise the Occupational Balance Questionnaire (OBQ) (34, 35), health-related quality of life (European Quality of Life-5 Dimensions-5 Levels [EQ-5D-5L]) (36), fatigue measured by the Bristol Rheumatoid Arthritis Fatigue questionnaire (BRAF) numerical rating scales (NRSv2) for fatigue severity, impact and coping (37), the WHO-5 Well-being Index (38), questions about physical activity level and sleep problems (how the patient sleeps and whether the patient feels rested after sleep) from a Danish National Health Profile (39) and pain measured on a visual analogue scale (0-10) (40). For an overview of the data collection and outcomes, see Tables 1 and 2.

[*Table 1 near here*: *SPIRIT Flowchart: Schedule of assessments*]

Table 1 SPIRIT Flowchart: Schedule of assessments

Time point	Baseline	6	12	18	30	Every month
Sociodemographic data	x					
Primary outcome						
WAI single item	x	x	x	x	x	
Key secondary outcomes						
WAI question 2	x	x	x	x	x	
WAI question 6	x	x	x	x	x	
Work hours per week	x	x	x	x	x	
Job loss			x	x	x	
WPAI:GH	x	x	x	x	x	
Sickness absenteeism						x*
Secondary outcomes						
OBQ-11	x	x	x			
EQ-5D-5L	x	x	x			
VAS pain	x	x	x			
BRAF-NRSv2	x	x	x			
Physical activity	x	x	x			
WHO-5 Well-being Index	x	x	x			
Sleep	x	x	x			

BRAF-NRSv2 = Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales version 2; EQ-5D-5L = European Quality of Life-5 Dimensions-5 Levels; VAS = visual analogue scales; OBQ-11 = Occupational Balance Questionnaire; WAI = Work Ability Index; WPAI:GH = Work Productivity and Activity Impairment Questionnaire: General Health; WHO = World Health Organization. *every month for the first six months.

[*Table 2 near here*: *Demographic data and outcome measures*]

Table 2 Demographic data and outcome measures

Sociodemographic data		***Description***
Age		In years
Sex		Female, male, other
Height		In centimetres (cm)
Weight		In kilograms (kg)
Living status		Single/cohabitant
Diagnosis		RA, PsA, axSpA
Disease duration		In years
Work level		Employee, in flexi-job, working hours, self-employed or a student
Educational level		Primary school High school Short-term further education (< 3 years) Higher education (> 3 years) Long-term higher education (≥ 5 years)
Support schemes		§56, personal assistance, other*
Comorbidities		Diabetes Hypertension Heart disease Stroke Chronic obstructive pulmonary disease Cancer Osteoarthritis Osteoporosis Asthma Depression Anxiety Other
Primary outcome		
Variable	*Measure*	*Description*
Work ability	WAI single item (41)	A visual analogue scale that compares perceived work ability with lifetime best score. The score ranges from 0 (completely unable to work) to 10 (work ability at its best).
Key secondary outcomes		
Work hours per week		Number of work hours per week.
Job loss		The participant is asked if they currently have a job.
Absenteeism Presenteeism Overall work impairment Activity impairment	WPAI:GH (33)	Includes six questions that measure absenteeism, presenteeism and the effect of health problems on the participants' work ability and performance of regular activities during the previous 7 days. The WPAI:GH outcomes are expressed as time impaired (%), with higher numbers indicating greater impairment and less productivity, that is, worse outcomes because of health problems.

Work ability in relation to demands	WAI question 2 (41)	'How do you rate your current work ability with respect to the physical demands of your work?' and 'How do you rate your current work ability with respect to the mental demands of your work?' Include five response categories: 1 = very poor, 2 = rather poor, 3 = moderate, 4 = rather good and 5 = very good
Job insecurity	WAI question 6 (41)	'Do you believe, according to your present state of health, that you will be able to do your current job two years from now?' Includes three response categories: 1 = unlikely, 2 = not certain and 3 = yes
Sickness absenteeism		Reported each month during the intervention period via text message reminders. Reported as number of days and hours.
Secondary outcomes		
Physical activity while at work		Standing or walking with lifting or carrying Physically demanding job Mostly stationary work Mostly standing or walking
Occupational balance	OBQ-11 (34, 35)	Measures the participant's experience of balance in the amount and variation of their everyday activities. Consists of 11 items and four response levels: 0 = completely disagree, 1 = tend to disagree, 2 = tend to agree and 3 = completely agree. Higher scores are better.
Health-related quality of life	EQ-5D-5L (36)	Usual generic measure to assess population health. Includes five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with five response levels in each dimension: 1 = no problems, 2 = slight problems, 3 = moderate problems, 4 = severe problems and 5 = extreme problems; and a visual analogue scale: EQ-VAS, 0–100 (100 is best), reporting the participant's self-rated health.
Pain	VAS pain (40)	Visual analogue scale, measuring self-rated pain at the moment. 0–10: 0 = no pain to10 = worst pain
	One question about pain experienced over the previous four weeks and the extent to which physical pain affected work and household chores (39)	Includes five response levels: 1 = no pain, 2 = slight pain, 3 = moderate pain, 4 = severe pain and 5 = extreme pain.
Fatigue	BRAF-NRSv2 (37)	Three separate numerical rating scales, scored from 0–10, higher is better, which cover three items: fatigue level (severity), effect on life (impact), and coping, anchored by 'no fatigue' and 'totally exhausted', 'no effect' and 'a great deal of effect', and 'very well' and 'not at all well', respectively
Physical activity	Over the previous year, how would you describe your physical activity?	Four response categories with one response opportunity: 1 = hard exercise, 2 = sports, heavy gardening, etc., 3 = walking, cycling, etc. and 4 = seated activities

	How many days a week are you physically active for at least 30 minutes?	Eight response levels: 0–7 days
Well-being	WHO-5 Well-being Index (38)	The 5-item Well-being Index is a generic rating scale measuring subjective well-being. The items are: 1 = 'I have felt cheerful and in good spirits', 2 = 'I have felt calm and relaxed', 3 = 'I have felt active and vigorous', 4 = 'I woke up feeling fresh and rested' and 5 = 'My daily life has been filled with things that interest me'. Respondents are asked to rate how well each of the five statements applies to them when considering the previous 14 days. Each of the five items is scored from 5 = all the time to 0 = none of the time. The raw score ranges from 0 to 25 multiplied by 4 to give a final score from 0 = worst imaginable well-being to 100 = best imaginable well-being.
Sleep	How many hours and minutes did you sleep during a normal night the previous 4 weeks? During the previous 4 weeks, did you get enough sleep to feel rested?	Three response levels: 1 = yes, 2 = yes, but not often enough, and 3 = no, never.
	Questions about how you sleep: Did you have trouble falling asleep? Did you wake up several times at night and have difficulty falling asleep? Did you wake up early and were unable to fall asleep again? Did you sleep restlessly? (39)	Four response levels: 1 = not in the last four weeks, 2 = less than once a week, 3 = 1–2 times a week and 4 = three or more times a week

AxSpA = axial spondyloarthritis; BRAF-NRSv2 = Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales version 2; EQ-5D-5L = European Quality of Life-5 Dimensions-5 Levels; EQ-VAS = EuroQol-visual analogue scales; OBQ-11 = Occupational Balance Questionnaire; PsA = psoriatic arthritis; RA = rheumatoid arthritis; WAI = Work Ability Index; WPAI:GH = Work Productivity and Activity Impairment Questionnaire: General Health; WHO = World Health Organization.

*Legislative support and compensatory schemes.

Sample size

At DHR, approximately 1,800 patients with IA are connected to the outpatient department, and it is estimated that 50% undertake paid work. From the feasibility test results, we assume that 20% consider themselves to be at risk of losing their job, leading to 180 potential participants. Based on the feasibility study, we assume that one-third of these individuals will meet the inclusion criteria

and agree to participate. In addition, we anticipate a low dropout rate of 10% based on the feasibility test. Assuming a standard deviation (SD) of 3 points on the Work Ability single item scale, a statistical power of 80%, and a significance level (alpha) of 0.05, the study is designed to detect a difference of 2.5 points on the Work Ability single-item scale (42). Thus, at least 25 participants are needed in each group. With an estimated 10% dropout rate, 28 participants are needed in each group. Preliminary results from the feasibility test showed that, on average, it is feasible to include 1–2 participants per week. Therefore, the recruitment period is expected to be one year, at maximum.

Statistics

Results from descriptive statistics will be reported by group as means and SD, or medians and interquartile ranges, depending on the distribution of the empirical data. Categorical variables will be reported as absolute counts and proportions (percentages) for each group. Differences in the primary and key secondary continuous outcomes will be analysed according to the intention-to-treat population using repeated-measures linear mixed models, including a factor for the treatment group (2 levels) and time, the interaction between both, and adjustments for baseline values and the stratification factor (diagnosis). For all mixed models, participant-specific random intercepts will be included, as well as random slopes if these improve the model fit significantly. The binary outcomes will be analysed using logistic mixed models, including a factor for the group and adjustment for the stratification factor. Odds ratios with 95% confidence intervals will be estimated, converted into approximate risk ratios and interpreted as number needed to treat (NNT) when appropriate. Mixed models incorporate all available data, making them particularly advantageous in handling missing data, assuming the missing data are missing at random. The intention-to-treat

analysis will be followed by a per-protocol analysis. *P*-values <0.05 are considered significant. All *p*-values and 95% confidence intervals will be two sided. We will not apply explicit adjustments for multiplicity but will perform prioritised analyses of key secondary outcomes. Before enrolment of the last participant, a full statistical analysis plan will be developed in collaboration with a statistician and uploaded to Clinicaltrials.gov.

ETHICS AND DISSEMINATION

The participants will be informed verbally and in writing about the study before they provide their written consent to participate prior to the first consultation. The leaflet, '*Research subjects' rights in health science research*', published by the Danish National Committee on Health Research Ethics, will be provided to all participants. The Regional Committees on Health Research Ethics waived the need for a formal approval (Journal number S-20232000–3). Data will be stored and managed in the research support system, OPEN, hosted by the Region of Southern Denmark. OPEN adheres to the European General Data Protection Regulations and the Danish data protection law (43, 44).

PERSPECTIVES

If the results from the RCT are significant, we will conduct cost-effectiveness and cost-utility analyses, in collaboration with health economists at the University of Southern Denmark. The cost-utility analysis will apply quality-adjusted life years, making use of the EQ-5D-5L instrument, based on Danish societal weights for the calculation of quality-adjusted life year (36). The cost-effectiveness analysis will apply days of sickness absenteeism and work ability as effect measures.

AUTHOR CONTRIBUTIONS

The first author took the lead in writing the manuscript in cooperation with the other two authors. All three authors read and approved the final manuscript.

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COMPETING INTERESTS

None declared.

FIGURE AND TABLE LEGENDS

Figure 1 Flowchart of the study

Figure 2 The WORK-ON intervention

Table 1 SPIRIT Flowchart: Schedule of assessments

Table 2 Demographic data and outcome measures

REFERENCES

1. Black RJ, Brooks PM, Kopansky-Giles DR, Abbasi-Kangevari M, Abolhassani H, Adesina MA, et al. Global, regional, and national burden of rheumatoid arthritis, 1990–2020, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. The Lancet Rheumatology. 2023;5(10):e594-e610. DOI: 10.1016/S2665-9913(23)00211-4
2. Scotti L, Franchi M, Marchesoni A, Corrao G. Prevalence and incidence of psoriatic arthritis: A systematic review and meta-analysis. Semin Arthrit Rheum. 2018;48(1):28-34. DOI: 10.1016/j.semarthrit.2018.01.003
3. Sieper JP, Poddubnyy DP. Axial spondyloarthritis. The Lancet (British edition). 2017;390(10089):73-84. DOI: 10.1016/S0140-6736(16)31591-4
4. Ishida M, Kuroiwa Y, Yoshida E, Sato M, Krupa D, Henry N, et al. Residual symptoms and disease burden among patients with rheumatoid arthritis in remission or low disease activity: a systematic literature review. Mod Rheumatol. 2018;28(5):789-99. DOI: 10.1080/14397595.2017.1416940
5. Smolen JS, Aletaha D, Barton A, Burmester GR, Emery P, Firestein GS, et al. Rheumatoid arthritis. Nat Rev Dis Primers. 2018;4:18001. DOI: 10.1038/nrdp.2018.1
6. Madsen CMT, Bisgaard SK, Primdahl J, Christensen JR, von Bülow C. A Systematic Review of Job Loss Prevention Interventions for Persons with Inflammatory Arthritis. J Occup Rehabil. 2021;31(4):866-85. DOI: 10.1007/s10926-021-09972-9
7. Verstappen SMM, Watson KD, Lunt M, McGrother K, Symmons DPM, Hyrich KL, et al. Working status in patients with rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis: Results from the British Society for Rheumatology Biologics Register. Rheumatology. 2010;49(8):1570-7. DOI: 10.1093/rheumatology/keq131
8. Sokka T, Kautiainen H, Pincus T, Verstappen SMM, Aggarwal A, Alten R, et al. Work disability remains a major problem in rheumatoid arthritis in the 2000s: Data from 32 countries in the QUEST-RA Study. Arthritis Res Ther. 2010;12(2):R42-R. DOI: 10.1186/ar2951
9. Boonen A, Webers C, Butink M, Barten B, Betteridge N, Black DC, et al. 2021 EULAR points to consider to support people with rheumatic and musculoskeletal diseases to participate in healthy and sustainable paid work. Ann Rheum Dis. 2022;82(1):57-64. DOI: 10.1136/ard-2022-222678
10. Hansen SM, Hetland ML, Pedersen J, Ostergaard M, Rubak TS, Bjorner JB. Effect of rheumatoid arthritis on longterm sickness absence in 1994-2011: A danish cohort study. J Rheumatol. 2016;43(4):707-15. DOI: 10.3899/jrheum.150801
11. Jørgensen MD, M. Christensen, AI. Buhelt, LP. Tolstrup, JS. Leddegigt i Danmark. Nøgletal 2018. (Rheumatoid Arthritis in Denmark. Key numbers 2018). . Statens Institut for Folkesundhed, SDU (National Institute for Public Health, University of Southern Denmark); 2018. [Avaliable from:https://www.sdu.dk/da/sif/rapporter/2018/leddegigt_i_danmark]

12. Holland P, Collins AM. "Whenever I can I push myself to go to work": a qualitative study of experiences of sickness presenteeism among workers with rheumatoid arthritis. Disabil Rehabil. 2018;40(4):404-13. DOI: 10.1080/09638288.2016.1258436
13. Feddersen H, Mechlenborg Kristiansen T, Tanggaard Andersen P, Hørslev-Petersen K, Primdahl J. Juggling identities of rheumatoid arthritis, motherhood and paid work - a grounded theory study. Disabil Rehabil. 2019;41(13):1536-44. DOI: 10.1080/09638288.2018.1433723
14. Madsen CMT, Christensen JR, Bremander A, Primdahl J. Perceived challenges at work and need for professional support among people with inflammatory arthritis - a qualitative interview study. Scand J Occup Ther. 2021:1-10. DOI: 10.1080/11038128.2021.1989483
15. Madsen CMT, Primdahl J, Bremander A, Eggen L, Christensen JR. Developing a complex vocational rehabilitation intervention for patients with inflammatory arthritis: the WORK-ON study. BMC Health Serv Res. 2023;23(1):739. DOI: 10.1186/s12913-023-09780-2
16. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. 2021;374:n2061. BMJ. DOI: 10.1136/bmj.n2061
17. Madsen CMT, Christensen JR, Bremander A, Eggen L, Primdahl J. Feasibility test of WORK-ON - a complex vocational rehabilitation for people with chronic inflammatory arthritis. Submitted to BMC Musculoskeletal Disorders 2023. Under review.
18. Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:e7586. DOI: 10.1136/bmj.e7586
19. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Inter Med. 2013;158(3):200-7. DOI: 10.7326/0003-4819-158-3-201302050-00583
20. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ (Online). 2017;358:j3453-j. DOI: 10.1136/bmj.j3453
21. Work Ability Index 2019 [Available from: http://www.arbeitsfaehigkeit.uni-wuppertal.de/index.php?wai-online-en.]
22. Xiao L, Lavori PW, Wilson SR, Ma J. Comparison of dynamic block randomization and minimization in randomized trials: a simulation study. Clin Trials (London, England). 2011;8(1):59-69. DOI: 10.1177/1740774510391683
23. Open Patient data Explorative Network 2023 [Available from: https://open.rsyd.dk/.
24. Hetland ML. **DANBIO—powerful research database and electronic patient record**. Rheumatology. 2011;50(1):69-77. DOI: 10.1093/rheumatology/keq309
25. Danish Centre for Expertise in Rheumatology 2024 [Available from: https://centerforvidenomgigt.dk/samarbejde/kommuner/fyraftensmoede/.]
26. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health (1971). 2014;104(8):e25-e31. DOI: 10.2105/AJPH.2014.302041
27. Wagman P, Håkansson C, Björklund A, Hhj Afr, välfärd HHJKoliho, Högskolan i J, et al. Occupational balance as used in occupational therapy: A concept analysis. Scand J Occup Ther. 2012;19(4):322-7. 10.3109/11038128.2011.596219

28. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision making: multistage consultation process. BMJ. 2017;359:j4891-j. DOI: 10.1136/bmj.j4891
29. Strohsal KD, Robinson PJ, Gustavsson T. Brief Interventions for radical behavior change: Principles and practice of focused acceptance and commitment therapy. Oakland, CA: New Harbinger Publications; 2021.
30. Engel GL. The Need for a New Medical Model: A Challenge for Biomedicine. Science (American Association for the Advancement of Science). 1977;196(4286):129-36. DOI: 10.1126/science.847460
31. Rollnick S, Miller WR, Butler C. Motivational interviewing in health care: helping patients change behavior. Second ed. New York, NY: The Guilford Press; 2022.
32. Lundgren T, Louma J, Dahl J, Strohsal K, Melin L. The Bull's-Eye Values Survey: A Psychometric Evaluation. Cognitive and Behavioral Practice. 2012;19. DOI: 10.1016/j.cbpra.2012.01.004
33. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. PharmacoEconomics. 1993;4(5):353-65. DOI: 10.2165/00019053-199304050-00006
34. Morville A-L, Håkansson C, Wagman P, Hansen T, editors. Validity of the Danish version of Occupational Balance Questionnaire (OBQ-DK)2016. [Avaliable from: Validity of the Danish version of Occupational Balance Questionnaire (OBQ-DK) (diva-portal.org)]
35. Håkansson C, Wagman P, Hagell P. Construct validity of a revised version of the Occupational Balance Questionnaire. Scand J Occup Ther. 2020;27(6):441-9. DOI: 10.1080/11038128.2019.1660801
36. Jensen MB, Jensen CE, Gudex C, Pedersen KM, Sørensen SS, Ehlers LH. Danish population health measured by the EQ-5D-5L. Scandinavian journal of public health. 2021:14034948211058060-. DOI: 10.1177/14034948211058060
37. Primdahl J, Esbensen BA, Pedersen AK, Bech B, de Thurah A. Validation of the Danish versions of the Bristol Rheumatoid Arthritis Fatigue Multi-Dimensional Questionnaires (BRAFs). Scand J Rheumatol. 2021;50(5):351-9. DOI: 10.1080/03009742.2020.1869301
38. Topp CW, Østergaard SD, Søndergaard S, Bech P. The WHO-5 Well-Being Index: A Systematic Review of the Literature. Psychother Psychosom. 2015;84(3):167-76. DOI: 10.1159/000376585
39. The National Healthprofile (How are you?) 2021 [Available from: https://www.sdu.dk/da/sif/forskning/projekter/den_nationale_sundhedsprofil.
40. Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, et al. Validation of Digital Visual Analog Scale Pain Scoring With a Traditional Paper-based Visual Analog Scale in Adults. J Am Acad Orthop Surg Glob Res Rev. 2018;2(3):e088. DOI: 10.5435/JAAOSGlobal-D-17-00088
41. Tuomi K IJ, Jahkola A, Katajarinne L, Tilkki A. Work Ability Index, 2nd Edition: Finish Institute of Occupational Health, Helsinki; 1998. DOI: 10.1093/occmed/kqm008
42. Sell L, Bültmann U, Rugulies R, Villadsen E, Faber A, Søgaard K. Predicting long-term sickness absence and early retirement pension from self-reported work ability. International archives of occupational and environmental health. 2009;82(9):1139-. DOI: 10.1007/s00420-009-0417-6

43. European General Data Protection Regulations 2023 [Available from: https://gdpr.eu/what-is-gdpr/.]
44. Datatilsynet. Generelt om databeskyttelse 2018 [Available from: https://www.datatilsynet.dk/generelt-om-databeskyttelse/.]

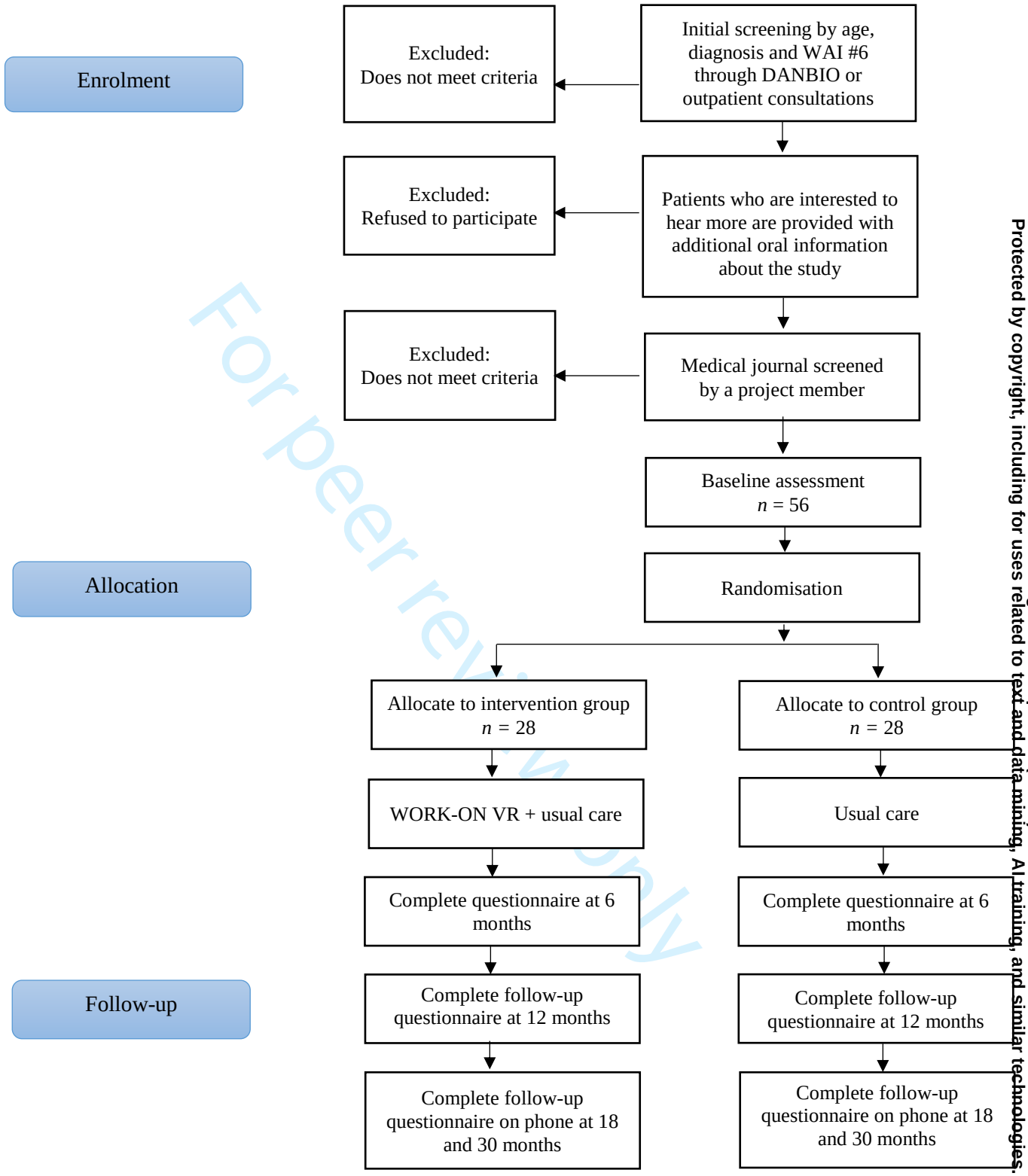

Figure 1 Flowchart of the study

WAI: Work Ability Index; DANBIO: Danish national rheumatology quality database

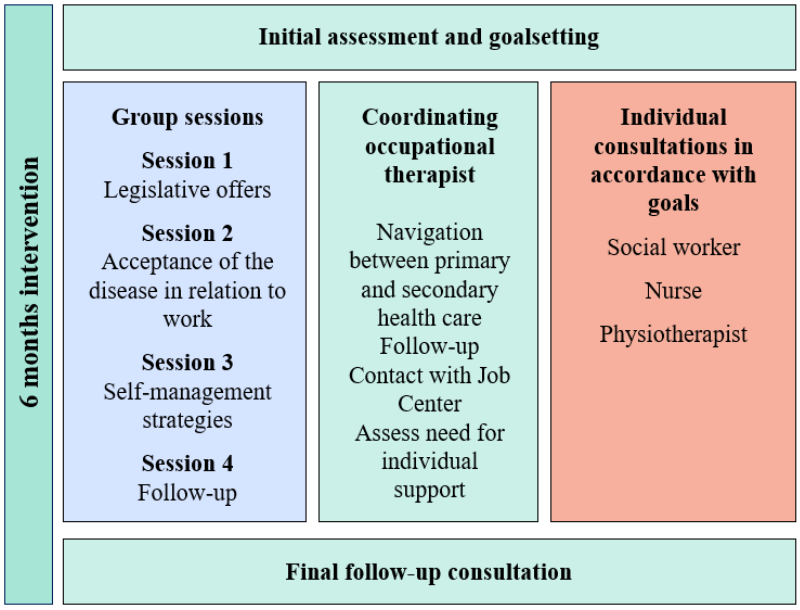

Figure 2 Illustration of the WORK-ON intervention

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Testing the efficacy of WORK-ON: Vocational rehabilitation for people with chronic inflammatory arthritis in Denmark - protocol for a randomised controlled trial

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Testing the efficacy of WORK-ON: Vocational rehabilitation for people with chronic inflammatory arthritis in Denmark - protocol for a randomised controlled trial

Short running title: Protocol for WORK-ON RCT

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ABSTRACT

Introduction

Among people with chronic inflammatory arthritis (IA) up to 40% lose their job in the first few years after diagnosis of this condition and are hence at high risk of being permanently excluded from the labour market. Therefore, we developed a new context-specific vocational rehabilitation (VR) for people with IA. This six-month VR (WORK-ON) includes: 1) an initial assessment and goalsetting by a coordinating occupational therapist, who supports cooperation and coordination between relevant partners and navigation across primary and secondary care, 2) four group sessions with peers and 3) individual sessions with a social worker, nurse or physiotherapist. The objective of this trial is to test the overall efficacy of WORK-ON as an add-on to usual care and compare it with usual care provided to a control group.

Methods and analysis

A randomised controlled trial has been planned. Patients with IA, aged at least 18 years and experiencing job insecurity will be randomised to one of two groups: 1) the intervention group receiving WORK-ON VR as an add-on to usual care and 2) the control group receiving usual care. The primary outcome is the difference in work ability 12 months after baseline, which will be measured using the Work Ability Index single item. The key secondary outcome measures are absenteeism, presenteeism, overall work impairment, activity impairment, and job loss measured at baseline and at 6, 12, 18- and 30-month follow-up. Secondary outcomes measures are quality of life, mental well-being, fatigue, sleep, physical activity, occupational balance, and pain, which will be measured at baseline and at 6- and 12-month follow-up.

Ethics and dissemination

The Regional Committees on Health Research Ethics in Southern Denmark waived the requirement for a formal approval (Journal number S-20232000–3). The participants will provide informed consent prior to participating in the trial.

Trial registration number

NCT06299917

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The WORK-ON intervention was thoroughly developed and feasibility tested using the Medical Research Council's framework for development and testing of complex interventions.
- The WORK-ON intervention is preventive and targets patients with inflammatory arthritis who consider they are at risk of losing their job.
- The WORK-ON intervention may be followed by a cost-effectiveness analysis.
- There may be a risk of exclusion of patients with a lower social status.

KEYWORDS

Axial spondyloarthritis, psoriatic arthritis, rheumatoid arthritis, complex interventions, Medical Research Council, job loss, sick leave, work ability, presenteeism, work rehabilitation.

INTRODUCTION

Worldwide, the prevalence of rheumatoid arthritis (RA) is 0.21% [1], of psoriatic arthritis (PsA) 0.13% [2] and of axial spondyloarthritis (axSpA) 0.3–1.4% [3]. We refer to these diagnoses together as chronic inflammatory arthritis (IA). More women than men are diagnosed with RA [4, 5]. The prevalence of RA in Denmark is 0.6%, and the global prevalence has ranged from 0.38% to 0.67%. The mean age for people with RA is 61 years [5-7]. For PsA, women and men are equally affected, the prevalence in Denmark is 0.22%, the global prevalence is 0.01% to 0.19% and the mean age for people with PsA is 47 [8, 9]. For axSpA, the prevalence in Denmark is 1.5% [10] and the global prevalence is 0.20% to 1.61% [9]. Men are overrepresented, and the mean age for people diagnosed with axSpA is 33 [11]. Despite major advances in the pharmacological treatment, people with IA still have unmet needs [12]. Many experience pain, fatigue, sleep problems, psychological distress, physical limitations and problems with participation in everyday activities, including paid work [13, 14].

Up to 40% lose their job in the first few years after IA is diagnosed [15, 16]. Several factors affect the risk for unemployment and job loss such as long-term sick leave, disease activity, job type, personal factors, socioeconomic status, and age [15, 17, 18]. After becoming unemployed, people with RMDs, including IA, are less likely to return to work [19-23]. Therefore, early identification of people with IA experiencing reduced work ability and early implementation of supportive interventions, are crucial to enable people with IA to remain in paid employment [22, 23].

Rheumatic and musculoskeletal diseases account for up to 60% of prolonged sick leave and work disability in Europe [22]. In 2013, people in Denmark with RA were absent from work for 5.6 more days than those without RA [24]. This corresponds to more than 50,000 days of

sickness absence per year and a productivity loss of DKK67.3 million (approximately EUR9 million) [24].

Being able to work is of great importance to individuals' identity and quality of life [25-27]. People with IA often struggle to find a balance between their disease, paid work and other aspects of everyday life [26, 28]. A systematic review on job loss prevention interventions among people with IA found that strategies such as job accommodation, job coaching, physical exercise and vocational counselling may have an effect on job loss, work ability and sick leave [14]. The review showed inconsistency in the results in the included studies, which may be due to heterogeneity in the content and duration of the interventions and outcome measures used. Further, the interventions were sparsely described in the included studies and therefore difficult to replicate. Given that vocational rehabilitation (VR) depends on the context and that countries have different social security systems, the review pointed to the need for context-specific VR tailored for people with IA [14].

Therefore, we developed a VR called 'WORK-ON' for people with IA, who considered they were at risk of losing their job within the following two years [29]. The development of WORK-ON was based on the Medical Research Council's updated framework for developing and evaluating complex interventions [30]. The development process involved relevant stakeholders, including patient research partners (PRPs) and various professionals from the hospital and municipalities.

In 2022–2023, we tested the feasibility of the WORK-ON intervention in 19 participants [31]. Based on the results from this study, as well as qualitative evaluations with patients and rehabilitation clinicians (not yet published), we have slightly adjusted the initial version of WORK-ON [29]. The adjustments include an additional group session, an increased focus on the reduction of sick leave, the management of fatigue and the involvement of the participants'

employers. Based on the adjustments and the results from the feasibility study, the aim of the present study is to test the efficacy of the adjusted WORK-ON intervention as an add-on to usual care and compare it with usual care in a randomised controlled trial (RCT).

METHODS AND ANALYSIS

This study protocol was developed in accordance with the Usual Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guideline [32, 33]. The trial is planned as an RCT with a two-group parallel design.

Study hypothesis

Building on the findings from our feasibility study, we hypothesise that WORK-ON will be effective in increasing work ability at 6-, 12-, 18- and 30-month follow-up. Work ability and job loss are associated and work ability can be considered as a proxy for job loss [31, 34]. The primary outcome is the difference between the two groups in work ability at 12 months, measured by the Work Ability Index (WAI) single item. The key secondary outcomes are decreases in sickness absence and job loss at 12-, 18- and 30-month follow-up. For secondary outcomes, we expect an improvement in quality of life, fatigue, mental well-being, physical activity level and pain measured at 6 and 12 months after baseline. Further, the association between work hours per week, compensatory schemes, work ability and job loss at 12-, 18- and 30-month follow-up will be investigated.

Study setting

The WORK-ON RCT will be conducted at the Danish Hospital for Rheumatic Diseases (DHR), which is a specialised hospital for rheumatic diseases and rehabilitation. The hospital has an outpatient department and offers inpatient rehabilitation for patients with rheumatic diseases..

Patient and public involvement

Four PRPs, all diagnosed with IA, have been involved in the development and the feasibility test of WORK-ON. The details are described elsewhere [29, 31]. In the WORK-ON RCT, these four PRPs will be involved in all aspects of the study. They will continue to assist in tasks such as reading and providing feedback on documents provided to participants that contain information on the study and lay descriptions of the RCT for funding applications. Furthermore, before initiating the RCT study, the PRPs will read and try to fill the questionnaires to ensure that all the questions are appropriate, relevant and easily understandable. The PRPs will also be involved in discussions about recruitment and in interpretation and dissemination of the results and will be offered co-authorship on publications deriving from the trial. The involvement of PRPs will be reported in accordance with the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) guidelines [35].

Inclusion criteria

- Aged 18–65 years.
- Diagnosed with RA, PsA or axSpA by a rheumatologist.
- Undertakes paid work (full- or part-time work or studying).
- Able to read and understand Danish.
- Answers ‘unlikely’ or ‘not certain’ to question #6 from the WAI questionnaire: ‘Do you believe, according to your present state of health, that you will be able to do your current job two years from now?’ [36].

- Willing to participate in an RCT of the modified WORK-ON VR.

Exclusion criteria

- Planned or present adjustments of the pharmacological anti-rheumatic treatment (DMARDs, glucocorticoid) within the last three months.
- Presence of morbidities other than IA that may explain reduced work ability.
- Is under examination for comorbidities that influence work ability.
- Major surgery was conducted within the past six months, or a surgery has been planned.
- Is unable to understand or speak Danish at a sufficient level to participate.
- Has cognitive or psychological impairments that may affect participation.
- Planned or ongoing participation in another rehabilitation program (apart from physiotherapy).
- Has participated in the WORK-ON feasibility study.
- Retirement application process is ongoing or plans to retire within the next five years.
- Has taken long-term sick leave (>4 weeks).

Randomisation and blinding

Participants will be allocated 1:1 to either the WORK-ON VR (the intervention group) or usual care (the control group) stratified by diagnosis. Typically, block randomisation is used to secure a balanced randomisation to the two groups and to ensure that the randomisation is unpredictable. An algorithm calculates the balance within and between blocks [37]. Block randomisation and data collection will be performed using the Research Electronic Data Capture (REDCap) hosted by the Open Patient data Explorative Network (OPEN) [38]. OPEN is a safe storage and analysis environment in the Region of Southern Denmark. REDCap is a secure web application to be used

for randomisation and for building and managing online surveys. Given the nature of the intervention, neither the rehabilitation clinicians nor the participants can be blinded. The statistical analyses will be performed blinded to group allocation to reduce this potential bias.

Adverse events

All participants will continue receiving usual care regardless of the group to which they are allocated, and any unintended events will be registered in the medical journal at the DHR throughout the trial period. This journal will be read after the participant completes the intervention. No health or safety risks associated with participation in the WORK-ON feasibility test have been identified. Therefore, we consider that the risk of adverse events is low.

Recruitment

Before each outpatient consultation at the DHR, all patients with IA need to complete questionnaires, which are collected in the national rheumatology quality database, DANBIO [39]. Patients can complete these either using a touchscreen in the hospital's waiting area or on their own mobile phone, tablet or computer at home. An initial screening for eligible patients will be performed using DANBIO. For patients with a diagnosis of RA, axSpA or PsA and age ≥ 18, the regular questionnaires at the current visit will be followed by a question regarding whether they are in paid work/studying. If they reply 'yes', they will be asked question #6 from the WAI questionnaire [36]: 'Do you believe, according to your present state of health, that you will be able to do your current job two years from now?' If a patient answers 'unlikely' or 'not certain', a pop-up text with brief information about WORK-ON will be displayed on the screen. If the patients indicate that they are interested to hear more about the trial, they will be prompted to insert their phone number and email address. Rheumatologists and nurses in the outpatient clinic will also be

requested to identify their patients who are eligible to participate in the WORK-ON RCT. Then, interested patients will be contacted on phone within the following week by a project member in order to offer more information about the study. Patients who are still interested in participating in the study will be screened for eligibility by a project member in accordance with the remaining inclusion and exclusion criteria. Those who meet all the eligibility criteria will be sent the participant information via email to allow them time for consideration before they give their written consent. Then, patients who confirm their willingness to participate in this study will be requested to provide their written consent, which will be collected through REDCap (see Figure 1).

[*Figure 1 near here: Flowchart of the study*]

Control group

Usual care will comprise planned outpatient consultations every 3 to 12 months, depending on the patient's needs, provided alternately by a rheumatologist and rheumatology nurses. In addition, the participants will have access to support from the rheumatology nurses via a telephone helpline. The planned consultations will include a review of blood tests; joint examinations; a review of completed questionnaires in DANBIO [39]; a review of the side effects of, and adherence to, the pharmacological treatment; and an evaluation of whether pharmacological adjustment is necessary. The nurses will occasionally provide limited patient education on the management of the disease, medications and symptoms, which will be tailored to the specific patient. Further, the participants in the control group will be offered pamphlets for their employer and colleagues, titled 'Dear employer – I have arthritis' and 'Dear colleague – I have been diagnosed with arthritis'. The pamphlets were developed at the Danish Centre for Expertise in Rheumatology at the DHR in 2023 and describe some of the challenges people with IA may face at work [40].

The intervention group

WORK-ON is offered as an add-on to usual care. The six-month VR will include consultations with a coordinating occupational therapist (OT), group sessions and need-based individual consultations with different rehabilitation clinicians [29, 31] (see Figure 2).

[*Figure 2 near here: The WORK-ON* intervention]

Coordinating occupational therapist:

Consultations with the coordinating OT, who will perform an initial two-hour physical consultation at the DHR with an initial assessment and goal setting process, are mandatory. The coordinating OT has experience with the rehabilitation of patients with IA and the challenges they face in the labour market. The two-hour consultation includes an interview guided by the Work Experience Survey for Patients with Rheumatic Conditions, which is a survey targeting problems at work [54]. Guided by this Survey, an assessment will be performed of the participants' work barriers, activity limitations, roles and tasks in relation to their work and at home, values and balance in activities in everyday life. Goal setting and prioritisation of activities will be performed using the Canadian Occupational Performance Measure. [55]. The participants' wish regarding involvement of relatives will be clarified.

The participants will be able to contact the coordinating OT through a phone call or an email at agreed-upon hours (also outside the participants' working hours). The coordinating OT will support the participants to establish contact with relevant partners and to navigate offers in the municipality (i.e. the municipal jobcentre). The participant will be encouraged to involve their employer, and the coordinating OT will participate in meetings between the participant and their

employer, if the participant agrees. The coordinating OT will also assess whether a workplace assessment or specific aids are required. In Denmark, an OT at the municipal jobcentre performs workplace assessments and assessment for specific aids, and the coordinating OT will help establish contact. These participants will also be offered the pamphlets given to the control group, titled 'Dear employer – I have arthritis' and 'Dear colleague – I have been diagnosed with arthritis', for easing dialogue about IA and the challenges they experience at work. In addition, each participant's need for individual offers (e.g. individual support from a physiotherapist, nurse or social worker) will be evaluated together by the participant and the OT.

The coordinating OT will provide individual support in relation to the agreed-upon goals, and personal challenges at home and at work that limit their work ability.The coordinating OT will also assess and guide in the need for hand exercises, small aids and bandages, and guidance on ergonomic positions in relation to work, pain and sleep.

A final follow-up consultation (for a maximum of two hours, including documentation) with the participant and relevant partners (e.g. social workers, consultants from the municipality jobcentre, employers or relatives) will be planned to evaluate and to discuss future needs for rehabilitation or self-management support.

The coordinating OT and the participant can use up to 10 hours throughout the six months, including the initial assessment and goalsetting, the final follow-up consultation, individual support including the initial assessment and follow-up.

Twelve months after baseline, the coordinating OT will invite the participant for a follow-up consultation via phone (for maximum 45 minutes, including documentation) to discuss the participant's challenges and goals and will enquire about any further difficulties in relation to work.

Group sessions:

Four two-hour group sessions will be held to provide self-management support and to give the participants the opportunity for peer support. This part is mandatory. The coordinating OT who has conducted the initial assessment and goalsetting with 7–10 participants will host the group sessions together with a social worker, a nurse or a physiotherapist to secure coherence. The first three group sessions will be held at one-week intervals after the initial assessment and goalsetting consultation. The fourth group session will be held by the end of the six-month VR and before the final follow-up consultation with the coordinating OT. The group sessions encompass:

1. *Legislative offers.* The first session will focus on legislative offers and will be held by a social worker and the coordinating OT. The focus will be on the general legislative offers for patients with IA, such as various opportunities for support and compensatory schemes, offers in the municipal jobcentre and possibilities for a flexi-job. A flexi-job is an offer individuals can apply for in Denmark. The municipality pays a subsidy to the employer for citizens who have decreased work ability and are only able to work for less than half the usual time (in Denmark, a full-time job is for 37 hours/week). Furthermore, they will discuss the participants' values in relation to work and everyday life, guided by the Bulls Eye's Exercise that helps prioritise values as part of the Focused and Accepted Commitment Therapy approach [47].
2. *Acceptance of the disease in relation to work.* The second session will be held by the coordinating OT and a rheumatology nurse with experience in rheumatology rehabilitation. They will focus on dealing with lack of understanding from the employer or colleagues at the workplace, providing information and understanding about the disease, including fatigue management.

3. *Self-management strategies.* An experienced rheumatology physiotherapist and the coordinating OT will hold the third session. The focus will be on managing fatigue, managing energy and balancing work as part of everyday life; pain management; physical activity; and energy-saving techniques.
4. *Follow-up.* A rheumatology nurse and the coordinating OT will hold the fourth session. The focus will be on how the participants have achieved their goals, follow-up on the Bulls Eye's Exercise, ways to retain new habits, and follow-up on the second session regarding acceptance of the disease in relation to work.

Individual consultations:

If needed, the patient will be offered up to eight consultations (each lasting 60 minutes, including documentation) with relevant rehabilitation clinicians to achieve their goals. This part is optional and will involve the following:

- *Social worker:* Discussion on specific legislative offers of relevance for the individual participant..
- *Rheumatology nurse*: Provision of information about the disease, comorbidities, treatment, side effects of, adherence to, and concerns about the pharmacological treatment, as well as about ways to manage pain, fatigue and sleep problems.
- *Rheumatology physiotherapist:* Provision of information about individually tailored physical activity and exercise; discussions about motivation for, and barriers to, exercise and where and how to be physically active; and examination of the feet and guidance regarding foot health and footwear.

WORK-ON is not expected to interfere with usual care.

Outcomes and data collection

Sociodemographic and disease-related information will be collected at baseline (Table 2). The primary outcome measure, work ability measured by the WAI single item, will be measured at baseline, 6 and 12 months after baseline through a questionnaire, and 18 and 30 months after baseline through a phone call (Table 1).

Key secondary outcome measures will be measured at baseline and 6, 12, 18 and 30 months after baseline and consist of the questionnaire for Work Productivity and Impairment: General Health (WPAI:GH) [48], WAI questions 2 and 6 and number of work hours per week. In addition, the number of days and hours of sickness absence will be collected through text messages with a one-month interval after baseline during the six-month WORK-ON intervention period. Job loss will be measured at 12, 18 and 30 months after baseline (Table 1 and Table 3).

The secondary outcome measures comprise the Occupational Balance Questionnaire (OBQ) [49, 50], health-related quality of life (European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L)) [51], fatigue measured by the Bristol Rheumatoid Arthritis Fatigue questionnaire (BRAF) numerical rating scales (NRSv2) for fatigue severity, impact and coping [52], the WHO-5 Well-being Index [53], questions about physical activity level and sleep problems (how the patient sleeps and if rested after sleep) from a Danish National Health Profile [54] and pain measured on a visual analogue scale (0-10) [55] (Table 2). For an overview of the data collection and outcomes, see Table 1, 2 and 3.

[*Table 1 near here*: *SPIRIT Flowchart: Schedule of assessments*]

Table 1 SPIRIT Flowchart: Schedule of assessments

Time point	Baseline	6	12	18	30	Every month
Sociodemographic data	x					

Primary outcome						
WAI single item	x	x	x	x	x	
Key secondary outcomes						
WAI question 2	x	x	x	x	x	
WAI question 6	x	x	x	x	x	
Work hours per week	x	x	x	x	x	
Job loss			x	x	x	
WPAI:GH	x	x	x	x	x	
Sickness absenteeism						x*
Secondary outcomes						
OBQ-11	x	x	x			
EQ-5D-5L	x	x	x			
VAS pain	x	x	x			
BRAF-NRSv2	x	x	x			
Physical activity	x	x	x			
WHO-5 Well-being Index	x	x	x			
Sleep	x	x	x			

BRAF-NRSv2 = Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales version 2; EQ-5D-5L = European Quality of Life-5 Dimensions-5 Levels; VAS = visual analogue scales; OBQ-11 = Occupational Balance Questionnaire; WAI = Work Ability Index; WPAI:GH = Work Productivity and Activity Impairment Questionnaire: General Health; WHO = World Health Organization. *every month for the first six months.

[*Table 2 near here*: *Demographic data*]

Table 2 Demographic data

Sociodemographic data	***Description***
Age	In years
Sex	Female, male, other
Height	In centimetres [cm]
Weight	In kilograms [kg]
Living status	Single/cohabitant
Diagnosis	RA, PsA, axSpA
Disease duration	In years
Work level	Employee, in flexi-job, working hours, self-employed or a student
Educational level	Primary school High school Short-term further education [< 3 years] Higher education [> 3 years] Long-term higher education [≥ 5 years]
Support schemes	§56, personal assistance, other*
Comorbidities	Diabetes Hypertension Heart disease Stroke Chronic obstructive pulmonary disease Cancer Osteoarthritis Osteoporosis Asthma Depression Anxiety Other

AxSpA = axial spondyloarthritis; PsA = psoriatic arthritis; RA = rheumatoid arthritis; *Legislative support and compensatory schemes.

[*Table 3 near here*: *Outcome measures*]

Table 3 Outcome measures

Variable	*Measure*	*Description*	*Reliability and validity*
Primary outcome			
Work ability	WAI single item [56]	A visual analogue scale that compares perceived work ability with lifetime best score. The score ranges from 0 (completely unable to work) to 10 (work ability at its best).	Good reliability and validity [57]
Key secondary outcomes			
Work hours per week		Number of work hours per week.	
Job loss		The participant is asked if they currently have a job.	
Absenteeism Presenteeism Overall work impairment Activity impairment	WPAI:GH [48]	Includes six questions that measure absenteeism, presenteeism and the effect of health problems on the participants' work ability and performance of regular activities during the previous 7 days. The WPAI:GH outcomes are expressed as time impaired [%], with higher numbers indicating greater impairment and less productivity, that is, worse outcomes because of health problems.	Good reliability and validity [48]
Work ability in relation to demands	WAI question 2 [56]	'How do you rate your current work ability with respect to the physical demands of your work?' and 'How do you rate your current work ability with respect to the mental demands of your work?' Include five response categories: 1 = very poor, 2 = rather poor, 3 = moderate, 4 = rather good and 5 = very good	Not applicable.
Job insecurity	WAI question 6 [56]	'Do you believe, according to your present state of health, that you will be able to do your current job two years from now?' Includes three response categories: 1 = unlikely, 2 = not certain and 3 = yes	Not applicable
Sick leave		Reported each month during the intervention period via text message reminders. Reported as number of days and hours.	Not applicable
Secondary outcomes			
Physical activity while at work		Standing or walking with lifting or carrying Physically demanding job Mostly stationary work Mostly standing or walking	*Not reported
Occupational balance	OBQ-11 [49, 50]	Measures the participant's experience of balance in the amount and variation of their everyday activities. Consists of 11 items and four response levels: 0 = completely disagree, 1 = tend to disagree, 2 = tend to agree and 3 = completely agree. Higher scores are better.	Not validated in Danish. A Swedish study concluded OBQ-11 has good reliability [49, 50]
Health-related quality of life	EQ-5D-5L [51]	Usual generic measure to assess population health. Includes five dimensions [mobility, self-care, usual activities, pain/discomfort, and anxiety/depression] with five response levels in each dimension: 1 = no problems, 2 = slight problems, 3 = moderate problems, 4 = severe problems and 5 = extreme problems; and a visual analogue scale: EQ-VAS, 0–100 [100 is best], reporting the participant's self-rated health.	Moderate to strong reliability and validity [51]
Pain	VAS pain [58]	Visual analogue scale, measuring self-rated pain at the moment. 0–10: 0 = no pain to10 = worst pain	Good reliability. Validity not confirmed [58]
	One question about pain experienced over		*Not reported

	the previous four weeks and the extent to which physical pain affected work and household chores [54]	Includes five response levels: 1 = no pain, 2 = slight pain, 3 = moderate pain, 4 = severe pain and 5 = extreme pain	
Fatigue	BRAF-NRSv2 [52]	Three separate numerical rating scales, scored from 0–10, higher is better, which cover three items: fatigue level (severity), effect on life (impact), and coping, anchored by 'no fatigue' and 'totally exhausted', 'no effect' and 'a great deal of effect', and 'very well' and 'not at all well', respectively	Valid and reliable for use in a Danish setting [52]
Physical activity	Over the previous year, how would you describe your physical activity?	Four response categories with one response opportunity: 1 = hard exercise, 2 = sports, heavy gardening, etc., 3 = walking, cycling, etc. and 4 = seated activities	*Not reported
	How many days a week are you physically active for at least 30 minutes? [54]	Eight response levels: 0–7 days	
Well-being	WHO-5 Well-being Index [53]	The 5-item Well-being Index is a generic rating scale measuring subjective well-being. The items are: 1 = 'I have felt cheerful and in good spirits', 2 = 'I have felt calm and relaxed', 3 = 'I have felt active and vigorous', 4 = 'I woke up feeling fresh and rested' and 5 = 'My daily life has been filled with things that interest me'. Respondents are asked to rate how well each of the five statements applies to them when considering the previous 14 days. Each of the five items is scored from 5 = all the time to 0 = none of the time. The raw score ranges from 0 to 25 multiplied by 4 to give a final score from 0 = worst imaginable well-being to 100 = best imaginable well-being.	Adequate validity [53]
Sleep	How many hours and minutes did you sleep during a normal night the previous 4 weeks?	Three response levels: 1 = yes, 2 = yes, but not often enough, and 3 = no, never.	*Not reported
	During the previous 4 weeks, did you get enough sleep to feel rested?		
	Questions about how you sleep: Did you have trouble falling asleep?		
	Did you wake up several times at night and have difficulty falling asleep?	Four response levels: 1 = not in the last four weeks, 2 = less than once a week, 3 = 1–2 times a week and 4 = three or more times a week	
	Did you wake up early and were unable to fall asleep again?		
	Did you sleep restlessly? [54]		

BRAF-NRSv2 = Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales version 2; EQ-5D-5L = European Quality of Life-5 Dimensions-5 Levels; EQ-VAS = EuroQol-visual analogue scales; OBQ-11 = Occupational Balance Questionnaire; WAI = Work Ability Index; WPAI:GH = Work Productivity and Activity Impairment Questionnaire: General Health; WHO = World Health Organization: * from a Danish national health profile questionnaire 'How are you?'[54]

Sample size

At DHR, approximately 1,800 patients with IA are connected to the outpatient department, and it is estimated that 50% undertake paid work. From the feasibility test results, we assume that 20% consider themselves to be at risk of losing their job, leading to 180 potential participants. Based on the feasibility study, we assume that one-third of these individuals will meet the inclusion criteria and agree to participate. In addition, we anticipate a low dropout rate of 10% based on the feasibility test. Assuming a standard deviation (SD) of 3 points on the Work Ability single item scale, a statistical power of 80%, and a significance level (alpha) of 0.05, the study is designed to detect a difference of 2.5 points on the Work Ability single-item scale [34]. Thus, at least 25 participants are needed in each group. With an estimated 10% dropout rate, 28 participants are needed in each group. Preliminary results from the feasibility test showed that, on average, it is feasible to include 1–2 participants per week. Therefore, the recruitment period is expected to be one year, at maximum.

Statistics

Results from descriptive statistics will be reported by group as means and SD, or medians and interquartile ranges, depending on the distribution of the empirical data. Categorical variables will be reported as absolute counts and proportions (percentages) for each group. Differences in the primary and key secondary continuous outcomes will be analysed according to the intention-to-treat population using repeated-measures linear mixed models, including a factor for the treatment group (2 levels) and time, the interaction between both, and adjustments for baseline values and the stratification factor (diagnosis). For all mixed models, participant-specific random intercepts will be included, as well as random slopes if these improve the model fit significantly. The binary outcomes will be analysed using logistic mixed models, including a factor for the group and

adjustment for the stratification factor. Odds ratios with 95% confidence intervals will be estimated, converted into approximate risk ratios and interpreted as number needed to treat (NNT) when appropriate. Mixed models incorporate all available data, making them particularly advantageous in handling missing data, assuming the missing data are missing at random. The intention-to-treat analysis will be followed by a per-protocol analysis. *P*-values <0.05 are considered significant. All *p*-values and 95% confidence intervals will be two sided. We will not apply explicit adjustments for multiplicity but will perform prioritised analyses of key secondary outcomes. Before enrolment of the last participant, a full statistical analysis plan will be developed in collaboration with a statistician and uploaded to Clinicaltrials.gov.

ETHICS AND DISSEMINATION

The participants will be informed verbally and in writing about the study before they provide their written consent to participate prior to the first consultation. The leaflet, '*Research subjects' rights in health science research*', published by the Danish National Committee on Health Research Ethics, will be provided to all participants. The Regional Committees on Health Research Ethics waived the need for a formal approval (Journal number S-20232000–3). Data will be stored and managed in the research support system, OPEN, hosted by the Region of Southern Denmark. OPEN adheres to the European General Data Protection Regulations and the Danish data protection law [59, 60].

PERSPECTIVES

If the results from the RCT are significant, we will conduct cost-effectiveness and cost-utility analyses, in collaboration with health economists at the University of Southern Denmark. The cost-utility analysis will apply quality-adjusted life years, making use of the EQ-5D-5L instrument,

based on Danish societal weights for the calculation of quality-adjusted life year [51]. The cost-effectiveness analysis will apply days of sickness absenteeism and work ability as effect measures. The results from this RCT can be generalized to other settings with competencies in rehabilitation and where access to the interdisciplinary team can be organised and proper reimbursement is available.

AUTHOR CONTRIBUTIONS

The first author, Christina Merete Tvede Madsen, took the lead in writing the manuscript in cooperation with the other two authors, Jette Primdahl and Jeanette Reffstrup Christensen. All authors read and approved the final manuscript. Christina Merete Tvede Madsen is responsible for the overall content as guarantor.

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COMPETING INTERESTS

None declared.

FIGURE AND TABLE LEGENDS

Figure 1 Flowchart of the study

Figure 2 The WORK-ON intervention

Table 1 SPIRIT Flowchart: Schedule of assessments

Table 2 Demographic data

Table 3 Outcome measures

REFERENCES

1. Black RJ, Brooks PM, Kopansky-Giles DR, Abbasi-Kangevari M, Abolhassani H, Adesina MA, et al. Global, regional, and national burden of rheumatoid arthritis, 1990–2020, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. The Lancet Rheumatol. 2023;5[10]:e594-e610.
2. Scotti L, Franchi M, Marchesoni A, Corrao G. Prevalence and incidence of psoriatic arthritis: A systematic review and meta-analysis. Sem Arthrit Rheum. 2018;48[1]:28-34.
3. Sieper JP, Poddubnyy DP. Axial spondyloarthritis. The Lancet [British edition]. 2017;390[10089]:73-84.
4. Mairey IP, Bihrmann K, Holmberg T, Davidsen M, Lassen TH. Muskel- og skeletlidelser i Danmark. Syddansk Universitet; 2022.
5. Pedersen JK, Svendsen AJ, Hørslev-Petersen K. Incidence of Rheumatoid Arthritis in the Southern part of Denmark from 1995 to 2001. Open Rheumatol J. 2007;1[1]:18-23.
6. Soussi BG, Cordtz RL, Kristensen S, Bork CS, Christensen JH, Schmidt EB, et al. Incidence and prevalence of rheumatoid arthritis in Denmark from 1998 to 2018: a nationwide register-based study. Scand J Rheumatol. 2022;51[6]:481-9.
7. Finckh A, Gilbert B, Hodkinson B, Bae S-C, Thomas R, Deane KD, et al. Global epidemiology of rheumatoid arthritis. Nat Rev Rheumatol. 2022;18[10]:591-602.
8. Egeberg A, Kristensen LE, Thyssen JP, Gislason GH, Gottlieb AB, Coates LC, et al. Incidence and prevalence of psoriatic arthritis in Denmark: a nationwide register linkage study. Ann Rheum Dis. 2017;76[9]:1591-7.

9. Stolwijk C, van Onna M, Boonen A, van Tubergen A. Global Prevalence of Spondyloarthritis: A Systematic Review and Meta-Regression Analysis. Arthritis Care Res [Hoboken]. 2016;68[9]:1320-31.
10. www.danskreumatologi.dk. [cited 2024 19.09].
11. Nygaard A, Ljungdalh PS, Iachina M, Nikolov TN, Schiøttz-Christensen B. Incidence of ankylosing spondylitis and spondyloarthritis in 2000-2013: a nationwide Danish cohort study. Scand J Rheumatol. 2020;49[1]:21-7.
12. Ishida M, Kuroiwa Y, Yoshida E, Sato M, Krupa D, Henry N, et al. Residual symptoms and disease burden among patients with rheumatoid arthritis in remission or low disease activity: a systematic literature review. Mod Rheumatol. 2018;28[5]:789-99.
13. Smolen JS, Aletaha D, Barton A, Burmester GR, Emery P, Firestein GS, et al. Rheumatoid arthritis. Nat Rev Dis Primers. 2018;4:18001.
14. Madsen CMT, Bisgaard SK, Primdahl J, Christensen JR, von Bülow C. A Systematic Review of Job Loss Prevention Interventions for Persons with Inflammatory Arthritis. J Occup Rehabil. 2021;31[4]:866-85.
15. Verstappen SMM, Watson KD, Lunt M, McGrother K, Symmons DPM, Hyrich KL, et al. Working status in patients with rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis: Results from the British Society for Rheumatology Biologics Register. Rheumatology. 2010;49[8]:1570-7.
16. Sokka T, Kautiainen H, Pincus T, Verstappen SMM, Aggarwal A, Alten R, et al. Work disability remains a major problem in rheumatoid arthritis in the 2000s: Data from 32 countries in the QUEST-RA Study. Arthrit Res Ther. 2010;12[2]:R42-R.
17. Escorpizo R, Burghardt E, Richards C. Type of job, personal factors, and disease status are important contextual factors when measuring worker productivity in people with arthritis: a Delphi study. Disabil Rehabil. 2020;42[24]:3496-503.
18. Verstappen SMMP. Rheumatoid arthritis and work: The impact of rheumatoid arthritis on absenteeism and presenteeism. Best Pract Res: Clinical Rheumatology. 2015;29[3]:495-511.
19. Hansen SM, Hetland ML, Pedersen J, Ostergaard M, Rubak TS, Bjorner JB. Effect of rheumatoid arthritis on longterm sickness absence in 1994-2011: A danish cohort study. J Rheumatol. 2016;43[4]:707-15.
20. Hansen SM, Hetland ML, Pedersen J, Østergaard M, Rubak TS, Bjorner JB. Work ability in rheumatoid arthritis patients: a register study on the prospective risk of exclusion and probability of returning to work. Rheumatology [Oxford, England]. 2017;56[7]:1135-43.
21. Wynne-Jones G, Chen Y, Croft P, Peat G, Wilkie R, Jordan K, et al. Secular trends in work disability and its relationship to musculoskeletal pain and mental health: a time-trend analysis using five cross-sectional surveys [2002–2010] in the general population. Occup Environmen Med. 2018;75[12]:877-83.
22. Boonen A, Webers C, Butink M, Barten B, Betteridge N, Black DC, et al. 2021 EULAR points to consider to support people with rheumatic and musculoskeletal diseases to participate in healthy and sustainable paid work. Ann Rheum Dis. 2022;82[1]:57-64.
23. Kirkeskov L, Bray K. Employment of patients with rheumatoid arthritis - a systematic review and meta-analysis. BMC Rheumatol. 2023;7[1]:41-.
24. Jørgensen MD, M. Christensen, AI. Buhelt, LP. Tolstrup, JS. Leddegigt i Danmark. Nøgletal 2018. [Rheumatoid Arthritis in Denmark. Key numbers 2018]. Statens

Institut for Folkesundhed, SDU [National Institute for Public Health, University of Southern Denmark]; 2018.
25. Holland P, Collins AM. "Whenever I can I push myself to go to work": a qualitative study of experiences of sickness presenteeism among workers with rheumatoid arthritis. Disabil Rehabil. 2018;40[4]:404-13.
26. Feddersen H, Mechlenborg Kristiansen T, Tanggaard Andersen P, Hørslev-Petersen K, Primdahl J. Juggling identities of rheumatoid arthritis, motherhood and paid work - a grounded theory study. Disabil Rehabil. 2019;41[13]:1536-44.
27. Codd Y, Coe Á, Mullan RH, Kane D, Stapleton T. 'You don't want to be seen as a burden' experiences of working with early inflammatory arthritis: a qualitative study. Disabil Rehabil. 2023;45[17]:2761-9.
28. Madsen CMT, Christensen JR, Bremander A, Primdahl J. Perceived challenges at work and need for professional support among people with inflammatory arthritis - a qualitative interview study. Scand J Occup Ther. 2021:1-10.
29. Madsen CMT, Primdahl J, Bremander A, Eggen L, Christensen JR. Developing a complex vocational rehabilitation intervention for patients with inflammatory arthritis: the WORK-ON study. BMC Health Serv Res. 2023;23[1]:739.
30. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. 2021;374:n2061.BMJ
31. Madsen CMT, Christensen JR, Bremander A, Eggen L, Primdahl J. Feasibility test of WORK-ON - a complex vocational rehabilitation for people with chronic inflammatory arthritis. BMC Musculoskelet Disord 2024.
32. Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ : British Medical Journal. 2013;346:e7586.
33. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Intern Med. 2013;158[3]:200-7.
34. Sell L, Bültmann U, Rugulies R, Villadsen E, Faber A, Søgaard K. Predicting long-term sickness absence and early retirement pension from self-reported work ability. Int Arc Occup Environ Health. 2009;82[9]:1139-.
35. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ [Online]. 2017;358:j3453-j.
36. Work Ability Index 2019 [Available from: http://www.arbeitsfaehigkeit.uni-wuppertal.de/index.php?wai-online-en.
37. Xiao L, Lavori PW, Wilson SR, Ma J. Comparison of dynamic block randomization and minimization in randomized trials: a simulation study. Clinical trials [London, England]. 2011;8[1]:59-69.
38. Open Patient data Explorative Network 2023 [Available from: https://open.rsyd.dk/.
39. Hetland ML. **DANBIO—powerful research database and electronic patient record**. Rheumatology. 2011;50[1]:69-77.
40. Danish Centre for Expertise in Rheumatology 2024 [Available from: https://centerforvidenomgigt.dk/samarbejde/kommuner/fyraftensmoede/.
41. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health [1971]. 2014;104[8]:e25-e31.

42. Wagman P, Håkansson C, Björklund A, Hhj Afr, välfärd HHJKoliho, Högskolan i J, et al. Occupational balance as used in occupational therapy: A concept analysis. Scand J Occup Ther. 2012;19[4]:322-7.
43. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision making: multistage consultation process. BMJ. 2017;359:j4891-j.
44. Strohsal KD, Robinson PJ, Gustavsson T. Brief Interventions for radical behavior change: Principles and practice of focused acceptance and commitment therapy. Oakland, CA: New Harbinger Publications; 2021.
45. Engel GL. The Need for a New Medical Model: A Challenge for Biomedicine. Science [American Association for the Advancement of Science]. 1977;196[4286]:129-36.
46. Rollnick S, Miller WR, Butler C. Motivational interviewing in health care: helping patients change behavior. Second ed. New York, NY: The Guilford Press; 2022.
47. Lundgren T, Louma J, Dahl J, Strohsal K, Melin L. The Bull's-Eye Values Survey: A Psychometric Evaluation. Cognitive and Behavioral Practice. 2012;19.
48. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. PharmacoEconomics. 1993;4[5]:353-65.
49. Morville A-L, Håkansson C, Wagman P, Hansen T, editors. Validity of the Danish version of Occupational Balance Questionnaire [OBQ-DK]2016.
50. Håkansson C, Wagman P, Hagell P. Construct validity of a revised version of the Occupational Balance Questionnaire. Scand J Occup Ther. 2020;27[6]:441-9.
51. Jensen MB, Jensen CE, Gudex C, Pedersen KM, Sørensen SS, Ehlers LH. Danish population health measured by the EQ-5D-5L. Scand J Pub Health. 2021:14034948211058060-.
52. Primdahl J, Esbensen BA, Pedersen AK, Bech B, de Thurah A. Validation of the Danish versions of the Bristol Rheumatoid Arthritis Fatigue Multi-Dimensional Questionnaires [BRAFs]. Scand J Rheumatol. 2021;50[5]:351-9.
53. Topp CW, Østergaard SD, Søndergaard S, Bech P. The WHO-5 Well-Being Index: A Systematic Review of the Literature. Psychother Psychosom. 2015;84[3]:167-76.
54. The National Healthprofile [How are you?] 2021 [Available from: https://www.sdu.dk/da/sif/forskning/projekter/den_nationale_sundhedsprofil.
55. Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, et al. Validation of Digital Visual Analog Scale Pain Scoring With a Traditional Paper-based Visual Analog Scale in Adults. J Am Acad Orthop Surg Glob Res Rev. 2018;2[3]:e088.
56. Tuomi K IJ, Jahkola A, Katajarinne L, Tilkki A. Work Ability Index, 2nd Edition: Finish Institute of Occupational Health, Helsinki; 1998.
57. Gupta N, Jensen BS, Søgaard K, Carneiro IG, Christiansen CS, Hanisch C, et al. Face validity of the single work ability item: comparison with objectively measured heart rate reserve over several days. Int J Environ Res Pub Health. 2014;11[5]:5333-48.
58. Boonstra AM, Schiphorst Preuper HR, Reneman MF, Posthumus JB, Stewart RE. Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain. Int J Rehabil Res. 2008;31[2]:165-9.
59. European General Data Protection Regulations 2023 [Available from: https://gdpr.eu/what-is-gdpr/.
60. Datatilsynet. Generelt om databeskyttelse 2018 [Available from: https://www.datatilsynet.dk/generelt-om-databeskyttelse/.

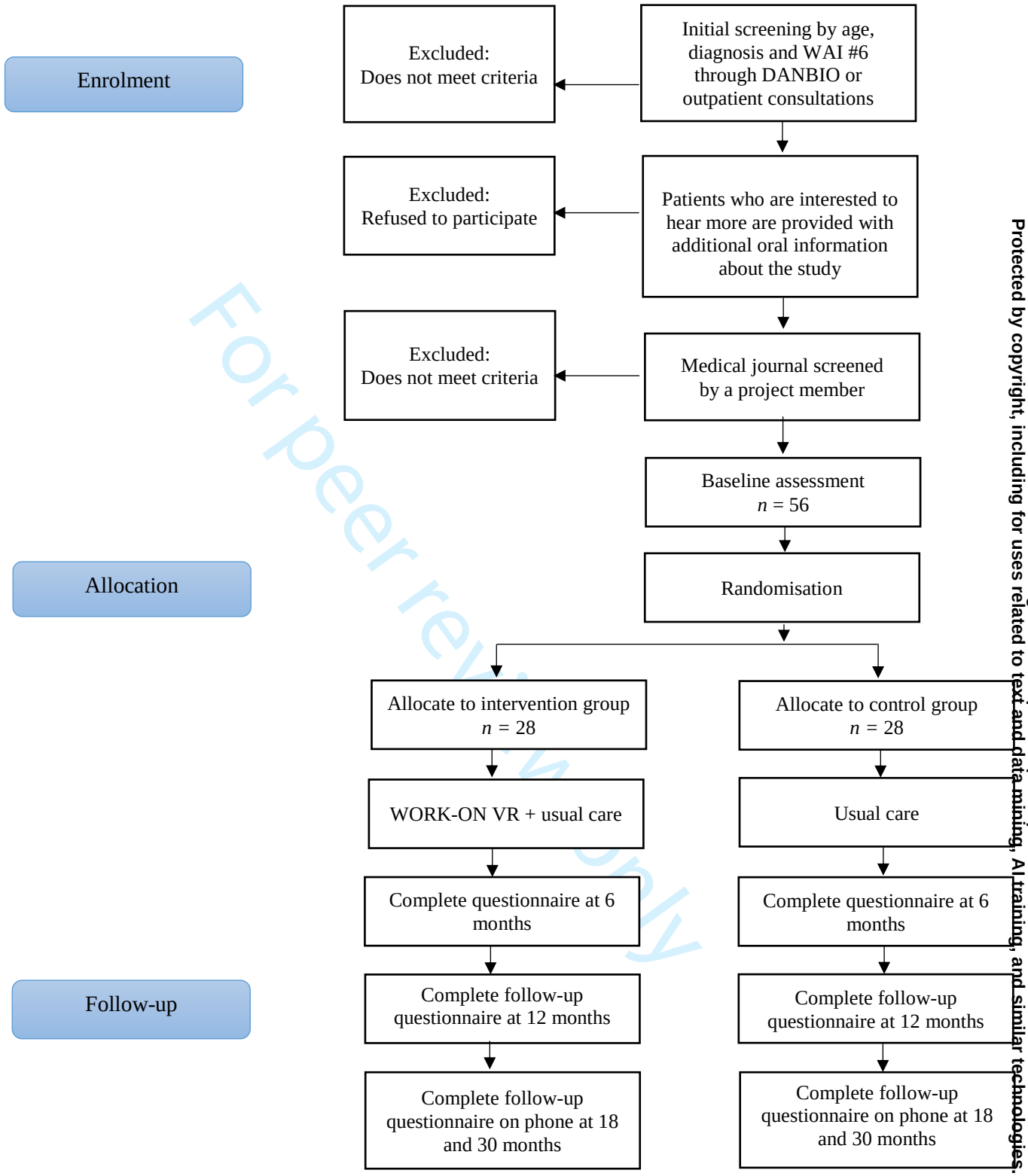

Figure 1 Flowchart of the study

WAI: Work Ability Index; DANBIO: Danish national rheumatology quality database

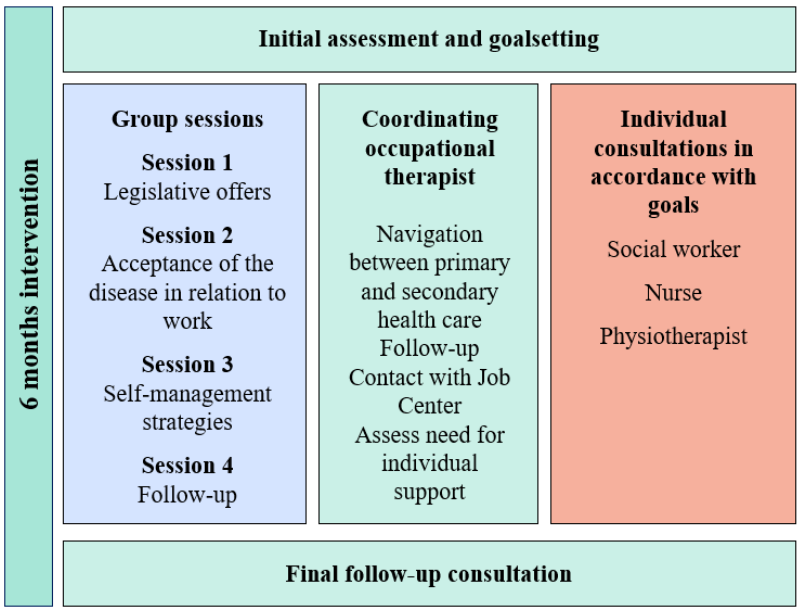

Figure 2 Illustration of the WORK-ON intervention