Statistical Analysis Plan

NCT06299917: WORK-ON Vocational Rehabilitation for People With Inflammatory Arthritis

Full title:
WORK-ON – vocational rehabilitation for persons with inflammatory arthritis – a randomized controlled trial

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Administrative information

Title

WORK-ON – vocational rehabilitation for persons with inflammatory arthritis – a randomized controlled trial

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Background

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 three diagnoses as chronic inflammatory arthritis (IA). IA comprises autoimmune diseases characterised by joint swelling, tenderness, pain, fatigue, stiffness in the joints, and reduced mobility (3-5). Despite major advances in the pharmacological treatment, people with IA still have unmet needs (6). Many experience fatigue, sleep problems, psychological distress, and problems with participation in everyday activities, including paid work (4, 7).

Up to 40% lose their job in the first few years after being diagnosed with IA (8, 9). Thus, this group of people needs early support to enable them to retain their jobs as it is difficult to resume work after long-term sick leave (10, 11). In 2013, people with RA were absent from work for 5.6 more days than those without RA in Denmark (12). This corresponds to more than 50,000 days of sickness absence per year and a productivity loss of DKK 67.3 million (approximately EUR 9 million) (12). A similar burden is expected for people with PsA and axSpA.

Being able to work is of great importance to most individuals' identity and quality of life (13, 14). People with IA struggle to find a balance between their disease, paid work and other aspects of everyday life (14, 15). 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 (7). 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 (7).

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 (16). The development of WORK-ON was based on the Medical Research Council's updated framework for developing and evaluating complex interventions (17). The development process involved relevant stakeholders including patient research partners (PRPs) and various professionals from the Danish Hospital for Rheumatic Diseases (DHR), municipalities and researchers from the University of Southern Denmark (SDU). As part of the development, we created a logic model to help explain the associations between the resources and outcomes of the intervention.

Between 2022-2023, we tested the feasibility of the WORK-ON intervention in 19 participants (18). Based on the results from the feasibility study (19), as well as qualitative evaluations from patients and rehabilitation clinicians (to be published later), we have adjusted the initial version of WORK-ON (16). The adjusted WORK-ON includes an additional group session, increases focus on the reduction of sickness absence, the management of fatigue, and the involvement of the participants' employers (20).

Objectives

The primary objective of this trial is to test the efficacy of the WORK-ON intervention as an add-on to usual care compared to usual care.

Study design

The study is planned as a single center RCT with a two-group parallel design.

Control group (Usual care)

Usual care comprises planned outpatient consultations every 3 to 12 months, depending on the patient's needs. The consultations are held with a rheumatologist, physician or a rheumatology nurse. In addition, the participants have access to support from the rheumatology nurses via a telephone helpline and they can call the secretaries if they experience a flare up and need an acute consultation by a physician. The planned consultations include a review of blood tests; joint examinations; a review of completed standard patient reported outcome measures in DANBIO (21); review of the side effects of, and adherence to, the pharmacological treatment; and evaluation of whether pharmacological adjustment is necessary. The nurses will occasionally provide limited tailored patient education on the management of the disease, medications and symptoms. 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 (22).

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), including an initial bio-psycho-social assessment and goal setting guided by the Work Experience Survey for Patients with Rheumatic Conditions, which is a survey targeting problems at work (23), four face-to-face group sessions and need-based individual consultations with different rehabilitation clinicians (RC) (see Figure 1). WORK-ON was developed using the following theories and approaches: self-management (24), occupational balance (25), shared decision-making (26), and Focused Acceptance and Commitment Therapy (FACT) (27). All rehabilitation clinicians at the DHR use a biopsychosocial approach in their work (28) and are trained in FACT and motivational interviewing (29).

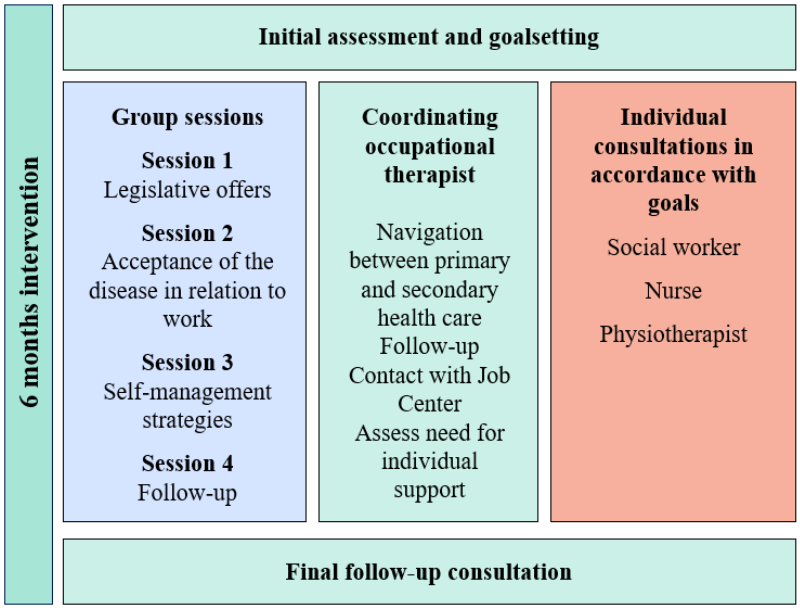


Figure 1 Illustration of the WORK-ON intervention

Randomization 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. Screening and recruitment started 01.03.2024. Last patient first visit is expected to be 01.03.2025 and last patient last visit is expected to be 01.09.2025. Typically, block randomisation is used to secure a balanced randomisation and to ensure the randomisation is unpredictable. Block randomisation in blocks between 2 and 6 are performed using the Research Electronic Data Capture (REDCap) hosted by the Open Patient data Explorative Network (OPEN) (30). An algorithm calculates the balance within and between blocks (31). 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.

Sample size and power considerations

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 change of 2.5 points on the Work Ability single-item scale (32). Thus, at least 25 participants are needed in each group. With an estimated 10% dropout rate, 28 participants are needed in each group.
At DHR, approximately 1,800 patients with IA are connected to the outpatient department, and it is estimated that 50% undertake paid work. Based on the feasibility study, we assume that 20% consider themselves to be at risk of losing their job, leading to 180 potential participants. We assume that one-third of these will meet the inclusion criteria and agree to participate based on our

experiences from the feasibility study. The feasibility test showed that, on average, it is feasible to include and manage 1–2 participants per week. Therefore, the recruitment period is expected to be approximately one year.

Framework

The trial is based on a two-sided superiority framework where the primary null hypothesis is that there is no immediate change in work-ability measured by the WAI single item (33) from baseline to 12 months after baseline. A secondary hypothesis is that there is no change in job loss at 18 and 30 months after baseline and sick leave from baseline to 6 after baseline. Work ability and job loss are associated and work ability can be considered as a proxy for job loss (18, 32).

For secondary outcomes, we expect an improvement in the interventions group 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.

Timing of outcome assessments

Table 1 SPIRIT Flowchart: Schedule of assessments

Time point	Baseline	6 months after baseline	12 months after baseline	18 months after baseline	30 months after baseline	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	
Sick leave						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 during the first six months.

Confidence intervals and P values

All statistical analyses on the primary and key secondary endpoints will be accompanied by two-sided % Confidence Intervals (CI) and corresponding *P*-values. Significance level is set to 95% (*P*-values <0.05 are considered significant).

We will not apply explicit adjustments for multiplicity but will perform prioritised analyses of key secondary outcomes.

Analysis methods

Changes in the primary and key secondary continuous outcomes (WAI single item, WAI question 2 and 6, work hours per week, WPAI:GH, sick leave, OBQ-11, EQ-5D-5L, VAS pain, BRAF-NRSv2, physical activity, WHO-5 Well-being Index and sleep), 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. Model assumptions, such as normality of residuals and homoscedasticity, will be checked. In cases of minor violations, bootstrap methods or robust standard errors will be applied to ensure valid statistical inference. In the case of major violations of model assumptions, alternative strategies will be considered.

The binary outcome (job loss) 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. An intention-to-treat analysis will be followed by a per-protocol analysis. Lost to follow-up and missing data for various reasons is difficult to avoid in randomized (pragmatic) trials. The mixed effect models will accommodate for missing data under the missing at random (MAR) assumption, meaning that missingness can depend on observed data but not on unobserved data. This will allow for inclusion of all available data in the analyses and thus reducing potential bias.

The least squares mixed means, along with their corresponding standard errors, will be reported for each group based on the estimates derived from the repeated measures using mixed effects models. All intergroup differences will be explored by the main statistical approach including the interaction between time and group. Intergroup differences at various timepoints will be available as least squares means adjusted for baseline levels to minimize random variation.

The per-protocol population from the intervention group will be defined as participants who participated in minimum three out of the four planes group. The participants from the control group

will be considered per protocol individuals if data is available from all five time points (baseline, 6, 12, 18 and 30 months after baseline).

We will summarize the number of group sessions each participant attends and the number, time use and form of individual sessions with the coordinating occupational therapist, a physiotherapist, social worker and nurse.

Screening data

Table 2 Sociodemographic 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.

Eligibility

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?' (34).
- 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).

Recruitment

All patients with IA complete questionnaires for the national quality database DANBIO (21) at a touchscreen or at a mobile phone, tablet or computer before each outpatient consultation at the DHR. An initial screening based on age (≥ 18) and diagnosis (RA, axSpA or PsA) is performed based on the patients' responses to the questionnaires from DANBIO. The regular questionnaires are followed by a question whether the patient is in paid work or not or studying. If yes, question #6 from the Work Ability Index questionnaire (WAI) (34) follows 'Do you believe, according to your present state of health, that you will be able to do your current job two years from now?'. Patients who answer "unlikely" or "not certain" are prompted to insert their phone number if they are interested to hear about a new offer for support, the WORK-ON. Further, rheumatologists and nurses in the outpatient clinic can introduce WORK-ON during consultations with eligible patients. Interested patients are contacted by phone and screened for eligibility during the following weeks. Eligible patients are offered further information about the study by phone and the written participant information and consent material are sent to the patients e-Boks to allow time for consideration. If the patient wants to participate, a written consent is collected through REDCap.

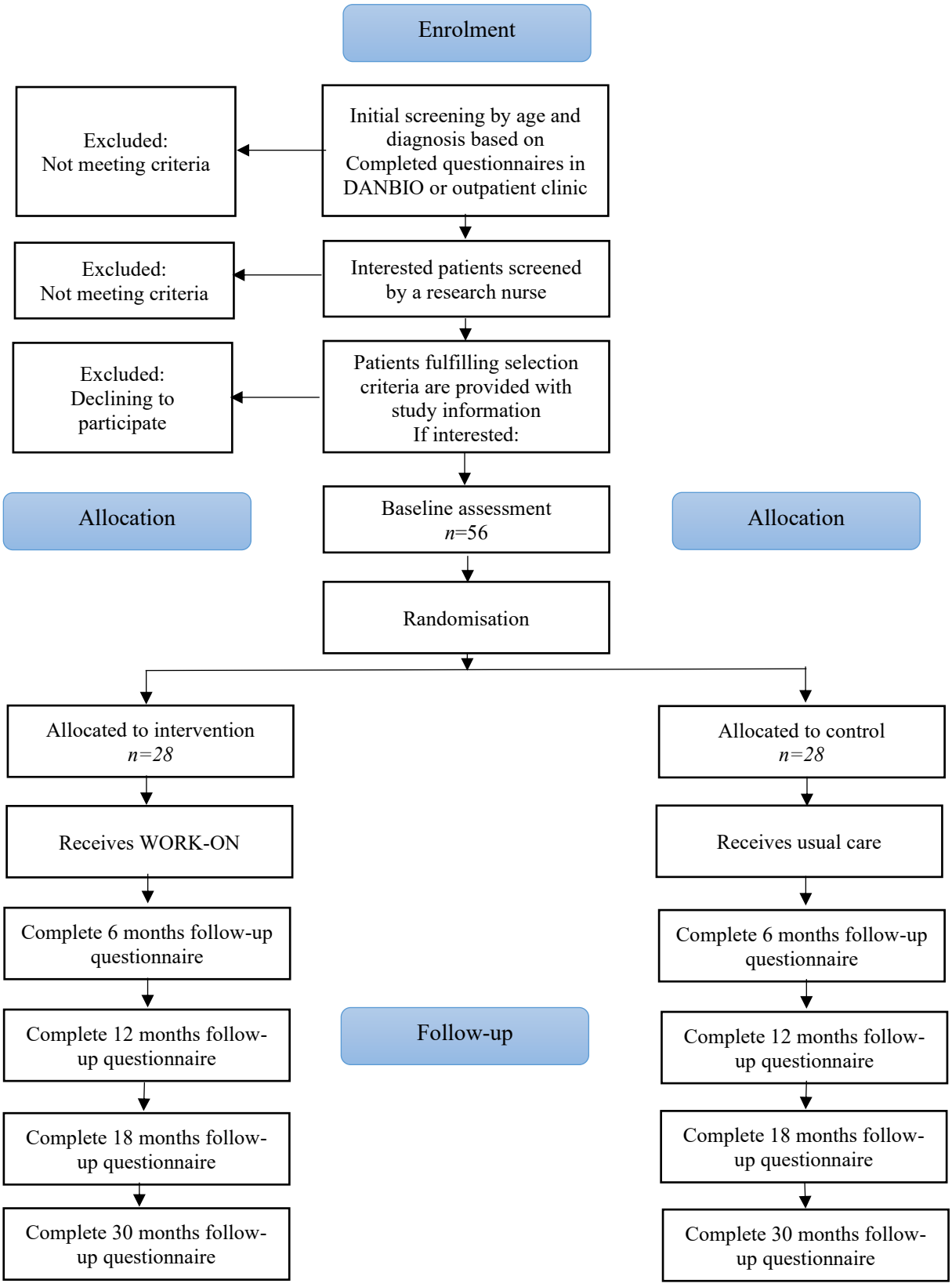


Figure 2 Flowchart of participants

Withdrawal/ Follow-up

If a participant wants to withdraw from the study, this is possible until analysis of data and the timing is registered. We will still try to collect outcome measures at the scheduled timepoints if the participant agrees.

Baseline patient characteristics and outcome definitions

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. For information on sociodemographic data, please see Table 2.

Table 3 Outcome measures

Primary outcome			
Variable	*Measure*	*Description*	*Reliability and validity*
Work ability	WAI single item (33)	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 (35)
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 (36)	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 (36)
Work ability in relation to demands	WAI question 2 (33)	'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 (33)	'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
Sickness absenteeism		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 (37, 38)	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 (37, 38)
Health-related quality of life	EQ-5D-5L (39)	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 (39)
Pain	VAS pain (40) One question about pain experienced over the previous four weeks and the extent to which physical pain affected work and household chores (41)	Visual analogue scale, measuring self-rated pain at the moment. 0–10: 0 = no pain to10 = worst pain Includes five response levels: 1 = no pain, 2 = slight pain, 3 = moderate pain, 4 = severe pain and 5 = extreme pain.	Good reliability. Validity not confirmed (40).
Fatigue	BRAF-NRSv2 (42)	Three separate numerical rating scales, scored from 0–10, higher is better, which cover three items: fatigue level (severity), effect on life	Valid and reliable for use in a Danish setting (42)

		(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	**Not reported
	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 (43)	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 (43)
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?	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	
	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? (41)

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?'(41)

Adverse events and harms

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. Adverse events and mortality will be registered. Umiddelbart er der ingen adverse events.

Statistical software

STATA version 17

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