

Original research

Effectiveness of adding motivational interviewing or a stratified vocational advice intervention to usual case management on return to work for people with musculoskeletal disorders: the MI-NAV randomised controlled trial

Fiona Aanesen (\bigcirc , ¹ Margreth Grotle (\bigcirc , ^{2,3} Tarjei Langseth Rysstad (\bigcirc , ¹ Anne Therese Tveter (\bigcirc , ^{1,4} Alexander Tingulstad (\bigcirc , ¹ Ida Løchting (\bigcirc , ³ Milada C Småstuen (\bigcirc , ⁵ Maurits W van Tulder (\bigcirc , ⁶ Rigmor Berg (\bigcirc , ^{7,8} Nadine E Foster (\bigcirc , ^{9,10} Gwenllian Wynne-Jones (\bigcirc , ¹⁰ Gail Sowden (\bigcirc , ^{10,11} Egil Fors (\bigcirc , ¹² Gunnhild Bagøien (\bigcirc , ¹³ Roger Hagen (\bigcirc , ^{14,15,16} Kjersti Storheim (\bigcirc , ^{1,3} Britt Elin Øiestad (\bigcirc)

ABSTRACT

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For numbered affiliations see end of article.

Correspondence to

Dr Fiona Aanesen, Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, 0130 Oslo, Norway; fionaa@oslomet.no

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To cite: Aanesen F, Grotle M, Rysstad TL, *et al. Occup Environ Med* Epub ahead of print: [please include Day Month Year].doi:10.1136/ oemed-2022-108637 **Objectives** To evaluate if adding motivational interviewing (MI) or a stratified vocational advice intervention (SVAI) to usual case management (UC), reduced sickness absence over 6 months for workers on sick leave due to musculoskeletal disorders.

Methods We conducted a three-arm parallel pragmatic randomised controlled trial including 514 employed workers (57% women, median age 49 (range 24–66)), on sick leave for at least 50% of their contracted work hours for ≥7 weeks. All participants received UC. In addition, those randomised to UC+MI were offered two MI sessions from social insurance caseworkers and those randomised to UC+SVAI were offered vocational advice from physiotherapists (participants with low/medium-risk for long-term sickness absence were offered one to two sessions, and those with high-risk were offered three to four sessions).

Results Median sickness absence was 62 days, (95% CI 52 to 71) in the UC arm (n=171), 56 days (95% CI 43 to 70) in the UC+MI arm (n=169) and 49 days (95% CI 38 to 60) in the UC+SVAI arm (n=169). After adjusting for predefined potential confounding factors, the results showed seven fewer days in the UC+MI arm (95% CI -15 to 2) and the UC+SVAI arm (95% CI -16 to 1), compared with the UC arm. The adjusted differences were not statistically significant.

Conclusions The MI-NAV trial did not show effect on return to work of adding MI or SVAI to UC. The reduction in sickness absence over 6 months was smaller than anticipated, and uncertain due to wide CIs. **Trial registration number** NCT03871712.

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Two previous trials have tested the effect of motivational interviewing (MI), to facilitate return to work (RTW), for people with musculoskeletal disorders, with conflicting results.
- ⇒ One previous trial has shown that a low intensity vocational advice intervention, reduced sickness absence by 5 days over 4 months for workers with musculoskeletal disorders in the UK.

WHAT THIS STUDY ADDS

⇒ The MI-NAV trial showed that adding MI or a stratified vocational advice intervention (SVAI) to usual case management resulted in a non-statistically significant reduction in sickness absence over 6 months for workers on sick leave due to musculoskeletal disorders in Norway.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The MI and SVAI interventions should be replicated in future trials, powered to detect smaller differences between groups. Prior to conducting new trials, a minimal important difference for RTW outcomes should be decided through involvement of patients and other stakeholders.

Norway, musculoskeletal disorders are the main cause of sick leave,² and are associated with a significant burden on individuals and economic costs to society.³ Work disability and sick leave are influenced by healthcare, individual, social and work-related factors.⁴ To address the large burden related to sick leave, effective individually-tailored

INTRODUCTION

Musculoskeletal disorders are the main contributors to years lived with disability worldwide.¹ In

interventions targeting barriers to return to work (RTW) are needed. $^{\rm 5}$

One intervention recommended in vocational rehabilitation is motivational interviewing (MI).⁶ MI is a person-centred counselling style aimed at increasing motivation for change.⁷ MI has been successful in increasing treatment adherence for people with musculoskeletal disorders⁸ and chronic pain conditions,⁹ and can be effective when provided as a brief intervention.¹⁰ However, there is sparse evidence on the effectiveness of MI to facilitate RTW.¹¹¹²

Another intervention to help workers with musculoskeletal disorders to RTW, was developed and tested in the Study of Work And Pain (SWAP) trial in the UK.¹³ The vocational advice intervention was based on the principles of case management to help participants overcome obstacles to RTW.¹³ The SWAP intervention was offered to patients with musculoskeletal disorders consulting in general practices, who were struggling at work or on sick leave for less than 6 months.

Providing interventions to all workers on sick leave is extremely resource demanding, and may not be justified in a Norwegian context given that approximately 80% of the workers RTW during the first 8 weeks of sick leave.² The optimal time window for providing vocational interventions for people with musculoskeletal disorders seems to be between weeks 8 and 12 of sick leave.¹⁴

It is not known if the SWAP intervention could be effective when delivered as a stratified intervention, tailored according to risk for long-term sickness absence. Therefore, we aimed to assess if adding either MI or a stratified vocational advice intervention (SVAI) to usual case management (UC) reduced sickness absence days over 6 months, for workers with musculoskeletal disorders on sick leave for more than seven consecutive weeks. We conducted two independent comparisons:

- 1. UC compared with UC+MI.
- 2. UC compared with UC+SVAI.

METHOD

Design

The MI-NAV trial was a three-arm, pragmatic randomised controlled trial (RCT) with 6 months follow-up, including an internal pilot. We conducted the trial in cooperation with the Norwegian Labour and Welfare Administration (NAV). The methods have been reported previously in the study protocol,¹⁵ in the process evaluation of the SVAI,¹⁶ and in the fidelity evaluation of the MI intervention.¹⁷ The Norwegian Centre for Research Data approved the project (861249), and the trial was conducted in accordance with the Helsinki declaration and the General Data Protection Regulation (GDPR). The trial is reported according to the Consolidated Standards of Reporting Trials extension statement for reporting multi-arm trials,¹⁸ and CONSORT and SPIRIT Extension for RCTs Revised in Extenuating Circumstanses, (CONSERVE).¹⁹

Participants

Participants were workers aged 18–67 years, employed full-time or part-time, on sick leave with musculoskeletal disorders for at least 50% of their contracted work hours for at least seven consecutive weeks. We included workers diagnosed with musculoskeletal disorders listed in the second edition of the International Classification of Primary Care (ICPC-2).²⁰ We excluded: those with serious somatic or mental health disorders affecting their work ability and in need of specialised treatment (eg, cancer, psychotic disorders), pregnant women, unemployed, freelancers and self-employed workers and those lacking sufficient Norwegian or English language skills to answer the questionnaires or communicate by telephone.

Recruitment, stratification and randomisation

From April 2019 to October 2020 workers on sick leave due to musculoskeletal disorders were phoned from the NAV directorate. Every week the recruiters received lists of workers in week seven of sick leave, affiliated to eight NAV offices in South-Eastern Norway. Eligible candidates were informed about the trial and assured that participation was voluntary and did not affect sick leave benefits or UC provided by the NAV. Workers who agreed to participate received an electronic link to written information about the trial, an electronic informed consent form and the baseline questionnaire.

We used the Örebro Musculoskeletal Pain Screening Questionnaire Short Form (ÖMPSQ-SF),²¹ and the Keele STarT MSK Tool,^{22,23} to stratify the participants into two risk groups of longterm sick leave (described in online supplemental appendix 1). Participants with \geq 9 on the Keele STarT MSK Tool and \geq 60 on the ÖMPSQ-SF were stratified to a 'high-risk group', all others were stratified to a 'medium/low-risk group'. After stratification to the risk-group, participants were randomly allocated (1:1:1 allocation within each stratum of low/medium and high-risk). Group allocation was concealed for the recruitment staff. A statistician (MCS), with no involvement in the running of the trial, prepared a computer-generated allocation sequence for each risk-group, only available for the person in charge of group allocation (TLR).

Interventions

The interventions are described in detail in online supplemental appendix 1, and in the published fidelity and process evaluation.^{16 17} All participants were offered UC for people on sick leave in Norway. In Norway, workers on sick leave are entitled to full wage replacement benefits for up to 12 months. The first 16 days are covered by the employer, the rest by the social security system administered through the NAV. In addition, participants randomised to the UC+MI arm were offered two face-to-face sessions of MI from a NAV caseworker. The first session was delivered at a local NAV office as soon as possible after inclusion, and the second session was held 2 weeks later. The participants in the UC+SVAI arm were offered vocational advice and case management from physiotherapists. Those stratified to the low/medium-risk group were offered one to two telephone sessions. Participants in the high-risk group were offered three to four sessions. The first session was held as soon as possible after inclusion. The duration of the follow-up period was flexible but ended when the participant reached 6 months of consecutive sick leave or had RTW in his/her contracted work hours for four consecutive weeks.

Training and fidelity evaluation

The MI training was a 6-day course provided by a clinical psychologist (RH) and psychiatrist (GB). The caseworkers were offered group mentoring from another psychologist, every other month during the intervention period. All were experienced MI trainers. In addition, the caseworkers could request individual feedback based on submitted recordings of MI sessions. The eight main caseworkers providing the MI were all women, aged between 27 and 65 years, with 2–20 years of work experience. The SVAI training was a 5-day course provided by a consultant physiotherapist and work and health researcher (GS). The

physiotherapists were offered online group mentoring approximately every month during the intervention period. The four main physiotherapists providing the SVAI were all women, aged between 28 and 45 years, with 4–21 years of work experience.

To assess the fidelity of the MI and SVAI, we recorded intervention sessions of approximately 10% of the participants receiving the interventions. In addition, the physiotherapists documented the follow-up they provided for each participant in an intervention log. The recordings of the MI sessions were scored by an independent MI analysis centre using the Motivational Interviewing Treatment Integrity code.²⁴

Data collection

We obtained data from national registries including information on: sick leave benefits, sick leave certificates, disability pensions and contracted work hours. The primary outcome was the number of sickness absence days over 6 months defined as lost workdays. In Norway, people may combine part-time disability pensions with work. Therefore, any increase in disability pensions from baseline was also counted as sick leave. To convert time on sick leave to actual time away from work we accounted for the participants' contracted work hours and the amount of sick leave. This was summed up and converted to lost workdays, according to a 5-day working week when working full-time.

The participants completed a questionnaire at baseline covering: age, gender, education level, marital status, first language, height, weight, smoking, follow-up from employer (yes/no), conflict with employer (yes/no), work ability (single question from the Work Ability Index, 0–10 scale),²⁵ work satisfaction (single question from the original version of the ÖMPSQ, 0-10 scale²⁶), physical activity in the previous week (single question from the Musculoskeletal Health Questionnaire (MSK-HQ), 0–7 scale^{27 28}), musculoskeletal health (MSK-HQ, $0-56 \text{ scale}^{2728}$), health literacy (Health Literacy Scale Questionnaire 12, 12-72 scale²⁹) and self-rated health (EuroQol Visual Analogue Scale 0-100), in addition to the Keele STarT MSK tool,²²²³ and the ÖMPSQ-SF.²¹ For all scale variables, low values indicate low levels of the construct. To assess the representativeness of the trial sample, we obtained anonymised registry data covering sex, age, occupation, and contracted work hours from all eligible candidates.

Sample size

The sample size calculation was conducted for the number of sickness absence days over 6 months. There is no agreed minimal important difference for this outcome described in the literature. Therefore, we based the power calculations on results from trials evaluating similar interventions for people with musculoskeletal disorders (the UK SWAP trial,¹³ and a trial conducted in Sweden with a similar welfare system to Norway³⁰). Based on these trials we anticipated a difference of 10 days (two full work weeks) over 6 months between UC and UC+MI or UC+SVAI, with an expected SD of 28 days. Given a statistical power of 80% and a two-tailed 5% significance level, we estimated needing 125 participants in each arm. After adjustment for expected skewed data and 5% loss to follow-up we estimated needing to include 150 participants in each trial arm.

Data analyses

Analyses were performed in accordance with the published statistical analysis plan,¹⁵ in Stata/MP V.16.1 by the first and last author (FA and BEØ) and a statistician (MCS) masked to treatment allocation. We performed descriptive statistics on

all data and investigated the distributions of the variables with histograms and the Shapiro-Wilk and skewness-kurtosis tests for normality.

Analyses of differences in the primary outcome

The primary intention-to-treat (ITT) analysis was conducted using robust multiple linear regression, with sickness absence days as the dependent variable. We entered the 'trial-arms' and possible confounders (predefined in the statistical analysis plan¹⁵) as independent variables. To include participants with missing values, 10 data sets were imputed using multiple imputations by chained equations, following the guidance by White and colleagues.³¹ Auxiliary variables included in the imputation model were: duration of sick leave at baseline, Keele STarT MSK risk group, ÖMPSQ-SF risk group, work satisfaction and selfrated health. We checked normal probability plots, residual scatterplots and values for leverage, Cook's distance and variance inflation factors to see if the assumptions for linear regression were met. If necessary, variables were log-transformed.

In addition, we conducted a complete case analysis. Unadjusted analyses of the differences in median and mean sickness absence days were investigated with Mann-Whitney Wilcoxon tests and t-tests. We conducted 10 000 bootstrap samples to estimate 95% CIs for the median value of sickness absence days in each trial arm.

All the statistical tests were two-sided and a p value <0.05 was regarded as statistically significant. We did not adjust for multiple comparisons as the trial evaluated the difference between UC+MI and UC+SVAI versus UC separately,¹⁸ and a single model was used for the multiple analyses.

Sensitivity analyses

Three unadjusted sensitivity analyses were performed: (1) excluding the participants recruited during the internal pilot, (2) excluding participants who had RTW for >50% of their contracted work hours 1 week after baseline (as the protocol stated that the MI and SVAI should not be delivered to participants who had RTW for >50% before the first session), (3) a moderation analysis to test if the COVID-19 pandemic moderated the effectiveness of MI or SVAI. The analysis was conducted using robust multiple linear regression including 'trial arms', and a variable indicating if the 6-month follow-up was completed before or after the government-imposed restrictions due to the COVID-19 pandemic, plus interaction terms between these two variables.

Patient involvement

Patient representatives with various musculoskeletal disorders were involved in the planning of the trial. They provided guidance related to the relevance, aim and conduct of the trial and helped with the wording of the information provided to trial participants.

RESULTS

Enrolment

A total of 514 workers participated in the trial. An overview of enrolment and flow of participants is shown in online supplemental appendix 2 and figure 1. No major changes were made during the pilot phase, and the pilot participants (n=101) were included in the analyses. Recruitment was halted between 12 March 2020 and 30 March 2020 due to COVID-19 containment strategies, and we made some minor trial modifications (listed in online supplemental appendix 3). Five participants withdrew

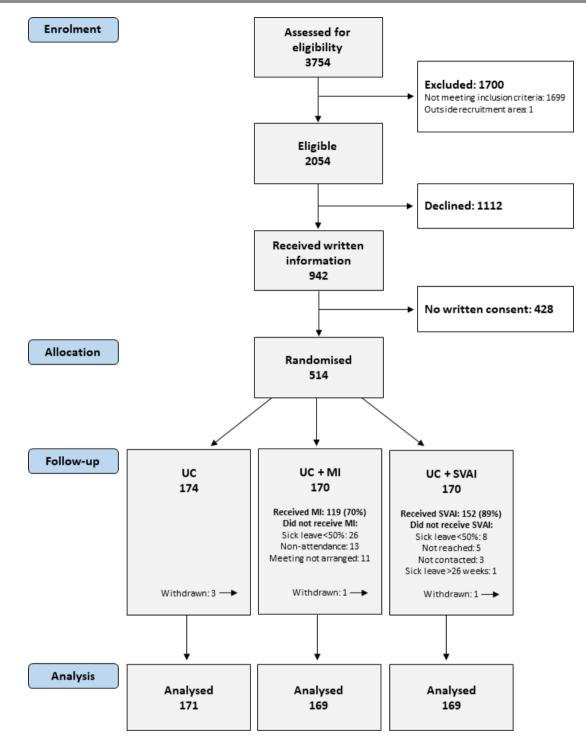


Figure 1 Flow chart of inclusion and follow-up of trial participants. MI, motivational interviewing; SVAI, stratified vocational advice intervention; UC, usual case management.

from the trial. Due to the GDPR, we could not obtain registry data from withdrawals, leaving 509 (99%) participants for the ITT analyses. No adverse events were reported during the trial.

Baseline characteristics of the participants

Baseline characteristics are summarised in table 1. The median age of participants was 49 years (range 24–66 years) and 57% were women. Totally, 341 participants (66%) worked in full-time positions, and 315 (62%) were on full sick leave at baseline. Overall, the baseline characteristics were similar across the three trial arms. The trial sample was representative regarding age,

sex and occupation compared with all eligible candidates (online supplemental appendix 4).

Intervention delivery

The number of sessions and duration of the MI and SVAI interventions are listed in table 2. Following the COVID-19 pandemic 22 (10%) of the MI sessions were provided by telephone or video call. All the SVAI sessions were provided by telephone and none of the physiotherapists attended workplace meetings.

Practi

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Table 1 Baseline characteristics of participants

Characteristic	Missing n (%)	UC (n = 174)	UC+MI (n = 170)	UC+SVAI (n = 170)
Age (years), median (IQR)		49 (40–55)	49 (41–56)	49 (41–56)
Women, n (%)		94 (54)	99 (58)	100 (59)
Married/living with partner, n (%)	1 (0.2)	120 (69)	119 (70)	119 (70)
Norwegian as first anguage, n (%)	2 (0.4)	151 (87)	154 (91)	145 (86)
Education, n (%)				
Compulsory education		21 (12)	14 (8)	20 (12)
High school		92 (53)	95 (56)	84 (49)
College or university <4 years		40 (23)	46 (27)	49 (29)
College or university ≥4 years	10 (10)	21 (12)	15 (9)	17 (10)
lealth literacy* (12–72), nedian (IQR)	49 (10)	51 (44–60)	53 (45–59)	52 (44–59)
Smokers, n (%)		39 (22)	35 (21)	36 (21)
Body mass index (kg/m²), nedian (IQR)	13 (3)	28 (24–31)	27 (24–31)	27 (24–31)
Days of physical activity previous week, n (%)	1 (0.2)			
0 days		65 (37)	54 (32)	64 (38)
1-2 days		46 (26)	43 (25)	39 (23)
3-4 days		38 (22)	45 (27)	41 (24)
5-7 days		25 (14)	27 (16)	26 (15)
Musculoskeletal health† (0–56), mean (SD)	21 (4)	27 (9)	27 (8)	27 (8)
Vork ability‡ (0–10), nedian (IQR)	3 (0.6)	2 (0–5)	3 (1–5)	3 (0–5)
ÒMPSQ-SF§ (≥60), n (%)		65 (37)	55 (32)	59 (35)
eele STarT MSK tool 0–12)				
High risk (≥9), n (%)		61 (35)	49 (29)	48 (28)
Medium risk (5–8), n (%)		85 (49)	86 (51)	98 (58)
Low risk (<5), n (%)		28 (16)	35 (21)	24 (14)
ligh-risk for long-term ick leave¶, n (%)		38 (22)	36 (21)	35 (21)
Vork satisfaction**)—10), median (IQR)	1 (0.2)	8 (6–9)	8 (7–9)	8 (6–9)
n conflict with employer, es n (%)	4 (0.8)	6 (3.5)	5 (3.0)	14 (8.3)
Followed-up by employer, n (%)	7 (1)			
No follow-up		65 (38)	72 (44)	72 (43)
Dialogue meeting or follow-up plan		64 (37)	53 (32)	65 (38)
Dialogue meeting and follow-up plan		44 (25)	40 (24)	32 (19)
White-collar workers, n (%)		58 (33)	56 (33)	61 (36)
Blue-collar workers, n (%)		116 (67)	114 (67)	109 (64)
Nork, n (%)				
Full-time		120 (69)	110 (65)	111 (65)
Part-time 50–99% of full work hours per week		39 (22)	53 (31)	48 (28)
Part-time <50% of full work hours per week		15 (9)	7 (4)	11 (6)
Graded disability pension††, yes n (%)	5 (1)	15 (9)	12 (7)	9 (5)
Sickness absence days previous year (work days‡‡), median (IQR)	5 (1)	38 (30–50)	35 (31–50)	36 (26–50)
	5 (1)	51 (50–55)	51 (50–55)	51 (49–56)
Duration of consecutive sick leave at baseline (calendar days), median (IQR)				
sick leave at baseline (calendar days), median	5 (1)			

continued

Aanesen F, et al. Occup Environ Med 2022;0:1-9. doi:10.1136/oemed-2022-108637

Table 1 continued

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Characteristic	Missing n (%)	UC (n = 174)	UC+MI (n = 170)	UC+SVAI (n = 170)							
Sick leave 50–99% of contracted work hours		65 (38)	54 (32)	63 (37)							
Sick leave <50% of contracted work hours		3 (2)	6 (4)	3 (2)							
Area of body pain, n (%)	14 (3)										
Lower limb		6 (4)	18 (11)	15 (9)							
Upper limb		30 (18)	30 (18)	30 (18)							
Neck		12 (7)	12 (7)	10 (6)							
Back		34 (20)	42 (25)	43 (26)							
Multisite pain		12 (7)	8 (5)	10 (6)							
Joint disorders		20 (12)	13 (8)	10 (6)							
Fractures		14 (8)	16 (10)	11 (7)							
Other		40 (24)	26 (16)	38 (23)							
The distribution was skewed f *Measured with the Health Li			ISK-HQ.								

tMeasured with the Musculoskeletal Health Questionnaire (MSK-HQ)

#Measured with a single question from the Work Ability Index

SÖMPSQ-SF: The Örebro MSK Pain Screening Questionnaire Short Form (0–100). ¶High-risk group in the MI-NAV trial: ≥60 on the ÖMPSQ-SF and ≥9 on the Keele STarT MSK Tool.

**Work satisfaction: 0=not satisfied at all, 10=totally satisfied. t†Individuals who work part-time and receive a graded disability pension.

##Lost workdays due to sick leave, adjusted for work hours per week and amount of sick leave. MI, motivational interviewing; n, number of participants; SVAI, stratified vocational advice intervention; UC, usual case management.

Primary outcome

Three participants did not have any sickness absence from baseline to 6 months follow-up (some participants were late in answering the baseline questionnaire and had RTW before inclusion in the trial) (figure 2). Thirteen participants reached the maximum amount of sickness absence possible during the follow-up period (131 days). The distribution of sickness absence days from baseline to 6 months follow-up was skewed in all three trial arms.

Unadjusted analyses

The UC+MI arm had 6 fewer median days of sick leave compared with the UC arm (not statistically significant (ns)) and the mean difference was 7 fewer days (95% CI -16 to 2) (ns) (table 3). The UC+SVAI arm had 13 fewer median days of sick leave compared with the UC arm (p=0.04), the mean difference

Table 2 Summary of delivery of MI and	Table 2 Summary of delivery of MI and SVAI									
	UC+MI (n=170)	UC+SVAI (n=170)								
Received intervention, n (%)	119 (70)	152 (89)								
Number of sessions*, n (%)										
One session	3 (2)	13 (8)								
Two sessions	106 (62)	106 (62)								
Three sessions	n.a.	10 (6)								
Four sessions	n.a.	19 (11)								
Days until first session*, mean (SD)	21 (13)	6 (5)								
Intervention period* (days), mean (SD)	36 (17)	50 (27)								
Intervention period low/medium-risk group	n.a.	42 (21)								
Intervention period high-risk group	n.a.	74 (30)								
Duration of first session t (min), median (IQR)	41 (26–45)	45 (35–60)								
Duration of follow-up sessions‡ (min), median (IQR)	46 (45–49)	25 (20–30)								
*We did not have data on 4 of the participants receivin MI. †We only had data from 15 MI sessions. ‡We only had data from 6 MI sessions. %, per cent of participants randomised to the intervent interview for the participants randomised to the intervent	ion arm; MI, motiva	itional								

interviewing; n, number; n.a., not applicable; SVAI, stratified vocational advice intervention; UC, usual case management.

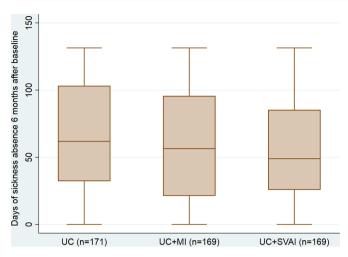


Figure 2 Distribution of sickness absence days (median, IQR and range) for participants in each of the trial arms. MI, motivational interviewing; SVAI, stratified vocational advice intervention; UC, usual case management.

was 9 fewer days (95% CI -17 to -0.1) (p=0.04) compared with UC (table 3).

Adjusted analyses

The assumptions for linear regression were met apart from several outliers. We conducted robust linear regressions to reduce the outliers' effect on the estimates (table 4). The primary imputed analysis (n=509) showed that the UC+MI arm had 7 fewer days of sickness absence (95% CI -15 to 2) compared with UC (ns). The UC+SVAI arm also had 7 fewer days (95% CI -16 to 1) compared with the UC arm (ns). In the complete case analysis (n=479) the difference was 9 fewer days for both the UC+MI arm (95% CI -18 to -0.4) and the UC+SVAI arm (95% CI -18 to -0.7), compared with the UC arm (p<0.05).

Sensitivity analyses

We only observed minor differences in the sensitivity analyses compared with the ITT analysis (table 3). The interaction terms in the moderation analysis to test if the COVID-19 moderated the effect of MI or SVAI had large CIs and were not statistically significant.

DISCUSSION

Principal findings

The MI-NAV trial showed a 7-day reduction in sickness absence over 6 months of adding either MI or SVAI to UC, for workers

on sick leave due to musculoskeletal disorders. However, the results were estimated with low precision reflected in wide CIs, the differences were smaller than anticipated and not statistically significant.

The MI intervention compared with previous studies

Although our findings were not statistically significant, they are in line with findings from a Canadian cluster RCT, indicating that MI could reduce sickness absence among people with musculoskeletal disorders.^{32 33} In the Canadian trial MI was added to interdisciplinary rehabilitation at a rehabilitation centre, and reduced the recurrence of wage replacement benefits by 5% over 12 months for employed workers.³² In the Canadian study MI was provided by occupational and exercise therapists.^{32 33} However, the role of a NAV caseworker differs from a healthcare professional and they do not have medical training. A recent study, interviewing workers on sick leave who had received MI from NAV caseworkers, showed that although the workers had negative expectations to the NAV (because of their role as gatekeepers to sickness benefits), they developed a good relationship to the NAV caseworkers and experienced the MI sessions as positive and helpful in the RTW process.³⁴ Similar findings have been shown among workers on sick leave in Sweden,³⁵ and an RCT from the USA has shown that MI training can improve working alliance between clients and RTW counsellors.³⁶

The NAV caseworkers in our trial provided the MI in addition to their usual workload. This may explain the long duration from baseline until the first MI session, and was the main reason that 30% of the participants in the MI arm did not receive MI. Four caseworkers dropped out during our trial due to an otherwise high workload or lack of MI experience.¹⁷ The evaluation of the 21 recorded MI sessions from the MI-NAV trial revealed that although the NAV caseworkers had high adherence to the MI guideline, they had low MI proficiency levels throughout the trial.¹⁷ This is in line with findings from a similar Norwegian study.³⁷ These factors may have reduced the effectiveness of the MI intervention in our study.

The SVAI compared with previous studies

The results from the MI-NAV trial support the findings of the SWAP trial indicating that vocational advice could reduce sickness absence among workers with musculoskeletal disorder. However, our results were not statistically significant after adjusting for possible confounders. The SWAP trial showed a reduction of 5 days of sickness absence over 4 months of adding a vocational advice intervention to best current primary care in the UC.¹³ In both trials the vocational intervention was provided

		UC			UC+	MI		UC+SVAI			
	n	Median n Mean (SD) (95% CI)		n	n Mean (SD) (95% CI)		n	Mean (SD)	Median (95% CI)		
ITT	171	66 (41)	62 (52–71)	169	59 (41)	56 (43–70)	169	57 * (38)	49 * (38–60)		
Low/medium-risk group	135	63 (41)	58 (48–69)	133	55 (41)	45 (29–61)	134	55 (37)	48 (37–59)		
High-risk group	36	76 (40)	79 (60–97)	36	73 (42)	71 (52–90)	35	66 (40)	61 (33–90)		
Sensitivity analysis 1	137	66 (41)	62 (49–74)	139	58 (41)	57 (43–71)	132	58 (39)	53 (41–65)		
Sensitivity analysis 2	163	68 (40)	65 (57–74)	158	62 (41)	59 (47–71)	154	59 (37)	54 (43–65)		

ITT, intention-to-treat analysis (five missing: three in UC arm, one in UC+MI arm, one in UC+SVAI arm).

Sensitivity analysis 1: excluding pilot participants.

Sensitivity analysis 2: excluding participants who returned to work ≥50% within 1 week after baseline.

^{*}Statistically significant difference (p<0.05) compared with UC only, tested with t-test or Mann-Whitney Wilcoxon test.

^{95%} CI, 95% confidence interval (estimated with 10 000 bootstrap resamples); MI, motivational interviewing; n, number of participants in analysis; SVAI, stratified vocational advice intervention; UC, usual case management.

Table 4 Robust linear regression analyses. Estimation of differences in sickness absence days over 6 months between UC and UC+MI or UC+SVAI

	Unadjus (n=509)	ted ITT ana	Ilysis	Adjusted c (n=479)	omplete case	analysis*	Adjusted primary ITT analysis with imputations*† (n=509)			
Variable	Coef. B	95% CI		Coef. B	95% CI		Coef. B	95% CI		
UC+MI	-7.3	-16.6	1.9	- 9.2 ‡	-17.9	-0.4	-6.6	-15.0	1.8	
UC+SVAI	-9.3‡	-18.5	-0.1	-9.4‡	-18.0	-0.7	-7.0	-15.4	1.4	
Sex, male				11.2‡	3.8	18.7	11.8‡	4.6	19.1	
Age				-0.1	-0.4	0.3	-0.0	-0.4	0.3	
Secondary school§				2.6	-9.6	14.8	1.9	-9.7	13.5	
Higher education <4 years§				2.8	-10.3	16.0	2.9	-9.7	15.5	
Higher education ≥4 years§				-11.0	-26.9	4.9	-10.3	-25.4	4.8	
Meeting or follow-up plan¶				-7.2	-15.3	0.9	-5.6	-13.5	2.2	
Meeting and follow-up plan¶				-5.0	-14.4	4.4	-3.5	-12.6	5.7	
Physical activity 1–2 days**				0.7	-8.8	10.1	1.1	-8.1	10.3	
Physical activity 3–4 days**				6.5	-3.2	16.3	3.5	-4.1	18.0	
Physical activity 5–7 days**				8.1	-3.3	19.5	7.0	-4.1	18.0	
Work ability††				-3.5‡	-5.0	-2.1	-3.8‡	-5.2	-2.4	
Musculoskeletal health‡‡				-0.8‡	-1.3	-0.3	-0.7‡	-1.2	-0.02	
Sickness absence days previous year§§				19.5‡	13.1	25.8	19.1‡	12.9	25.3	

n, number of participants in analysis (ITT analysis: UC n=171, UC+MI n=169, UC+SVAI n=169, complete case analysis: UC n=158, UC+MI n=157, UC+SVAI n=159)

*Multiple robust linear regression analyses adjusted for predefined possible confounding factors.

tValues for missing on the independent variables were imputed with multiple imputations by chained equations with 10 imputations. Imputations were not conducted for the five missing outcome values.

‡p<0.05.

§Education: dummy variables compared with compulsory education.

¶Follow-up from employer, dummy variables compared with no follow-up.

**Physical activity 1 week prior to baseline, dummy variables compared with no physical activity.

 \pm +Measured with single question from the Work Ability Index (0–10).

‡‡Measured with the Musculoskeletal Health Questionnaire (0-56).

§§Number of days away from work due to sickness absence 12 months prior to baseline, logarithmic transformed variable.

Coef., Coefficient.; ITT, Intention-to-treat; MI, motivational interviewing; SVAI, stratified vocational advice intervention; UC, usual case management.

by physiotherapists mostly by telephone, and a median of two sessions was provided. However, the SVAI was delivered as stratified care with one to two sessions provided for the low/ medium-risk group, and three to four sessions for the high-risk group. The SWAP intervention, on the other hand, was delivered as stepped care, with the possibility of providing more sessions if necessary. In the SWAP trial 57% of the participants were doing their usual job, while the participants in the MI-NAV trial had been on sick leave for more than seven consecutive weeks. Therefore, the participants in our trial might have needed more RTW support, compared with the workers in the SWAP trial and it might have been preferable to deliver the intervention as stepped care (with the possibility of providing more sessions to participants who needed more help to RTW).

Although the SVAI was mainly delivered according to protocol, some intervention elements were poorly implemented.¹⁶ The physiotherapists did not attend workplace meetings or arrange face-to-face meetings with participants. They also had few contacts with important RTW stakeholder such as NAV caseworkers, employers and general practitioners.¹⁶ Previous studies have shown that cooperation between RTW stakeholders is important,³⁸ and the physiotherapists limited liaison with stakeholders may have reduced the effectiveness of the SVAI in our trial.¹⁶

Strengths and limitations of the MI-NAV trial

The multi-arm RCT design made it possible to compare two additional interventions with a single UC arm, optimising the use of limited research resources.³⁹ We obtained detailed national registry data for 99% of the trial participants and conducted thorough fidelity evaluations. To reduce the risk of intervention contamination, the NAV offices had not trained their caseworkers

in MI prior to the trial. The caseworkers were instructed not to use MI in usual follow-up of people on sick leave with musculoskeletal disorders. The physiotherapists delivering the SVAI only provided vocational follow-up to participants randomised to the SVAI arm.

Our trial had limitations in addition to those previously discussed. First, we had a low inclusion rate of 25% of those eligible. However, registry data showed that our sample was representative of the larger population regarding important factors associated with sick leave (sex, age and occupation). Furthermore, there is no agreed minimal important difference for sickness absence. A 7-day difference may be considered an important effect. However, our trial was not powered to detect this difference as statistically significant. Large variability in the data may also have reduced the statistical power of our trial. Another limitation is that the trial was not powered to perform subgroup analyses to detect possible differences in effects of adding MI or SVAI to UC for the low/medium-risk group and the high-risk group separately, or to compare UC+MI with UC+SVAI. This would have required an unrealistically large sample size. The participants in the UC+MI arm and the UC+SVAI arm received more follow-up compared with participants in the UC arm. Therefore, we cannot rule out that it was the extra follow-up and not the intervention elements that facilitated RTW. This will be controlled for in a recent RCT using the same MI intervention as the MI-NAV trial.⁴⁰ Lastly, possible intervention contamination from the NAV caseworkers was not evaluated in the process evaluation of the trial. However, the risk for contamination with the UC arm was low since NAV caseworkers usually do not convene a meeting with workers during the first 6 months of sick leave.

CONCLUSION

Adding MI or SVAI to UC for workers on sick leave for at least 7 weeks due to musculoskeletal disorders, reduced sickness absence by an average of 7 workdays over 6 months. The differences were not statistically significant, and the results were uncertain due to wide CIs. Efforts should be made to improve implementation of the MI and SVAI in future trials, and it might be preferable to provide the interventions as stepped care. The acceptability of the MI and SVAI to those providing and receiving the interventions should be investigated.

Author affiliations

¹Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, Oslo, Norway

²Centre for Intelligent Musculoskeletal Health, Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, Oslo, Norway

³Research and Communication Unit for MSK Health (FORMI), Division of Clinical Neuroscience, Oslo University Hospital, Oslo, Norway

⁴Norwegian National Advisory Unit on Rehabilitation in Rheumatology,

Diakonhjemmet Hospital, Oslo, Norway

⁵Department of Nursing and Health Promotion, Oslo Metropolitan University, Oslo, Norway

⁶Faculty Behavioural and Movement Sciences, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands

⁷Reviews and Health Technology Assessments, Norwegian Institute of Public Health, Oslo, Norway

⁸Department of Community Medicine, University of Tromsø, Tromsø, Norway ⁹STARS Education and Research Alliance, Surgical Treatment and Rehabilitation Service (STARS), The University of Queensland and Metro North Health, Brisbane, Queensland, Australia

¹⁰School of Medicine, Keele University, Keele, UK

¹¹Connect Health, Newcastle upon Tyne, UK

¹²General Practice Research Unit, Department of Public Health and Nursing,

Norwegian University of Science and Technology, Trondheim, Norway

¹³Nidelv Community Mental Health Center, Tiller, Clinic of Mental Health, St Olavs University Hospital, Trondheim, Norway

¹⁴Department of Psychology, University of Oslo, Oslo, Norway

¹⁵Department of Psychology, Norwegian University of Science and Technology, Trondheim, Norway

¹⁶Modum Bad, Research Institute, Vikersund, Norway

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Contributors MG and EF had the idea for the MI-NAV trial and wrote the funding application. MG, EF, BEØ, GW-J, NEF, MWvT and KS were involved in designing the trial. BEØ was responsible for organising the randomised controlled trial. FA and AT were responsible for cooperation with the patient engagement panel, recruitment of participants and physiotherapists and organisation of the SVAI mentoring. GS, GW-J, FA, AT, BEØ and MG developed the SVAI materials. GS was responsible for the SVAI training and contributed to the mentoring of the SVAI physiotherapists. GB and RH designed the MI intervention, wrote the MI guideline, developed the MI training material and were responsible for the initial training of the NAV caseworkers. IL organised the audio recordings of the intervention sessions. AT was responsible for the data collection from the questionnaires. TLR was responsible for the randomisation process and organised the registry data. MCS, FA and BEØ were responsible for the data analyses. The first draft of the manuscript was written by FA. All authors critically revised and commented on the manuscript drafts and read and approved the final manuscript. FA and BEØ are guarantors for the study and accept full responsibility for the work and conduct of the study. The corresponding author FA attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Data availability statement Data are available upon reasonable request. Requests to access data should be addressed to the last author: brielo@oslomet.no. Anonymised individual participant data (including data dictionary) will be available on request, from January 2023 to December 2028, to researchers who provide a methodologically sound scientific proposal that has been approved by an ethics committee and by the scientific board of the MI-NAV study.

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ORCID iDs

Fiona Aanesen http://orcid.org/0000-0002-3284-8060 Margreth Grotle http://orcid.org/0000-0001-8243-1143 Tarjei Langseth Rysstad http://orcid.org/0000-0003-2630-4136 Anne Therese Tveter http://orcid.org/0000-0003-1701-9835 Alexander Tingulstad http://orcid.org/0000-0001-6985-3827 Ida Løchting http://orcid.org/0000-0001-9656-2398 Milada C Småstuen http://orcid.org/0000-0001-8947-8649 Maurits W van Tulder http://orcid.org/0000-0002-7589-8471 Rigmor Berg http://orcid.org/0000-0002-6915-0993 Nadine E Foster http://orcid.org/0000-0003-4429-9756 Gwenllian Wynne-Jones http://orcid.org/0000-0002-0283-6632 Gail Sowden http://orcid.org/0000-0003-0765-0551 Egil Fors http://orcid.org/0000-0002-0980-8247 Gunnhild Bagøien http://orcid.org/0000-0001-6079-8622 Roger Hagen http://orcid.org/0000-0003-1824-6271 Kjersti Storheim http://orcid.org/0000-0002-6887-6901 Britt Elin Øiestad http://orcid.org/0000-0002-0547-9781

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Supplemental material

APPENDIX 1: INTERVENTIONS IN THE MI-NAV TRIAL

Usual case management (UC) according to guidelines from the Norwegian Labour and Welfare Administration (NAV)

All Norwegian citizens and people working in Norway are entitled to health care through the Norwegian National Insurance Scheme. Workers on sick leave are entitled to full wage replacement benefits for up to 12 months. The first 16 days are covered by the employer, the rest by the social security system administered through the NAV. To be entitled to sickness benefits from the NAV a sick note is required, usually issued by a medical doctor. Employers and employees are obliged to cooperate to try to prevent long-term sickness absence. During the first six months of sick leave the employer has the main responsibility for follow-up and should make a follow-up plan in cooperation with the worker within the first four weeks of sick leave. The plan should include information about the employee's work duties, workability, and possible work adaptations. Within week eight of sick leave, the employee should start work-related activity (unless it is not possible due to medical reasons). If the worker is still on full-time sick leave after eight weeks, the NAV may request documentation that work related activity is not possible. The employer is responsible for arranging a dialogue meeting with the employee within week seven of fulltime sick leave (unless it is clearly unnecessary). The purpose of the meeting is to prevent long-term sickness absence and discuss if workplace modifications are required. Within six months of sick leave the local NAV office is responsible for arranging a second dialogue meeting, including the employee, employer, and sick-leave certifier (if appropriate). The second dialogue meeting can be arranged earlier if requested by any of the parties.

Motivational interviewing (MI) according to the protocol

The MI intervention was a replication of an intervention, evaluated in a Norwegian trial conducted concurrently in Trondheim (Aasdahl et al. 2018). MI is a practical tool for counselors developed by William Miller and Stephen Rollnick to help people change. It is rooted in the person-centered approach of Carl Rogers and is inspired by several social and behavioral models. MI is based on the principle that people have the resources within themselves to change (self-determination theory). Motivation for change is activated through the person's own change talk.

The participants randomised to the UC+MI arm were offered two face-to-face sessions of MI from NAV caseworkers, in addition to UC. The sessions could last up to one hour. The first session was delivered at a local NAV office as soon as possible after enrolment in the study, and the second session was held 2 weeks later. The NAV caseworkers followed a MI guideline developed for return to work (RTW) by Gunnhild Bagøien (a psychiatrist and member of the motivational interviewing network of trainers) and Roger Hagen (a clinical psychologist). The guideline was based on MI principles to build a collaborative relationship with the participants, including communication skills such as asking open-ended questions, providing reflections, and summaries to evoke and enhance change talk. In the first session, an agenda was set in cooperation with the participant through 'agenda mapping' (the participant decided the agenda for the conversation from a menu of topics, based on what they considered to be most relevant for their situation). The participants' readiness to return to work was assessed (using the MI tools: 'importance ruler' and 'confidence ruler'), and the intervention was tailored according to motivational stage (stages of change). If the participant

was ambivalent about RTW, the pros and cons of sickness absence were explored in an accepting and compassionate manner. In the second session, the participant's current work situation, obstacles to RTW and previous attempts at RTW were discussed. The caseworkers provided information about available RTW support from the NAV in a MI-consistent manner. If the participant was ready for RTW, the NAV caseworker offered to help them develop an action plan for RTW. Summaries of each session were made available to the participants on the NAV's secure online communication platform.

Stratified vocational advice intervention (SVAI) according to the protocol

Stratification

We used the 10-item version of the Örebro Musculoskeletal Pain Screening Questionnaire Short Form (ÖMPSO-SF) (Linton et al 2011), and the 10-item Keele STarT MSK Tool (Dunn et al. 2021), to stratify the participants into two risk groups of long-term sick leave. Participants with ≥ 9 on the Keele STarT MSK Tool and ≥ 60 on the ÖMPSQ-SF were stratified to a 'high-risk group', all others were stratified to a 'medium/low-risk group'. The cut-off points were based on preliminary data from a prospective cohort study conducted as part of the MI-NAV project. The preliminary results from this cohort study showed that the combination of these tools had the greatest accuracy in distinguishing between short versus long-term sick leave in workers on sick leave due to musculoskeletal disorders in Norway (unpublished results). The ÖMPSQ-SF assesses five psychosocial risk factors related to future disability: 1) self-perceived function, 2) pain experience, 3) distress, 4) fear-avoidance beliefs, and 5) RTW expectancy. Sum scores range from 1-100 points with higher scores indicating higher estimated risk of future work disability. The Keele STarT MSK tool consists of 10 items assessing: pain intensity, pain self-efficacy, pain bothersomeness, disability, comorbid pain, expected duration of the condition, self-perceived health, depression, fear avoidance and pain duration (during the last two weeks). Sum scores range from 0-12 points, with values from 0-4 points indicating low risk, 5-8 points indicating medium risk, and 9-12 points indicating high risk for poor prognosis.

Intervention

The SVAI was a modified version of an intervention developed for the SWAP trial (Sowden et al. 2019). The theoretical underpinning of the intervention was social cognitive theory, self-determination theory and the common-sense model of self-regulation (Aanesen et al. 2021).

The participants stratified to the low/medium-risk group were offered up to two telephone sessions. The sessions could last up to one hour. Participants in the high-risk group were offered three to four sessions, the first by telephone, the remaining sessions either by telephone or face-to-face, including an optional workplace meeting. The first session was held as soon as possible after the baseline assessment. The duration of the follow-up period was flexible but ended when the participants reached 6 months of consecutive sick leave or had RTW in their contracted work hours for 4 consecutive weeks. During the first session, the physiotherapists followed a semi-structured conversation guide with open-ended questions to clarify the participants' work and health situation and identify obstacles to RTW. During the sessions, the physiotherapists provided evidence-based advice on the management of musculoskeletal disorders and supported problem-solving to overcome modifiable obstacles to RTW. The follow-up provided by the physiotherapists was tailored according to the participants' needs and individual RTW barriers. They collaborated with the participants to decide goals for RTW, developed and implemented action plans, facilitated communication,

collaboration and coordination with stakeholders and signposted to other services if necessary.

Information leaflet for participants receiving SVAI

Research study aiming to help sick listed people with musculoskeletal disorders back to work

The research study is led by researchers from the MUSK health research group at Oslo Metropolitan University, OsloMet. The aim of the study is to find ways to help people who are sick-listed with musculoskeletal disorders. The study will test two different types of dialogue based interventions. All participants will receive usual follow up from NAV in addition to the interventions given in the study. They can also receive medical treatment from other health care professions during the trial if they wish. You can find more information about the study on the following link: <u>https://www.muskhealth.com/minav3</u>

Vocational advice from physiotherapist

You have agreed to participate in the study and have been randomly assigned to receive vocational advice from a physiotherapist. The physiotherapist will discuss topics related to your health and work situation and try to help you get back to work.

The physiotherapist does not have any connection to the NAV or your employer. Confidentiality: The physiotherapist is bound by law to follow high standards of confidentiality and can't share information with your employer or the NAV without your consent.

What can the physiotherapist do?

- Discuss concerns you have regarding health and work.
- Help you make a return to work plan.
- Identify barriers for returning to work.
- Suggest actions to help you return to work, e.g. suggest adaptions to your work situation, give advice regarding treatment, and how to cope with your health problems.

If you consent the physiotherapist can also:

- Collaborate with you doctor or other health care professionals.
- Collaborate with your employer.

What can you do to get back to work sooner?

• Keep in contact with your workplace and colleagues. You and your employer are responsible for making a follow up plan. Your employer is also responsible for making adaptions to your work if this is necessary for you to be able to return. Your duty is to collaborate with your employer to make this possible.

- Talk to your doctor or physiotherapist about how they can help you get back to work. You know your work best. Discuss which parts of your job you can do with your health problem. Ask for treatment designed to get you ready for work.
- Gradually increase your activity level. Start with the activities you find easy, and do a bit more each day. You will have good days and bad days. Try to keep active also on the bad days. Vary between rest and activity. It is common to have set backs so don't give up!

Evidence based information about work and health

- Research shows that in general work is good for mental and physical health. Work is important for self-esteem and quality of life.
- Being absent from work can have negative effects for health and wellbeing.
- Musculoskeletal disorders are very common and all of us suffer these kinds of problems at some time in our life.
- The pain can be very distressing and may make life difficult, but there is usually no serious disease or lasting damage. Most episodes end quickly, though some symptoms may continue or come back from time to time.
- We have good evidence that returning to work as soon as possible helps recovery, and is the best way to avoid long-term sickness absence.

There are many unhelpful myths about health and work, which can cause unnecessary fear and uncertainty:

- 1. Common health problems are caused by work. Usually they are not. Everyone has these kinds of problems. Some type of work can make the symptoms feel worse, but usually work does not cause the problem.
- Work will make my condition worse: Most people with musculoskeletal disorders can continue working. In many cases going back to work can help you feel better.
- 3. You should not go back to work until you are fully recovered: Usually the opposite is true. Work can be part of treatment. Getting back to work and activity can help you recover. Adjustments to your work can make it possible to return to work sooner.
- A sick certificate means that you must not work:
 A sick certificate is not an order from your doctor to stay away from work, it only means you are entitled to sick pay. You can return to work as soon as you are ready.

Conversation guide for the SVAI physiotherapists

	INTRODUCTION									
Sugges	ted introduction in first telephone	e contact								
good time to talk? IF NO: Make new appointment.	ist from the MI NAV research proje g in our study. Could you please tell									
s it OK that I tell you a bit about the research project and the part of the study you have been assigned										
Is it OK that I tell you a bit about the research project and the part of the study you have been assigned to? The research project is led by researchers from the MUSK health research group at OsloMet (Oslo Metropolitan University). The aim of the study is to find ways to improve follow-up for people who are on sick leave with musculoskeletal disorders. In the study we are testing two different interventions and compare these to usual follow-up from the NAV. I am calling you because you are in the group who will get help from a physiotherapist trained to give vocational advice. My job is to help you get back to work, but I do not have any connection with the NAV or with your employer. Do you have any questions regarding this? During our conversation today I wish to get to know your situation and any problems you have regarding returning to work. I am bound by law to keep anything you tell me confidential and can't share information with NAV or your employer without your consent. I know that you have answered a questionnaire for this project, but I don't have access to your answers. Is it OK if I ask you some questions regarding your health and your situation at home and at work?										
CLARIFY CUR	RENT WORK AND HEAL	TH SITUATION								
work situation. Gather information regarding al be asked when appropriate/if yo	Gather information regarding all the questions in red on this form, the rest of the questions can be asked when appropriate/if you need more information. Write notes for every topic. You do not need to follow the order of the form, but you should									
	WORK SITUATION									
Sick-listed date	% sick listed	End of sick certificate								
Can you describe your currer	nt work situation?									
 What is your current occupation/title? What are your contracted hours of work? (contract work %, days and hours at work, shift pattern) Do you usually work more than your contracted hours? Do you usually work overtime? What does a typical day at work for you look like?/ What does your job involve? (Physical job demands, emotional and cognitive job demands). 										
IDENTIFY	OBSTACLES TO RETURN	N TO WORK								
	lection and summarising to ident	ify obstacles to return to work.								
Note any identified obstacles in How are your symptoms /con	the action plan. Idition affecting your ability to	work?								
• What do you think about	working with your present pain/ sy	mptoms?								

 Are you worried about any repeat episodes of symptoms/problems once you return to work? How do you feel about the prospect of returning to work at some point?
What are your main concerns about RTW?
What would make RTW difficult now?
• Are there stressful elements to your job that might be difficult when you first return to work?
• Aside from your symptoms are there any other reasons why it would be difficult to RTW now?
Have you had a dialogue meeting with your employer?
- Maating hald
Meeting held
Meeting planned
What other contact have you had with work since you have been off sick?
What contact have you had with NAV?
Has your employer made a return-to-work plan? Has the plan been sent to the person who gave you the sick note?
How is the plan working?
• What are they doing at work to help?
• Have you discussed with your employers when you might return to work or start working more?
 When do you think you will go back to work/start working more hours?
 Do you have an occupational health service at work?
Have you had involvement with them?
How happy are you with your work and workplace?
 How would you describe your relationship with your collogation and employer?
 How would you describe your relationship with your colleagues and employer? Did you have any conflicts with your employer or co-workers before you were sick listed?
 What kind of response do you expect from co-workers and supervisors when you return?
 Is your job at risk?
 Do you enjoy your job?
 What is it that you value about working or your job?
• What else does work do for you/ do you get from work?
• Why did you choose the job/career you did?
• How important to you is it to get back to work?
OVERCOMING OCCUPATIONAL OBSTACLES TO RTW
Collaborate with the worker to problem solve and overcome obstacles (see separate obstacles and actions sheet). Note any actions in the action plan.
What could be done at the workplace to help you return to work/increase your work
hours?
• What elements / hours of your job are you already doing?
 What elements / hours do you think you could manage now?
 Are you doing lighter or modified hours or duties?
 Do you expect your work could be modified temporarily so you could return to work sooner?
Are you able to build back into work gradually? Are light duties an option?
How many hours do you think you could manage to begin with?
When do you think you could start?
Short term work goal
Long term work goal

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	HEALTH SITUATION
	d you please tell me briefly about the main health problem that you are struggling at the moment?
•	When did this episode of pain start?
•	Have you had any previous episodes?
•	
•	Do you have any other important health problems?
•	What do you think has caused your health problem?
•	Is your pain related to an injury? Was it an injury/accident at work? Is there a litigation case or
	insurance claim related to the accident?
How	is your health condition affecting you day to day?
•	Are you avoiding doing anything or particularly struggling with anything?
٠	How are you sleeping?
•	How well do you feel you are managing at the moment?
•	What do you think would help you better manage your symptoms/ condition?
•	How is the situation affecting your mood?
Can y	you describe any treatment you are receiving or have received for your condition?
•	Ongoing treatment.
•	Previous treatment.
•	Are you waiting for any appointments, tests or treatments?
•	Do you think you should be having any tests or treatment for your symptoms/condition?
•	Do you feel you understand your condition and any treatment you are receiving?
•	What contact have you had with the person who gave you your sick note since you were sick listed?
•	Is anyone else helping you with your health problem?
	FAMILY SITUATION
•	Do you live alone or with somebody?
•	Do you have any children?
•	How old are they?
٠	Is there anything going on at home or to do with your current circumstances that would make it
	difficult to RTW now?
•	What arrangements might need to be made at home in order to help you return to work? (carer, childcare, transport etc?)

Action sheet for the SVAI physiotherapists

OBSTACLES AND ACTIONS Identify potential obstacles and actions during phone call and write them down in the action plan. ASK FOR CONSENT BEFORE CONTACTING OTHER STAKEHOLDERS (HEALTHCARE PROFESSIONALS, EMPLOYERS OR NAV CASEWORKER)										
POTENTIAL OBSTACLES	SUGGESTED ACTIONS FROM SVAI PHYSIOTHERAPIST									
High severity of symptoms/health condition. Comorbid health is a potential obstacle to RTW. Delays in health care. Lack of work focus to health care.	 Ask if participant is taking his/her medication as prescribed by their GP. Suggest that worker makes appointment to see GP. Contact health care providers in order to: a) suggest an appointment/investigation b) expedite an appointment c) ensure the HCP facilitates RTW d) post evidence based information to the health care provider 									
Current physical functioning not compatible with RTW.	 Suggest that participant sees a physiotherapist, if necessary help to set up appointment. Do values based goal setting. 									
Avoiding activities. Unhelpful beliefs about health and work.	 Provide reassurance to participant regarding hurt and harm. Advises the participant about how to gradually increase activity and exercise and return to avoided activities. Send leaflet with evidence based information to participant. Provide evidence based information, advice and reassurance to address knowledge gaps, misconceptions or unhelpful beliefs verbally. 									
Current day/night rest and sleep pattern not compatible with working.	 Provide verbal information about sleep. Inform participant about online resource to deal with sleep disturbance. 									
Doesn't value work sufficiently to RTW.	 Use motivational interviewing to help the participant decide whether to RTW or not. Explore and built the value of work. Convey positive but realistic messages about their ability to work now or in the future. Encouraged participant to be pro-active in taking steps to resolve the situation. 									
Lack of or unsupportive contact with the workplace. Other workplace issues.	 Suggest that participant makes contact with employer. Take direct contact with employers if participant needs help with this. Arrange and attend meeting between SVAI physiotherapist, worker and employers. Inform the NAV caseworker about the worksite meeting/visit if NAV caseworker is involved in the case. 									

Lack of a RTW plan.	 Support participant to develop RTW plan with employers. Build participant self-efficacy to collaborate with employer to make RTW plan, e.g. help make a list of what they want to discuss with employer, roleplay meeting etc Liaise with participant and employer in developing RTW plan.
Poor implementation of RTW plan.	 Review RTW plan with participant. Ask participant to liaise with employers to commence already agreed RTW plan. Discuss with participant how they will work with employers to stick to plan, review plan, modify plan and seek help early, if needed. Liaise with participant and employer to implement existing plan.

RECRUITMENT OF PARTICIPANTS TO THE MI-NAV TRIAL APPENDIX 2:

Year	2019 Intern	al pilot#				2020						Cov.¤								
Month	Apr	Мау	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar 1-11	Mar 12-31	Apr	Мау	June	July	Aug	Sept	Oct
Recruited	11	17	17	34	31	33	65	50	15	46	34	28	4	22	14	4	7	24	37	21
Total	11	28	45	79	110	143	208	258	273	319	353	381	385	407	421	425	432	456	493	514

[#] Internal pilot including the first 101 participants = Cov. COVID-19 containment strategies were implemented by the Norwegian government on the 12th of March 2020 and recruitment was halted between 12-30 of March

APPENDIX 3: TRIAL MODIFICATIONS DUE TO THE COVID-19 PANDEMIC IMPLEMENTED AFTER THE 12TH OF MARCH 2020, Planned by the trial team and reviewed and approved by the scientific board

Modification	Reason for modification	Consequence of modification
The MI intervention may be delivered by telephone or video call, rather than in-person only.	The Norwegian government implemented wide- reaching COVID-19 containment strategies on the 12 th of March 2020 to decrease physical contact between individuals.	22 (10%) MI sessions were delivered by telephone or video call, 203 sessions were delivered in-person.
New sample size calculations were made, and the sample size reduced from 750 to 450 participants.	The sample size had to be reduced to make it possible to complete the trial due to increased workload for the NAV.	Not possible to compare the MI and SVAI interventions head-to-head due to reduced power.
Sensitivity analysis to test if the COVID-19 pandemic moderated the effectiveness of the MI or SVAI compared to UC.	The sensitivity analysis was conducted to investigate if the COVID-19 pandemic affected the trial results.	An exploratory analysis was conducted.
MI: motivational interviewing		

SVAI: stratified vocational advice intervention

BASELINE CHARACTERISTICS OF PARTICIPANTS Appendix 4: IN THE MI-NAV TRIAL, ELIGIBLE INDIVIDUALS IN THE **RECRUITMENT AREA AND IN THE WHOLE OF NORWAY**

Registry data	MI-NAV trial	Recruitment area ¤	Norway ¤
	<i>n</i> = 514	<i>n</i> = 6329	n = 140259
Women, n (%)	293 (57)	3334 (53)	75412 (54)
Age, mean (SD)	48 (10)	47 (12)	46 (12)
Occupations, n (%)			
Legislator, senior officials, managers	9 (2)	448 (7)	9175 (7)
Professionals	94 (18)	918 (15)	22438 (16)
Technicians, associate professionals	30 (6)	653 (10)	14872 (11)
Clerks	41 (8)	395 (6)	8806 (6)
Service, shop and market sales workers	175 (34)	1835 (29)	39839 (28)
Agricultural, forestry and fishery workers	6 (1)	51 (1)	1474 (1)
Craft and related trade workers	63 (12)	847 (13)	17542 (13)
Plant and machine operators, assemblers	64 (13)	606 (10)	14108 (10)
Elementary occupations	31 (6)	565 (9)	11694 (8)
Armed forces and unspecified	1 (0.2)	11 (0.2)	311 (0.2)
Work, <i>n</i> (%)			
Full time: 100%	120 (69)	3788 (60)	87209 (62)
Part time: 50-99%	39 (22)	1339 (21)	27786 (20)
Part time: <50%	15 (9)	1202 (19)	25264 (18)

¤ Persons on sick leave for seven consecutive weeks for more than half of their contracted work hours due to a musculoskeletal disorder during the recruitment period of the MI-NAV Study: 5th of April 2019 to 14th of October 2020

n: SD: number

standard deviation

Supplemental material

APPENDIX I: INTERVENTIONS IN THE MI-NAV TRIAL

Usual case management (UC) according to guidelines from the Norwegian Labour and Welfare Administration (NAV)

All Norwegian citizens and people working in Norway are entitled to health care through the Norwegian National Insurance Scheme. Workers on sick leave are entitled to full wage replacement benefits for up to 12 months. The first 16 days are covered by the employer, the rest by the social security system administered through the NAV. To be entitled to sickness benefits from the NAV a sick note is required, usually issued by a medical doctor. Employers and employees are obliged to cooperate to try to prevent long-term sickness absence. During the first six months of sick leave the employer has the main responsibility for follow-up and should make a follow-up plan in cooperation with the worker within the first four weeks of sick leave. The plan should include information about the employee's work duties, workability, and possible work adaptations. Within week eight of sick leave, the employee should start work-related activity (unless it is not possible due to medical reasons). If the worker is still on full-time sick leave after eight weeks, the NAV may request documentation that work related activity is not possible. The employer is responsible for arranging a dialogue meeting with the employee within week seven of fulltime sick leave (unless it is clearly unnecessary). The purpose of the meeting is to prevent long-term sickness absence and discuss if workplace modifications are required. Within six months of sick leave the local NAV office is responsible for arranging a second dialogue meeting, including the employee, employer, and sick-leave certifier (if appropriate). The second dialogue meeting can be arranged earlier if requested by any of the parties.

Motivational interviewing (MI) according to the protocol

The MI intervention was a replication of an intervention, evaluated in a Norwegian trial conducted concurrently in Trondheim (Aasdahl et al. 2018). MI is a practical tool for counselors developed by William Miller and Stephen Rollnick to help people change. It is rooted in the person-centered approach of Carl Rogers and is inspired by several social and behavioral models. MI is based on the principle that people have the resources within themselves to change (self-determination theory). Motivation for change is activated through the person's own change talk.

The participants randomised to the UC+MI arm were offered two face-to-face sessions of MI from NAV caseworkers, in addition to UC. The sessions could last up to one hour. The first session was delivered at a local NAV office as soon as possible after enrolment in the study, and the second session was held 2 weeks later. The NAV caseworkers followed a MI guideline developed for return to work (RTW) by Gunnhild Bagøien (a psychiatrist and member of the motivational interviewing network of trainers) and Roger Hagen (a clinical psychologist). The guideline was based on MI principles to build a collaborative relationship with the participants, including communication skills such as asking open-ended questions, providing reflections, and summaries to evoke and enhance change talk. In the first session, an agenda was set in cooperation with the participant through 'agenda mapping' (the participant decided the agenda for the conversation from a menu of topics, based on what they considered to be most relevant for their situation). The participants' readiness to return to work was assessed (using the MI tools: 'importance ruler' and 'confidence ruler'), and the intervention was tailored according to motivational stage (stages of change). If the participant

was ambivalent about RTW, the pros and cons of sickness absence were explored in an accepting and compassionate manner. In the second session, the participant's current work situation, obstacles to RTW and previous attempts at RTW were discussed. The caseworkers provided information about available RTW support from the NAV in a MI-consistent manner. If the participant was ready for RTW, the NAV caseworker offered to help them develop an action plan for RTW. Summaries of each session were made available to the participants on the NAV's secure online communication platform.

Stratified vocational advice intervention (SVAI) according to the protocol

Stratification

We used the 10-item version of the Örebro Musculoskeletal Pain Screening Questionnaire Short Form (ÖMPSO-SF) (Linton et al 2011), and the 10-item Keele STarT MSK Tool (Dunn et al. 2021), to stratify the participants into two risk groups of long-term sick leave. Participants with ≥ 9 on the Keele STarT MSK Tool and ≥ 60 on the ÖMPSQ-SF were stratified to a 'high-risk group', all others were stratified to a 'medium/low-risk group'. The cut-off points were based on preliminary data from a prospective cohort study conducted as part of the MI-NAV project. The preliminary results from this cohort study showed that the combination of these tools had the greatest accuracy in distinguishing between short versus long-term sick leave in workers on sick leave due to musculoskeletal disorders in Norway (unpublished results). The ÖMPSQ-SF assesses five psychosocial risk factors related to future disability: 1) self-perceived function, 2) pain experience, 3) distress, 4) fear-avoidance beliefs, and 5) RTW expectancy. Sum scores range from 1-100 points with higher scores indicating higher estimated risk of future work disability. The Keele STarT MSK tool consists of 10 items assessing: pain intensity, pain self-efficacy, pain bothersomeness, disability, comorbid pain, expected duration of the condition, self-perceived health, depression, fear avoidance and pain duration (during the last two weeks). Sum scores range from 0-12 points, with values from 0-4 points indicating low risk, 5-8 points indicating medium risk, and 9-12 points indicating high risk for poor prognosis.

Intervention

The SVAI was a modified version of an intervention developed for the SWAP trial (Sowden et al. 2019). The theoretical underpinning of the intervention was social cognitive theory, self-determination theory and the common-sense model of self-regulation (Aanesen et al. 2021).

The participants stratified to the low/medium-risk group were offered up to two telephone sessions. The sessions could last up to one hour. Participants in the high-risk group were offered three to four sessions, the first by telephone, the remaining sessions either by telephone or face-to-face, including an optional workplace meeting. The first session was held as soon as possible after the baseline assessment. The duration of the follow-up period was flexible but ended when the participants reached 6 months of consecutive sick leave or had RTW in their contracted work hours for 4 consecutive weeks. During the first session, the physiotherapists followed a semi-structured conversation guide with open-ended questions to clarify the participants' work and health situation and identify obstacles to RTW. During the sessions, the physiotherapists provided evidence-based advice on the management of musculoskeletal disorders and supported problem-solving to overcome modifiable obstacles to RTW. The follow-up provided by the physiotherapists was tailored according to the participants' needs and individual RTW barriers. They collaborated with the participants to decide goals for RTW, developed and implemented action plans, facilitated communication,

collaboration and coordination with stakeholders and signposted to other services if necessary.

Information leaflet for participants receiving SVAI

Research study aiming to help sick listed people with musculoskeletal disorders back to work

The research study is led by researchers from the MUSK health research group at Oslo Metropolitan University, OsloMet. The aim of the study is to find ways to help people who are sick-listed with musculoskeletal disorders. The study will test two different types of dialogue based interventions. All participants will receive usual follow up from NAV in addition to the interventions given in the study. They can also receive medical treatment from other health care professions during the trial if they wish. You can find more information about the study on the following link: <u>https://www.muskhealth.com/minav3</u>

Vocational advice from physiotherapist

You have agreed to participate in the study and have been randomly assigned to receive vocational advice from a physiotherapist. The physiotherapist will discuss topics related to your health and work situation and try to help you get back to work.

The physiotherapist does not have any connection to the NAV or your employer. Confidentiality: The physiotherapist is bound by law to follow high standards of confidentiality and can't share information with your employer or the NAV without your consent.

What can the physiotherapist do?

- Discuss concerns you have regarding health and work.
- Help you make a return to work plan.
- Identify barriers for returning to work.
- Suggest actions to help you return to work, e.g. suggest adaptions to your work situation, give advice regarding treatment, and how to cope with your health problems.

If you consent the physiotherapist can also:

- Collaborate with you doctor or other health care professionals.
- Collaborate with your employer.

What can you do to get back to work sooner?

• Keep in contact with your workplace and colleagues. You and your employer are responsible for making a follow up plan. Your employer is also responsible for making adaptions to your work if this is necessary for you to be able to return. Your duty is to collaborate with your employer to make this possible.

- Talk to your doctor or physiotherapist about how they can help you get back to work. You know your work best. Discuss which parts of your job you can do with your health problem. Ask for treatment designed to get you ready for work.
- Gradually increase your activity level. Start with the activities you find easy, and do a bit more each day. You will have good days and bad days. Try to keep active also on the bad days. Vary between rest and activity. It is common to have set backs so don't give up!

Evidence based information about work and health

- Research shows that in general work is good for mental and physical health. Work is important for self-esteem and quality of life.
- Being absent from work can have negative effects for health and wellbeing.
- Musculoskeletal disorders are very common and all of us suffer these kinds of problems at some time in our life.
- The pain can be very distressing and may make life difficult, but there is usually no serious disease or lasting damage. Most episodes end quickly, though some symptoms may continue or come back from time to time.
- We have good evidence that returning to work as soon as possible helps recovery, and is the best way to avoid long-term sickness absence.

There are many unhelpful myths about health and work, which can cause unnecessary fear and uncertainty:

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- 3. You should not go back to work until you are fully recovered: Usually the opposite is true. Work can be part of treatment. Getting back to work and activity can help you recover. Adjustments to your work can make it possible to return to work sooner.
- A sick certificate means that you must not work:
 A sick certificate is not an order from your doctor to stay away from work, it only means you are entitled to sick pay. You can return to work as soon as you are ready.

Conversation guide for the SVAI physiotherapists

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good time to talk? IF NO: Make new appointment. IF YES: Thank you for participating	pist from the MI NAV research proje g in our study. Could you please tell						
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CLARIFY CUF	RENT WORK AND HEAL	TH SITUATION					
work situation. Gather information regarding a be asked when appropriate/if y	Gather information regarding all the questions in red on this form, the rest of the questions can be asked when appropriate/if you need more information. Write notes for every topic. You do not need to follow the order of the form, but you should						
	WORK SITUATION						
Sick-listed date	% sick listed	End of sick certificate					
Can you describe your current	nt work situation?						
 What is your current occupation/title? What are your contracted hours of work? (contract work %, days and hours at work, shift pattern) Do you usually work more than your contracted hours? Do you usually work overtime? What does a typical day at work for you look like?/ What does your job involve? (Physical job demands, emotional and cognitive job demands). 							
IDENTIFY OBSTACLES TO RETURN TO WORK							
Use open ended questions, reflection and summarising to identify obstacles to return to work.							
Note any identified obstacles in the action plan. How are your symptoms /condition affecting your ability to work?							
• What do you think about	working with your present pain/ sy	mptoms?					

 Are you worried about any repeat episodes of symptoms/problems once you return to work? How do you feel about the prospect of returning to work at some point?
What are your main concerns about RTW?
 What would make RTW difficult now? Are there stressful elements to your job that might be difficult when you first return to work? Aside from your symptoms are there any other reasons why it would be difficult to RTW now? Have you had a dialogue meeting with your employer?
Trave you had a dialogue meeting with your employer:
 Meeting held Meeting planned
What other contact have you had with work since you have been off sick?
What contact have you had with NAV?
Has your employer made a return-to-work plan? Has the plan been sent to the person who gave you the sick note? How is the plan working?
• What are they doing at work to help?
 Have you discussed with your employers when you might return to work or start working more? When do you think you will go back to work/start working more hours? Do you have an occupational health service at work? Have you had involvement with them?
How happy are you with your work and workplace?
 How would you describe your relationship with your colleagues and employer? Did you have any conflicts with your employer or co-workers before you were sick listed? What kind of response do you expect from co-workers and supervisors when you return? Is your job at risk? Do you enjoy your job? What is it that you value about working or your job? What else does work do for you/ do you get from work? Why did you choose the job/career you did?
How important to you is it to get back to work?
OVERCOMING OCCUPATIONAL OBSTACLES TO RTW
Collaborate with the worker to problem solve and overcome obstacles (see separate obstacles and actions sheet). Note any actions in the action plan.
What could be done at the workplace to help you return to work/increase your work hours?
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Short term work goal
Long term work goal

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	HEALTH SITUATION
	d you please tell me briefly about the main health problem that you are struggling at the moment?
•	When did this episode of pain start?
•	Have you had any previous episodes?
•	Do you think there is a high risk of your current pain becoming persistent?
•	Do you have any other important health problems?
•	What do you think has caused your health problem?
•	Is your pain related to an injury? Was it an injury/accident at work? Is there a litigation case or
	insurance claim related to the accident?
How	is your health condition affecting you day to day?
•	Are you avoiding doing anything or particularly struggling with anything?
•	How are you sleeping?
•	How well do you feel you are managing at the moment?
•	What do you think would help you better manage your symptoms/ condition?
•	How is the situation affecting your mood?
Can y	you describe any treatment you are receiving or have received for your condition?
•	Ongoing treatment.
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	FAMILY SITUATION
•	Do you live alone or with somebody?
•	
•	
•	Is there anything going on at home or to do with your current circumstances that would make it
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Action sheet for the SVAI physiotherapists

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High severity of symptoms/health condition. Comorbid health is a potential obstacle to RTW. Delays in health care. Lack of work focus to health care.	 Ask if participant is taking his/her medication as prescribed by their GP. Suggest that worker makes appointment to see GP. Contact health care providers in order to: a) suggest an appointment/investigation b) expedite an appointment c) ensure the HCP facilitates RTW d) post evidence based information to the health care provider
Current physical functioning not compatible with RTW.	 Suggest that participant sees a physiotherapist, if necessary help to set up appointment. Do values based goal setting.
Avoiding activities. Unhelpful beliefs about health and work.	 Provide reassurance to participant regarding hurt and harm. Advises the participant about how to gradually increase activity and exercise and return to avoided activities. Send leaflet with evidence based information to participant. Provide evidence based information, advice and reassurance to address knowledge gaps, misconceptions or unhelpful beliefs verbally.
Current day/night rest and sleep pattern not compatible with working.	 Provide verbal information about sleep. Inform participant about online resource to deal with sleep disturbance.
Doesn't value work sufficiently to RTW.	 Use motivational interviewing to help the participant decide whether to RTW or not. Explore and built the value of work. Convey positive but realistic messages about their ability to work now or in the future. Encouraged participant to be pro-active in taking steps to resolve the situation.
Lack of or unsupportive contact with the workplace. Other workplace issues.	 Suggest that participant makes contact with employer. Take direct contact with employers if participant needs help with this. Arrange and attend meeting between SVAI physiotherapist, worker and employers. Inform the NAV caseworker about the worksite meeting/visit if NAV caseworker is involved in the case.

Lack of a RTW plan.	 Support participant to develop RTW plan with employers. Build participant self-efficacy to collaborate with employer to make RTW plan, e.g. help make a list of what they want to discuss with employer, roleplay meeting etc Liaise with participant and employer in developing RTW plan.
Poor implementation of RTW plan.	 Review RTW plan with participant. Ask participant to liaise with employers to commence already agreed RTW plan. Discuss with participant how they will work with employers to stick to plan, review plan, modify plan and seek help early, if needed. Liaise with participant and employer to implement existing plan.

APPENDIX II: RECRUITMENT OF PARTICIPANTS TO THE MI-NAV TRIAL

Year	2019 2020 Internal pilot# Cov. ¤																			
Month	Apr	Мау	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar 1-11	Mar 12-31	Apr	Мау	June	July	Aug	Sept	Oct
Recruited	11	17	17	34	31	33	65	50	15	46	34	28	4	22	14	4	7	24	37	21
Total	11	28	45	79	110	143	208	258	273	319	353	381	385	407	421	425	432	456	493	514

[#] Internal pilot including the first 101 participants = Cov. COVID-19 containment strategies were implemented by the Norwegian government on the 12th of March 2020 and recruitment was halted between 12-30 of March

APPENDIX III: TRIAL MODIFICATIONS DUE TO THE COVID-19 PANDEMIC IMPLEMENTED AFTER THE 12TH OF MARCH 2020, Planned by the trial team and reviewed and approved by the scientific board

Modification	Reason for modification	Consequence of modification
The MI intervention may be delivered by telephone or video call, rather than in-person only.	The Norwegian government implemented wide- reaching COVID-19 containment strategies on the 12 th of March 2020 to decrease physical contact between individuals.	22 (10%) MI sessions were delivered by telephone or video call, 203 sessions were delivered in-person.
New sample size calculations were made, and the sample size reduced from 750 to 450 participants.	The sample size had to be reduced to make it possible to complete the trial due to increased workload for the NAV.	Not possible to compare the MI and SVAI interventions head-to-head due to reduced power.
Sensitivity analysis to test if the COVID-19 pandemic moderated the effectiveness of the MI or SVAI compared to UC.	The sensitivity analysis was conducted to investigate if the COVID-19 pandemic affected the trial results.	An exploratory analysis was conducted.
MI: motivational interviewing		

SVAI: stratified vocational advice intervention

BASELINE CHARACTERISTICS OF PARTICIPANTS Appendix IV: IN THE MI-NAV TRIAL, ELIGIBLE INDIVIDUALS IN THE **RECRUITMENT AREA AND IN THE WHOLE OF NORWAY**

Registry data	MI-NAV trial	Recruitment area ¤	Norway ¤
	<i>n</i> = 514	<i>n</i> = 6329	n = 140259
Women, n (%)	293 (57)	3334 (53)	75412 (54)
Age, mean (SD)	48 (10)	47 (12)	46 (12)
Occupations, n (%)			
Legislator, senior officials, managers	9 (2)	448 (7)	9175 (7)
Professionals	94 (18)	918 (15)	22438 (16)
Technicians, associate professionals	30 (6)	653 (10)	14872 (11)
Clerks	41 (8)	395 (6)	8806 (6)
Service, shop and market sales workers	175 (34)	1835 (29)	39839 (28)
Agricultural, forestry and fishery workers	6 (1)	51 (1)	1474 (1)
Craft and related trade workers	63 (12)	847 (13)	17542 (13)
Plant and machine operators, assemblers	64 (13)	606 (10)	14108 (10)
Elementary occupations	31 (6)	565 (9)	11694 (8)
Armed forces and unspecified	1 (0.2)	11 (0.2)	311 (0.2)
Work, <i>n</i> (%)			
Full time: 100%	120 (69)	3788 (60)	87209 (62)
Part time: 50-99%	39 (22)	1339 (21)	27786 (20)
Part time: <50%	15 (9)	1202 (19)	25264 (18)

¤ Persons on sick leave for seven consecutive weeks for more than half of their contracted work hours due to a musculoskeletal disorder during the recruitment period of the MI-NAV Study: 5th of April 2019 to 14th of October 2020

n: SD: number

standard deviation