

Original research

Mechanisms of vocational interventions for return to work from musculoskeletal conditions: a mediation analysis of the MI-NAV trial

Aidan G Cashin ^{1,2}, Britt Elin Øiestad,³ Fiona Aanesen ⁴, Kjersti Storheim,⁵ Alexander Tingulstad,³ Tarjei Langseth Rysstad,³ Hopin Lee,⁶ James H McAuley,^{1,2} Gail Sowden,^{7,8} Gwenllian Wynne-Jones ⁸, Anne Therese Tveter,^{3,9} Margreth Grotle^{5,10}

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/oemed-2022-108716>).

For numbered affiliations see end of article.

Correspondence to

Dr Aidan G Cashin, Neuroscience Research Australia, Randwick, NSW 2031, Australia; a.cashin@neura.edu.au

Received 27 October 2022
Accepted 11 February 2023
Published Online First
2 March 2023

ABSTRACT

Objectives To investigate whether and to what extent, return to work (RTW) expectancy and workability mediate the effect of two vocational interventions on reducing sickness absence in workers on sick leave from a musculoskeletal condition.

Methods This is a preplanned mediation analysis of a three-arm parallel randomised controlled trial which included 514 employed working adults with musculoskeletal conditions on sick leave for at least 50% of their contracted work hours for ≥ 7 weeks. Participants were randomly allocated (1:1:1) to one of three treatment arms; usual case management (UC) (n=174), UC plus motivational interviewing (MI) (n=170) and UC plus a stratified vocational advice intervention (SVAI) (n=170). The primary outcome was the number of sickness absence days over 6 months from randomisation. Hypothesised mediators included RTW expectancy and workability assessed 12 weeks after randomisation.

Results The mediated effect of the MI arm compared with UC on sickness absence days through RTW expectancy was -4.98 days (-8.89 to -1.04), and workability was -3.17 days (-8.55 to 2.32). The mediated effect of the SVAI arm compared with UC on sickness absence days through RTW expectancy was -4.39 days (-7.60 to -1.47), and workability was -3.21 days (-7.90 to 1.50). The mediated effects for workability were not statistically significant.

Conclusions Our study provides new evidence for the mechanisms of vocational interventions to reduce sickness absence related to sick leave due to musculoskeletal conditions. Changing an individual's expectation that RTW is likely may result in meaningful reductions in sickness absence days.

Trial registration number NCT03871712.

INTRODUCTION

Musculoskeletal conditions are the leading contributor to years lived with disability worldwide.¹ In 2019, an estimated 1.71 billion people (95% CI 1.68 to 1.80) globally had a musculoskeletal condition, most commonly spinal pain and osteoarthritis.² These conditions are characterised by pain and reduced physical function, and often lead to significant decline in mental health, increased

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Results from a randomised controlled trial indicated that adding motivational interviewing (MI) or a stratified vocational advice intervention (SVAI) to usual case management (UC) reduced sickness absence days by seven workdays over 6 months for workers on sick leave due to musculoskeletal conditions.
- ⇒ These effects were not statistically significant and uncertain due to wide CIs and require further investigation into their mechanisms of action for optimisation and implementation into clinical practice and policy.

WHAT THIS STUDY ADDS

- ⇒ The results from this mediation analysis of a randomised controlled trial that included 514 employed workers on sick leave with musculoskeletal conditions, showed that adding MI or SVAI to UC, reduced sickness absence days predominately through changing an individual's return to work expectancy.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Our findings provide evidence for a key treatment mechanism of vocational interventions, which may provide important reductions in sickness absence days for people on sickness benefits with one or more musculoskeletal conditions.

risk of developing other chronic health conditions and increased risk of all-cause mortality.³ Musculoskeletal conditions contribute substantial costs to individuals and society, mainly due to healthcare use, reduced productive life years in the workforce and sickness benefits.⁴⁻⁶ There is a pressing need to reduce costs related to sick leave through effective, individually tailored interventions.⁷

One promising intervention for reducing sick leave from musculoskeletal conditions is motivational interviewing (MI),^{8,9} which is a person-centred counselling style aimed at increasing motivation for change.¹⁰ Another promising intervention is



© Author(s) (or their employer(s)) 2023. No commercial re-use. See rights and permissions. Published by BMJ.

To cite: Cashin AG, Øiestad BE, Aanesen F, et al. *Occup Environ Med* 2023;**80**:246–253.

vocational advice to overcome modifiable barriers to return to work for people with musculoskeletal conditions,¹¹ which could be more efficiently delivered as a stratified intervention where treatment is matched to patient risk of long-term sick leave.¹²

The MI-NAV trial,¹³ a recent pragmatic, three-arm parallel randomised controlled trial evaluated the effectiveness of these two interventions in addition to usual case management (UC) in 514 employed workers on sick leave due to a musculoskeletal condition who received follow-up from the Norwegian Labour and Welfare Administration (NAV). Both the MI and stratified vocational advice intervention (SVAI), compared with UC, reduced sickness absence days by seven workdays over 6 months. Despite no agreed minimal important difference for sickness absence, a reduction of seven workdays may be a clinically important effect considering the minimal additional resources required for providing the interventions above UC alone. Although encouraging, there remains uncertainty in the effectiveness of these interventions due to statistically non-significant differences and wide CIs; MI compared with UC (−7 days, 95% CI −15 to 2) and the SVAI compared with UC (−7 days, 95% CI −16 to 1).

There is a need to investigate how the interventions reduced sickness absence days to optimise future vocational interventions and facilitate the implementation of effective interventions to clinical and public health practice.¹⁴ Mediation analysis is a quantitative approach to understand how an intervention changes an outcome. Through mediation analysis, we can separate the total effect of the intervention into; the indirect effect, the intervention's effect on the outcome through the mediator and the direct effect, the interventions effect on the outcome if the mediator were fixed at a particular level. Mediation analyses can be particularly useful in understanding why a particular intervention might have failed to produce effects. For example, an intervention may not be effective because it did not change the mediator, or because the mediator was not related to the outcome as hypothesised.

Both the MI and SVAI interventions incorporated cognitive and behavioural components. These were hypothesised to reduce sickness absence days by increasing two mediators: return to work expectations, defined as an individual's perception of the likelihood to return to normal work duties in 3 months and workability, defined as an interaction between the person, the task and the working environment.^{7-9 11 15} Therefore, this study aimed to investigate whether and to what extent, the hypothesised, theory-driven mechanisms (return to work expectancy and workability) mediated the effect of the interventions on reducing sickness absence days.

METHODS

Study registration and ethical approval

The study protocol and statistical analysis plan for this mediation analysis were registered prior to analysis. The MI-NAV trial was prospectively registered (NCT03871712). This study is reported in accordance with A Guideline for Reporting Mediation Analyses.¹⁶

Study design and data source

The MI-NAV trial design has been reported elsewhere,⁷ and the primary analyses have been published.¹³ Briefly, the MI-NAV trial was a pragmatic, three-arm parallel randomised controlled trial with two separate comparisons; UC compared with MI, and UC compared with SVAI. Workers on sick leave due to a musculoskeletal disorder were recruited from eight participating

NAV offices in South-Eastern Norway between April 2019 and October 2020. Potential participants were identified from weekly updated lists of workers in week 7 of sick leave and contacted by recruiters from the NAV directorate. Eligible individuals who confirmed participation via telephone were sent an electronic link with informed consent and questionnaires to be completed before allocation to groups (baseline). Participants were next stratified¹⁷ into a medium/low or a high risk of long-term sick leave group.¹⁷ Using a combination of the 10-item version of the Örebro Musculoskeletal Pain Screening Questionnaire Short Form (ÖMPSQ-SF)¹⁸ and the 10-item Keele STarT MSK Tool,¹⁹ participants were stratified to the high-risk group if they had ≥ 9 points (out of 12) on the Keele STarT MSK Tool and ≥ 60 points (out of 100) on the ÖMPSQ-SF at baseline and all others stratified to the medium-risk/low-risk group.¹⁷ Within each stratum of risk group, participants were randomly allocated through concealed computer-generated allocation (1:1:1) to one of the three treatment arms; UC, MI or SVAI.

Participants

The MI-NAV trial included 514 (25%) of the 2054 identified eligible employed working adults (full-time or part-time) on sick leave with a musculoskeletal condition for at least 50% of their contracted work hours for at least seven consecutive weeks. Participants were required to be aged between 18 and 67 years, diagnosed with any musculoskeletal conditions listed in the second edition of the International Classification of Primary Care, and have sufficient Norwegian or English language skills to answer questionnaires and communicate by telephone. The MI-NAV trial excluded people with serious somatic or mental health conditions, women who were pregnant and people who were unemployed, freelancers or self-employed.

Interventions and control

Usual case management

All participants were offered UC for people on sick leave in Norway. This should entail a return-to-work plan made by the employer and worker within the first 4 weeks of sick leave; a dialogue meeting between the worker, employer and other relevant stakeholders such as general practitioner, arranged by the employer within 7 weeks of sick leave, and if necessary, a second dialogue meeting between the worker, the employer and other relevant stakeholders, arranged by the NAV caseworker after approximately 26 weeks of sick leave.

Motivational interviewing plus usual case management

The participants in the MI arm were offered two face-to-face MI sessions provided by trained NAV caseworkers in addition to UC. The first session was delivered at the local NAV office shortly after random allocation, and the second session was held 2 weeks later. The MI sessions were delivered according to a guideline and based on MI principles to build a collaborative relationship with the participant, for example, asking open-ended questions, providing reflections and summaries to evoke and enhance change talk. The sessions involved discussion of the participants' readiness, existing support and previous attempts to return to work, and provided information and support to co-develop an action plan for return to work in a MI consistent manner. A comprehensive description of the MI intervention is provided in the published fidelity evaluation.²⁰

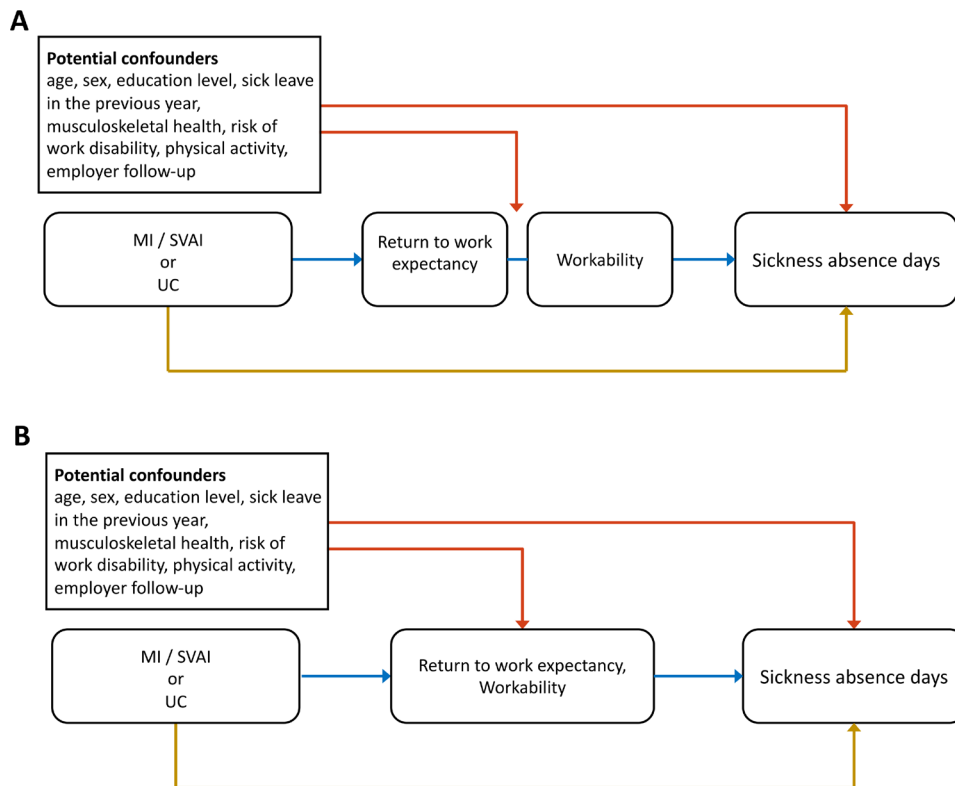


Figure 1 Diagram of the assumed associations between MI/SVAI and UC on sickness absence days through the potential mediators (return to work expectancy and workability). The mediators were assessed at 12 weeks after randomisation, the outcome was measured at 26 weeks after randomisation and the potential confounders were measured at baseline. Panel A represents the multiple mediator model and panel B represents the single mediator models. The intervention-mediator association is represented by the blue line from the interventions to the mediators. The mediator-outcome association is represented by the blue line from the mediators to the outcome. The potential confounders of the mediator-outcome association are represented by the red arrows. The direct effect of interventions on the outcome is represented by the yellow line. MI, motivational interviewing; SVAI, stratified vocational advice intervention; UC, usual case management.

Stratified vocational advice intervention plus usual case management

The participants in the SVAI arm were offered vocational advice and case management from trained physiotherapists in addition to UC. Participants stratified in the medium-risk/low-risk group were offered up to two telephone sessions. Participants stratified in the high-risk group were offered up to four sessions, the first by telephone and the remaining by telephone or face-to-face, including an optional workplace meeting. The first session was delivered shortly after random allocation and the treatment stopped by week 26 of the sick leave period or if the participant had returned to their contracted work hours for four consecutive weeks. The sessions involved the provision of evidence-based advice on the management of musculoskeletal conditions, supportive problem-solving to overcome modifiable obstacles for return to work, collaborative goal setting and the development and implementation of a return-to-work action plan. The physiotherapists were also supposed to facilitate collaboration and coordination with stakeholders and signposted to additional services where necessary. A comprehensive description of the SVAI intervention is provided in the published process evaluation.²¹

Measurement

Data were collected at baseline (prior to randomisation), 12 and 26 weeks after randomisation, using a secure online data-capture software and from national registries.

Outcome

The primary outcome was sickness absence days from registry data delivered by the NAV, measured as lost workdays over 6 months from randomisation. Any increase in disability pensions from baseline was also counted as sick leave. We converted the number of sickness absence days to actual time away from work using the participants' contracted work hours and amount of sick leave. This was summed up and converted to lost workdays, according to a 5-day working week when working full-time.

Mediators

Two potential mediators were selected a priori based on preliminary evidence and expert opinion on how the interventions may reduce sickness absence.^{7 8 22 23} A mediator is an intermediate variable that may be affected by an exposure (intervention) and may in turn affect an outcome.¹⁶ The potential mediators were (i) return to work expectancy, self-assessed by one question from the ÖMPSQ-SF¹⁸ ("In your estimation, what are the chances you will be working your normal duties in three months", scale range 0–10, lower scores indicate worse work expectancy) and (ii) workability, self-assessed by one item from the Finnish Work Ability Index²⁴ ('current workability compared with the lifetime best', scale range 0–10, lower scores indicate worse workability), both assessed at 12 weeks after randomisation.

Table 1 Baseline characteristics

Characteristic*	Usual case management, n=174	Motivational interviewing, n=170	Stratified vocational advice, n=170
Age, years (mean (SD))	47.5 (9.9)	48.3 (10.5)	47.9 (9.9)
Women	94 (54)	99 (58)	100 (59)
Pain intensity† (mean (SD))	6.3 (2.2)	6.3 (1.9)	6.4 (2.0)
BMI mean (mean (SD))	28.2 (5.1), n=171	28.3 (5.8), n=164	28.2 (5.4), n=166
Current smoker			
Yes	39 (22)	35 (21)	36 (21)
Physical activity, days previous week			
None	65 (37)	54 (32)	64 (38)
1–2	46 (26)	43 (25)	39 (23)
3–4	38 (22)	45 (26)	41 (24)
5–7	25 (14)	27 (16)	26 (15)
Education			
Primary school	21 (12)	14 (8)	20 (12)
Secondary school	92 (53)	95 (56)	84 (49)
Higher education up to <4 years	40 (23)	46 (27)	49 (29)
Higher education ≥4 or greater	21 (12)	15 (9)	17 (10)
White-collar workers	58 (33)	56 (33)	61 (36)
Blue-collar workers	116 (67)	114 (67)	109 (64)
Risk group			
Low/Medium	136 (78)	134 (79)	135 (79)
High	38 (22)	36 (21)	35 (21)
Employer follow-up			
No follow-up	65 (37)	72 (42)	72 (42)
Dialogue meeting or follow-up plan	64 (37)	53 (31)	65 (38)
Dialogue meeting and follow-up plan	44 (25)	40 (24)	32 (19)
Sickness absence days previous 12 months, work days (median (IQR))	38.5 (29.8–49.9), n=171	35.1 (30.7–50.0), n=169	36.2 (26.4–50.0), n=169
Workability‡ (mean (SD))	2.8 (2.5), n=173	3.3 (2.8)	3.1 (2.7), n=168
Return to work expectancy (mean (SD))	6.9 (2.8)	7.2 (2.6)	7 (2.8)

*Data are presented as n (%) unless otherwise stated.

†11-point numerical rating scale, scale range 0–10, higher scores indicate more severe pain.

‡11-point numerical rating scale, scale range 0–10, higher scores indicate better workability.

§11-point numerical rating scale, scale range 0–10, higher scores indicate better return to work expectancy.

BMI, body mass index.

Confounders

We identified potential confounders of the mediator-outcome association by selecting measured pretreatment covariates that are hypothesised to be a cause of the mediator, the outcome or both.²⁵ The minimum sufficient adjustment set included age, sex, education level, sick leave in the previous year, musculoskeletal health, risk of work disability, physical activity and employer follow-up all assessed at baseline.

Assumed causal model and assumptions

Figure 1 describes the assumed causal model of the associations between the interventions and control on sickness absence days through the potential mediators. We assumed no confounding of the intervention-mediator and intervention-outcome effects due to random allocation of the interventions. We assumed no confounding of the mediator-outcome effects due to statistical adjustment for a minimum set of potential confounders and that the mediators were independent of each other.

Statistical analysis

We estimated the intervention-mediator and mediator-outcome effects and corresponding uncertainty estimates for each of the potential mediators using two linear regression models: the mediator model and the outcome model. Both the mediator and outcome models included baseline measures of the selected mediator and outcome in the models in addition to the identified potential confounders.²⁶ We also included an interaction term (allocation×mediator) in the outcome models to increase model flexibility.²⁷

All mediation analyses were conducted under the counterfactual-based framework using a model-based inference approach.²⁸ Within this approach, all causal effects were estimated through direct counterfactual imputation estimation and SEs of causal effects were estimated through bootstrapping. We estimated the average causal mediation effect (ACME) and the average direct effect (ADE) with corresponding uncertainty estimates considering each mediator independently and considering all mediators simultaneously as a joint mediator. We also estimated if the ACME and ADE varied between participant risk stratification subgroup (medium-risk/low-risk and high-risk).

Although we assumed missing data to be missing at random, we addressed this through performing multiple imputation by chained equations, generating 10 separate imputed data sets for analysis.

Statistical analyses were performed in R V.3.4.4 (The R Foundation) and specific packages (*mediation*²⁸ for mediation effects and *mice* package²⁹ for multiple imputations). Two-sided $p < 0.05$ indicated statistical significance.

Sensitivity analyses

We conducted sensitivity analyses to examine the robustness of the ACME to possible bias introduced by unmeasured mediator-outcome confounding. The mediational E-value³⁰ was used to assess the minimum strength of the association between an unmeasured confounder and the mediator, conditional on measured confounders, that would reduce the ACME to zero.

RESULTS

A total of 514 participants were assessed at baseline and randomised into the UC (n=174), MI (n=170) and SVAI (n=170) treatment arms. Three hundred and eighty (74%) participants provided data for potential mediators at 12 weeks after randomisation, and 509 (99%) participants provided outcome data at 26 weeks after randomisation. The mean (SD) age of participants was 48 (10.1) years, 293 participants were women (57%) and 221 participants were men (43%). Most participants (n=341, 66%) worked in full-time positions, were on full sick leave at baseline (n=315, 62%) and reported mean (SD) pain intensity rated as moderate-to-severe (6.3 (2.0)). Most participants did not currently smoke (n=404, 79%), were physically active for at least 1 day in the past week (n=331, 64%)

Table 2 Effect decomposition for the effect of the interventions compared with UC on sickness absence days considering the mediators independently

Mediator	Intervention-mediator effect (95% CI)	Mediator-outcome effect (95% CI)	Average causal mediation effect (95% CI)	Average direct effect (95% CI)	Average total effect (95% CI)	Proportion mediation
MI versus UC (n=344)						
Workability	0.49 (−0.15 to 1.23)	−7.85 (−9.68 to −6.02)	−3.17 (−8.55 to 2.32)	−1.67 (−8.00 to 4.68)	−4.84 (−13.04 to 4.01)	57%
Return to work expectancy	0.69 (0.04 to 1.33)	−4.65 (−6.43 to −2.87)	−4.98 (−8.89 to −1.04)	−0.16 (−7.97 to 7.16)	−5.14 (−13.51 to 3.11)	80%
SVAI versus UC (n=344)						
Workability	0.55 (−0.07 to 1.17)	−7.89 (−9.61 to −6.17)	−3.21 (−7.90 to 1.50)	−4.65 (−11.43 to 1.90)	−7.87 (−16.41 to 0.45)	41%
Return to work expectancy	0.76 (0.11 to 1.41)	−4.57 (−6.43 to −2.71)	−4.39 (−7.60 to −1.47)	−3.82 (−11.32 to 3.58)	−8.21 (−16.08 to 0.07)	51%

All effects unstandardised and presented with their 95% CIs.
MI, motivational interviewing; SVAI, stratified vocational advice intervention; UC, usual case management.

and had a mean (SD) body mass index of 28.2 (5.4). Baseline characteristics are summarised in [table 1](#).

The proportion of missing data was <5% for all variables except the potential mediators which had 26% missing data. The missing data were imputed for all analyses.

The MI intervention compared with UC was associated with statistically significant improvement in the mediator return to work expectancy (0.69 (95% CI 0.04 to 1.33), 0–10 scale) and a non-statistically significant improvement for the mediator workability (0.49 (95% CI −0.15 to 1.23), 0–10 scale) ([table 2](#)). Both mediators were associated with a statistically significant reduction in sickness absence days; return to work expectancy −4.65 (95% CI −6.43 to −2.87) days and workability −7.85 (95% CI −9.68 to −6.02) days ([table 2](#)).

The SVAI intervention compared with UC was associated with statistically significant improvement in the mediator return to work expectancy (0.76 (95% CI 0.11 to 1.41), 0–10 scale) and a non-statistically significant improvement in the mediator workability (0.55 (95% CI −0.07 to 1.17), 0–10 scale) ([table 2](#)). Both mediators were associated with a statistically significant reduction in sickness absence days; return to work expectancy −4.57 (95% CI −6.43 to −2.71) days and workability −7.89 (−9.61 to −6.17) days ([table 2](#)).

Mediation effects

Effect decomposition for the MI versus UC and SVAI versus UC comparisons for the outcome sickness absence days considering each mediator independently and combined are presented in [table 2](#) and [table 3](#), respectively. [Figure 2](#) compares the ACME for each intervention comparison on the outcome considering each mediator independently and combined.

MI versus UC comparison

The ACME of return to work expectancy for the MI intervention compared with UC was −4.98 (95% CI −8.89 to −1.04)

sickness absence days, whereas the ACME of workability was −3.17 (95% CI −8.55 to 2.32) days (not statistically significant). When both mediators were considered simultaneously, the joint mediation effect was −6.22 (95% CI −12 to −0.44) days.

SVAI versus UC comparison

The ACME of return to work expectancy for the SVAI intervention compared with UC was −4.39 (95% CI −7.60 to −1.47) sickness absence day, whereas the ACME of workability was −3.21 (95% CI −7.90 to 1.50) days (not statistically significant). When both mediators were considered simultaneously, the joint mediation effect was −5.19 (95% CI −10.82 to −0.44) days.

There was no evidence that risk stratification subgroup (medium-risk/low-risk or high-risk) moderated the ACME for the MI versus UC or SVAI versus UC comparisons.

Sensitivity analyses

The sensitivity analyses (online supplemental table 1) suggest that the statistically significant ACMEs for the MI versus UC and SVAI versus UC comparisons on outcome sickness absence days are robust to potential unmeasured mediator-outcome confounding. The mediational E-values for these ACME on the risk ratio scale ranged from 1.63 to 1.75 for the MI versus UC comparison and 1.57 to 1.65 for the SVAI versus UC comparison. That is, the strength of the association of an unmeasured confounder with both the mediator and the outcome, conditional on the measured covariates, would need to be at minimum, >1.57 on the risk ratio scale to reduce the ACME to zero.

DISCUSSION

In our study, we found that the addition of two sessions of MI or one to four sessions of SVAI to UC reduced sickness absence days predominately through changing individuals' return to work expectancy. Neither intervention was able to sufficiently

Table 3 Effect decomposition for the effect of the interventions compared with UC on sickness absence days considering the mediators combined

	Average causal mediation effect (95% CI)	Average direct effect (95% CI)	Average total effect (95% CI)	Proportion mediation
MI versus UC (n=344)				
Return to work+workability	−6.22 (−12 to −0.44)	−1.15 (−8.49 to 6.18)	−7.38 (−16.79 to 2.04)	84%
SVAI versus UC (n=344)				
Return to work expectancy+workability	−5.19 (−10.82 to −0.44)	−5.82 (−12.77 to 1.13)	−11.01 (−23.59 to 0.69)	47%

All effects unstandardised and presented with their 95% CIs.
MI, motivational interviewing; SVAI, stratified vocational advice intervention; UC, usual case management.

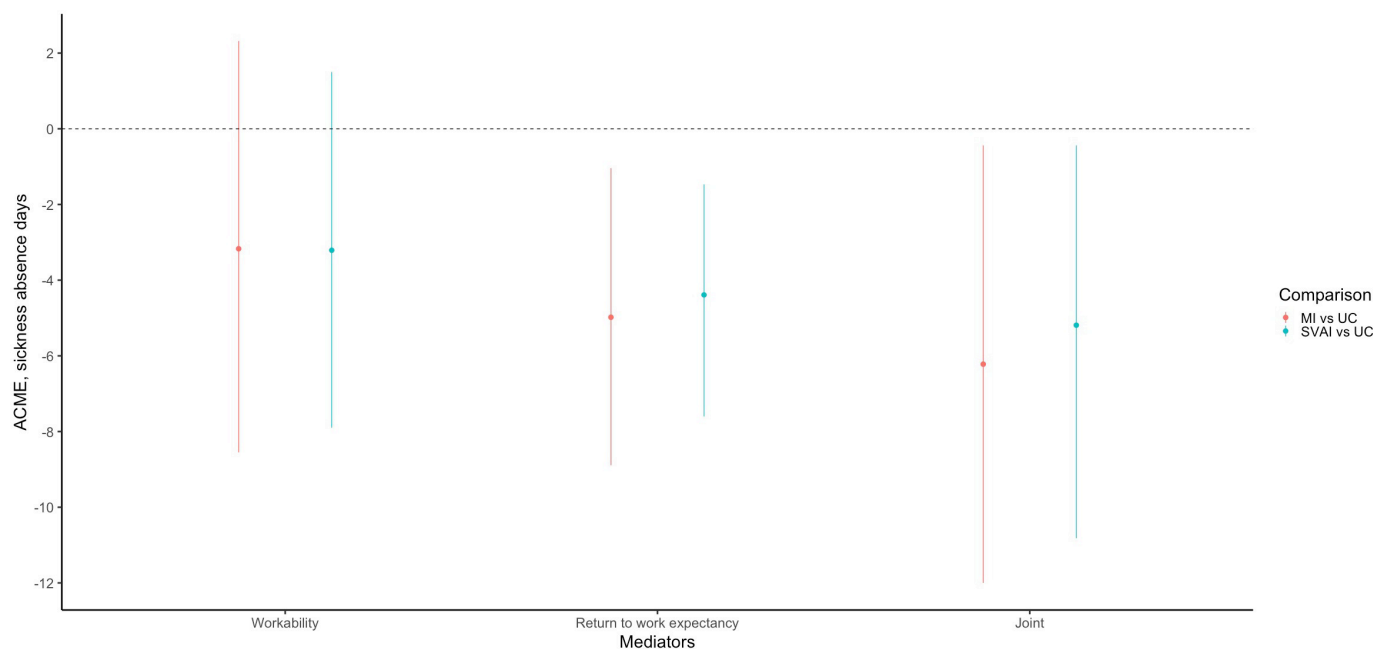


Figure 2 Average causal mediation effect (ACME) for the effect of the interventions compared with usual case management (UC) on sickness absence days considering the mediators independently and combined. Estimates are ACME with 95% CIs estimated through direct counterfactual imputation estimation and bootstrapping, respectively. Effects are expressed as sickness absence days. MI, motivational interviewing; SVAI, stratified vocational advice intervention.

change an individual's perception of their workability, which if targeted, is likely to lead to greater reductions in sickness absence days. Together, our findings provide evidence for key mechanisms of vocational interventions, which if optimised, may provide important reductions in sickness absence days for people on sickness benefits due to a musculoskeletal condition.

Although return to work expectations and self-assessed workability are considered important predictors of return to work outcomes for people with musculoskeletal conditions,^{31 32} our findings suggest that they are also important treatment mechanisms which should be specifically targeted by vocational rehabilitation programmes. To our knowledge, this is the first study to investigate how vocational interventions reduce sickness absence days using mediation analysis in individuals with musculoskeletal conditions. Although several studies have shown that return to work expectancies²³ and workability³³ mediated the effect of workplace exposures on work absence among injured and non-injured workers, only one previous study has investigated the mechanisms of a vocational intervention.³⁴ This study found no evidence of mediation with any of their proposed mechanisms (fear-avoidance beliefs, perceived muscle strength, use of assistive devices at work and perceived physical exertion at work) on clinical outcomes.³⁴ There is a need for future trials of vocational interventions to prospectively include mediation analyses to build on this limited evidence base.

One way to optimise vocational interventions is to identify and improve targeting of important treatment mechanisms. Mediation analysis involves estimating the intervention-mediator and mediator-outcome effects which can help to provide insight into possible treatment mechanisms and potential treatment targets. For example, the intervention-mediator effect describes how the intervention affects the mediator (action theory) and the mediator-outcome effects describes how the mediator affects the outcome (conceptual theory). Our mediation analysis found that the MI or SVAI interventions did not sufficiently change workability relative to UC (intervention-mediator effect). Considering

the large association between changes in workability and reduced sickness absence days (mediator-outcome effect), future iterations of MI or SVAI should aim to better target an individual's perception of workability to produce a greater reduction in sickness absence days.

Our results emphasise the need to shift an individual's return to work expectations and improve their perception of workability. The concept of expectancies has been linked to several factors that impact return to work outcomes, such as self-efficacy and pain catastrophising.³⁵ An individual's previous negative experiences (eg, work and/or pain experiences) may reduce the level of confidence to perform a specific behaviour or actively engage in the return-to-work process. According to Bandura,³⁶ negative expectancies can be improved through expectancy-disconfirming experiences using, for example, graded activity to enhance the individual's thoughts of positive experiences and lead them to expect positive experiences in the future. Workability can be improved through coordinated efforts to change an individual's perception of their work demands and environment, their functional capacities and their mental resources,³⁷ such as through a combination of educational, rehabilitation and workplace engagement strategies. Return to work stakeholders (eg, clinician, caseworker, employer) should also be mindful of how they communicate to workers with musculoskeletal conditions because their language can positively or negatively influence return to work expectations and perceptions of workability.³⁸ For example, language which suggests that the worker on sick leave is now fragile, vulnerable and unfit to move can reduce their perception of workability and return to work expectations, negatively influencing future treatment engagement and recovery.

Strengths and limitations

Strengths of this study include using data from a large, high-quality, pragmatic randomised controlled trial which tested

the addition of two interventions to standardised, UC control. This design strengthens inferences about the causal mechanisms for each intervention by minimising risks of confounding and controlling for non-specific elements of receiving UC.^{14 39} We used an evidence-based and consensus-based approach to our mediation analysis and transparently reported our findings following recommended reporting guidance.¹⁶

Although we had almost complete outcome data (99%), a limitation of our study is that there was 26% missing data for the two potential mediators. Missing data were assumed to be missing at random and were managed through multiple imputation for all analyses. In addition, we cannot know if all relevant mediator-outcome confounders were accounted for in the analyses. For example, we did not assess and adjust for the potential confounders psychological distress or physical and psychological occupational demands which could bias the indirect and direct effects. However, results from our sensitivity analyses suggest that our findings are robust to unmeasured confounding. Finally, there were small differences in the baseline characteristics between groups (eg, education and employer follow-up). However, any differences in baseline characteristics, including mediators return to work expectancy and workability, are the result of chance.⁴⁰

CONCLUSIONS

Overall, our study provides new evidence for the mechanisms of vocational interventions to reduce sickness absence days and address substantial costs related to sick leave due to musculoskeletal conditions. We found that adding vocational interventions to UC, reduced sickness absence days predominately through changing an individual's return to work expectancy. Our results suggest that changing an individual's expectation that return to work is likely and their perception of workability may result in meaningful reductions in sickness absence days.

Author affiliations

¹Centre for Pain IMPACT, Neuroscience Research Australia, Randwick, Sydney, Australia

²School of Health Sciences, University of New South Wales, Sydney, New South Wales, Australia

³Department of Rehabilitation Science and Health Technology, Faculty of Health Sciences, Oslo Metropolitan University, Oslo, Norway

⁴National Institute of Occupational Health, Oslo, Norway

⁵Research and Communication Unit for Musculoskeletal Health (FORMI), Division of Clinical Neuroscience, Oslo University Hospital, Oslo, Norway

⁶Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, UK

⁷Connect Health Ltd, Newcastle upon Tyne, UK

⁸School of Medicine, Keele University, Keele, UK

⁹Norwegian National Advisory Unit on Rehabilitation in Rheumatology, Diakonhjemmet Hospital, Oslo, Norway

¹⁰Centre for Intelligent Musculoskeletal Health, Department of Rehabilitation Science and Health Technology, Oslo Metropolitan University, Oslo, Norway

Twitter Aidan G Cashin @AidanCashin

Contributors AGC, BEØ and MG conceptualised the study and devised the methodology. All authors contributed to and approved the study protocol. BEØ was principal investigator of the MI-NAV trial, whereas MG was responsible for the larger MI-NAV project with three work packages, including receiving funding for the project. FA and AT recruited the trial participants. ATT oversaw data storage. TLR and FA prepared the data for analysis. AGC designed and conducted the formal analysis. AGC interpreted analyses and wrote the original manuscript draft. All authors contributed to reviewing and editing the original manuscript draft. All authors read and approved the final draft of the manuscript. AGC is the corresponding author and full access to the data and had final responsibility for the decision to submit for publication. AGC is the guarantor for the study and accepts full responsibility for the finished work and conduct of the study.

Funding The Research Council of Norway was the main funder of the trial (grant no. 280431). The Norwegian Labour and Welfare Administration (NAV) and Oslo Metropolitan University contributed with personal, infrastructure and coordination of the trial.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval The MI-NAV trial was judged by the Regional Committee for Medical and Health Research Ethics not to be subject to the ACT 2008-06-20 no. 44: Act on medical and health research. The trial was conducted in accordance with the Helsinki Declaration and was assessed in line with the General Data Protection Regulation by the Norwegian Centre for Research Data (identifier: 861249). All participants gave electronic informed consent before study entry.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Anonymised individual participant data (including data dictionary) will be available on reasonable 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. Requests to access data should be addressed to brielo@oslomet.no.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

ORCID iDs

Aidan G Cashin <http://orcid.org/0000-0003-4190-7912>

Fiona Aanesen <http://orcid.org/0000-0002-3284-8060>

Gwenllian Wynne-Jones <http://orcid.org/0000-0002-0283-6632>

REFERENCES

- 1 Abbafati C, Machado DB, Cislighi B. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet* 2020;396:1204-22.
- 2 Cieza A, Causey K, Kamenov K, et al. Global estimates of the need for rehabilitation based on the Global Burden of Disease Study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet* 2021;396:2006-17.
- 3 Briggs AM, Woolf AD, Dreinhöfer K, et al. Reducing the global burden of musculoskeletal conditions. *Bull World Health Organ* 2018;96:366-8.
- 4 Schofield DJ, Shrestha RN, Cunich M, et al. Lost productive life years caused by chronic conditions in Australians aged 45-64 years, 2010-2030. *Medical Journal of Australia* 2015;203:260. 10.5694/mja15.00132 Available: <https://onlinelibrary.wiley.com/doi/10.5694/mja15.00132>
- 5 del, Vroonhof P, Snijders J, et al. *Work-related musculoskeletal disorders: prevalence, costs and demographics in the EU*. 2019.
- 6 Bevan S. Economic impact of musculoskeletal disorders (MSDs) on work in Europe. *Best Pract Res Clin Rheumatol* 2015;29:356-73.
- 7 Øiestad BE, Aanesen F, Løchting I, et al. Study protocol for a randomized controlled trial of the effectiveness of adding motivational interviewing or stratified vocational advice intervention to usual case management on return to work for people with musculoskeletal disorders. the MI-NAV study. *BMC Musculoskelet Disord* 2020;21:496.
- 8 Page KM, Tchernitskaia I. Use of motivational interviewing to improve return-to-work and work-related outcomes: a review. *The Australian Journal of Rehabilitation Counselling* 2014;20:38-49.
- 9 Aanesen F, Berg R, Løchting I, et al. Motivational interviewing and return to work for people with musculoskeletal disorders: a systematic mapping review. *J Occup Rehabil* 2021;31:63-71.
- 10 Miller WR, Rollnick S. *Motivational interviewing: helping people change*. 3rd edn. New York: Guilford press, 2013.
- 11 Wynne-Jones G, Artus M, Bishop A, et al. Effectiveness and costs of a vocational advice service to improve work outcomes in patients with musculoskeletal pain in primary care: a cluster randomised trial [SWAP trial ISRCTN 52269669]. *Pain* 2018;159:128-38.
- 12 Nicholas MK, Costa DSJ, Linton SJ, et al. Implementation of early intervention protocol in Australia for "high risk" injured workers is associated with fewer lost work days over 2 years than usual (stepped) care. *J Occup Rehabil* 2020;30:93-104.
- 13 Aanesen F, Grotle M, Rysstad TL, et al. 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. *Occup Environ Med* 2023;80:42–50.
- 14 Cashin AG, Lee H. An introduction to mediation analyses of randomized controlled trials. *J Clin Epidemiol* 2021;133:161–4.
 - 15 Ilmarinen J. Work ability -- a comprehensive concept for occupational health research and prevention. *Scand J Work Environ Health* 2009;35:1–5.
 - 16 Lee H, Cashin AG, Lamb SE, et al. A guideline for reporting mediation analyses of randomized trials and observational studies: the AGReMA statement. *JAMA* 2021;326:1045–56.
 - 17 Tveter AT, Øiestad BE, Rysstad TL, et al. Risk assessment for prolonged sickness absence due to musculoskeletal disorders: protocol for a prospective cohort study. *BMC Musculoskelet Disord* 2020;21:326.
 - 18 Linton SJ, Nicholas M, MacDonald S. Development of a short form of the Örebro musculoskeletal pain screening questionnaire. *Spine (Phila Pa 1976)* 2011;36:1891–5.
 - 19 Dunn KM, Campbell P, Lewis M, et al. Refinement and validation of a tool for stratifying patients with musculoskeletal pain. *Eur J Pain* 2021;25:2081–93.
 - 20 Løchting I, Hagen R, Monsen CK, et al. Fidelity of a motivational interviewing intervention for improving return to work for people with musculoskeletal disorders. *Int J Environ Res Public Health* 2021;18:10324.
 - 21 Aanesen F, Øiestad BE, Grotle M, et al. Implementing a stratified vocational advice intervention for people on sick leave with musculoskeletal disorders: a multimethod process evaluation. *J Occup Rehabil* 2022;32:306–18.
 - 22 Main CJ, Foster N, Buchbinder R. How important are back pain beliefs and expectations for satisfactory recovery from back pain? *Best Pract Res Clin Rheumatol* 2010;24:205–17.
 - 23 Carrière JS, Thibault P, Adams H, et al. Expectancies mediate the relationship between perceived injustice and return to work following whiplash injury: A 1-year prospective study. *Eur J Pain* 2017;21:1234–42.
 - 24 Ilmarinen J. The work ability index (WAI). *Occup Med (Chic Ill)* 2006;57:160.
 - 25 VanderWeele TJ. Principles of confounder selection. *Eur J Epidemiol* 2019;34:211–9.
 - 26 Landau S, Emsley R, Dunn G. Beyond total treatment effects in RCTs: why we need to measure outcomes at baseline when investigating mediation. *Trials* 2015;16:16–7.
 - 27 Vanderweele TJ. *Explanation in causal inference*. Oxford: Oxford University Press, 2015.
 - 28 Tingley D, Yamamoto T, Hirose K, et al. Mediation: R package for causal mediation analysis. *J Stat Softw* 2014;59.
 - 29 van Buuren S, mice G-OK. Multivariate imputation by chained equations in R. *J Stat Softw* 2011;45:1–67.
 - 30 Smith LH, VanderWeele TJ. Mediation E-values. *Epidemiology* 2019;30:835–7.
 - 31 Rashid M, Kristofferzon M-L, Nilsson A, et al. Factors associated with return to work among people on work absence due to long-term neck or back pain: a narrative systematic review. *BMJ Open* 2017;7:e014939.
 - 32 Carrière JS, Donayre Pimentel S, Bou Saba S, et al. Recovery expectations can be assessed with single-item measures: findings of a systematic review and meta-analysis on the role of recovery expectations on return-to-work outcomes after musculoskeletal pain conditions. *Pain* 26, 2022.
 - 33 van Hoffen MFA, Rijnhart JJM, Norder G, et al. Distress, work satisfaction, and work ability are mediators of the relation between psychosocial working conditions and mental health-related long-term sickness absence. *J Occup Rehabil* 2021;31:419–30.
 - 34 Stevens ML, Boyle E, Hartvigsen J, et al. Mechanisms for reducing low back pain: a mediation analysis of a multifaceted intervention in workers in elderly care. *Int Arch Occup Environ Health* 2019;92:49–58.
 - 35 Sullivan MJ, Thorn B, Haythornthwaite JA, et al. Theoretical perspectives on the relation between catastrophizing and pain. *Clin J Pain* 2001;17:52–64.
 - 36 Bandura A. Self-Efficacy: toward a unifying theory of behavioral change. *Psychol Rev* 1977;84:191–215.
 - 37 Tuomi K, Huuhtanen P, Nykyri E, et al. Promotion of work ability, the quality of work and retirement. *Occup Med (Lond)* 2001;51:318–24.
 - 38 Sullivan M, Tanzer M, Reardon G, et al. The role of presurgical expectancies in predicting pain and function one year following total knee arthroplasty. *Pain* 2011;152:2287–93.
 - 39 Cashin AG, McAuley JH, Lamb SE, et al. Disentangling contextual effects from musculoskeletal treatments. *Osteoarthritis Cartilage* 2021;29:297–9.
 - 40 Altman DG, Doré CJ. Randomisation and baseline comparisons in clinical trials. *Lancet* 1990;335:149–53.

Supplementary Table 1. Mediation E-values for average causal mediation effect on the risk ratio scale.

Mediator(s)	E-value point effect	E-value lower bound
MI vs UC		
Workability	1.46	1
Return to work expectancy	1.63	1.23
Joint	1.75	1.14
SVAI vs UC		
Workability	1.46	1
Return to work expectancy	1.57	1.26
Joint	1.65	1.02

E-values were considered small (risk ratio <1.25), medium (risk ratio 1.25 to 2) and large (risk ratio >2)¹

¹ Rubinstein SM, Terwee CB, Assendelft WJJ, de Boer MR, van Tulder MW. Spinal manipulative therapy for acute low-back pain. *Cochrane Database of Systematic Reviews* 2012, Issue 9. Art. No.: CD008880.