

ORIGINAL ARTICLE

Long-term effects on income and sickness benefits after work-focused cognitive-behavioural therapy and individual job support: a pragmatic, multicentre, randomised controlled trial

Simon Øverland,^{1,2} Astrid Louise Grasdal,³ Silje Endresen Reme^{4,5}

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¹Division of Mental and Physical Health, Norwegian Institute of Public Health, Oslo, Norway

²Department of Psychosocial Science, University of Bergen, Bergen, Norway

³Department of Economics, University of Bergen, Bergen, Norway

⁴Uni Research Health, Uni Research, Bergen, Norway

⁵Department of Psychology, University of Oslo, Oslo, Norway

Correspondence to

Professor Simon Øverland, Division of mental and physical health, Norwegian Institute of Public Health, Bergen 5808, Norway; simon.overland@fhi.no

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ABSTRACT

Background There is moderate quality evidence that integrating work-directed interventions and components from psychological therapies reduces sickness absence in the medium term. We aimed to extend this evidence by examining objectively ascertained income and work participation status up to 4 years after an intervention to improve outcomes among people who struggle with work from common mental disorder.

Methods The intervention combined components from cognitive behavioural therapy with principles from supported employment, and compared its efficacy with usual care. Outcomes were derived from registry data with no attrition, in a pragmatic multisite randomised controlled trial (N=1193).

Results The intervention group had higher income, higher work participation and more months without receiving benefits over the 10-month to 46-month long-term follow-up period after end of treatment, but differences were not statistically significant. For the group on long-term benefits at inclusion, effect sizes were larger and statistically significant.

Conclusion There were no statistically significant differences between the two groups in the primary outcome in the total population. In a secondary analysis for the subgroup most at risk of permanent work exclusion, long-term outcomes were favourable in the intervention group compared with usual care. The results support integrated work and health services for people on the severe end of work participation challenges.

Trial registration number NCT01146730.

INTRODUCTION

Anxiety and depression are highly prevalent and disabling conditions. They often first present in adolescence or young adulthood,¹ are prevalent in the working-age groups and rank high in terms of years lived with disability.² These conditions are prominent among causes for long-term sickness absence,³ both in absolute terms and years of working life lost.⁴

Cost-effective interventions against anxiety and depression are established,⁵ but it is not given that successful treatment or symptom remission translates to higher work participation,⁶ and treatment modalities may have differential effects on work-related outcomes beyond symptom reduction and remission.⁷ A 2014 Cochrane systematic review⁸ of

Key messages

What is already known about this subject?

- A 2014 Cochrane systematic review concluded that work-directed psychological interventions reduces sickness absence compared with usual care for patients with depression in the short to medium term.
- Long-term effects on work and income are arguably more important, but reliable data to study this are scarce.

What are the new findings?

- Registry data provided objective long-term data on income and social security benefits, ruling out selection bias from attrition.
- Compared with treatment as usual, psychological interventions that target work participation can yield benefits in terms of income and work participation in the long term.

How might this impact on policy or clinical practice in the foreseeable future?

- The results support policy shifts towards integrating work and health services for people with common mental disorders and on long-term benefits.
- Provision of evidence-based approaches to help people return to work may have long-term positive effects.
- Future studies should aim to improve such interventions for common mental disorders, specify target populations and address how to maintain effects over time.

23 studies found that work-directed interventions and cognitive behavioural therapy (CBT) components reduce sickness absence compared with usual care for patients with depression in the short to medium term.⁸ A 2012 review from Pomaki *et al*⁹ indicated benefits from psychological interventions and disability management on work outcomes for patients with common mental disorders. Several recent single studies have expanded the evidence for adding or integrating work-related aspects to CBT-based interventions to reduce days of work incapacity and return to work latency, without compromising effects on health.^{10–13} Other recent



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trials based on similar approaches have however come up negative.^{14 15}

In a previous study, we tested the effect of a multisite work-directed CBT and job support intervention, At Work and Coping (AWaC), at a 12-month follow-up, compared with usual care. Usual care included standard treatment from general practitioners (GPs), any other employment scheme and/or intervention offered by the Norwegian Labour and Welfare Administration (NAV), and services offered by other health professionals and providers. This should be considered an active control condition. This was to date the largest trial in this area (N=1193), and we observed an overall effect of the intervention and a substantial effect for the subgroup further along a pathway towards permanent work disability.¹²

In this study, we extended our previous analysis beyond timeframes of previous studies and examined long-term effects on objective outcomes up to 4 years after baseline. Outcome data were derived from registry data with no attrition. Specifically, and based on the results at 12 months, we wanted to examine if there were differences between the intervention group and the control group in terms of (1) work participation from 12 to 46 months after study inclusion, (2) use of social security 12–46 months after study inclusion and (3) net income in calendar years 2 and 3 after inclusion.

Finally, and for all outcomes, we examined differences in effects between three predefined subgroups based on work status at baseline.

METHODS

The Norwegian public insurance system includes all lawful residents of Norway and provides health services, social service benefits and pensions for all members of the National Insurance Scheme, administered by the NAV. The workers' compensation programme is part of the scheme and provides 100% coverage for lost income due to medically acknowledged sickness, disease or injury (including mental illness) from day 1 until the person can work again, up to 52 weeks. After that, long-term benefits provide approximately 66% of former income.

The target population for the trial was people aged 18–60 years old struggling with work participation due to common mental disorders, primarily anxiety and depression. This included people on and at self-assessed risk of sick leave, as well as people on long-term benefits (primarily participants on work assessment allowance after >12 months of sick leave). Eligible participants had to express a motivation to return to/stay at work. Participants were excluded if other reasons than common mental disorders were the primary cause of problems with work participation, such as no motivation to participate in working life, severe psychiatric disorders, high suicide risk, pregnancy and ongoing substance abuse. Inability to read Norwegian and engagement in psychotherapy elsewhere also led to exclusion. Further and more detailed information about the study design is available in the study protocol published alongside our main results paper in 2015.¹²

The intervention was set in six established centres located in different counties. The centres were formally organised under the NAV. Participants could be referred by their GP or case manager or self-refer to receive the AWaC programme. There were 1416 potential participants referred and considered for inclusion from 2010 to 2012. Of these, 197 did not fulfil the inclusion criteria, 17 did not consent to participate, and 9 withdrew their consent and required data deletion (see flow chart in online supplementary file). In total, 1193 participants were

randomised and could be included in the analyses, 52.8% (n=630) in the intervention group and 47.2% (n=563) in the control group. The unbalanced allocation (a 2:1 randomisation ratio the first 5 months of recruitment) ensured the centres could run according to maximal capacity. The randomisation procedure strictly adhered to the formal requirements of adequate randomisation at all times. Only 5% dropped out of treatment (defined as receiving less than three treatment sessions) in the AWaC group. Adherence to services in the control group was not registered.

Of the 1193 participants, 336 (32 %) were referred from NAV, 238 (23 %) from their GP, 351 (22 %) were self-referred, 124 (12 %) got referred from other service providers and 144 participants did not inform on pathway to the trial.

Ethics

Potential participants were informed about the project, and were screened for inclusion and exclusion criteria at the centres by a clinical psychologist. Eligible and willing participants who signed the informed consent and completed the baseline questionnaire were randomised. Consent included use of registry data used to define outcomes in this study. The study complied with the principles of the Helsinki Declaration. All participants signed an informed consent form that emphasised the right to withdraw from the study at any time without any explanation. Granted permissions to use registry data did not open for data sharing, and data sets were anonymous to the researchers.

Interventions

The AWaC programme combines individual CBT and job support. Mini-teams of therapists and employment specialists ensured integration at each site. Within the AWaC framework, 'integration' refers to combination of therapy and an explicit work focus as one process to avoid parallel lines of action. The CBT module focused on managing mental health problems as they related to work situations, and addressing work situation and participation as an integrated component in the therapeutic process. The individual job support adhered to the principles established in the 'Individual Placement and Support (IPS)' model developed for people with severe mental illness.¹⁶ It did however not follow the strict IPS protocol or include running fidelity measures on adherence. Individual job support was offered to those in need of individual job support (primarily participants on long-term disability) to facilitate workplace adaptations or identification of appropriate employment.

Patients allocated to the control group received standard treatment from their GP, NAV or other health professionals. They also got a letter informing them about available services, and encouraging them to seek services and use provided self-help resources. Services would typically involve follow-up by a psychologist or primary care physician, and/or participation in NAV-initiated employment schemes. All workers with reduced work capacity are entitled to services offered by the NAV. The control group was allowed to cross over and receive the AWaC programme 1 year after inclusion.

Outcomes

Based on national social insurance register and the employee register, we constructed three outcome variables: (1) The first outcome—*work, no benefits*—was defined per month per participant. This was coded '1' if the participant had employment or income and did not receive any benefit during that calendar month. This variable allowed us to plot the

proportion of this outcome over time for the intervention and control groups. (2) The second outcome used the same dichotomous information as in the first outcome, but summed this up over the entire follow-up period from 10 to 46 months after baseline for each participant. We counted the number of months when the participant both had a registered job or an income, and received no social security benefits. If a participant was coded '1' for at least 24 of the 36 months (two-thirds of the time), the variable *work over time* was coded '1'. For sensitivity analyses, we constructed similar variables with adjacent thresholds (22 of 36 months and 26 of 36 months). (3) The third outcome—*annual income*—was derived from annual earnings in the second and third year after inclusion. Annual earnings from tax records were calculated in Norwegian krone (as of 2015). Income prior to inclusion was also provided in Norwegian krone (2015). In the Results section, we also present these figures in euros, as per an exchange rate of January 2017 (in parentheses).

Randomisation

Randomisation of participants was computer-generated stratified by centre. We used block size of 10, and two versions of the randomisation list (with 2:1 and 1:1 ratio) were generated for each centre. At each centre, the person responsible for inclusion secured informed consent and emailed the participants' project ID number to the research unit. A blinded technician at the research unit carried out the randomisation and returned the result by email.

Statistical methods

For the primary outcome analysis, we observed rates of work participation among the participants in the two groups. The observations were further examined in logit regression where we adjusted for study centre and by-chance differences between the intervention and the control group. Covariates with considerable prediction of the outcomes were included as controls to reduce residual variance in the models. P values were based on SEs corrected for clustering by site. As we use registry data for all analyses, follow-up data are complete for all who entered the study and provided consent, and all participants were analysed according to randomisation. The authors in charge of the data analysis were blinded for intervention assignment. Data were analysed using STATA V.12.

Eligibility criteria for care providers

All therapists were monitored, videotaped and scored according to the Cognitive Therapy Adherence and Competence Scale¹⁷ in training prior to the trial enrolment. The AWaC used a CBT protocol already established and in use prior to study initiation. The employment specialists were required to have relevant qualifications and broad experience with supported employment, and extensive knowledge of the IPS principles¹⁸ and the job market in the team's region.

RESULTS

Participants were predominately female (67%), and the mean age was 40.4 years. Of the 1193 participants, 31.4% were working at the time of study inclusion, 39% were on sick leave, 21.7% were on long-term social security benefits and 7.9% were unemployed. The mean annual income of the participants at year of inclusion was Kr363 000. With the exception of a higher rate of 'poor' self-rated health among the controls ($p=0.023$), there were no significant differences between the intervention and control groups (table 1).

Table 1 Baseline characteristics of participants

	AWaC*		Control	
	n	%	n	%
Female	437	69.37	365	65.01
Married	189	30	184	32.68
Age				
<30	105	16.66	87	15.45
30–39	220	34.92	169	30.01
40–49	198	31.42	185	32.85
50+	107	16.98	122	21.66
Education				
Primary	49	7.78	36	6.39
Senior high	196	31.11	187	33.21
University/college	353	56.03	304	54.00
Other	30	4.76	35	6.22
Missing data	2	0.32	1	0.18
Self-assessed health				
Good	236	37.46	208	36.94
Medium	301	47.78	248	44.05
Poor	86	13.65	104	18.47
Missing data	7	1.11	3	0.53
Employment status				
Work (partly or fully)	260	41.33	227	40.39
Fully on sick leave	237	37.68	199	35.41
Long-term benefits	132	20.98	136	24.19
Income†				
Baseline	361.0	(175.0)	365.0	(196.5)

*The intervention package labelled 'At Work and Coping'.

†Annual income, measured in Kr1000 as of 2015. Mean, SD in parentheses.

Plots of the rates of the first outcome—*work, no benefits*—indicated that in the total sample, a higher rate of those in the intervention group achieved work participation over the observation period (figure 1). After 10 months, the intervention group had superior outcomes compared with the usual care across the follow-up period up to 46 months. The CIs however overlapped, and for many of the months, CIs also overlapped with effect estimates for the other group. For the subgroup on long-term benefits ($n=267$), differences between the groups were larger, but CIs overlapped for most of the months during the observation period (figure 2). In the full sample, the average (median) number of months with *work, no benefits* were 18.5 (15) for the control group and 20.3 (21) for the intervention group. For the subgroup on long-term benefits, the corresponding numbers were 6.0 (0) and 8.8 (0), respectively.

For the second outcome, *work over time*, 450 (37.9%) participants accumulated at least 24 of 36 months in work and without receiving benefits (table 2). The crude rate of a positive outcome was 4.8% higher in the intervention group than in the control group, and 3.5% higher after controlling for covariates and clustering on site. The differences were not statistically significant. For the subgroup on long-term benefits at baseline, 28 (10.5%) had a positive outcome for the same duration, and the crude rate was 9.2% ($p<0.05$) higher for the intervention group, and reduced to 7.1% ($p<0.05$) in the model controlled for covariates and clustering on site.

The mean annual earnings for the full sample was Kr370 300 (SD=Kr180 000) at year 2 after inclusion and Kr370 500 (SD=Kr199 700) at year 3 after inclusion. Analyses of differences in the third outcome—*annual income*—found that the intervention group on average had a higher annual income 2

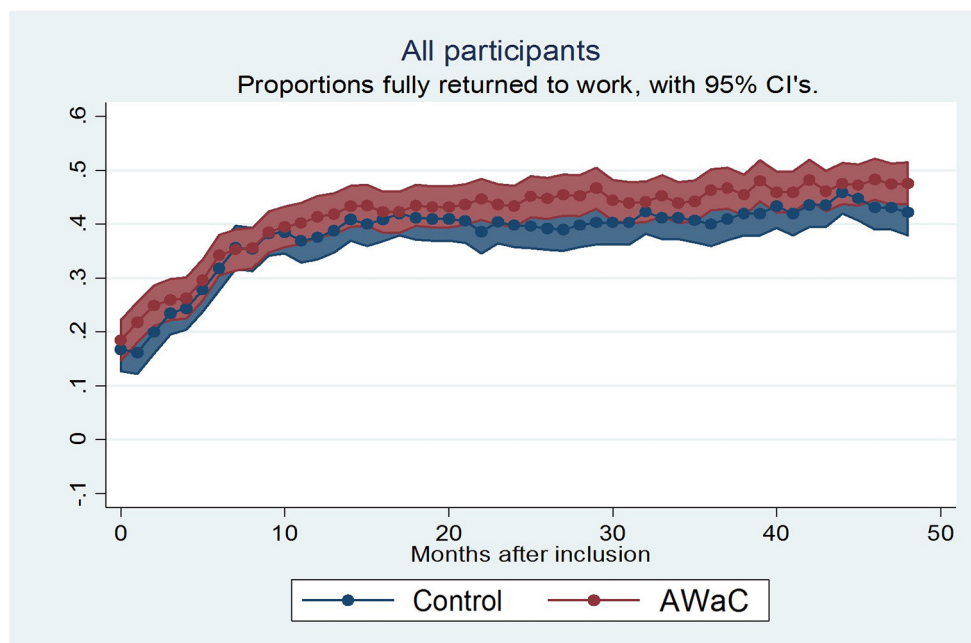


Figure 1 All participants, proportions fully returned to work, with 95% CIs. AWaC, At Work and Coping.

and 3 years after baseline (mean difference year 2 Kr14 272 (€1586) and year 3 Kr11 165 (€1241), respectively). The group differences increased after adjusting for covariates (mean difference year 2 Kr15 494 (€1721) and year 3 Kr12 148 (€1350)) (table 3). The differences were not statistically significant. In the subgroup comprising those on long-term benefits, the differences between the intervention and the control groups were larger. At year 2 the intervention group had on average Kr34 629 (€3848) higher income than the controls, and the statistically significant difference remained after controlling for site and covariates at Kr31 627 (€3515). At year 3, the crude difference for this subgroup was Kr40 093 (€4455) ($p < 0.01$)

and Kr37 197 (€4133) after controlling for site and covariates. The latter difference was not statistically significant (table 3).

DISCUSSION

Our results extend our previously reported effects of a work-directed CBT and job support intervention at 12 months.¹² The trend of an effect difference in favour of the intervention remained over time, but was weaker and mostly not statistically significant for the full sample comparisons. For the group on long-term social security benefits, the effects remained statistically significant in terms of net annual income and a higher

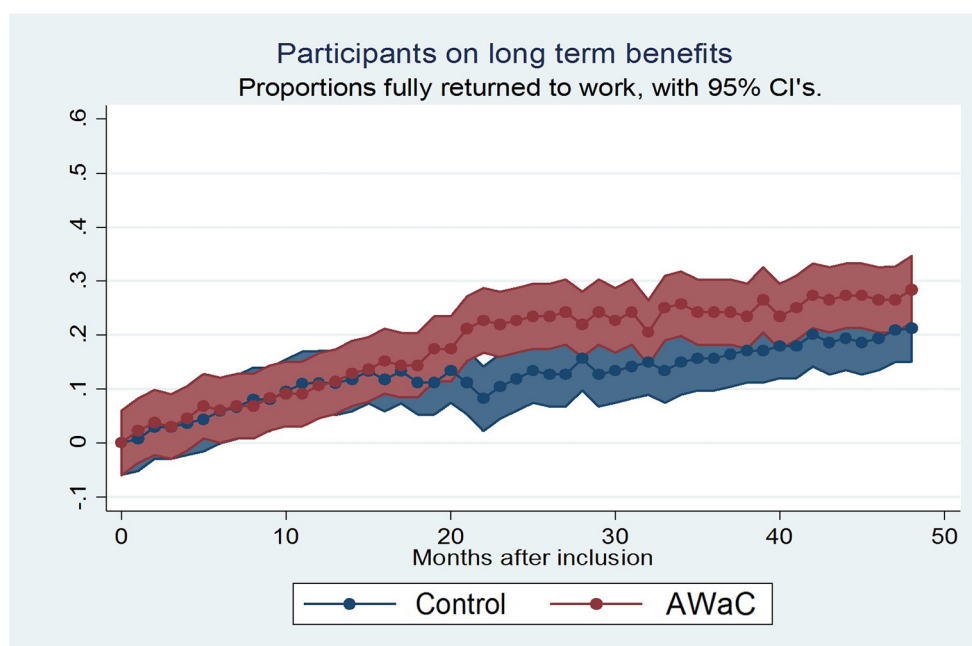


Figure 2 Participants on long-term benefits, proportions fully returned to work, with 95% CIs. AWaC, At Work and Coping.

Table 2 Difference in rates (SE) of work over time for the intervention group compared with the controls in the full sample and subsample on long-term benefits (LTB sample)

Time interval without benefits	Sample	n (%) positive†	Model 1	Model 2	Model 3
24 of 36 months	Full sample	450 (37.9)	0.048 (0.036)	0.047 (0.036)	0.035 (0.039)
	LTB sample	28 (10.5)	0.092** (0.044)	0.092** (0.037)	0.071** (0.031)
22 of 36 months	Full sample	485 (40.82)	0.060* (0.032)	0.059* (0.032)	0.045 (0.037)
	LTB sample	34 (12.7)	0.093*** (0.032)	0.098*** (0.029)	0.077*** (0.028)
26 of 36 months	Full sample	404 (34.1)	0.018 (0.033)	0.017 (0.033)	0.007 (0.036)
	LTB sample	23 (8.61)	0.054 (0.043)	0.051 (0.037)	0.029 (0.031)

Model 1: crude.

Model 2: cluster effect by site.

Model 3: cluster effect by site, adjusted for gender, age, education, positive work expectations and self-assessed health.

*P<0.1, **p<0.05, ***p<0.001.

†Number and percentage of participants in the estimation coded '1' (positive outcome).

rate of work participation over time. For this subgroup, the results support a beneficial effect of the intervention in objective outcome data, unbiased by selection effects and attrition, and over a long follow-up period.

Strengths and limitations

The use of registry information to define outcomes is an important strength as it reduces problems with attrition and selection bias beyond consent to participate at baseline. The administrative importance of registry data promotes accuracy and relevance. A previous analysis suggested that the study population was similar to those who sought the same services outside the trial,¹⁹ increasing external validity. A limitation is the complexity regarding outcomes that can make it harder to compare results across studies, a common problem in this area.²⁰ Work-related outcomes that also reflect receipt of benefits will vary between policy systems. To simplify the main outcome measure, we modified it from our previously published main effects paper.¹² In that analysis, we factored in baseline work status, and examined individual departures from that status and any development towards higher work participation or status quo as a positive indicator. In light of the long-term observation window here, we chose to present data that reflect full return to work regardless of baseline work status. This is also a more conservative outcome measure, and group differences appear later in time in this analysis compared with our previously published results.

We also constructed an outcome variable on receipt of social insurance benefits in at least 24 of 34 months. This reflects a pragmatic goal regarding work participation, where we do not require complete work participation from a group that was

included based on their known occupational struggles in the past. We ran sensitivity analyses where we varied the required number of months without benefits within the preceding 3 years. Stricter requirements for defining a positive outcome weakened the effect sizes but also reduced statistical power in the analysis. This outcome variable was not described in the initial study protocol or trial registration, which is a limitation.

The secondary outcome on net annual income is a major strength in that regard as it is a less complicated outcome measurement and based on tax reports. It does not include unreported income, which is a limitation, but we have no reason to believe that should vary between the intervention and control groups.

Interpretation

We argue studies based on long-term real-life functional outcomes are of high value and importance in extending the evidence base of approaches. The Organisation for Economic Co-operation and Development has argued for policies that integrate work and health approaches as an important shift to increase work participation in mental health.²¹ Our intervention is an example of such an approach, and our long-term outcome data should be of relevance and encourage further developments.

Significant effects were confined to those on long-term benefits at baseline. Currently, there is a strong policy push towards early intervention.²¹ Our results challenge this, as the intervention was not effective for groups one typically would target in 'early intervention', namely those still at work and struggling or sickness absent. This prompts a discussion of what drives the observed effects. One important issue could relate to the relative difference between the intervention and usual care for those in early stages and those closer to permanent work exclusion. Many sickness absentees receive targeted services with coordination and responsibilities for employers, physicians and welfare officers to shorten the sickness absence and prevent transfer to long-term benefits. For those on long-term benefits, fewer stakeholders are involved. Work focus is likely less explicit, and work rehabilitation would commonly conform to train-and-place approaches rather than place-and-train, as emphasised in the efficacious IPS model.¹⁶ Further, among those on long-term benefits, few would have an employer with active engagement on the individual and work place potential to help towards recovery and potential workplace adaptations. It is thus possible that the relative difference between the intervention and usual care is larger for those further along the trail towards permanent work exclusion. Sickness absences and struggles while at work

Table 3 Net difference in annual income years 2 and 3 after baseline in 2015 Norwegian kroner (SE) for the intervention group compared with the control group

Year	Sample	Model 1	Model 2	Model 3
Net income year 2	Full sample	14 272 (13 716)	14 120 (13 701)	15 494 (12 102)
	LTB sample	34 629 (10 481)**	36 781** (11 119)	31 627** (10 488)
Net income year 3	Full sample	11 165 (14 156)	10 831 (14 297)	12 148 (12 780)
	LTB sample	40 093* (16 352)	42 263* (16 822)	37 859 (19 132)

Model 1: crude.

Model 2: cluster effect by site.

Model 3: cluster effect by site, adjusted for gender, age, education, positive work expectations and self-assessed health.

*P<0.1 **p<0.05.

LTB, long-term benefit.

might be more transient states, with possibly less potential for these types of interventions.

The effect sizes were modest, in line with our results at 12 months and the previously reviewed evidence.⁸ A recent similar study from Sweden also demonstrated comparable effect sizes, but with less statistical power and non-significant differences as result.¹⁴ Our study contributes with a longer follow-up time than the previous in this area. Duration of any effect is of major importance, and true differences between the intervention and control group could dilute over time. For our study, the intervention programme continued as ordinary practice after the trial, with the embargo for the control group participants to cross over and receive the intervention ending 1 year after completed study inclusion. Also, models of integrated health and work services were incrementally promoted in this period and could increasingly have been incorporated into usual care. Both factors could imply that some in the control group over time received the intervention or services similar to it. Given a true effect of the intervention, such factors could weaken our observed effect estimates over time.

Various forms of worklessness are consistently associated with high morbidity and increased mortality.^{22,23} Although both causal mechanisms and health selection effects are involved,²⁴ interventions that help people remain part of the workforce are likely to benefit society and individuals through improving health and quality of life, and curb costs for society.

Contributors SNØ drafted the paper and led the process. ALG carried out the data analysis. SER was the principal investigator. All authors were involved in the AWaC trial from initiation to completion. All authors collaborated with the design and performed the current paper, the data analyses, interpretation of results and manuscript write-up. All authors read and approved of the final version of the manuscript.

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Competing interests None declared.

Patient consent Not required.

Ethics approval The Norwegian Regional Ethical Committee approved the study (reference number: 2010/1130).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The permission to use registry data restricts data sharing beyond published results.

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