

STAMI-rapport

Effekter av Arbeidstilsynets virkemiddelbruk på arbeidsmiljø og helse i hjemmetjenestene

En klyngerandomisert
kontrollert studie



Bjørnar Finnanger Garshol
Stein Knardahl
Jan S. Emberland
Øivind Skare
Håkon A. Johannessen

STAMI

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Denne rapporten er skrevet av

Bjørnar Finnanger Garshol

Stein Knardahl

Jan S. Emberland

Øivind Skare

Håkon A. Johannessen

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0304 Oslo

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FORORD

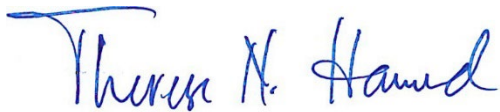
Det er økende krav til at statsforvaltningens virksomhet er kunnskapsbasert, slik at aktivitetene innrettes på en mest mulig effektiv måte med hensyn til ressursbruk og måloppnåelse. For å sikre en kunnskapsbasert tilnærming i sin virkemiddelbruk tok Arbeidstilsynet initiativ til at Statens arbeidsmiljøinstitutt (STAMI) oppsummerte den internasjonale forskningen på området i 2017. Målet var å få økt kunnskap om hvilke virkemidler som mest effektivt bidrar til å påvirke det systematisk forebyggende arbeidsmiljøarbeidet og arbeidsmiljøtilstanden.

Forskningsrapporten fra STAMI viste at det forelå få relevante studier av god metodekvalitet på området. Studiene med god kvalitet gav holdepunkter for at tilsyn med reaksjon fører til økt etterlevelse av lovkrav og redusert hyppighet av arbeidsskader. Imidlertid var to av hovedkonklusjonene at det var begrenset dokumentasjon av (1) effekter av andre typer virkemidler og (2) effekter av tilsyn og/eller veiledning på arbeidsfaktorer av betydning for muskel- og skjelettlidelser og psykiske lidelser. Dessuten viste kunnskapsoppsummeringen at svært få av studiene var gjennomført i en nordeuropeisk eller nordisk kontekst, noe som gjør at dokumentasjonens overførbarhet til Norge er begrenset.

På bakgrunn av dette besluttet man å gjennomføre en omfattende evaluering av effekten av Arbeidstilsynets virkemiddelbruk på arbeidsmiljøtilstanden i Norge. Det store helseproblemet i arbeidsmiljøssammenheng i Norge er arbeidsmiljøfaktorer som gir økt risiko for muskel- og skjelettlidelser og psykiske lidelser. Henholdsvis 40 prosent av korttidssykefraværet og 60 prosent av langtidssykefraværet kan tilskrives slike lidelser, og forskning fra STAMI viser at en betydelig andel av disse sykefraværstilfellene er arbeidsrelaterte og kan tilskrives mekaniske, organisatoriske og psykososiale faktorer i arbeidsmiljøet. Høyest sykefravær grunnet disse diagnosene finnes i kvinneorienterte yrker i helse- og sosialsektoren, og fraværet er aller høyest blant ansatte i hjemmetjenesten.

Med et antatt høyt forebyggingspotensial ble derfor evalueringsstudien besluttet gjennomført i kommunale hjemmetjenester. Prosjektet hadde som mål å evaluere ulike virkemidler som Arbeidstilsynet har til rådighet, og vurdere om virkemidlene gav tilsiktet effekt, og om noen var mer effektive enn andre når det gjaldt å påvirke arbeidsmiljøtilstanden.

Prosjektet ble gjennomført som et samarbeid mellom Arbeidstilsynet, som stod for gjennomføringen av selve tiltakene, og STAMI, som stod for evalueringen. STAMI ønsker å takke Monica Seem, Gunn Robstad Andersen og Marianne Elvsaa Nordtømme ved Arbeidstilsynet for godt samarbeid og bistand under gjennomføringen. Vi ønsker også å takke prosjektmedarbeiderne Shahrooz Elka og Anne-Marthe Indregard. Prosjektet ble gjennomført i perioden 2019 til og med 2023, og resultatene fra evalueringen foreligger nå i denne rapporten.



Therese N. Hanvold

Direktør - Statens Arbeidsmiljøinstitutt



FORKORTELSER

Effekter av Arbeidstilsynets virkemidler på arbeidsmiljø og helse (prosjekttittel)	EAVH
Helse, miljø og sikkerhet	HMS
Den internasjonale arbeidsorganisasjonen	ILO
Arbeids- og velferdsetaten	Nav
Organisasjonen for økonomisk samarbeid og utvikling	OECD
Statens arbeidsmiljøinstitutt	STAMI
Verdens helseorganisasjon	WHO

Sammendrag

Arbeidsmiljøets påvirkning på arbeidstakeres helse er godt dokumentert. Dette ser en tydelig i hjemmetjenestene, som er preget av høy arbeidsbelastning og fysisk krevende arbeidsoppgaver. Ansatte i hjemmetjenestene rapporterer om høye nivåer av muskel- og skjelettplager og psykiske plager, og de har også et høyere sykefravær enn ansatte i andre sektorer. Arbeidsmiljølovgivning og håndheving av denne er en måte å sikre arbeidsmiljøet på. Både WHO og ILO ser det som essensielt for å sikre arbeidstakeres helse og sikkerhet. I Norge er det Arbeidstilsynet som har ansvaret for å håndheve arbeidsmiljøloven. Tidligere forskning har vist at håndheving i form av tilsyn leder til økt etterlevelse av lovkrav og nedgang i skader. Lite av den tilgjengelige forskningen er gjort i helse- og omsorgssektoren, og lite er også gjort på effekter av ulike former for håndheving på psykososiale og mekaniske arbeidsmiljøfaktorer.

Dette prosjektet hadde derfor som mål å evaluere to av Arbeidstilsynets virkemidler: tilsyn og veiledningsseminar. Prosjektet evaluerte gjennomføringen av virkemidlene, hvordan de ble mottatt av målgruppen i hjemmetjenestene, og hvilke effekter de hadde på arbeidsmiljøet i hjemmetjenestene og på de ansattes helse og sykefravær.

Prosjektet benyttet seg av et klyngerandomisert kontrollert studiedesign, med før- og etterundersøkelser, for å evaluere tiltakene. Aktuelle kommuner og deres hjemmetjenester, 96 kommuner totalt, ble tilfeldig fordelt på to tiltaksgrupper, tilsyn og veiledningsseminar, og en kontrollgruppe. Alle ansatte i hjemmetjenestene i kommunene ble invitert til å delta. 1669 takket ja til deltakelse, og 1202 av disse samtykket til innhenting av registerdata på legemeldt sykefravær fra Nav. Prosjektet hadde fire hovedkilder til data: (1) sjekklister fra gjennomførte tilsyn i virksomhetene, (2) kartlegging av organisatoriske, psykososiale og mekaniske arbeidsmiljøfaktorer og helse gjennomført i tre runder blant de ansatte, (3) prosessevaluerings-skjema sendt ut etter gjennomførte tiltak til aktører med HMS-ansvar, dvs. ledere, tillitsvalgte og verneombud, (4) registerdata på legemeldt sykefravær innhentet fra Nav.

Resultatene viser at både ledere og ansattrepresentanter i hjemmetjenesten opplevde Arbeidstilsynets virkemidler som relevante, nyttige og lærerike. Veiledningsseminaret og tilsynet ble vurdert som like relevante, nyttige og lærerike. Det ble etter tiltakene blant annet rapportert om økt forståelse for sammenhenger mellom spesifikke arbeidsmiljøfaktorer og helse, økt kunnskap om lovens krav samt hva som må gjøres for at lovens krav skal kunne betraktes som innfridd. Videre viste studien at ledere i tilsynsgruppen i signifikant større grad enn kontrollgruppen hadde til hensikt å iverksette spesifikke forebyggende tiltak som var

relevante for å innfri lovens krav. Tilsvarende funn forelå ikke for veiledningsgruppen. Studiens resultater viste også at tilsynsgruppen hadde en generell nedgang i antall lovbrudd fra første til andre tilsyn, og at det var en signifikant nedgang i antall brudd relatert til lovens krav om et fullt forsvarlig psykososialt arbeidsmiljø. Sammenlignet med kontrollgruppen hadde tilsynsgruppen signifikant færre brudd både totalt og i underkategoriene ergonomiske arbeidsbetingelser og psykososiale arbeidsbetingelser. I veiledningsgruppen var det ingen signifikante forskjeller i antall brudd sammenlignet med kontrollgruppen. Til sist viste studien at ingen av tiltakene hadde statistisk påvisbare forebyggende effekter på psykososiale og ergonomiske risikofaktorer i arbeidsmiljøet. Studien kunne heller ikke påvise at Arbeidstilsynets tiltak hadde noen forebyggende effekter på selvrapporterte helseplager eller sykefravær grunnet muskel- og skjelettlidelser eller psykiske lidelser.

Det er noe overraskende at vi ikke fant noen forebyggende effekt av tiltakene på arbeidsmiljø og helse, gitt at vi fant gunstige effekter knyttet til de mekanismer som må ligge til grunn for å forebygge potensielt skadelige faktorer i arbeidsmiljøet. Det som kjennetegner vellykkede intervensjoner, er at målgruppen anerkjenner at de har problemer som de må ta tak i, og at de opplever at intervensjonene har gitt dem kunnskap og redskaper til å kunne gjennomføre egnede forbedringstiltak. Studien viser at målgruppen rapporterer økt innsikt, kompetanse og motivasjon til å gjennomføre endringer.

Vi vil peke på fem forhold som vi tenker kan bidra til å forklare at vi ikke finner noen statistisk påvisbare effekter på arbeidsmiljø og helse i hjemmetjenesten:

- 1) Det gikk for kort tid fra tilsyn til måling av disse effektene. Det er komplekse arbeidsmiljøfaktorer og helseutfall som inngår i studien, og det kan ta tid før endringer i virksomheten i etterkant av tilsynet gir seg utslag i forbedret opplevelse av psykososialt arbeidsmiljø og helsetilstand. Når Arbeidstilsynet for eksempel gir pålegg om at virksomheten må iverksette nødvendige forebyggende tiltak, kan dette innebære ressurskrevende prosesser for virksomheten som det tar tid å få gjennomført. Så skal disse tiltakene ha tid til å virke slik at arbeidstakerne opplever en forbedring i det psykososiale arbeidsmiljøet og egen helsetilstand.
- 2) Hjemmetjenesten er en utfordrende bransje for måling av effekt. Arbeidet utføres i stor grad i brukernes hjem, og av den grunn kan det være vanskeligere for arbeidsgiver å få tilstrekkelig kontroll på arbeidsmiljøet. Hjemmetjenesten må også forholde seg til andre lover enn arbeidsmiljøloven, for eksempel pasientrettighetsloven, i sin tjenesteyting. Dette kan trumfe hensynet til arbeidsmiljøet.

- 3) Pandemien, som inntraff i prosjektperioden, skapte en svært krevende situasjon for helseinstitusjoner og helsepersonell. Selv om en randomisert kontrollert studie gjør at alle andre forhold enn det implementerte tiltaket er like i tiltaksgruppene og kontrollgruppen, kan den vedvarende ekstreme unntakssituasjonen ha medført at hjemmetjenestene som mottok tilsyn eller veiledningsseminar fra Arbeidstilsynet, ikke hadde ressurser nok til å iverksette og gjennomføre alle tiltakene som var nødvendige for å oppnå forebyggende arbeidsmiljøeffekter.
- 4) Det er svakheter i regelverket. Arbeidstilsynet er avhengig av å hjemle sin kontrollvirksomhet. Studien har målt spesifikke faktorer med dokumenterte effekter på arbeidshelsen. Arbeidstilsynet har ikke i dag hjemmel til å pålegge direkte knyttet til disse spesifikke faktorene. Arbeidsmiljøloven er generell på det psykososiale området, og tilsynet med loven på området preges av det, jamfør Arbeidstilsynets operasjonalisering av loven i deres sjekkliste som anvendes på tilsyn.
- 5) For at Arbeidstilsynets virkemidler skal kunne ha tilsiktet effekt, er det nødvendig med tettere oppfølging av virksomhetene, for eksempel i form av gjentatte tilsyn eller veiledningsseminarer. Det vil kreve mer ressurser, men kan tenkes å være normdannende på sikt og gi en allmennpreventiv effekt.

Summary

The impact of the working environment on workers' health is well documented. This is particularly evident in home-care services, where the workload is high and the work physically taxing. Home care workers report higher levels of musculoskeletal disorders and mental health issues, and they also take more sick leave than other sectors. Working environment legislation and enforcement is one way of safeguarding the working environment. The WHO and ILO both deem this to be essential in order to protect workers' health and safety. The Norwegian Labour Inspection Authority is responsible for enforcing the Working Environment Act in Norway. Past research has found that enforcement in the form of inspections results in improved statutory compliance and fewer injuries. Hardly any of the available research was carried out in the health and social care sector, however, and there has been limited scrutiny of the effects of different forms of enforcement on psychosocial and mechanical working environment factors.

This project therefore sought to evaluate two of the interventions available to the Labour Inspection Authority: inspection and guidance-through-workshops. We evaluated how the interventions were administered, how they were received by the target group in home care services, and what effects they had on the working environment in home care services and on employees' health and sickness absence rates.

The project used a cluster randomised controlled study design with preliminary and follow-up surveys in order to evaluate the interventions. Relevant municipalities and their respective home care services, 96 of them in total, were randomly assigned to two intervention groups – inspection and guidance-through-workshops – and one control group. Every home care worker in each municipality was invited to take part. A total of 1,669 individuals accepted the invitation, and 1,202 of those consented to register data on physician-certified sickness absence being obtained from the Norwegian Labour and Welfare Administration (NAV). The project drew on four main sources of data: (1) Checklists from completed inspections of the organisations; (2) Identification of organisational, psychosocial and mechanical working environment factors and health conducted in three stages amongst employees; (3) Process evaluation forms distributed after the intervention to stakeholders with HSE responsibilities, i.e. leaders, employee representatives and health and safety officers; (4) Register data on doctor-certified sickness absence obtained from NAV.

The results show that both leaders and employee representatives in home care services found the Labour Inspection Authority's interventions to be relevant, useful and enlightening.

Workshops and inspections were deemed to be equally relevant, useful and enlightening. After the interventions the informants reported having a better understanding of the correlations between specific working environment factors and health, heightened knowledge of statutory requirements and of what steps are needed for the statutory requirements to be deemed to have been met. The study also found that leaders in the inspection group were significantly more likely to want to implement concrete precautionary measures that were relevant to ensuring statutory compliance. There were no equivalent findings amongst the workshop group. The results of the study also show that the inspection group generally saw a drop in the number of law breaches between the first and second inspections relating to the statutory requirement for a "thoroughly sound working environment". Compared with the control group, the inspection group saw significantly fewer breaches overall, including in the categories of ergonomic working conditions and psychosocial working conditions. In the workshop group there were no significant differences in the number of breaches compared with the control group. Finally, the study found that none of the interventions had any statistically significant preventative effects on psychosocial and ergonomic risk factors in the working environment. Nor was the study able to show that the interventions by the Labour Inspection Authority had any preventative effect on self-reported health problems or on sickness absence due to musculoskeletal disorders or mental health issues.

The lack of any preventative effect of the interventions on the working environment and health was surprising given that we did identify beneficial effects linked to the mechanisms required to prevent potentially harmful factors in the working environment. One common characteristic of successful interventions is that the target group acknowledges that they have issues that they must address and that they feel the interventions have given them knowledge and tools to take appropriate measures to improve. The study shows that the target group reported enhanced insight, skill and motivation to bring about change.

We should like to point to five issues that we believe could help explain why we were unable to identify statistically significant effects on the working environment and health in home care services.

- 1) There was not enough time between the inspection and the measuring of effects. The study addresses complex working environment factors and health outcomes, and it can take some time before changes in the organisation after the intervention begin to manifest themselves in the form of improved perception of the psychosocial working environment

and state of health. When the Labour Inspection Authority instructs an organisation to take necessary precautionary measures, it can involve resource-intensive processes on the part of the organisation and take some time to complete. The measures must then be given time to take effect so that the workers see an improvement in the psychosocial working environment and in their own health.

- 2) Home care services are a challenging sector in which to measure effects. The work is largely carried out in the users' homes, and it can therefore be more difficult for employers to obtain sufficient insights into the working environment. As well as the Working Environment Act, home care services must also comply with other legislation, such as the Patients' Rights Act, in their service delivery. This can trump working environment concerns.
- 3) The pandemic, which struck during the project period, caused immense difficulties for healthcare institutions and healthcare workers. Even though the randomised controlled study design means that all factors other than the implemented intervention are identical in both the intervention groups and the control group, the prolonged, extreme and exceptional situation may have led to those home care services being inspected or given training seminars by the Labour Inspection Authority not having sufficient resources to instigate and implement all the measures necessary to achieve a preventative working environment effect.
- 4) There are regulatory weaknesses. The supervisory activities of the Labour Inspection Authority must be provided for in law. The study measured specific factors with documented effects on occupational health. The Labour Inspection Authority is currently not authorised to issue directives directly linked to these specific factors. The Norwegian Working Environment Act describes the psychosocial working environment in general terms, and regulatory supervision of the act in this particular area reflects this, cf. the Labour Inspection Authority's implementation of the act in its inspection check lists.

Bakgrunn

Arbeidsmiljøets påvirkning på ansattes helse, sykefravær og uføretrygd er godt dokumentert [1–4], og en anseelig andel av muskel- og skjelettplager og psykiske plager kan tilskrives arbeidsmiljøfaktorer [5, 6]. Arbeidsrelatert uhelse og sykefravær har store kostnader både på samfunns- og individnivå [7, 8]. Dette ser en tydelig i hjemmetjenestene, hvor arbeidsmiljøet er karakterisert av høy arbeidsbelastning [9, 10] og fysisk krevende arbeidsoppgaver [11]. Hjemmetjenesten er også blant de sektorene med høyest kombinert eksponering av psykososiale og mekaniske arbeidsmiljøfaktorer [12]. Subjektive helseplager som muskel- og skjelettplager og psykiske plager er generelt utbredt blant ansatte i helse- og sosialtjenestene [10], deriblant hjemmetjenestene [13, 14]. Blant sykepleiere i de kommunale tjenestene er det relativt stor gjennomtrekk – ca. 10,5 prosent – og et sykefravær på 11 prosent [15]. I tillegg til eksisterende utfordringer vil sektorens brukergruppe øke på grunn av demografiske endringer som gir en aldrende befolkning, samtidig som det vil være færre arbeidstakere å rekruttere [16]. Dette kan medføre økte belastninger i sektoren og økte arbeidsmiljøutfordringer [17].

En måte å sikre arbeidsmiljøet på er gjennom lovverk og reguleringer som stiller krav til hvordan arbeidsmiljøet skal være, hvordan en skal jobbe med det, og hvordan kravene skal håndheves. Både Den internasjonale arbeidsorganisasjonen (ILO) og Verdens helseorganisasjon (WHO) ser på håndheving av arbeidsmiljølover og HMS-forskrifter som essensielt for å beskytte arbeidstakeres sikkerhet og helse [18, 19]. Det er Arbeidstilsynet som kontrollerer at virksomhetene på det norske fastlandet følger opp sitt ansvar etter arbeidsmiljølovgivningen, gjennom tilsyn og veiledning hos virksomhetene i tillegg til andre virkemidler som kunnskapsformidling, godkjenningsordninger og regelverksutvikling. [20]

Tidligere forskning på myndighetstiltak og virkemidler har funnet at tilsyn kan bidra til reduksjon av skader og økt etterlevelse av lovkrav [21–24]. Tidligere forskning har imidlertid hovedsakelig undersøkt tilsyn i bygg- og anleggssektoren eller i industrien. Det er lite kunnskap om effekter i helse- og sosialsektoren. I tillegg er det svært begrenset forskning og dokumentasjon på effekten av tilsyn på andre helseutfall enn skader, samt på arbeidsmiljøeksponeringer som psykososiale og mekaniske arbeidsmiljøfaktorer. Når det gjelder veiledningsvirksomhet, er det svært lite forskning på etterlevelse av lovverk og generelt på arbeidsmiljøeksponeringer og helseutfall. Det er dermed flere kunnskapshull koblet til både virkemiddelbruk i ulike arbeidskontekster og til effekter av de ulike tiltakene.

For at en intervensjon skal være vellykket, er to forutsetninger viktige: (1) at målgruppen er klar over at det er utfordringer som må håndteres, og (2) at målgruppen opplever at tiltaket er en effektiv måte å håndtere disse utfordringene på [25, 26]. Prosjektet vil derfor evaluere gjennomføringen av tilsyn og veiledningsseminar og hvordan disse oppleves av målgruppen i hjemmetjenestene. Videre vil prosjektet undersøke om tilsyn og veiledningsseminar fører til økt etterlevelse av lovkrav, om de påvirker arbeidsmiljøfaktorer, og om de fører til færre helseplager og mindre legemeldt sykefravær blant ansatte i hjemmetjenestene.

Metode

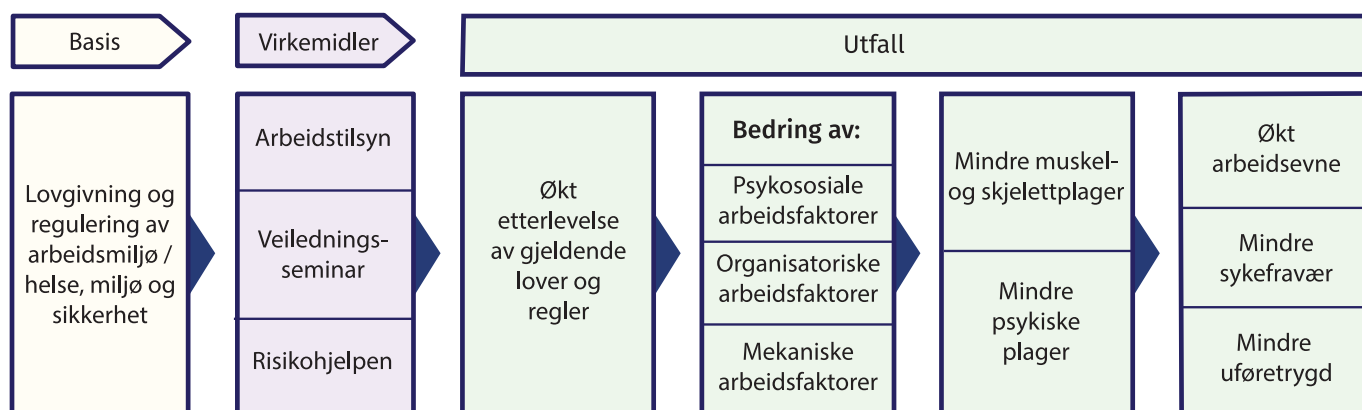
Prosjektet benyttet et klyngerandomisert kontrollert studiedesign, med før- og etterundersøkelser, for å evaluere tiltakene. I dette prosjektet er klyngene norske kommuner med ansatte i hjemmetjenestene. Et utvalg av kommunene ble i 2019 invitert til å delta i prosjektet. Disse utvalgte kommunene ble tilfeldig fordelt (randomisert) til prosjektets ulike tiltaksgrupper og til en egen kontrollgruppe som ikke mottok noen form for tiltak i prosjektperioden.

Prosjektet evaluerte to typer tiltak: (1) tilsyn i hjemmetjenestevirksomheter og (2) veiledning i form av seminarer. Førstnevnt var meldte tilsyn hvor to inspektører besøkte virksomhetene og gjennomgikk en standardisert sjekkliste sammen med ledere, verneombud og ansatte for å vurdere virksomhetenes etterlevelse av regelverket. Eventuelle brudd på regelverket ble fulgt opp i etterkant av tilsynsbesøket. Veiledningsseminarene bestod av et felles seminar hvor 5–7 kommuner ble invitert. Deltakere fra hjemmetjenestene i kommunene presenterte utfordringer i arbeidsmiljøet ved sin virksomhet, og inspektører fra Arbeidstilsynet gav på bakgrunn av dette, og gjeldende lovgivning, veiledning i hvordan en kunne arbeide med disse utfordringene, og hvordan virksomhetene kunne etterleve regelverket i praksis.

Figur 1 viser årsak–virkningsmodellen for virkemidlene i prosjektet. Disse virkemidlene baserer seg på at arbeidsmiljølovgivningen danner et fundament for et forsvarlig arbeidsmiljø. Ved håndheving av lovgivningen gjennom bruk av virkemidlene bidrar Arbeidstilsynet til at virksomhetene etterlever lovens krav. Økt etterlevelse vil kunne gi en bedring av det systematisk forebyggende arbeidsmiljøarbeidet i virksomhetene. Det vil kunne føre til økt forebygging av risikofaktorer i arbeidsmiljøet, for eksempel psykososiale risikofaktorer, som

igjen vil gi en bedring av arbeidsmiljøet for de ansatte. En slik bedring av arbeidsmiljøet vil kunne gi færre helseplager og mindre sykefravær blant de ansatte.

Figur 1 – Årsak-virkningsmodell for virkemidlene evaluert av prosjektet



Det var opprinnelig planlagt å inkludere det digitale selvhjelpsverktøyet «Risikohjelpen» i evalueringen som en tredje type tiltak, men siden færre kommuner enn antatt valgte å delta i prosjektet (104 av 132 inviterte kommuner), ble antallet enheter for lavt til å oppnå tilstrekkelig statistisk styrke. For å sikre nok deltakere i gruppene besluttet man derfor at kommunene i den tredje gruppen (Risikohjelpen) skulle fordeles tilfeldig på de andre gruppene. Ved prosjektoppstart deltok totalt 96 kommuner. Senere i prosjektet ble det gjennomført en tilleggsrekruttering for å undersøke Risikohjelpen, men blant de rekrutterte var det for få som tok verktøyet i bruk til at de kunne inkluderes i prosjektet. Alle ansatte i hjemmetjenesten i de deltakende kommunene ble invitert til å delta i prosjektet. Til sammen fikk vi et representativt utvalg på 1669 ansatte, hvorav 1202 ansatte samtykket til innhenting av registerdata fra Nav. Til prosessevalueringen rekrutterte man aktører i hjemmetjenestene med HMS-ansvar, dvs. ledere, tillitsvalgte og verneombud. Disse hadde deltatt ved tilsynene eller veiledningsseminarene, mens man fra kontrollgruppen rekrutterte lederne.

Prosjektet hadde fire hovedkilder til data: (1) Sjekklistene fra gjennomførte tilsyn innsamlet av inspektørene som gjennomførte tilsynene. I 2019 ble tilsynene kun gjennomført i tilsynsgruppen, mens det ble gjennomført i alle gruppene i 2021. Sjekklisten bestod av 20 ulike sjekkpunkter fordelt på ergonomiske, organisatoriske og psykososiale arbeidsbetingelser samt punkter relatert til det systematiske arbeidsmiljøarbeidet (se vedlegg 3). (2) Kartlegging av arbeidsmiljøfaktorer og helse gjennomført ved hjelp av spørreskjema i tre runder blant de

ansatte i hjemmetjenestene. Første runde ble gjennomført før tiltakene, mens runde to og tre ble gjennomført henholdsvis seks og tolv måneder etter gjennomførte tiltak. Det ble kartlagt organisatoriske, psykososiale og mekaniske arbeidsmiljøfaktorer med spørsmål fra

QPSNordic [27] og selvrapportert helse i form av psykiske plager og muskel- og skjelettplager.

(3) Prosessevalueringsspørreskjema sendt aktører med HMS-ansvar i virksomhetene, dvs.

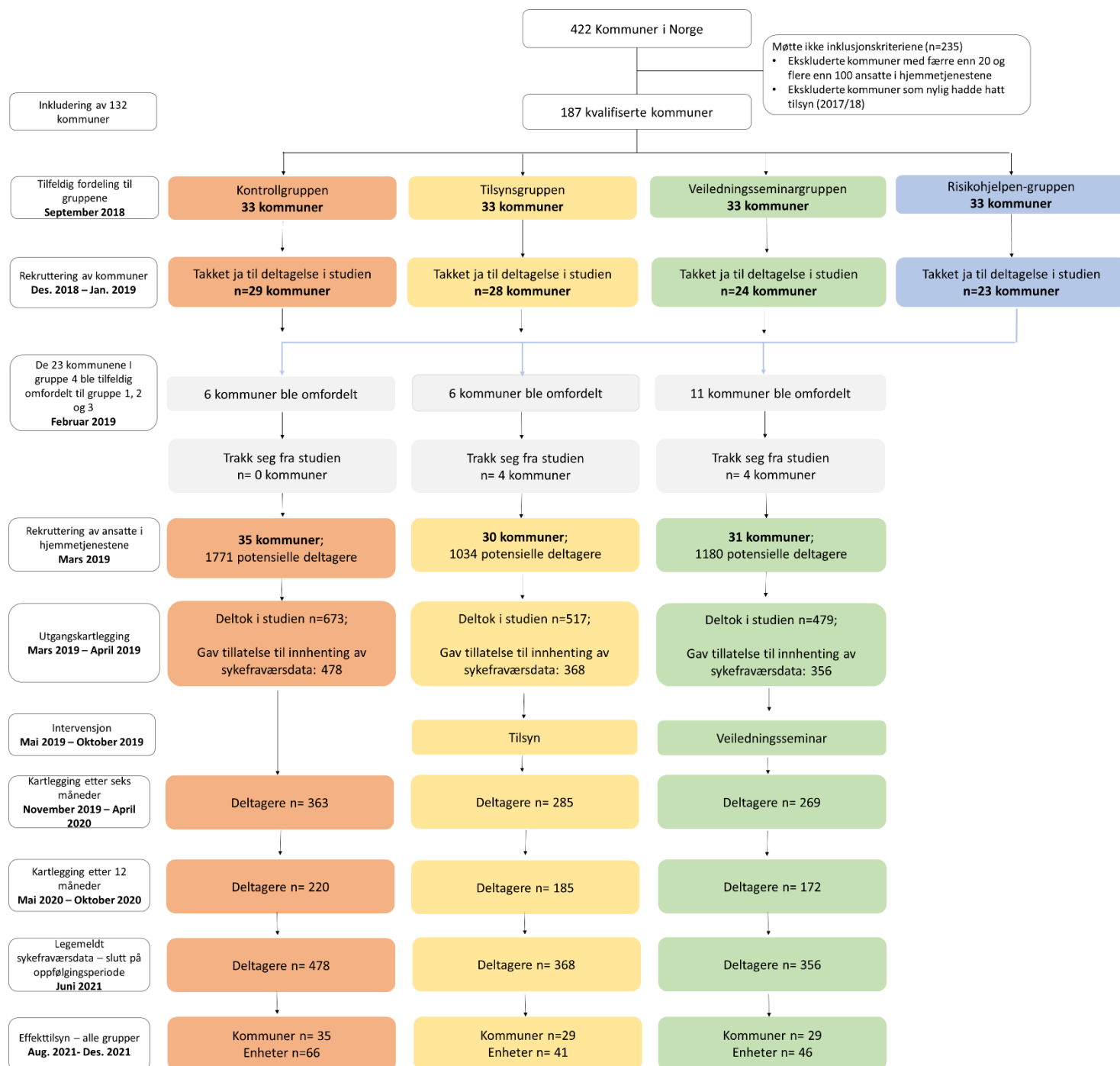
ledere, tillitsvalgte og verneombud, etter gjennomført tilsyn eller veiledningsseminar. Skjemaet inneholdt spørsmål om gjennomføringen av tiltakene, tiltakenes relevans og nytte samt om de gav økt kunnskap og forståelse for systematisk arbeidsmiljøarbeid og gjeldende lovkrav.

Lederne i kontrollgruppen fikk spørsmål om arbeidsmiljøarbeidet i sin virksomhet.

(4) Registerdata med informasjon om diagnosebasert legemeldt sykefravær innhentet fra Nav.

Flyttdiagrammet på neste side (Figur 2) viser gjennomføringen av prosjektet. Denne illustrerer gangen i rekrutteringsprosessen og fordelingen av kommuner og hjemmetjenester til de ulike prosjektgruppene. Videre ser en hva som har blitt gjennomført i de ulike gruppene og til hvilke tidspunkt, samt hvor mange deltagere og hvor mange kommuner og hjemmetjenester som deltok på de ulike tidspunktene.

Figur 2 – Flytdiagram for gjennomføringen av prosjektet



Resultater

Prosessevalueringen viste at både tilsynene og veiledningsseminarene ble gjennomført som planlagt (Se vedlegg 2). I både tilsynsgruppen og veiledningsgruppen rapporterte ledere og ansattrepresentanter at tiltakene var relevante og konkrete og hadde gitt dem økt kunnskap om hva arbeidsmiljølovgivningen krever av et fullt forsvarlig arbeidsmiljø, og om viktige aspekter ved det systematisk forebyggende arbeidsmiljøarbeidet, som for eksempel risikovurderinger (tabell 1). Sammenlignet med kontrollgruppen rapporterte ledere i tilsynsgruppen oftere å ha gjennomført tiltak, eller at de planla å gjennomføre tiltak, for å forbedre arbeidsmiljøet. Ledere i tilsynsgruppen rapporterte også oftere om spesifikke planer for å forbedre arbeidsmiljøet, for eksempel gjennomføring av risikovurderinger. Man fant ikke lignende forskjeller mellom ledere i veiledningsgruppen sammenlignet med dem i kontrollgruppen.

Tabell 1 – Prosessevalueringsspørsmål besvart av ledere og ansattrepresentanter med gruppegjennomsnitt		
	Tilsyn (N=76)	Veiledningsseminar (N=93)
	Gjennomsnitt (SD)	Gjennomsnitt (SD)
Nytte, relevans og tydelighet (1= svært liten grad til 5= svært stor grad)	4,06 (0,51)	3,89 (0,71)
<i>Da tilsynet/veiledningsseminaret ble gjennomført, i hvilken grad opplevde du at ...</i>		
... hensikten med tilsynet/veiledningsseminaret ble forklart på en forståelig måte?	4,19 (0,56)	3,99 (0,76)
... tilsynet/veiledningsseminaret dreide seg om temaer som var viktige for deres arbeidsplass?	4,37 (0,61)	4,07 (0,76)
... du fikk god forklaring på risikoen ved de ulike arbeidsmiljøutfordringene som ble påpekt under tilsynsbesøket?	3,96 (0,67)	3,93 (0,74)
... det var lett å forstå hva du/dere må gjøre for å ha et arbeidsmiljø i tråd med gjeldende regelverk?	3,92 (0,73)	3,83 (0,95)
... tilsynet/veiledningsseminaret gav et godt grunnlag for å arbeide systematisk med arbeidsmiljøet på din arbeidsplass?	3,95 (0,70)	3,67 (0,95)

Økt kunnskap (1 = svært liten grad til 5 = svært stor grad)	3,86 (0,65)	3,66 (0,86)
<i>Alt i alt, har tilsynet/veiledningsseminaret bidratt til ...</i>		
... økt forståelse for hvorfor det er viktig å kartlegge risikofaktorer i arbeidsmiljøet?	4,10 (0,68)	3,78 (0,94)
... økt kompetanse for å bedre arbeidsmiljøet?	3,73 (0,75)	3,60 (0,94)
... økt kunnskap om arbeidsmiljøloven og forskriftene?	3,73 (0,79)	3,61 (0,91)

Analysene knyttet til etterlevelse av regelverket (tabell 2) viste at tilsynsgruppen hadde en generell bedring i etterlevelse fra 2019 til 2021, men denne var kun statistisk signifikant for etterlevelse relatert til psykososiale arbeidsbetingelser. Når en derimot sammenlignet tilsynsgruppen med kontrollgruppen, var det en statistisk signifikant høyere etterlevelse totalt, samt for ergonomiske og psykososiale arbeidsbetingelser. For veiledningsgruppen så man en generell bedring i etterlevelse sammenlignet med kontrollgruppen, men denne var ikke statistisk signifikant (Se vedlegg 3).

Tabell 2 – Resultater fra analyser av etterlevelsedata som viser endringer i tilsynsgruppen og tiltaksgruppene sammenlignet med kontrollgruppen på utvalgte variabler	
	Forskjell i antall brudd
Tilsynsgruppen i 2021 sammenlignet med 2019	
- Generelt	-1,60
- Psykososiale arbeidsbetingelser	-1,12
Tilsynsgruppen sammenlignet med kontrollgruppen ¹	
- Generelt	-2,91
- Ergonomiske arbeidsbetingelser	-0,65
- Psykososiale arbeidsbetingelser	-1,63
Veiledningsgruppen sammenlignet med kontrollgruppen ¹	
- Generelt	-1,17
¹ Justert for antall ansatte per 1000 innbyggere og kommunesammenslåing	- Signifikante funn i fet skrift

Av de 1669 deltakerne i prosjektet som besvarte kartleggingen av arbeidsmiljø og helse, var 96 prosent kvinner, gjennomsnittsalderen var 45,3 år, 93,5 prosent hadde fast stilling, og 76 prosent hadde ingen form for lederansvar. Analysene av effekter av tilsyn eller veiledningsseminar på arbeidsmiljøfaktorene fant ingen effekt på noen av arbeidsmiljøfaktorene sammenlignet med kontrollgruppen. Analysene viste at det ikke var

påvisbare effekter av tilsyn eller veiledningsseminar på selvrapporterte helseplager. For legemeldt sykefravær grunnet muskel- og skjelettdiagnoser eller psykiske diagnoser viste analysene ingen effekt av tiltakene på verken antall sykedager eller sykeperioder. Ytterligere detaljer samt tabeller finnes i vedlegg 4 for arbeidsmiljøfaktorene og i vedlegg 5 for helse og sykefravær.

Diskusjon

Resultatene viser at tiltakene ble gjennomført som planlagt, at de ble godt mottatt av deltakerne, og at tilsynsgruppen igangsatte handlinger for å forbedre sitt systematiske forebyggende arbeidsmiljøarbeid og arbeidsmiljø. Videre fant man økt etterlevelse av lovkrav i tilsynsgruppen og en liten, men ikke signifikant, økning i veiledningsgruppen. Derimot fant man ingen effekter av tiltakene på de undersøkte arbeidsmiljøfaktorene og ikke på selvrapporterte helseplager eller legemeldt sykefravær.

Ser en funnene opp imot årsak–virkningsmodellen presentert i metodedelen (figur 1), ser en at funnene stemmer overens med modellen i de første leddene. Tiltakene blir godt mottatt av målgruppen, og tilsyn gir økt etterlevelse. Dermed kan man si at de to viktige forutsetningene for en vellykket intervensjon som er nevnt tidligere, er innfridd: (1) at målgruppen er blitt oppmerksom på at det er utfordringer som må tas tak i, og (2) at intervensjonen kan hjelpe til med dette. Derimot førte ikke økt etterlevelse av lovkrav til reduksjon i arbeidsmiljøeksponeringene slik som er hypotesen i modellen. Siden vi ikke observerer noen effekt av tiltakene på arbeidsmiljøfaktorene, er det heller ingen grunn til å forvente færre rapporterte subjektive helseplager eller sykdomstilfeller.

En mulig forklaring på at vi ikke observerer noen effekter av tiltakene på arbeidsmiljøfaktorene, kan knyttes til tidsaspektet, det vil si hvor lang tid det tar før et tiltak gir endringer. Det er ingen kjent konsensus rundt hvor lang tid det tar før en ser utslag av endringer i arbeidsmiljøet, enten på selve arbeidsmiljøfaktorene eller på utfall som helse, skader eller sykdom. Tidligere forskning [21] på tilsyn og skader har funnet liten effekt på kort sikt (≤ 1 år), men større effekt på lang sikt (≥ 3 år). Det er derfor mulig at oppfølgingstiden i dette prosjektet – tolv måneder – har vært for kort til å kunne observere substansielle endringer i arbeidsmiljøfaktorene. For eksempel vil virksomhetenes tiltak rettet mot psykososiale faktorer, slik som å redusere

rollekonflikt, gjerne ta lengre tid både å utarbeide og gjennomføre enn å sikre at virksomheten oppfyller kravet om verneombud.

En annen mulig forklaring på den manglende effekten kan være eksterne faktorer. Både den utstrakte kommunereformen med kommunesammenslåinger og covid-19 inntraff i løpet av prosjektperioden. Kommunesammenslåingene kan ha medført reorganiseringer av hjemmetjenestene, noe som kan ha fungert som en barriere for det systematiske arbeidsmiljøarbeidet [28]. På den annen side inntraff kommunesammenslåingene veldig tidlig i prosjektet, og analysene knyttet til etterlevelse av lovkrav gir ingen indikasjoner på at kommunesammenslåingene har påvirket resultatene. Covid-19 pågikk derimot over en lengre tidsperiode, og pandemien førte med seg omfattende smitteverntiltak. Begge tiltakene i prosjektet ble gjennomført i løpet av 2019 og ble dermed ikke rammet av pandemien som sådan. Det som derimot kan sies å ha blitt påvirket, er arbeidsmiljøet og det systematiske arbeidsmiljøarbeidet hos virksomhetene i etterkant av tiltakene. I Sverige er det dokumentert at pandemien medførte en økning i arbeidsmengde og arbeidstid i helsetjenestene [29] samt økt arbeidsbelastning og mindre tid til arbeidsmiljøarbeid i hjemmetjenestene [30]. Tilsyn gav en vedvarende bedring i etterlevelse på tross av pandemiperioden, men det kan tenkes at denne bedringen hadde vært større dersom pandemien ikke hadde inntruffet. Den potensielle forstyrrelsen av det systematiske arbeidsmiljøarbeidet som pandemien representerer, kan dermed være en viktig årsak til den manglende effekten på arbeidsmiljø og helse.

Rammebetingelsene i hjemmetjenestene kan også ha spilt en rolle. Hjemmetjenestene kan sies å ha et fragmentert arbeidsmiljø. I motsetning til kommunale institusjoner som for eksempel et sykehjem er ikke arbeidsmiljøet i hjemmetjenestene en enkelt lokasjon. De ansatte har sin base der hvor hjemmetjenestene er lokalisert, men størsteparten av tiden er de geografisk sett spredt da arbeidsoppgavene foregår hjemme hos brukere og under ulike forutsetninger [17]. Det kan medføre utfordringer med å igangsette endringer i arbeidsmiljøet og innføre nye rutiner. I møtet med brukerne må tjenestene også ta hensyn til annet lovverk enn kun arbeidsmiljøloven, slik som helsetjenesteloven og pasientrettighetsloven. En utfordring man kan møte når man skal innføre hjelpemidler i forbindelse med forflytning av brukere, er at noen brukere av ulike årsaker ikke samtykker til at disse hjelpemidlene brukes hos seg.

Utfordringer knyttet til gjennomføringen av det påfølgende systematiske forebyggende arbeidsmiljøarbeidet i virksomhetene kan også være en forklaring, kanskje særlig koblet til det psykososiale arbeidsmiljøet. Psykososiale arbeidsmiljøfaktorer er viktige aspekter ved arbeidsmiljøet, og en tredjedel av sjekkpunktene undersøkt ved tilsynene var om psykososiale arbeidsbetingelser. En SINTEF-rapport fra 2022 som kartla hvordan norske virksomheter

forstod, prioriterte og arbeidet med psykososialt arbeidsmiljø, fant at begrepet oppleves som bredt og delvis komplisert [31]. Den fant også at det er stor variasjon i hva virksomhetene legger i begrepet, og hvordan de kartlegger og risikovurderer psykososiale arbeidsfaktorer [31]. Dette kan tyde på at det er en utfordrende tematikk å jobbe med. Enkelte forskere har argumentert for at psykososiale risikofaktorer kan sees på som et såkalt gjenstridig problem [32], med uklare årsak-virkningsforhold og løsninger, som det dermed er utfordrende å håndtere. Samtidig viser resultatene for tilsynsgruppen at det var for psykososiale arbeidsbetingelser man så en signifikant økning i etterlevelse fra første til andre tilsyn. Selv om dette tyder på at virksomhetene har klart å ta tak i psykososiale utfordringer påpekt under tilsynene, er det verdt å merke seg at sjekklisten kun dekker enkelte av de psykososiale arbeidsmiljøfaktorene målt i arbeidsmiljøkartleggingen. Sjekklisten tar eksplisitt for seg viktige faktorer som vold, trusler og trakassering. Imidlertid blir andre viktige faktorer som kvantitative krav, kontroll, rollekonflikt og emosjonelle krav indirekte behandlet under betegnelse «risikoforhold som kan påvirke ansattes psykiske helse» og «uheldige belastninger». Det blir dermed vanskelig å si hvorvidt økt etterlevelse indikerer at virksomhetene har i igangsatt tiltak spesifikt rettet mot de psykososiale risikofaktorene som er blitt målt i denne studien. Funnene fra prosessevalueringen tilsier også at virksomhetene satte i gang tiltak for å bedre arbeidsmiljøet, men vi har dessverre mindre informasjon om hvilke tiltak som ble igangsatt, og ikke informasjon om hvordan det systematiske forebyggende arbeidsmiljøarbeidet foregikk i prosjektperioden. Vi kan derfor ikke med sikkerhet konkludere om hvor godt tiltakene har truffet, gitt den komplekse utfordringen psykososiale arbeidsmiljøfaktorer representerer.

Årsaken til at en del psykososiale risikofaktorer ikke ble eksplisitt spesifisert i sjekklisten brukt ved tilsynene, er at Arbeidstilsynets tilsyn og sjekkpunkter må være hjemlet i lovverket. I arbeidsmiljøloven er nettopp vold, trusler og trakassering eksplisitt nevnt, mens de andre risikofaktorene målt i dette prosjektet, som for eksempel rollekonflikt, ikke er det. Sjekklisten representerer altså den best mulige operasjonaliseringen, gitt gjeldende regelverk, men fanger muligens ikke opp kompleksiteten i det psykososiale arbeidsmiljøet. Problemstillingen har allerede blitt løftet frem av Arbeidstilsynet i utredningen «Behov for bedre regulering av arbeidsmiljølovens krav til psykososialt arbeidsmiljø – utredning av Arbeidstilsynet 2023» [33]. Her pekes det på at for at et regelverk skal ha en ønsket effekt, er det viktig at målgruppen forstår sine forpliktelser. Regelverket må derfor være kjent, og det må være klart hva som er lovens krav, og hva virksomhetene skal jobbe med for å etterleve reglene. Arbeidstilsynet har foreslått en mer presis og utfyllende regulering av det psykososiale arbeidsmiljøet. Lignende grep med spesifikke forskrifter er gjennomført i både Sverige og Danmark [33]. Den svenske forskriften er evaluert, mens den danske evalueringen ikke er fullført enda. Den svenske

evalueringen fant at forskriften ble godt mottatt blant virksomhetene. Regelverket opplevdes som klart og forståelig, og begrepene som ble brukt i forskriften, gav et samlende språk for hvordan man kunne snakke om tematikken [34]. Dette tyder på at et klarere og mer utfyllende rammeverk – det være seg som forskrift eller en veileder – muligens vil kunne avhjelpe noen av utfordringene ved psykososialt arbeidsmiljø nevnt ovenfor. Det vil kunne gjøre begrepene og forventningene klarere og gi Arbeidstilsynet mer presise verktøy for å håndtere denne tematikken.

Den manglende effekten på arbeidsmiljø og ansattes helse og sykefravær i veiledningsgruppen kan også dels forklares av punktene ovenfor. I denne gruppen var det heller ingen statistisk signifikant økning i etterlevelse sammenlignet med kontrollgruppen. Det er lite forskning på bruk av veiledning som et virkemiddel for å håndheve arbeidsmiljøregelverk og ingen tidligere forskning som ser spesifikt på veiledningsseminarer. En grunn til den manglende effekten på etterlevelse kan være den mindre formelle rammen rundt veiledningsseminarene sett opp imot tilsynene. Tilsynene medfører juridiske konsekvenser dersom det avdekkes brudd på lovkravene, mens deltakelse på veiledningsseminarene ikke får noen lignende konsekvens. Dermed kan det tenkes at virksomhetene i veiledningsgruppen ikke opplevde det samme presset for å gjennomføre endringer i det systematisk forebyggende arbeidsmiljøarbeidet. En manglende formell ramme og juridisk konsekvens kan også være grunnen til at Risikohjelpen i svært liten grad ble tatt i bruk av målgruppen. En annen grunn til den manglende effekten av veiledningsseminarene kan være at veiledning krever tettere oppfølging over tid. Et enkelt seminar alene vil muligens ikke kunne gi nok informasjon. Informasjonen som blir gitt, må også bearbeides og inkorporeres i virksomhetenes systematiske arbeidsmiljøarbeid. Sånn sett ville kanskje en serie med veiledningsseminarer hvor virksomhetene fikk veiledning over tid, sammen med tilbakemeldinger og dialog om arbeidsmiljøarbeidet, ha vært mer utslagsgivende.

Implikasjoner

Resultatene fra forskningsprosjektet viser at innholdet i Arbeidstilsynets virkemidler, tilsyn og veiledningsseminar, oppleves som relevant og nyttig med hensyn til å forbedre det systematisk forebyggende arbeidsmiljøarbeidet. Ledere og ansattrepresentanter i hjemmetjenestene rapporterer om økt kunnskap om arbeidslovgivningens krav til et fullt forsvarlig arbeidsmiljø samt innsikt i nødvendige tiltak for å imøtekomme disse kravene. Tilsynsgruppen rapporterte også om gjennomførte tiltak for å bedre arbeidsmiljøet i etterkant av tilsynene. Og denne gruppen hadde også økt etterlevelse av lovkrav. Virkemidlene hadde derimot ingen observert

effekt på arbeidsmiljøfaktorene eller på ansattes helse og sykefravær. Det er her viktig å poengtere at dette er resultatene fra én studie, gjennomført i én sektor, og at en dermed ikke kan konkludere med at tilsyn eller veiledningsseminar generelt ikke har noen effekt. I tillegg har tidligere forskning vist at tilsyn *har* en effekt, mellom annet på skader, og gir økt etterlevelse av lovkrav også i andre sektorer. Samtidig kan man utlede enkelte implikasjoner fra funnene sett sammen med tidligere forskning.

En implikasjon av funnene kan være at det trengs ulike tilnærminger til gjennomføringen av tilsyn og veiledningsseminar. Det som har vist seg å fungere i andre sektorer, er kanskje ikke like effektivt i helse- og omsorgssektoren. Psykososiale problemstillinger kan virke mindre håndgripelige enn problemstillinger koblet til sikkerhet, som manglende stillas etc. Det kan være at det ved slike problemstillinger kreves gjentatte tilsyn eller veiledningsseminarer med et mer langsiktig perspektiv for å oppnå ønsket effekt. En kombinasjon av virkemidlene kan også være en mulig løsning, for eksempel gjennom å tilby veiledningsseminar enten i forkant eller etterkant av tilsyn. Dermed ville man ha fått effekten av tilsynene samtidig som man, gjennom seminarene, fikk veiledet virksomhetene. Gjennom å ha veiledningsseminar i forkant av tilsyn kunne virksomhetene ha opplevd et økt press for å igangsette forbedringsprosesser, noe som kunne ha ført til færre reaksjoner i form av pålegg og mindre ressurser brukt til oppfølging. Å tilby veiledningsseminar i etterkant kunne ha bidratt med støtte og avklaring til virksomhetene i forbedringsprosessen etter påviste brudd. Gitt hvor uklart og bredt psykososialt arbeidsmiljø oppleves å være blant virksomhetene, vil økt opplæring kunne gjøre inspektørene bedre stilt både til å føre tilsyn på dette området og til å veilede virksomhetene. Det kan også være at innholdet i tilsynene og veiledningsseminarene må justeres for å bedre effekten inn mot arbeidsmiljøeksponeringer og helseutfall. Her kan man se for seg at et økt fokus på gjennomføringen av det systematiske arbeidsmiljøet i virksomhetene og hvordan man kan sikre etterlevelse av lovkrav i praksis, kan være en tilnærming. En slik justering av innholdet i tiltakene kan for eksempel skje innenfor eksisterende rammer i form av nevnte endringer i gjennomføringen av tiltakene, eller gjennom endringer i reguleringene som medfører endret innhold eller fokus for tilsynene og veiledningsseminarene.

Denne evalueringen avdekker også et behov for videre forskning på hvordan myndighetstiltak og tilhørende reguleringer på en effektiv måte kan påvirke og sikre arbeidsmiljøet i ulike sektorer og virksomheter. Dette kan for eksempel være forskningsprosjekter med lengre oppfølgingsstid for å bedre kunne fange opp endringer som skjer over tid, eller for å evaluere effekter av ulike tilnærminger til gjennomføringen av tiltakene. Mer generelt tyder funnene også på et behov for økt kunnskap om hvordan virksomhetene gjennomfører sitt systematisk forebyggende

arbeidsmiljøarbeid, hvordan dette gir seg utslag på arbeidsmiljøet i virksomhetene, og hvilke tiltak som har effekt inn mot dette arbeidet.

Konklusjon

Dette prosjektet fant at Arbeidstilsynets virkemidler – tilsyn og veiledningsseminar – ble godt mottatt av målgruppen i de kommunale hjemmetjenestene. De opplevdes som nyttige, gav økt kunnskap og kompetanse i arbeidsmiljøarbeid og førte til endringsprosesser rettet mot å bedre det systematisk forebyggende arbeidsmiljøarbeidet i virksomhetene. Tilsyn førte også til bedre etterlevelse av lovkrav. Man kunne derimot ikke påvise at tilsyn eller veiledningsseminar hadde noen effekt på de målte arbeidsmiljøfaktorene eller på helse og sykefravær blant ansatte i hjemmetjenestene. Funnene antyder et behov for å evaluere hvordan de undersøkte virkemidlene mer effektivt kan sikre etterlevelse av lovverk for å frembringe endringer i arbeidsmiljøet som bidrar til forebygging av helseplager hos de ansatte.

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Vedlegg

Prosjektets fem vitenskaplige publikasjoner er lagt ved som vedlegg til rapporten.

Vedlegg 1 - Protokollartikkel

Vedlegg 2 – Prosessevaluering

Vedlegg 3 – Etterlevelse av lovkrav


Vedlegg 4 – Effekter på arbeidsmiljøfaktorer

Vedlegg 5 – Effekter på selvrapporterte helseplager og legemeldt sykefravær

Effectiveness of the Labour Inspection Authority's regulatory tools for work environment and employee health: study protocol for a cluster-randomised controlled trial among Norwegian home-care workers

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BMJ Open Effectiveness of the Labour Inspection Authority's regulatory tools for work environment and employee health: study protocol for a cluster-randomised controlled trial among Norwegian home-care workers

Anne-Marthe R Indregard,¹ Stein Knardahl,² Jan Shahid Emberland,² Øivind Skare,³ Håkon A Johannessen ¹

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For numbered affiliations see end of article.

Correspondence to

Dr Håkon A Johannessen; hajo@stami.no

ABSTRACT

Introduction There is a need to evaluate whether, and to what degree, labour inspections or other regulatory tools have the desired effects on psychosocial, organisational and mechanical work environment, and employee health. The Norwegian Labour Inspection Authority (NLIA) uses different tools and strategies to enforce compliance with occupational safety and health (OSH) legislation. The aim of the present study is to evaluate the effects of labour inspections and other regulatory tools employed by the NLIA. The home-care service is one of the fastest growing occupations and a prioritised area for the NLIA, hence the present study will investigate regulatory tools in this sector.

Methods and analysis The research project has been designed as a longitudinal, cluster-randomised, controlled trial and will be conducted among Norwegian home-care workers. The objective of the research project is to evaluate the effects of the NLIA's regulatory tools (inspection and guidance) on: (1) compliance with OSH legislation and regulation; (2) psychosocial, organisational and mechanical work environment; (3) employee health in terms of musculoskeletal and mental health complaints; and (4) sickness absence. Public home-care services have been randomised to three intervention groups and one control group. Home-care services in the intervention groups will receive one of three intervention activities from the NLIA: (1) inspection from the Labour Inspection Authority; (2) guidance through an online interactive risk-assessment tool; and (3) guidance on psychosocial, organisational and mechanical work environment through workshops. The interventions will be performed at the organisational level (home-care service), and the effects of the interventions on the working environment and health complaints will be measured at the individual level (home-care employees).

Ethics and dissemination This project has been approved by the Regional Committees for Medical and Health Research Ethics (REC) in Norway (REC South East) (2018/2003/REK sør-øst C), the Norwegian Center for Research Data (566128), and will be conducted in

Strengths and limitations of this study

- Large-scale cluster-randomised controlled trial with an extended follow-up which may yield findings that are generalisable to real world-settings.
- National registry data on sickness absence will offer objective data on the effect of work place interventions on sickness absence rates.
- Adequate statistical power to detect small effects on measures of work environment and employee health associated with the work place interventions.
- Reliance on online and self-report assessments is likely to lead to higher levels of sample attrition and/or incomplete and missing data.

accordance with the World Medical Association Declaration of Helsinki. The results will be reported in international peer-reviewed journals.

Trial registration number NCT03855163.

INTRODUCTION

The burden of occupational injuries and work-related diseases remain unacceptably high worldwide. A recent study estimated that 2 million deaths annually can be attributed to work-related diseases and 0.3 million deaths annually to occupational injuries.¹ Both the International Labour Office and the World Health Organization view enforcement of occupational safety and health (OSH) legislation and regulation as essential to maintain employee safety and health.^{2,3} Recent reviews suggest that labour inspections improve compliance with OSH requirements and may reduce the incidence of occupational injuries.⁴⁻⁶ Nevertheless, two other reviews underlined the need for conducting experimental studies to produce decisive proof.^{7,8}

Moreover, there is a major research gap in the effect of labour inspections on psychosocial work environment and the ability of the inspections to prevent work-related musculoskeletal and mental health complaints.⁴ The overarching aim of the present study is to evaluate effectiveness of the Norwegian Labour Inspection Authority's (NLIA) regulatory tools for psychosocial, organisational and mechanical work environment, and employee health.

Non-fatal health losses caused by musculoskeletal and mental disorders constitute a large and increasing proportion of the disease burden in the Norwegian population.⁹ It is well documented that mechanical and psychosocial exposures at work can affect employee health and increase the risk of sickness absence and disability retirement.^{10–13} Recent studies of the Norwegian working population have suggested that 40% of cases involving lower back pain¹⁴ and 25% of those involving mental distress¹⁵ can be attributed to psychosocial or mechanical work factors.

The health and social sector in general, and the home-care sector in particular, show high levels of sickness absence and disability retirement related to musculoskeletal pain and mental distress,^{16 17} and home-care organisations continue to experience challenges recruiting and retaining employees.¹⁸ Due to reconstruction of health-care systems in many industrialised nations, there has been a shift from healthcare services provided in institutions to home based caring.¹⁹ In addition to a reconstruction of the healthcare system, a demographic shift due to an increasing proportion of elderly people, has led to a tremendous growth in the home care sector during the past decade,²⁰ and the growth is assumed to continue. Although the home-care service is one of the fastest growing occupations, there are limited research describing its' OSH experiences to provide an evidence base for a safe work environment that protect employee health.

The NLIA is a government agency under the authority of the Ministry of Labour and Social Affairs. The overarching goal for the NLIA is to ensure a fully adequate working environment, safe employment conditions and meaningful work for all employees. The NLIA is responsible for ensuring that enterprises comply with

the requirements in the OSH legislation and regulation. In addition, the NLIA provides information and advice to employers and workers concerning the most effective means of complying with the legal requirements. Research on labour inspections has mainly been limited to construction and manufacturing industries, which provide a limited base for generalisation to other sectors, such as the health and social sector.⁵ There is an urgent need for well-designed evaluations, such as randomised controlled trials, to be able to draw valid conclusions.⁸

Objectives and research questions

To respond to this research gap, the primary objective of the current research project is to evaluate the effects of the Labour Inspection Authority's regulatory tools (inspection and guidance) on the psychosocial, organisational and mechanical work environment and employee health. To fulfil this objective, the following research questions will be addressed by a longitudinal, cluster-randomised, controlled trial:

1. To what degree can the Labour Inspection Authority's regulatory tools (inspection, guidance through workshop or online risk-assessment tool) lead to compliance with OSH legislation and regulation?
2. To what degree can the Labour Inspection Authority's regulatory tools influence
 - a. Psychosocial work factors?
 - b. Organisational work factors?
 - c. Mechanical work factors?
3. To what degree can the Labour Inspection Authority's regulatory tools reduce
 - a. Musculoskeletal complaints among employees?
 - b. Mental health complaints among employees?
4. To what degree can the Labour Inspection Authority's regulatory tools reduce sickness absence?

Figure 1 illustrates the process through which OSH regulations are thought to provide the basis of a safe and healthy work environment and an important basis for primary prevention in terms of employee health and well-being. As shown in the figure, we will evaluate whether, and to what degree, the regulatory tools lead to compliance with OSH legislation and regulation (research

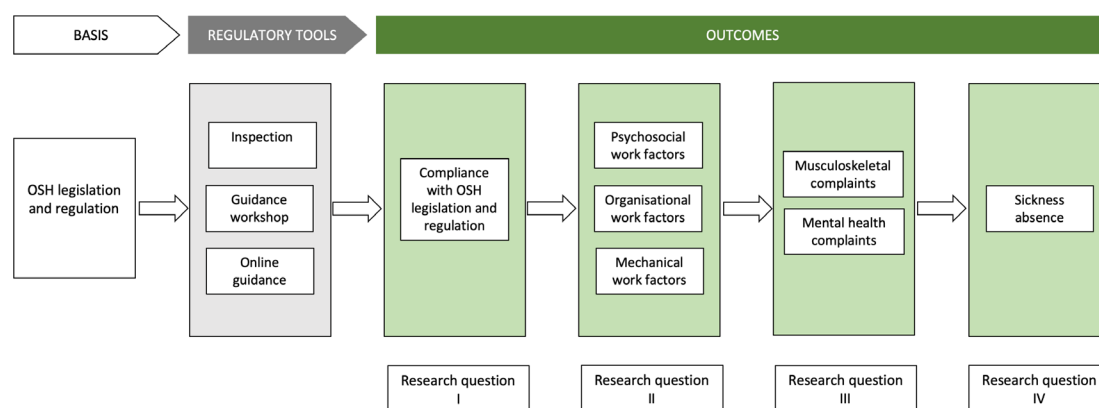


Figure 1 Illustration of the process from OSH legislation and regulation to the different outcomes. OSH, occupational safety and health.

question 1). We will investigate if this level of compliance with OSH legislation and regulation will have effects on psychosocial, organisational and mechanical work factors (research question 2) and an effect on employee health (research question 3). The last part of this study will be to evaluate whether, and to what degree, this process leads to increased work ability and reduction of sickness absence (research question 4).

METHODS AND ANALYSIS

The protocol for the current research project has been created in accordance with the recommendations outlined in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement guidelines.²¹

Trial design and research setting

The current project will be performed among public home-care workers. According to the Act Relating to Municipal Health Services²² each Norwegian municipality shall ensure that persons living in the municipality are offered the necessary health services. Therefore, each municipality has a public home-care service. For the current project, we contacted 132 municipalities in December 2018 and invited their public home-care services to participate in the project.

The current research project is designed as a longitudinal, cluster-randomised, controlled trial to evaluate the short-term and long-term effects of inspection and guidance on compliance with OSH legislation and regulation, the work environment and employee health.²³ Randomisation will be conducted at the organisational level with municipalities as units. The interventions will be performed at the organisational level. Outcome measures relating to the work environment factors

and health complaints will be assessed at the individual level (among home-care workers), and outcome measures to evaluate compliance with OSH legislation will be assessed at the group level (among home-care organisations).

Figure 2 shows a flow chart of the timeline for the three intervention groups and the control group, and shows the project's various activities starting with enrolment in autumn 2018 to the last follow-up assessment in November 2020. The trial will comprise four arms, and the eligible municipalities will be randomised to three intervention groups and one control group. The three different interventions given by the Labour Inspection Authority will be as follows: (1) Inspection by the Labour Inspection Authority; (2) guidance provided in workshops relating to the psychosocial, organisational and mechanical work environment; and (3) guidance provided as an online interactive risk-assessment tool.

Two months before the Labour Inspection Authority performs its interventions, a baseline questionnaire will be sent to all home-care workers employed in the included municipalities. This questionnaire assesses self-reported psychosocial, organisational and mechanical work factors, and employee health. The effects of the different interventions will be evaluated through questionnaires at 6, 12 and 20 months after the interventions.

To evaluate how the interventions have been implemented, process evaluation will be performed immediately and 2 months after the interventions. Finally, to evaluate the effects of the interventions on compliance with OSH legislation and regulation, all organisations will receive an inspection from the Labour Inspection Authority 14 months after the interventions.

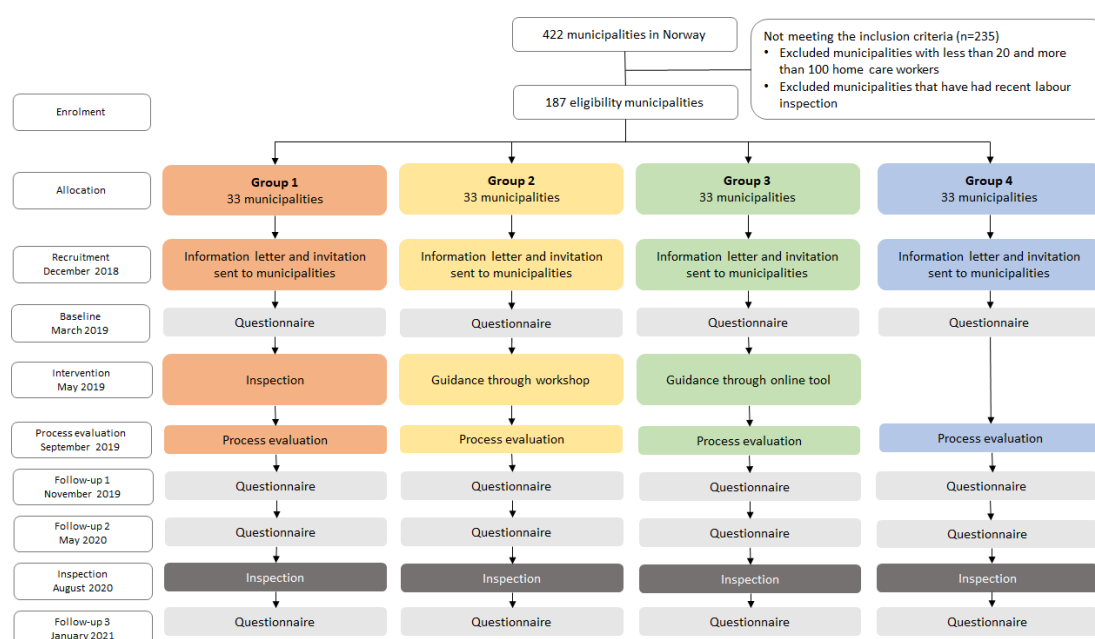


Figure 2 Flow chart illustrating the timeline of the research project.

Participants and procedure

Home-care can be defined as ‘professional care provided at home to adult people with formally assessed needs’,²⁴ and may include professional services (eg, nursing) and home support services (eg, personal care and housekeeping).

Eligibility criteria for municipalities (clusters)

Norway has 422 municipalities (1 January 2019). The number of home-care workers employed in the public home-care service in each municipality varies greatly, from three people employed in small municipalities to over 4000 employed in large municipalities. Nevertheless, in 75% of these 422 municipalities, the number of employed home-care workers are fewer than 126. To reduce intracluster variability and the sample size needed, only municipalities with 20–100 home-care workers employed in the public home-care service were assessed for eligibility. Municipalities that received an inspection from the Labour Inspection Authority in 2017 or 2018 were not eligible. After exclusion of 235 municipalities, 187 municipalities were eligible for the interventions (see figure 2).

Eligibility criteria for home-care workers (individuals)

All employees in the public home-care service in the included municipalities are eligible.

Randomisation of municipalities

Random sampling and allocation were performed using IBM SPSS Statistics version 25. Of the 187 eligible municipalities, 132 municipalities were drawn randomly and allocated to one of the interventions groups or the control group.

Recruitment of home-care workers

After the allocation of municipalities, participating municipalities will be required to complete and return a form providing an overview of their employees with contact information. Subsequently, all employees will receive an email with information about the study and an invitation to participate. The email will include a link to the web-based questionnaire. In addition, an SMS with short information about the study will be sent at the same time as the email. The SMS will contain a unique code for logging into the web-based questionnaire. The written information will explain the aims of the study and assurance that the responses will be treated confidentially and in strict accordance with the general guidelines and specific license from The Norwegian Data Protection Authority. Employees will be given the opportunity to complete the questionnaire at work, but it will also be possible for them to complete the questionnaire at home or any other location. Each respondent will have the opportunity to log into the web-based questionnaire an unlimited number of times to change or complete their answers during the survey period.

Interventions

Inspection

Labour inspection at the workplace is an essential part of the labour administration system, and a fundamental function of the Labour Inspection Authority is to enforce compliance with labour legislation. The NLIA performed nearly 14000 inspections in different sectors and organisations throughout 2017.²⁵ For the current project, the Labour Inspection Authority will perform inspections according to standard procedures in all public home-care services in the selected municipalities (group 1). Three weeks in advance of the inspection, a letter to announce the inspection and information about it will be sent to the participating workplaces. The inspections will target exposures related to the psychosocial, organisational and mechanical work environment. Two trained inspectors will visit each home-care unit to oversee that the enterprise complies with the requirements of The Working Environment Act. They will use a checklist that includes relevant items enshrined in the OSH legislation and regulation. In addition to the systematic observation of the work environment, the inspectors will give information and guidance to ensure compliance with labour requirements. After the inspection, the labour inspectors will prepare a report describing the current work environment and identifying the work factors that were checked, any non-compliance with legal requirements and how these should be followed up by the organisation. If necessary, the Labour Inspection Authority can enforce compliance with OSH legislation and regulation through a warning, an order to comply with the law or a citation. If necessary, it is also possible to close down the workplace.

Guidance

The Labour Inspection Authority has long experience in providing guidance on topics related to the means through which workplaces can ensure compliance with the OSH legislation and regulations. The current project will evaluate the effect of guidance through workshops and a new online interactive risk-assessment tool.

Guidance through workshops

Home-care organisations allocated to receive guidance through workshops (group 2) will receive an invitation to participate in a workshop arranged by the Labour Inspection Authority. The leader and representatives of the employees will be invited to participate. It is desirable that at least two employees from each home-care service participate at the workshop. Five to seven home-care services will be assigned to workshops based on geographical region. Before the workshop, each workplace will receive information on the topics (ie, psychosocial, organisational and mechanical work environment, and employee health) and will be asked to prepare a presentation on relevant issues arising from their own work environment. Two trained labour inspectors will participate in the workshop and give guidance based on the issues presented at that workshop. The main purposes of this method are to

highlight relevant issues in the home-care sector and to provide guidance as to how the organisation can work systematically to reduce adverse psychosocial, organisational and mechanical work exposures. The basis for the guidance will be the OSH legislation and regulations, and the overarching aim is to motivate and ensure that the psychosocial, organisational and mechanical work environment comply with the legislation requirements.

Guidance through an online interactive risk-assessment tool

The online interactive risk-assessment tool is a well-established, free tool that companies can use to improve their systematic OSH work in accordance with national OSH regulations. This tool was originally developed to aid employers and employee representatives in selected industries and sectors. The home-care sector was not initially selected as a target group. A custom tool was developed for the home-care sector parallel to designing the present study. During the study period, the tool will only be available for the municipalities allocated to intervention group assigned to get guidance through this risk-assessment tool.

The tool comprises a checklist with a set of questions about the organisational, mechanical and psychosocial work environment risks that are typical for the home-care sector. The questions are supplemented with guiding text explaining how and why the work environment factors may involve risk for work-related illness, injury and disease. The employer and employees answer the questions together, and the tool suggests measures to reduce the identified risks in the work environment of the company. At the end of the risk-assessment, an action plan that lists the measures, person responsible and deadline for implementation is produced.

The home-care organisations that are included in this intervention group (group 3) will each receive an email with information about the risk-assessment tool along with a link to the web page, a username and password. The main purpose of this method of guidance is to make statutory risk-assessments easier for enterprises by offering them a specific tool and to help them include relevant risk factors in the assessment by offering a check-list with predefined sector-specific risks. Although the predefined risks are based on well-known risks in the home-care sector, additional risk factors may be relevant and the companies can therefore add custom risk factors during the process. Ultimately, the tool assists home-care organisations in identifying risks present in their work environment and suggests relevant preventive measures that, in turn, may reduce the risk of work-related illness, injury and disease.

Control group

The control group will receive the usual care, meaning that no planned intervention will be implemented in the home-care services allocated to the control group (group 4). However, to evaluate any effect of the interventions on compliance with OSH legislation, all four groups will receive an inspection 14 months after the first interventions. The control group will also be asked to complete the

questionnaires about the work environment and employee health at the same four times as the intervention groups.

Effect evaluation

To evaluate the effect of the Labour Inspection Authority's regulatory tools on the work environment and employee health, the study will include measures of a wide range of work factors, employee health and registry data on sickness absence. The primary and secondary outcomes are listed in [table 1](#). These include psychosocial and mechanical working conditions, self-reported health complaints, work ability and sickness absence (a more detailed description of each measurement is given below [table 1](#)).

Data will be collected through questionnaire surveys before the interventions and at 6, 12 and 20 months after the interventions. To maximise retention of participants enrolled in the study and to minimise non-response error, employees will be given the opportunity to complete the questionnaires during working hours. Participants may complete the questionnaire in Norwegian or English. The questionnaire will be available electronically through the website or on paper, and it will also be possible to complete the questionnaire in an interview. The following measurements will be repeated at each data collection point (see [figure 2](#)). The questionnaire will contain scales and questions that can be classified into the following categories.

Primary outcomes

Psychosocial and organisational working conditions

Psychosocial and organisational work factors will be assessed mainly using scales adapted from the General Nordic Questionnaire for Psychological and Social Factors at Work (QPS^{Nordic}).²⁶ QPS^{Nordic} has been thoroughly tested for validity and reliability, and has shown good psychometric properties.^{26 27} The following scales from QPS^{Nordic} are included in the current questionnaire: *quantitative demands* (ie, time pressure and amount of work); *decision demands* (ie, demands for attention and making quick and complex decisions), *learning demands* (ie, demands on education and training), *decision control* (ie, influence on decisions regarding work tasks), *control over work intensity* (ie, influence on time, pace and breaks), *role conflict* (ie, conflicts between demands and resources, and conflicting requests), *role clarity* (ie, clarity of goals and objectives at work), *support from the immediate superior* (ie, instrumental and emotional support), *empowering leadership* (ie, encouragement to participate in important decisions, express different opinions and develop one's skills), *fair leadership* (ie, whether the immediate superior distributes work fairly and treats workers equally), *predictability during the next month* (ie, predictability related to tasks, co-workers and superiors), *organisational support* (ie, whether the social climate is encouraging/supportive and the organisation communicates its interest in employee health and well-being) and *positive challenge at work* (ie, usefulness of skills and knowledge, meaningfulness of work and whether work is challenging in a positive way). All scales from the QPS^{Nordic} comprise 3–5 items that

Table 1 Primary and secondary outcomes and time points for measurement

	Time points for measurement after interventions				Statistical analyses and reporting
	6	12	15	20	
Primary outcomes					
Self-reported work environment					
Psychosocial and organisational working conditions <i>Job demands, emotional demands, job control, social support, role expectations, leadership, bullying, violence, unwanted sexual attention</i>	✓	✓			Differences in means using linear mixed models/continuous outcomes
Mechanical working conditions <i>Squatting/kneeling, standing, upper body forward bending, awkward lifting, heavy lifting, lifting people</i>	✓	✓			Differences in means using linear mixed models/continuous outcomes
Self-reported health complaints					
Mental health complaints <i>Mental distress, exhaustion</i>	✓	✓			Differences in means using linear mixed models/continuous outcomes
Musculoskeletal complaints <i>Neck pain, back pain, headache, pain in the shoulder, upper arm, lower arm, wrist or hand, pain in hips, legs, knees or feet</i>	✓	✓			Differences in means using linear mixed models/continuous outcomes
Work ability	✓	✓			Differences in means using linear mixed models/continuous outcomes
Sickness absence*					
Risk ratios using Poisson mixed models/count outcomes					
Compliance with OSH legislation			✓		Differences in means using t-tests/count outcomes
Secondary outcomes					
Self-reported work environment					
New technology and work-related changes, predictability during the next month, positive challenges at work	✓	✓			Odds ratios using mixed logistic regression/dichotomous outcomes
Self-reported health complaints					
sleep	✓	✓			Differences in means using linear mixed models/continuous outcomes
Occupational injuries	✓	✓			Odds ratios using mixed logistic regression/dichotomous outcomes
Systematic safety and health work	✓	✓			Odds ratios using mixed logistic regression/dichotomous outcomes
Additional effects of labour inspection on work environment and health				✓	Differences in means using linear mixed models/continuous outcomes

*Sickness absence rates will be based on doctor-certified sickness absence 1 year before and the year following the interventions.

measure the frequency of occurrence with the following response categories: 1='very seldom or never', 2='seldom', 3='sometimes', 4='often' and 5='very often or always'.

Emotional dissonance (ie, a discrepancy between felt and expressed emotions) will be measured by four items adapted from the Frankfurt Emotion Work Scales.²⁸ Responses are provided on a five-point scale with the following response alternatives: 1='seldom or never',

2='once per week', 3='once per day', 4='several times per day' and 5='several times an hour'.

Workplace bullying will be measured by first presenting a formal definition of the bullying construct and then asking the employee, 'Have you been subjected to bullying or harassment at your workplace during the past 6 months?' The response alternatives will be given on a five-point scale ranging from 1='never' to 5='yes, on a daily basis'.

Violence and threats of violence will be measured by three items developed by Statistics Norway. Employees will be asked the following questions: 'Over the past 12 months (6 months when follow-up), have you been the victim of violence at the workplace?' and 'Over the past 12 months (6 months when follow-up), have you been threatened at the workplace in such a way that you felt scared?' The response alternatives will be given on a five-point scale ranging from 1='never' to 5='yes, on a daily basis'. Employees reporting any of the 'yes' alternatives will be asked who exposed them to violence or threats of violence.

Unwanted sexual attention will be assessed using one question developed by Statistics Norway: 'Are you ever exposed to unwanted sexual attention or comments at your workplace?' The response alternatives will be given on a five-point scale ranging from 1='never' to 5='yes, on a daily basis'. Employees reporting any of the 'yes' alternatives will be asked who exposed them to unwanted sexual attention.

Mechanical working conditions

Mechanical working conditions will be measured by five items developed by Statistics Norway and used in the Norwegian survey on living conditions (work environment).²⁹ These questions will assess the following mechanical exposures: *squatting/kneeling*, *standing*, *forward bending of the upper body*, *awkward lifting* and *heavy lifting*. The details have been described elsewhere.¹⁴ To account for mechanical working conditions known to be in particular relevant for home-care service employees, the following questions were adapted from Smedley and colleagues³⁰: 'In an average working shift, how often do you have to (1) manually transfer a client/patient between bed and chair? Or (2) manually move a client/patient around on the bed, chair or wheelchair?' (3) 'Do you perform work tasks that involve heavy physical efforts without the option of using mechanical aids?' Responses are provided on a five-point scale with response alternatives ranging from 1='never' to 5='at least 20 times'. Three other questions have been developed for the current project to measure how much time at work the employee usually spends on (1) *travelling to clients*, (2) *office work* and (3) *with clients/patients*. The responses are provided on a six-point scale with response alternatives ranging from 1='never' to 6='almost all of the time'.

Self-Rated health

Self-rated health will be measured by one item pertaining to each respondent's general perception of his or her health.³¹ The respondents will be asked, 'How would you rate your health in general?' and the response categories are 0='very bad', 1='bad', 2='moderate', 3='good' and 4='very good'.

Mental health complaints

Mental distress (symptoms of anxiety and depression) during the past week will be measured by the five-item version of the Hopkins Symptom Checklist (HSCL-10).³²

Responses are provided on a four-point scale with response alternatives ranging from 1='not at all' to 4='extremely'.

Exhaustion will be measured by a six-item sub-dimension adapted from the Copenhagen Burnout Inventory.³³ Responses are provided on a five-point scale ranging from 1='very seldom or never' to 5='nearly every day'.

Musculoskeletal complaints

Musculoskeletal complaints will be measured by six questions adapted from a symptom checklist³⁴ which asks, 'Have you been troubled by "neck pain", "back pain", "headache", "pain in the shoulder or upper arm", "pain in the lower arm, wrist or hand" or "pain in the hips, legs, knees or feet" during the past 4 weeks?' The response categories are 1='not troubled', 2='a little troubled', 3='intensely troubled' and 4='very intensely troubled'. Any employees who respond that they have been troubled by any complaint during the past 4 weeks will be asked whether the complaint worsens when they are at work.

To assess *pain*, employees will be asked to rate their general pain intensity throughout the past week using an 11-point (0–10) numeric rating scale with endpoints 0='no pain' and 10='worst possible pain'.³⁵

Work ability and sickness absence

To assess *work ability* the respondents will be asked to self-report their work ability at present using an 11-point (0–10) numeric rating scale with endpoints 0='not able to work' and 10='work ability at its best'.

Information on *sickness absence* will be accessed through the Norwegian Labour and Welfare Administration. This registry provides complete registrations of all medically certified sickness absence from the first day absent, including the length and medical diagnosis. After having secured informed consent from the employees, survey data will be linked to registrations on medically certified absence through the unique 11-digit national identity number.

Compliance with OSH legislation

To evaluate the effects of the different interventions on compliance with OSH legislation and regulation, all organisations will be given a compliance score based on the check-list that is used for the labour inspections.

Secondary outcomes

New technology and work-related changes

Introduction and use of new technology will be assessed by three questions on implementation of new technology during the past 12 months (6 months when follow-up), involvement of employees in the implementation process and training of the employees in the use of new technology.

To assess *work-related changes*, the questionnaire includes three questions related to changes at the workplace during the past 3 years. The first two questions consider whether changes at work have occurred and if so, to what degree these changes have affected the work situation of the employee. The third question asks whether the

employer has implemented a process by which all those affected by the changes can be heard.

Sleep

Sleep will be measured using the Bergen Insomnia Scale.³⁶ This scale comprises six items that assess symptoms of insomnia. The self-rating is repeated for each item, and the respondent gives a score on an eight-point scale indicating the number of days per week when a specific symptom is experienced (0–7 days, total score 0–42).

Occupational injuries

Information about *occupational injuries* will be collected by the following question, 'During the past 12 months (6 months when follow-up), have you been injured as a result of an accident at work which led to sick leave?'^{29 37}

Systematic safety and health work

Four questions will assess the degree to which the organisation works systematically to enforce the OSH regulations at work. Employees will be asked whether they have a safety representative and a working environment committee at their workplace. They will also be asked whether they have had appraisal interviews during the past year and whether they have participated in any kind of workplace interventions aiming to improve the work environment. The last part of the questionnaire will include three questions about notification of critical conditions in the workplace. Employees will be asked whether they have witnessed any critical conditions during the past 12 months (6 months when follow-up). Employees responding 'yes' to this question will be asked whether the condition was notified and what happened after the notification.

Demographics and work characteristics

Information on sex, age, marital status, years of education and years of employment in the current working position will be collected at the baseline. Employment status, information related to shift-work and perceived work affiliation (eg, intention to quit the job) will be collected at each data collection point.

Process evaluation

Process evaluation will be conducted to evaluate the implementation of the three interventions and the possible mechanisms by which the interventions achieve their effects. Process evaluation will combine questionnaire responses and data from employers, employees and labour inspectors. The recommendation for process evaluation of complex interventions published by the Medical Research Council guidance³⁸ will be used as a framework for conducting and reporting the process evaluation. As illustrated in [figure 2](#), the process evaluation will be conducted through survey questionnaires 3 months after the interventions. The questionnaires will include questions about how the intervention has been received which people in the workplace are involved in the intervention and what is being done in response to the intervention. The process evaluation will also ask to what degree the

participants perceive the intervention as relevant and useful for their workplace. The organisations allocated to the control group will be asked about changes at their workplace during the same period.

Statistical analyses

Planned analysis

Analysis and reporting of the results will follow the SPIRIT guidelines for reporting randomised controlled trials.²¹ Baseline tables will show the mean and SD for the outcome variables and baseline characteristics for the different intervention groups (ie, gender, age, marital status, formal education, part-time employment and geographic region) Separate analyses of the longitudinal data will be performed for each primary and secondary outcome.

The statistical analyses will be divided into four parts, each corresponding to a stated research question. Because our study is a randomised trial, we do not plan to make any adjustment for baseline characteristics. However, as recommended for randomised trials, we will adjust for the baseline value for each outcome variable. The post-baseline values (6, 12 and 20 months) will be analysed using a linear mixed model for continuous outcomes, Poisson mixed models for count models and logistic mixed models for binary outcomes. Participants, work units and municipalities will be included as nested random effects. When analysing more than one post-baseline value, we will include as a fixed effect an interaction between time (follow-up 6 and 12 months) and group. This interaction represents the effect of the intervention at the two follow-up times. The primary end-point is the 12-month follow-up, and the analyses focusing on this end-point will include data obtained at 6 and 12 months.

The protocol sets up a post-test-only control group whose inclusion is intended to evaluate the compliance with OSH legislation and regulation, which will be measured at the 15 month inspection.³⁹ Only post-test data will be used for group comparisons. Because of the randomisation, the expected compliance scores for the four groups will be equal if there is no intervention effect. We plan to use t tests to compare the control group with each of the three intervention groups.

We also plan to perform stratified analyses to determine whether an intervention has an effect on participants reporting the most problems at baseline. For each outcome, we will analyse the data for 25% of the participants reporting the most problems using the same analyses as described above. To control for multiple testing, we will use q values which is the false discovery rate equivalent for p values.⁴⁰

Sample size

Sample size calculations are based on the principles of cluster-randomised trials⁴¹ and will take into account interclass correlations of the outcome nested by the municipalities. We used the following formula to estimate the number of employees, m, per group⁴¹:

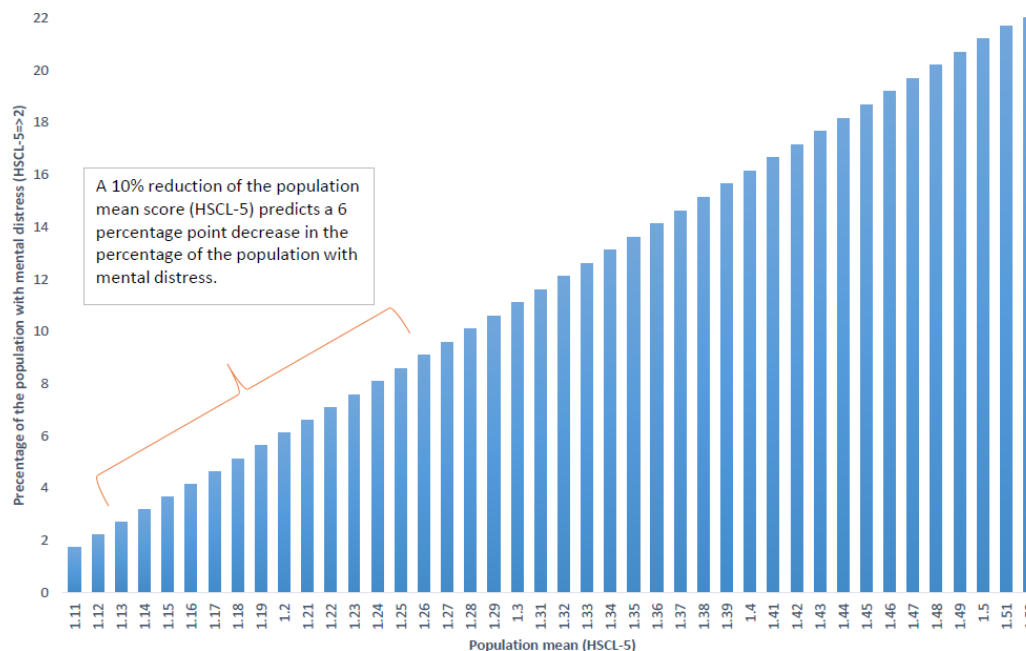


Figure 3 Percentage of the population with mental distress (HSCL-5 ≥ 2) according to the different population mean scores on the HSCL-5-scale. HSCL, Hopkins Symptom Checklist.

$$m = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 2\sigma^2}{\Delta^2} \left(1 + \left\{ (CV^2 + 1) \bar{n} - 1 \right\} \rho \right)$$

where Z_x is the x th percentage point of the standard normal distribution, Δ is the clinically important difference in the means of health complaints, σ^2 is the variance of the outcome, \bar{n} is the mean cluster size (home care service employees per municipality) and CV is the corresponding coefficient of variation, and ρ is the intracluster correlation coefficient (ICC).

Based on the level of ‘Living–Working Conditions Survey’ which was conducted by Statistics Norway in 2006,²⁸ we estimate the population mean scores for subjective musculoskeletal pain to be 1.53 (SD=0.58), and for mental distress (HSCL-5) to be 1.26 (SD=0.45), among social and health-care workers. Figures from Statistics Norway showed that each eligible municipality would recruit on average 52 employees (SD=21.9). The worksite level ICCs for a variety of outcomes have been estimated with a mean of 0.0163 and values ranging from 0 to 0.0650.⁴²

An individually randomised study would require 222 employees per group. To account for clustering effects from randomised municipalities, with a conservative ICC of 0.05, the estimate was inflated to 891 employees, with 17 municipalities recruiting 52 employees each per group. Finally, to allow for a response rate of 70% and loss to follow-up of 20%, we plan to recruit 1591 employees, with 31 municipalities recruiting 52 employees in each per group.

Figure 3 illustrates the clinical implication of a 10% reduction in the population mean score of the HSCL-5 scale. To obtain these estimates, we performed a resampling (bootstrapping) of subsamples from the Norwegian Life course survey.²⁹ This figure shows the percentage of people with an HSCL-score ≥ 2 according to given mean HSCL population scores. Figure 3 shows that a

population mean HSCL-score of 1.26 predicts that 9% of the population will have an HSCL-score ≥ 2. Moreover, a 10% reduction of this population mean score predicts a 6 percentage point decrease in the percentage of the population with mental distress.

DISCUSSION

To our knowledge, the current study will be one of the first, cluster randomised controlled trials to assess whether the Labour Inspection Authority’s regulatory tools have an effect on psychosocial work environment and employee health. The study has a sufficient sample size to detect small effects on work environment and employee health, and the work place interventions and outcomes are assessed using validated instruments. Nevertheless, there are also some limitations that should be addressed.

Intervention studies using simultaneous comparison populations may face problems related to contamination between intervention groups and the control group.⁴³ This study has municipalities as the ‘unit of randomisation’ and a certain degree of ‘contamination’ between the municipalities are unavoidable, that is, employees in the control group may receive information regarding ongoing or planned inspection in neighbouring municipalities and consequently take action to improve their own work environment. In addition, the work places will become familiar with the study before implementation of interventions through information letters and baseline questionnaires. Hence, to control for contamination between groups, the process evaluation will be used as an information source to detect possible prevention activities executed before the NLIA implement their planned interventions.

When designing studies and performing interventions within social science a common goal is to draw conclusion about the effects of specific interventions on some chosen outcome variables. However, the context studied often proposes complex relationships among variables and third variables may affect how and when OSH regulation have an effect on work environment and employee health. The current study includes different municipalities with their own organisation and policies that may affect how and under which conditions regulatory tools lead to compliance with OSH regulation. Nevertheless, the randomisation will balance both observed and unobserved characteristics between the groups of municipalities and thereby minimise the risk of confounding factors influencing the results.⁴⁴

The appropriate length of time lags between study waves is a crucial issue in longitudinal research methodology. However, a general rule regarding the appropriate length of time interval for a study do not exist.⁴⁵ We expect that an improvement in the work environment (ie, a reduction in a chronic work stressor) should have positive effect on employee health. To provide essential information about expected effects over time, several measurement occasions with short time-lags are recommended.⁴⁶ Thus, the current study measures work environment and employee health before the interventions and at 6, 12 and 20 months after the interventions.

As the current study use survey questionnaires to assess working conditions and employee health, potential problems arising from self-report instruments, such as response-set tendencies and recall bias have to be discussed. To reduce measurement error the questionnaire includes validated instruments with acceptable psychometric properties. In addition, the QPSNordic instrument used in the current study, do not address issues that are inherently positive or negative, nor degrees of satisfaction and agreement. Instead the respondents are asked how often a situation occurs.²⁶ Thus, the measurement should be insensitive to respondents' emotions and personality. Furthermore, when we use a combination of questionnaire survey and objective registry data on sickness absence, the results are less subjected to common-method bias/common method variance.⁴⁷

In summary, the current study will respond to a research gap regarding the effects of the NLIA's regulatory tools on psychosocial work environment and employee health. Despite the potential limitation listed above, the findings from the study may provide crucial information regarding different regulatory tools (inspection and guidance) which may have practical implications for NLIA in their work to enforce compliance with OSH legislation.

ETHICS AND DISSEMINATION

All participants are required to provide informed consent before they begin the questionnaire. The information letter explains that participation is voluntary and that participants may withdraw from the study at any time without

any consequences. Self-reported data are recorded in electronic files, and no identifying information is stored with the self-reported data. The study results will be presented at national and international meetings, and in peer-reviewed publications.

PATIENT AND PUBLIC INVOLVEMENT

We have ensured research involvement and engagement by establishing a research reference group. The reference group consists of representatives from the authorities and the social partners. This reference group has contributed to making the study design relevant, participant friendly and ethically sound, and the representatives will be involved in the dissemination of study results

COLLABORATION

The research project is a collaboration between the NLIA and the National Institute of Occupational Health (STAMI). The Labour Inspection Authority will perform their inspections and guidance in the randomised municipalities. STAMI is responsible for the process evaluation and for collecting data from home-care workers about their work environment and health.

Author affiliations

¹Department of Occupational Health Surveillance, National Institute of Occupational Health, Oslo, Norway

²Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway

³Department of Occupational Medicine and Epidemiology, National Institute of Occupational Health, Oslo, Norway

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Contributors HAJ and SK: first version of the study design. AMI: draft of the protocol manuscript. AMI, HAJ, SK, ØS and JSE: participation in the final design of the study and coordination. All authors read, revised and approved the final protocol manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This project has been approved by the Regional Committees for Medical and Health Research Ethics (REC) in Norway (REC South East) (2018/2003/REK sør-øst C), the Norwegian Center for Research Data (566128), and will be conducted in accordance with the World Medical Association Declaration of Helsinki.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data will be available 3 years after study completion. Data access request will be reviewed by NSD - Norwegian Centre for Research Data. URL: <https://nsd.no/nsd/english/index.html>.

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ORCID iD

Håkon A Johannessen <http://orcid.org/0000-0001-9974-4824>

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Vedlegg 2 – Prosessevaluering

Do regulatory tools instigate measures to prevent work-related psychosocial and ergonomic risk factors? A process evaluation of a Labour inspection authority trial in the Norwegian home-care services

*Håkon A. Johannessen , Stein Knardahl , Jan S. Emberland ,
Øivind Skare and Bjørnar Finnanger Garshol*

RESEARCH NOTE

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Do regulatory tools instigate measures to prevent work-related psychosocial and ergonomic risk factors? A process evaluation of a Labour inspection authority trial in the Norwegian home-care services

Håkon A. Johannessen^{1*} , Stein Knardahl², Jan S. Emberland¹, Øivind Skare³ and Bjørnar Finnanger Garshol¹

Abstract

Objective: There is a research gap regarding the way managers and employee representatives respond to Labour Authority interventions targeting work-related psychosocial and ergonomic risk factors. The present study aimed to determine if (I) labour inspections and (II) guidance-through-workshops led by inspectors were perceived by the target audience as equally useful and educational; and to determine if utility and enhanced knowledge were associated with the implementation of measures to prevent work-related risk factors. Finally, it aimed to determine if the managers in the intervention groups to a greater extent than the controls reported implementing such measures.

Results: Managers and employee representatives in both intervention groups reported a high level of perceived utility as well as a high level of enhanced knowledge. Both utility ($p < 0.05$) and enhanced knowledge ($p < 0.05$) were significantly associated with the implementation of, or plans to soon implement, measures to improve working conditions. When compared to controls, implemented measures, or plans to implement measures, were reported significantly more frequently by managers in the inspection group ($p < 0.05$).

Trial Registration ClinicalTrials.gov ID: NCT03855163 Registered on February 26, 2019.

Keywords: Cluster randomised controlled trial, Process evaluation, Occupational health and safety

Introduction

Psychosocial and ergonomic work factors contribute to the risk of developing musculoskeletal and mental disorders [1–5], which in turn are leading causes of reduced work ability and increased sick leave and disability pension [6–9]. Working conditions among home-care workers have been characterised by both high physical

workloads and adverse psychosocial conditions [10–13], which could explain the high levels of sickness absence and disability retirement observed in the sector [14, 15].

Recent reviews suggest that labour inspections improve compliance with occupational safety and health (OSH) requirements and may reduce the incidence of occupational injuries [16–18]. However, there is a paucity of properly designed studies that address the effectiveness of regulatory tools in improving OSH management of psychosocial risks [19], and primary prevention of work-related musculoskeletal and mental disorders [16, 18–20].

*Correspondence: hajo@stami.no

¹ Department of Work Psychology and Physiology, National Institute of Occupational Health, Majorstuen, 5330, N-0034 Oslo, Norway
Full list of author information is available at the end of the article



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The present study was carried out as a part of the cluster randomized controlled trial in Norwegian home-care services “Effectiveness of the Labour Inspection Authority’s Regulatory Tools for Work Environment and Employee Health” (EAVH project) [21]. The EAVH project hypothesises that inspection and guidance will increase compliance with OSH legislation and regulations, which in turn will lead to improved psychosocial and ergonomic working conditions and prevent employee ill health and sickness absence.

The present study aimed to evaluate the intervention implementation by testing three hypotheses: (I) Labour inspections and guidance workshops are perceived as equally useful (utility) and educational (enhanced knowledge); (II) Utility and enhanced knowledge are associated with intention to implement or having implemented changes to the work environment; (III) Participants in the labour inspection and guidance groups are more likely to report intention to implement or having implemented changes to the work environment than those in the control group.

Methods

Study design

We conducted a survey study to evaluate the implementation of the planned interventions in the EAVH project. These were (I) labour inspection, (II) guidance-through-workshop, and (III) an online risk-assessment tool [21]. Table 1 provides a summary of the planned interventions, see protocol for more information [21].

The clusters in the EAVH-project were municipalities, as they are the base administrative units of local government in Norway, and have a legal obligation to provide primary care, such as home care, for their inhabitants. Based on project sample size calculations, see protocol

for details, 132 eligible municipalities and their home-care services were randomly allocated to four trial arms in September 2018 [21]. Additional file 1: Fig. S1 provides a flowchart of the trial. Because the Labour Inspection Authority needed time to plan the interventions, eligible municipalities were allocated before recruitment started. In November 2018, these municipalities were informed about the planned study and invited to participate.

Three months before the planned implementation of the interventions, 28 municipalities withdrew from the study. Based on the previous sample size calculations, we considered the remaining number of 104 municipalities as too low, and we therefore elected to drop the planned online risk-assessment tool intervention as this was entirely new and as such a less important tool for the Labour Inspectorate compared to labour inspections and guidance. To retain statistical power, the 23 municipalities in the online risk-assessment group were randomly reallocated to the other trial arms (Additional file 1: Fig. S1). This reallocation was conducted 2 months before recruitment of any home-care personnel and 4 months before implementation of the interventions. In the end, 96 of the 132 municipalities agreed to participate in the study, giving an overall response rate of 73%.

In March 2019, staff at the allocated home-care services were invited to participate. The Labour Inspection Authority subsequently conducted the inspections and guidance workshops after closure of the baseline survey (Additional file 2: Material 1), starting in May 2019. Three months after the interventions were implemented, we started to invite home-care services managers and employee representatives to answer the process evaluation questionnaire (Additional file 3: Material 2).

Table 1 – A summary of the intervention components in the EAVH-project

Intervention component	Brief description	Delivered by	Delivery frequency
Labour inspection	Labour inspections conducted by trained inspectors using a standardized checklist based on relevant laws and regulations	Inspectors from the Labour inspectorate authority	One inspection per participating organization/service with follow-up of any non-compliance
Guidance workshop	Half-day sessions were services present perceived issues related to psychosocial, organisational and mechanical factors at their workplace. Trained inspectors provided feedback on the issues presented based relevant laws and regulations and invited to discussion and reflection	Inspectors from the Labour Inspectorate Authority	Once per organization/service
Online risk assessment tool	Online risk-assessment tool comprising a customized checklist of psychosocial, organizational and mechanical risk factors in the home care services. Based on the answers supplied by the employers and employees the tool provides an action plan listing measures to reduce risks, the person responsible and a deadline for implementation	Web-based	Once per organization/service, but available throughout the intervention period
Control	Care as usual, i.e., no planned inspection etc	N/A	N/A

Participants

Invited respondents of the present process evaluation were people from the participating services that had OSH-related roles, i.e., managers, employee representatives, or safety representatives, as systematic OSH management necessitates a cooperation between both employees and employers. In the labour inspection group, these were people who had interacted with, and provided information to, the inspectors. In the guidance-through-workshop group, these were people who had participated in the workshops. For the control group, we recruited managers in the services as we did not have any information available as to who were employee or safety representatives at those services.

In the labour inspection group, at least one respondent in 24 of the 30 municipalities completed the process evaluation questionnaire. Specifically, 39 (60%) of 65 managers, 14 (61%) of 23 employee representatives, 13 (50%) of 26 safety representatives, and 10 (28%) of 36 employees completed the questionnaire.

In the guidance-through-workshop group, at least one respondent in 28 of the 31 invited municipalities completed the process evaluation questionnaire. Specifically, 39 (63%) of 62 managers, 16 (50%) of 32 employee representatives, 21 (75%) of 28 safety representatives, and 17 (71%) of 27 employees completed the questionnaire.

In the control group, at least one respondent in 22 of the 35 invited municipalities completed the process evaluation questionnaire. In total, 52 (71%) of 73 managers completed the questionnaire.

Process questionnaire measures

We elected to create our own assessment questions as we wanted to use questions tailored to this trial instead of more general standardised ones, and such questions could more adequately capture the project-specific context [22]. Based on this process questionnaire (Additional file 3: Material 2), we created three dimensions, labelled utility, enhanced knowledge, and implemented measures. “Utility” aimed to capture whether the target audience perceived the interventions as useful and relevant in terms of OSH management at their workplace and was measured with five items (Table 2a). “Enhanced knowledge” aimed to capture whether the target audience perceived to have acquired improved skills to conduct OSH management at their workplace and was measured with three items (Table 2a). Response options for the items were 5-point scales ranging from (1) “a very small degree” to (5) “a very large degree”. Table 2a shows the item total correlations for these two constructs, that is, the correlation

between an individual item and the total score without that item [22]. The correlations were high, indicating that the individual items are part of the same construct.

“Implemented measures” was assessed with a single item. The general wording was: “Have you recently implemented, or are you in the near future planning to implement, measures to improve the working environment at your workplace?” (Table 3A). For both intervention groups, the wording referred to the period after the intervention had been implemented. The response options were “yes”, “no” and “do not know”. To define the reference period for those in the control group, the following response options were possible: “yes, we have recently implemented measures”; “yes, we are in the process of implementing measures”; “yes, we are planning to implement measures by 2019”; “no”; “do not know”. The question was recoded into a dichotomous variable (yes/no). Those who responded “yes”, received follow-up questions pertaining to what kind of measures that either were or planned to be implemented (Table 3B–C).

Intervention implementations

Data on conducted inspections and breaches of OSH regulations were provided by the Labour Inspection Authority. The inspectors applied a standardised checklist which comprised items relevant to psychosocial and mechanical working conditions (Additional file 4: Table S1) to record compliance with OSH regulations within the municipal home-care services. The items represent compliance with a specific relevant legal requirement, and any non-compliance would trigger a formal order and have legal ramifications for the service enterprise.

Inspections were conducted as planned in 29 of the 30 municipalities. One municipality did not receive an inspection visit, as the municipality requested a postponement due to ongoing reorganization. Contraventions of OSH-requirements were detected in 28 of the 29 inspected municipalities (Additional file 4: Table S1). All these municipalities had at least one contravention of sufficient gravity to result in an order. The mean number of contraventions per municipality was 7 (standard deviation (SD) 4).

In the *guidance-through-workshop group*, two specific process questions were posed to managers and employee representatives: (1) “Did you prepare and hold a presentation on relevant issues arising from your own work environment” and (2) “Did two trained labour inspectors give guidance based on the issues presented at the workshop” (Additional file 3: Material 2). The intervention was

Table 2 Individual item score and sum score for perceived utility and enhanced knowledge, and their associations with implementing preventive measures

a—Individual item score and sum score for perceived utility and enhanced knowledge among managers and employee representatives							
Process evaluation items	Mean (SD)	Item total correlation	Mean (SD)	Item total correlation	MD (SE)	t-test	Sig
Utility (1–5)	4.06 (0.51)		3.89 (0.71)		0.17 (0.10)	1.69	0.09
At the time of the inspection/workshop, to what extent did you experience that							
The purpose of the inspection/workshop was disseminated in a clear and understandable way?	4.19 (0.56)	0.62	3.99 (0.76)	0.71			
The inspection/workshop addressed issues relevant for health and safety at your workplace?	4.37 (0.61)	0.58	4.07 (0.76)	0.81			
The health risk associated with the work environmental issues uncovered at your workplace were properly explained?	3.96 (0.67)	0.70	3.93 (0.74)	0.81			
The necessary actions needed to be taken to provide working conditions in line with OSH legislation and regulation was disseminated in a clear and understandable way?	3.92 (0.73)	0.69	3.83 (0.95)	0.82			
The inspection/workshop provided useful information for a systematic approach to health, environment, and safety management at your workplace?	3.95 (0.70)	0.60	3.67 (0.95)	0.77			
Enhanced knowledge (1–5)	3.86 (0.65)		3.66 (0.86)		0.19 (0.13)	1.51	0.13
Overall, has the inspection/workshop, contributed to							
Increased awareness of the importance of conducting work environmental risk assessments?	4.10 (0.68)	0.67	3.78 (0.94)	0.86			
Increased skills to improve your work environment?	3.73 (0.75)	0.77	3.60 (0.94)	0.84			
Enhanced knowledge of work environmental laws and regulations?	3.73 (0.79)	0.76	3.61 (0.91)	0.91			
b—Utility and enhanced knowledge as predictors of implemented measures, or such plans, among managers and employee representatives							
	N	Coefficient	S.E	Sig			
Utility (1–5)	141	0.64	0.32	0.04			
Enhanced knowledge (1–5)	142	0.82	0.27	0.01			

Bold values denotes the sum score

conducted as intended in 26 of the 28 municipalities that completed the process questionnaire.

Statistical analyses

All analyses were performed using IBM SPSS Statistics (version 25; IBM Corp., Armonk, NY, USA). Item-total correlations were computed to explore whether a specific item is measuring the same construct as the other items included [23]. Student's *t* test was used to compare means. Associations between variables were calculated by logistic regression analyses.

Results

Equal high levels of utility (mean difference (MD) 0.17, $t=1.69$, $p>0.05$) and enhanced knowledge (MD 0.19, $t=1.51$, $p>0.05$) were reported by managers and employee representatives in both intervention groups (Table 2a). Both utility ($p<0.05$) and enhanced knowledge ($p<0.05$) were significantly associated with

self-report of implemented measures or plans for implementing measures. When compared to managers in the control group, managers in the inspection group reported significantly more frequently to have implemented, or having plans to soon implement, preventive measures ($p<0.05$) (Table 3A). A corresponding finding was not present between managers in the guidance-through-workshop group and managers in the control group ($p>0.05$). Regarding the nature of these preventive measures (Table 3B–C), significantly more managers in the inspection group confirmed to have implemented, or having plans to implement soon, measures of hazards identification and risk assessment ($p<0.05$). A corresponding finding was not present between managers in the guidance-through-workshop group and managers in the control group ($p>0.05$). There were no differences between the intervention groups and control group regarding developing plans for a systematic approach to OSH management ($p>0.05$).

Table 3 – Associations between intervention groups and self-report of implemented measures, or such plans, among home-care services managers

A	Have you implemented, or are you in near future planning to implement, measures to improve the working environment at your workplace? ^a					
	N	Yes n	%	Coefficient	S.E	Sig
Intervention groups	124	105	85			
Inspection	36	35	97	2.12	1.07	0.048
Guidance-through-workshops	36	28	78	−0.18	0.53	0.732
Controls	52	42	81	Reference		
Missing	6					
B	(If yes, what kind of measures) ...identifying hazards and assessing the risks at your workplace?					
	N	Yes n	%	Coefficient	S.E	Sig
Intervention groups	105	66	63			
Inspection	35	27	77	1.31	0.51	0.010
Guidance-through-workshops	28	19	68	0.84	0.51	0.098
Controls	42	20	48	Reference		
C	(If yes, what kind of measures) ...develop plans for a systematic approach to occupational safety and health management?					
	N	Yes n	%	Coefficient	S.E	Sig
Intervention groups	105	38	36			
Inspection	35	13	37	0.17	0.48	0.727
Guidance-through-workshops	28	11	39	4.07	0.51	0.611
Controls	42	14	33	Reference		

^a Specified as post-intervention for the inspection and guidance-through-workshop groups

Discussion

The way managers and employees with OSH responsibilities perceive and respond to labour inspectorate interventions targeting ergonomic and psychosocial risks at work is poorly understood [19, 24]. This study revealed that both managers and employee representatives in the home-care sector experienced the interventions provided by the Labour Inspection Authority as beneficial for managing workplace safety and health.

By law, it is essential and required, for enterprises to ensure a systematic, well-documented, and targeted approach to health, environmental, and safety activities at the workplace. For managers this includes an obligation to identify hazards and assess OSH risk factors. When compared to controls, significantly more managers from the inspection intervention group confirmed having implemented, or having plans to soon implement, preventive measures to ensure such an approach to OSH management (Table 3B). This finding may suggest that participating in the inspection intervention aided the managers to focus on relevant areas for change, whereas the lack of exposure to the intervention in the control group did not prompt such considerations.

There are few previous experimental or quasi-experimental studies that have addressed effectiveness of OSH management of psychosocial risk factors at work [19, 24].

The few studies that exist show results in line with findings in the present study [24–27], e.g., Weissbrodt and colleagues found that inspections improved OSH management, increased ability in psychosocial issues, perceived willingness to act, in addition to implementation of several psychosocial risk management measures [24].

Limitations

Self-reported data on enhanced knowledge and intentions to implement preventive measures may have been inflated by social desirability or demand characteristics [28, 29]. A structured interview or an examination of the managers and the employee representatives are probably a more valid approach to capture whether the interventions increased knowledge and instigated measures to improve working conditions.

We cannot discount that merely participating in the research project may have primed the control group to focus on work factors and instigate processes to implement changes. Still, implemented measures, or plans to implement measures, were significantly more frequently reported by managers in the inspection group than in the control group.

The present study could have been strengthened by including two measurement points, i.e., measures pre- and post-intervention. Yet, the random assignment

of services to intervention and control group, ensures no pre-intervention difference between the groups pertaining to OSH management, and we can rule out systematic differences between the groups pertaining to known and unknown confounding or prognostic factors.

Abbreviations

OSH: Occupational safety and health; EAVH: Effectiveness of the labour inspection authority's regulatory tools for work environment and employee health; M: Mean; SD: Standard deviation; MD: Mean difference; OR: Odds ratio.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13104-022-06244-4>.

Additional file 1: Figure S1. Flow of Clusters (municipal home-care services) and Participants (home-care workers) Through the Trial.

Additional file 2. Work environment and health questionnaire.

Additional file 3. Process evaluation Questionnaire.

Additional file 4: Table S1. Contravened regulations in the inspection group.

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Collaborators

The EAVH project is a collaboration between the Labour Inspection Authority and the National Institute of Occupational Health (STAMI). The Labour Inspection Authority was responsible for providing the interventions. STAMI was responsible for the trial design, randomization, collecting data, statistical analysis, data interpretation, and for drafting the manuscript.

Patient and public involvement

We have ensured research involvement and engagement by establishing a research reference group. The reference group consists of representatives from the authorities and the social partners. This reference group has contributed to making the study design relevant, participant friendly and ethically sound, and the representatives will be involved in the dissemination of study results.

Author contributions

HAI is the project leader of the EAVH-trial and was responsible for conception and design of the study, analysing data and writing the manuscript. BFG was involved in drafting of manuscript. JSE was responsible for database management. HAJ, BFG, SK, JSE and ØS made substantial contribution to the final design of the study and revised the manuscript for important intellectual content. All authors revised the final manuscript, and are accountable for all aspects of the work. All authors read and approved the final manuscript.

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Availability of data and materials

Data will be available 3 years after study completion. Data access request will be reviewed by NSD—Norwegian Centre for Research Data. URL: <https://nsd.no/nsd/english/index.html>.

Declarations

Ethics approval and consent to participate

The study was assessed by the Regional Committees for Medical and Health Research Ethics (REC Southeast) (2018/2003/ REK Sør-Øst C), and data handling and storage was approved by the Norwegian Centre for Data Research (566128). The study was conducted in accordance with the World Medical Declaration of Helsinki. Written informed consent was obtained from all participants in this study.

Consent for publications

Not required.

Competing interests

None declared.

Author details

¹Department of Work Psychology and Physiology, National Institute of Occupational Health, Majorstuen, 5330, N-0034 Oslo, Norway. ²National Institute of Occupational Health, Majorstuen, 5330, N-0034 Oslo, Norway. ³Department of Occupational Medicine and Epidemiology, National Institute of Occupational Health, Majorstuen, 5330, N-0034 Oslo, Norway.

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The Effect of the Labour Inspection Authority's Regulatory Tools on Compliance with Regulations in the Norwegian Home Care Services – a post-test-only control group study

*Bjørnar Finnanger Garshol, Jan Shahid Emberland, Stein
Knardahl, Øivind Skare, Håkon A. Johannessen*

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Bjørnar Finnanger Garshol, PhD, Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway

Corresponding author: bjga@stami.no, Gydas Vei 8, Majorstuen, 0363 Oslo

Jan Shahid Emberland, PhD, Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway

Stein Knardahl, PhD, National Institute of Occupational Health, Oslo, Norway

Øivind Skare, PhD, Department of Occupational Medicine and Epidemiology, National Institute of Occupational Health, Oslo, Norway

Håkon A. Johannessen, PhD, Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway

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The Effect of the Labour Inspection Authority's Regulatory Tools on Compliance with Regulations in the Norwegian Home Care Services – a post-test-only control group study

Abstract

Occupational Safety and Health (OSH) laws and regulations serves as fundamental pillars for OSH practices, playing a crucial role in safeguarding employee safety and wellbeing. However, little is known about the efficiency of regulatory tools intending to ensure compliance with OSH laws and regulations, especially within the health and social care sector. The current experimental study aimed to determine the effect of two specific regulatory tools on compliance. Municipal home-care services were allocated to one of three groups: (I) "Inspection", (II) "Guidance-through-workshops", and (III) "Control". At 24-30 months after the interventions all groups underwent formal inspections which recorded the numbers of contraventions with regulations to determine the difference in regulatory compliance between the groups. Analyses comparing the two intervention groups with the control group showed overall increased compliance in the inspection group (I), while no significant effects were found for the guidance group (II). The inspection group underwent inspections twice, and analyses of changes from the first to the second inspection also revealed improved compliance, but only statistically significantly for requirements pertaining to the addressed psychosocial factors. Future research should investigate how labour inspections can more effectively increase compliance and how to develop guidance as a tool for improving compliance.

Key words: Enforcement, OSH, Regulatory tools, Labour Inspection, Guidance, Compliance

Highlights

- A post-test-only control group design with randomised groups to assess intervention effects on compliance with OSH-regulations.
- Labour inspection group exhibited higher levels of compliance with regulations compared to the control group.
- Within-group analyses of the labour inspection group showed a significant change only for compliance with requirements related to psychosocial factors.
- Guidance-workshop group did not exhibit any significant differences in levels of compliance compared to the control group.

1. Introduction

National occupational safety and health (OSH) legislation and regulation provides a foundation for organisational OSH practices (Leka & Jain, 2014). Development of policy and engagement with stakeholders at different levels determine the degree to which awareness of relevant issues is raised, whether common understanding and norms develop, and which actions are undertaken (Leka & Jain, 2014). Enforcement of OSH laws and regulations is viewed as essential to ensure safety and health for employees in the workplace by both the ILO and the WHO (International Labour Office, 2004; World Health Organization, 2006).

The importance of regulating and enforcing in OSH is underscored by the impact that common occupational risk factors have on employee health and subsequent sickness absence. A significant number of cases involving back pain or mental distress among employees are attributable to just such risk factors. In Norway an estimated 40 % of lower back pain is attributable to mechanical and psychosocial work factors (Sterud & Tynes, 2013), while 25 % of mental distress is attributable to psychosocial work factors (Johannessen et al., 2013). One high-risk sector is the home-care service sector, where the work environment is characterised by risk factors such as job strain (Assander et al., 2022), high work intensity and emotional demands (Bakke et al., 2021) and strenuous work tasks (Quinn et al., 2016), and where both musculoskeletal pain and mental distress are prevalent (Carneiro et al., 2017; Sterling et al., 2021). As OSH-regulations are meant to aid in the prevention of such outcomes, there is a necessity to ensure efficient and effective enforcement of said regulations in the sector.

Previous research on regulatory tools has noted an effect of labour inspections on compliance and injuries (Andersen et al., 2019; Johannessen et al., 2017; Mischke et al., 2013; Tompa et al., 2016). However, the main focus of said research has primarily been the manufacturing and construction sectors, and little research has been conducted on the health and social care services (Andersen et al., 2019; Johannessen et al., 2017). The work environment in such services can be seen as qualitatively different from those in manufacturing and construction, with other exposures and potential risk factors and different outcomes being prioritized. Thus, the applicability and effectiveness of regulatory tools may also differ. Among regulatory tools, labour inspection is the most investigated one. The available research on guidance-related measures is sparse and has shown mixed results, ranging from a positive effect of consultation (Foley et al., 2012) or supporting inspections (Burstyn et al., 2010) to no effect of consultations (Baggs et al., 2003; Hogg-Johnson et al., 2012). Among these only Burstyn et al. (2010) specifically had compliance as an outcome. Lastly, there is little research on the effects of enforcement on compliance with requirements related to psychosocial and mechanical work exposures, as most previous research has reported on either unspecified or overall compliance (Andersen et al., 2019; Johannessen et al., 2017).

The aim of the present study was twofold: (1) to determine whether one-time inspection visits strengthen regulatory compliance; (2) to determine discrepancies in contraventions between home-care services that received a) no interventions (control group) and b) those being inspected or c) those participating in guidance-through-workshops. Based on previous research on regulatory tools

and compliance we hypothesise higher levels of compliance with OSH-regulations in the units in the inspection group and potentially higher levels in home-care units attending guidance-through-workshops.

Work environment regulations and enforcement – the Norwegian context

In Norway, the working environment is regulated by the Working Environment Act (Act Relating to the Working Environment, Working Hours and Employment Protection, etc.) (Arbeidsmiljøloven, 2005). Its purpose, among others, is to ensure a working environment that provides a basis for a healthy and meaningful working situation and provide a basis whereby employers and employees may themselves develop their working environment (Arbeidsmiljøloven, 2005). It stipulates requirements for the psychosocial, physical and chemical and biological work environment and constitutes, with attending regulations, a basis for systematic OSH-management in Norway.

The enforcement of OSH-regulations falls under the purview of the National Labour Inspection Authority (NLIA). Their two primary tools used in such enforcement are labour inspections and the provision of guidance. The main aim of labour inspections is to ensure that enterprises comply with relevant laws and regulation, primarily the Work Environment Act (Arbeidsmiljøloven, 2005), with attending regulations, such as the Internal Control Regulation (Internkontrollforskriften, 1996). This regulation mandates that enterprises adapt a systematic approach to OSH-management. This entails implementing measures ensuring that activities are planned, organised, and performed in compliance with relevant laws and regulations. Furthermore, the Internal Control Regulation (Internkontrollforskriften, 1996) specifies the necessity for enterprises to document, in writing, these measures. During labour inspections, compliance with these requirements and documentation thereof is assessed using a standardised checklist. As inspections and their content requires a legal basis, the check list is based on and constrained by current regulations. During the inspections any cases of non-compliance are then marked and followed-up by the inspectors. Such follow-up can have direct legal ramifications for the enterprises such as formal orders to rectify the situation, with continued non-compliance potentially leading to fines being levied against the offending enterprise (Hansen et al., 2015).

The NLIA provides guidance in various forms and in different forums. It ranges from information on their own website, online tools and to in-person guidance through seminars and workshops (Arbeidstilsynet, 2023b). The goal of said guidance is to provide information on relevant and current rules and regulations and to enable enterprises to follow these in practice. In particular, the NLIA convey information on occupational risk factors and the potential consequences of not addressing such risk factors and information on how to interpret and comply with laws and regulations (Arbeidstilsynet, 2023b).

2. Methods and materials

The present study is a part of the “(Anonymised for blinding purposes)”-project, a cluster randomised controlled trial investigating the effects of labour inspection and guidance-through-workshops on the

work environment and employee health. The published protocol article provides an overview of the project (Authors, 2019), and Figure 1. shows the projects conceptual model.

Figure 1 - Conceptual model for the project (Authors, 2019).

The present study employed a post-test-only control group design with randomised groups to assess intervention effects. Eligible municipalities and their public home care units were randomly assigned to one of three groups: two receiving specific interventions and one serving as a control group with no intervention. The NLIA carried out the interventions between May 2019 and October 2019. At the conclusion of the study period, all units underwent inspection visits to evaluate the primary outcome of interest, namely, compliance with OSH-regulations (See Figure 2 – Flowchart).

Interventions

The labour inspection intervention consisted of the NLIAs standardised labour inspections. Each unit was notified three weeks in advance of the impending inspections. Each inspection was conducted by two trained labour inspectors. The inspectors utilized a standardised checklist, specifying requirements pertaining to factors labelled “ergonomic”, “organisational”, “psychosocial”, and “occupational safety and health management” (See Table 1). In addition, the inspectors provided guidance on how the units could comply with relevant regulations and rectify any cases of non-compliance. Inspectors also wrote an inspection report highlighting any cases of non-compliance and steps taken to ensure compliance, such as a formal order to address these cases.

The guidance-through-workshop intervention consisted of one-time sessions facilitated by inspectors from the NLIA. Leaders and employee representatives from five to seven units were invited to participate based on their geographical location. For these joint workshops participants were tasked with preparing a presentation outlining the challenges they themselves identified in their respective work environments and their strategies for addressing these challenges. During the workshops inspectors offered guidance on systematically approaching said challenges, building upon the insights presented. Additionally, inspectors provided information and guidance on the relationships between work-related risk factors and health, pertinent laws and regulation, and how the units could comply with said laws and regulations in practice.

The control group consisted of home-care units that received ‘care as usual’, denoting that no labour inspections or guidance workshops were planned or provided for the units in the group during the period of participant follow-up.

Recruitment

Study recruitment started with identifying eligible clusters, i.e., municipalities that had more than 20 and less than 100 care workers. We chose this range of employee numbers order to reduce intra-cluster variability and thus reduce the needed sample size (Authors, 2019). Ineligible municipalities

were defined as municipalities that had recently (2017-18) received labour inspections. Based on sample size calculations (Authors, 2019) 132 of 187 eligible municipalities were randomly assigned to one of four trial arms. These were: (1) labour inspection, (2) Guidance-through-workshop, (3) Online risk assessment tool and (4) Control. The eligible municipalities, along with their public home-care units, were then informed, both through letters and by e-mail, about the planned study and invited to participate. The project also recruited employees at the home-care services in the participating municipalities, but these are not included in the current study.

Although three intervention groups were originally planned, fewer municipalities ($n=104$) than expected elected to participate. Therefore, the online risk assessment tool municipalities were randomly reallocated to any of the two other interventions or the control group. Eight municipalities dropped out pre-intervention. One municipality in the inspection group requested a postponement due to reorganization and were thus excluded pre-intervention. One guidance-through-workshop municipality elected not to participate, and another did not receive the end-of-study inspection due to a local Covid-19 outbreak. This resulted in 29 municipalities with 41 participating units in the inspection group, 29 municipalities with 46 participating units in the guidance-through-workshop group, and 35 municipalities with 66 participating units in the control group (See Fig. 2).

Fig 2. Flowchart illustrating cluster allocation, intervention implementation and follow-up inspections

Outcome measure – contraventions recorded during inspections

Data on the outcome measure was procured from the Norwegian Labour Inspection Authority and consisted of the check lists from labour inspections conducted at the end of the study, 24-30 months after the interventions had been conducted (See table 1). For the inspection group data from the intervention inspection was also available.

Table 1 – Standardised checklist used in the labour inspections by the NLIA

Ergonomic work factors	
1	Has the employer surveyed and assessed the risk factors of manual labour that can be harmful to employee's health, including musculoskeletal complaints?
2	Has the employer implemented measures and/or made plans to reduce or eliminate manual labour tasks that are taxing or harmful to the employees' health?
3	Are employees conducting ergonomically taxing work, such as heavy or repetitive tasks, given necessary information and training?
Organisational work factors	
4	Has the employer identified and assessed risks and, on this basis, prepared plans and implemented necessary measures to prevent employees from being exposed to unhealthy work-related stress?
5	Has the employer evaluated the employee work-scheduling related to possible negative physical and mental consequences, and, in such a way that safety has been prioritized?
6	Do employees with leadership responsibilities have the necessary competencies to address health and safety considerations within their area of responsibility?

Psychosocial work factors	
7	Has the employer as far as possible identified and assessed risks and, on this basis, prepared plans and implemented measures to protect employees from violence, threats of violence and unpleasant burdens arising from contact with others?
8	Has the employer ensured that employees and their representatives have been adequately informed about risk factors related to violence and threats of violence; implemented measures and routines for preventing, managing, and following up on violence and threat situations; implemented routines for denouncing and reporting of violence or threats of violence?
9	Has the organization implemented routines for how harassment or other improper conduct is to be prevented, reported, handled, and followed up?
10	Have workers received appropriate training and exercises so that they are protected as far as possible from violence and threats of violence?
11	Has the employer as far as possible identified and assessed risks and on this basis prepared plans and implemented measures to protect employees from violence, threats of violence and unpleasant burdens arising from contact with others?
12	Has the employer surveyed and risk-assessed factors in the working environment that may affect workers' mental health?
13	Has the employer implemented measures and/or prepared plans to reduce factors in the working environment that may affect workers' mental health?
Occupational safety and health management factors	
14	Has the organization elected a safety representative?
15	Has the safety representative been given adequate training?
16	Is the safety representative included in the organization's planning and implementation of measures that impact the work environment?
17	Does the employer ensure that employees and their representatives can participate in the systematic occupational health and safety work?
18	Has the organization prepared a plan for how occupational health services can assist them?
19	Has the employer implemented routines for how non-conformities (undesirable events) are to be reported and followed up?
20	Has the employer assessed the risk of working alone?

Contraventions of labour regulations were assessed by the inspectors using a standardised checklist. The checklist consisted of 20 different items, or requirements, (Table 1) developed by the NLIA based on relevant regulations, primarily the Working Environment Act (Arbeidsmiljøloven, 2005). The items were grouped by the NLIA into four main categories based on which aspects of the regulations they are meant to operationalise. As shown in table 1, these were: ergonomic work factors (three items), organisational work factors (three items), psychosocial work factors (seven items) and factors related to general systematic occupational safety and health management (seven items). During the inspections services were assessed on each item and were considered as either compliant or non-compliant, with a rating of non-compliant indicating a contravention of regulations. Information from the checklists on the number of contraventions was then used to generate a sum score based on all 20 items and one for each of the four main categories. The lower the score the more compliant the home care units were. Inspectors were instructed by the NLIA to check all 20 items, but in some instances fewer items were checked. This was primarily in settings where some of the items were deemed as irrelevant by the inspectors, such as items pertaining to heavy lifting in services that provided aid for people with psychiatric diagnoses. In order to account for this, a contravention index was also calculated based on Dahl et al. (2022), using the following formula:

$$\frac{\text{Total number of contraventions}}{\text{Total number of contravention points checked}}$$

This gives an index between 0 and 1, with a lower number signifying fewer contraventions with regulations.

Covariates

Previous research has noted that factors such as organisational size and ongoing reorganisations (Weissbrodt & Giauque, 2017) could influence level of compliance. To account for this, we included several covariates related to the municipalities the services were situated in. We collected data on number of staff in the municipal home care services and number of inhabitants in the municipality. All this information was acquired from Statistics Norway and are based on data from the municipalities as they were at the start of the study. To account for workload and available staff, which might impact resources available to conduct OSH-work, number of staff and number of inhabitants were used to generate the number of staff per 1000 inhabitants. We also collected information on whether the municipalities had undergone any mergers due to reform (Yes/No) from the Ministry of Local Government and Regional Development.

Statistics

Statistical analyses were conducted using STATA Version 16 (Stata Corp, College Station, TX, US), and the level of significance was set at 0.05. Descriptive statistics were used to provide characteristics of the three groups. In the inspection group paired t-tests were used to investigate differences between the first and second round of inspections. Additionally, we estimated Cohen's d to provide effect sizes. Linear regression was used to investigate differences between the two intervention groups and the control group, including separate analyses of the NLIA-defined categories. The analyses were conducted both unadjusted and adjusted for number of staff per 1000 inhabitants and municipal mergers. Adjusted analyses used variance-covariance matrix of the estimator to account for clustering (*vce cluster in STATA*), due to units belonging to the same municipality. Both the unadjusted and adjusted models are presented.

3. Results

Table 2 shows information on participating municipalities and home-care units including mean number of contraventions. The participating municipalities were similar across the three groups with regards to number of staff per 1000 inhabitants and whether they had experienced municipal mergers in the study-period. The home-care units in the inspection group exhibited significantly lower average number of contraventions compared with the control group, while the guidance-through-workshop group had similar numbers of contraventions compared to the control group.

Table 2 – Descriptive statistics on included municipalities and home-care units			
	Inspection	Guidance- through-workshop	Controls
Municipalities	29	29	35
Number of staff per 1000 inhabitants (SD)	14.94 (9.02)	13.59 (6.5)	12.33 (6.76)
Municipal mergers in the period (%)	6 (20.7)	6 (20.7)	7 (20.0)
Number of home-care units	41	46	66
Average number of contraventions – 2019 (SD)	6.9 (4.58)	N/A	N/A
Average number of contraventions – 2021 (SD)	5.29 (4.78)*	7.04 (3.53)	7.92 (4.65)
*Significantly different from control group, $p < 0.05$			

Differences in regulatory compliance in the inspection group between the first and second round of inspections is shown in table 3. There were fewer contraventions, but this was only statistically significant for compliance with requirements related to psychosocial factors (Diff: - 1,12, $p = 0.007$) with a moderate effect size (Cohen's d : 0.52).

Table 3 – Inspection group - Level of compliance with regulations in 2019 versus 2021					
	2019	2021	Difference	P-value	Cohens D
Sum – Contraventions	6.90	5.29	-1.60	0.11	0.34
Contraventions - Ergonomic factors	1.22	0.77	-0.45	0.09	0.40
Contraventions - Organisational factors	0.87	1.07	0.19	0.44	0.18
Contraventions - Psychosocial factors	3.29	2.17	-1.12	0.007	0.52
Contraventions - Factors relating to systematic OSH-management	1.53	1.24	-0.29	0.30	0.21
Contravention index	0.35	0.26	-0.08	0.09	0.39

Group differences in compliance with regulations between the inspection and guidance group and the control group is shown in table 4. There were significant differences between the inspection group and the control group in the unadjusted analyses with the inspection group having fewer contraventions overall (-2.63, 95% CI: -4.35 - -0.90) and fewer contraventions of requirements related to ergonomic (-0.59, 95% CI: -1.06 - -0.12) and psychosocial factors (-1.54, 95% CI: -2.39 - -0.68). The inspection group also had a significantly lower contravention index (-0.13, 95% CI: -0.22 - -0.04). Similar results were also seen in the adjusted analyses for contraventions overall (-2.91, 95% CI: -5.70 - -0.12) and contraventions of requirements related to ergonomic (-0.65, 95% CI: -1.28 - -0.03) and psychosocial factors (-1.63, 95% CI: -2.87 - -0.40), and the contravention index (-0.14, 95% CI: -0.28 - -0.01). There were no significant differences between the Guidance-through-workshop group and the control group in the unadjusted and adjusted analyses.

Table 4 – Linear regression analyses on number of contraventions in the labour inspection and guidance-through-workshop groups compared to the control group						
	Unadjusted			Adjusted ¹		
	Inspection		Guidance-through-workshop	Inspection		Guidance-through-workshop
	Coeff.	CI 95%	Coeff.	CI 95%	Coeff.	CI 95%
Sum Contraventions	-2.63*	-4.35 – -0.90	-0.88	-2.54 – 0.78	-2.91*	-5.70 – -0.12
Contraventions - Ergonomic factors	-0.59*	-1.06 – -0.12	-0.18	-0.63 – 0.27	-0.65*	-1.28 – -0.03
Contraventions - Organisational factors	-0.13	-0.53 – 0.25	0.01	-0.37 – 0.38	-0.22	-0.82 – 0.38
Contraventions - Psychosocial factors	-1.54*	-2.39 – -0.68	-0.40	-1.23 – 0.41	-1.63*	-2.87 – -0.40
Contravention - Factors related to the systematic OSH-management	-0.37	-0.87 – 0.11	-0.31	-0.79 – 0.16	-0.42	-1.22 – 0.37
Contravention Index	-0,13*	-0.22 – -0.04	-0.04	-0.12 – 0.04	-0.14*	-0.28 – -0.01
*Significant (p<0.05)						
¹ Adjusted for number of staff per 1000 inhabitants, municipal merger, clustering.						
					-0.05	-0.17 – 0.06

Discussion

This study aimed to: (1) to determine whether one-time inspection visits strengthen regulatory compliance; (2) to determine differences in contraventions between home-care services receiving a) no interventions (control group) and b) those being inspected or c) those participating in guidance-through-workshops. We found a significant increase in compliance with requirements related to psychosocial factors between the first and second round of inspections for the inspection group. Furthermore, we found that the inspection group had higher levels of compliance overall, higher levels of compliance with requirements related to ergonomic factors (i.e. measures addressing mechanical exposures) and psychosocial factors (i.e. measures addressing violence, harassment, and mental health), and a lower contravention index compared to the control group. We found no such group differences between the guidance-through-workshop group and the control group. The results thus support the hypothesis that inspections would lead to higher levels of compliance, however they do not lend support to the hypothesis that guidance-through-workshops could also show higher levels of compliance.

The increase in compliance with regulations, i.e., fewer contraventions, between first and second round of inspections for the inspection group is similar to previous research noting increased compliance after labour inspections (Andersen et al., 2019; Johannessen et al., 2017; Mischke et al., 2013; Tompa et al., 2016). It is also in line with findings from the projects process evaluation showing that managers in the inspection group were more likely to report instituting changes to the work environment or planning to institute changes after the inspections compared with the control group (Authors, 2022). However, in contrast with previous research, the present study only found a significant effect from the first to the second inspection on compliance with requirements related to psychosocial factors, and not a significant effect on overall compliance.

One reason for this discrepancy could be the impact of the Covid-19 pandemic that coincided with the latter parts of the project and the second rounds of inspections which were conducted in 2021. The effects of Covid-19 could have hampered the implementation of changes to the work environment in the home care services. Dealing with challenges brought about by the pandemic could have taken both time and resources away from working systematically towards bettering the work environment, thus attenuating the effects of the inspections. For example, managers in Swedish home-care services reported that during Covid-19, task related to handling challenges brought about by the pandemic took time away from task related to improving employee wellbeing (Rydenfalt et al., 2023). However, it is important to note that we did see an effect on compliance related to psychosocial factors, a key focus area for this project (Authors, 2019). As such, it could be said that this intervention did bring about change in the work environments in the home-care services.

Another reason for the difference between the present study and previous research could be differing contexts, both in terms of the type of work and exposures and in legal settings. Previous research has for example been conducted primarily in the construction and manufacturing setting (Andersen et al., 2019; Johannessen et al., 2017). In these settings other types of requirements might be in focus than those in a health and social service setting. In the construction sector the focus might be more on safety measures and requirements than risk assessments of ergonomic and

psychosocial factors. Such technical risks, e.g. a lack of guard rails, are potentially both more readily inspected and more readily fixed, than work factors pertaining to subjective psychological and social factors. The home care services encompass socially demanding interactions with patients/clients with a plethora of needs and personalities. Additionally, a majority of the previous research on OSH regulatory interventions has been conducted in a North American setting (Bondebjerg et al., 2023), where legal requirements might differ from the Norwegian setting. Differences in legal requirements gives differences in enforcement and what constitutes compliance. One example of how legal requirements shapes the context is the very content of the check list used in the present study (Table 1). This is defined by the Work Environment Act, which explicitly specifies violence, threats and harassment, while significant psychosocial work factors such as for example work demands, emotional demands and role conflict are not mentioned (Arbeidsmiljøloven, 2005). Hence the inspectors' check list explicitly specifies threats, violence and harassment, with other factors being implicitly included under the two items addressing general risk factors affecting workers mental health. Thus, while the concept of psychosocial work factors is both more elucidated and more encompassing in research, it is here constrained by the legal framework and what it considers necessary for compliance.

The inspection group had significantly higher compliance, i.e. fewer contraventions, than the control group. This was evident both overall and for some of the individual factors, namely contraventions of requirements related to ergonomic and psychosocial factors. This again is in line with previous research showing effects of labour inspections on compliance with regulations in other sectors (Andersen et al., 2019; Johannessen et al., 2017; Mischke et al., 2013; Tompa et al., 2016). The between-group differences for the inspection group versus control group were larger than the observed within-group differences for the inspection group which only found a significant effect on psychosocial factors. One potential reason for this difference could be external influences that affected all groups, but to which the inspection group might have proven more resilient. One such external influence could have been the previously mentioned Covid-19 pandemic, which had far-reaching consequences for the services in 2020-21. Dealing with the pandemic may have taken time and resources from work related to improving the work environment, or the pandemic could simply have worsened it through increased demands on staff. Healthcare personnel reported both increased workloads and working hours (Billings et al., 2021), and in the home care services personnel reported increased psychosocial strain during the pandemic (Rydenfalt et al., 2023). And, as mentioned above, managerial task related to the pandemic also took time away from task related to improving employee wellbeing (Rydenfalt et al., 2023). The main impact of the pandemic would have been from early 2020 onwards, while the interventions were conducted in 2019. Thus, the units in the inspection group could already have started working to improve their work environment when the pandemic struck. This assumption is also supported by the process evaluation findings mentioned previously, as leaders in the inspection group were significantly more likely to report having, or planning to, institute changes in the work environment after the intervention (Authors, 2022). Therefore, while all groups were affected by the pandemic, the inspection group was potentially less affected due instituting changes to the work environment beforehand as a result of the inspections. The guidance-through-workshops seems not to have given a similar resilience.

The guidance-through-workshop groups level of compliance with regulations was not statistically significantly different from the control group. Previous research on regulatory tools has not focused on guidance through workshops or seminars per se, but some studies have been conducted on

consultative activities or supportive and guiding types of inspections on differing outcomes. Among these, Burstyn et al. (2010) found some positive effects of supportive inspections, suggesting that guidance related activities can impact compliance with regulations. One reason why we observed no effect of guidance in our study could be due to the less formal approach that the guidance workshops entail. It had no potential legal ramifications for the participants, and thus perhaps did not provide the same immediacy and impetus to institute changes compared to labour inspections which have such ramifications. Furthermore, the goal of the guidance workshops was not to instruct the services on specific contraventions, as would be the case in inspections, but rather to provide guidance on challenges raised by the services themselves on the basis of current regulations. Thus, while the guidance provided at the workshops might have been both sound and relevant, it did not necessarily enable the services to avoid specific contraventions as operationalised by the checklist.

Implications

The implications of the current study are best seen in conjunction with previous results from the project. This study together with the results from the project's process evaluation (Authors, 2022) indicates that labour inspections are well received and perceived as useful and relevant and lead to increased compliance with regulations. However, this should be somewhat tempered by other results from the project on participant outcomes, such as work environment and health. Here the results show no effect of the interventions on psychosocial and mechanical factors (Authors, 2022), and no effect on self-reported health and physician certified sickness absence due to musculoskeletal or psychological diagnoses (Authors, 2024). Overall, this suggests a need for further research on how labour inspections can better impact work environment and employee health. The results on compliance with requirements related to psychosocial factors show promise and an implication for practice could be a need to strengthen the regulatory toolbox, for example through more specific laws and regulations which could facilitate inspections and improve compliance further. Weissbrodt and Giauque (2017) for example noted a need for more specific regulations of psychosocial factors, and in Norway the NLIA themselves have suggested that such factors should be better regulated in order to clarify and better specify the requirements regarding psychosocial factors (Arbeidstilsynet, 2023a). Clearer and more specific regulations could also decrease the discrepancy between how psychosocial work factors for example are understood in current occupational research and how they are understood in the current legal and enforcement context.

Limitations

One limitation of the present study is that the outcome measure, i.e., the check list, was developed for the purpose of enforcement and as an operationalisation of current regulations and is as such not a validated measure. It does, however, accurately represent the criteria for how the regulations (and contraventions) are interpreted, and the target areas of inspections in practice. Regarding the inspections, we also do not know if the same inspectors who performed the inspection intervention also performed the follow-up assessment of compliance/contraventions. Those inspectors who performed the intervention may possibly rate the results of their work more favourably. At follow-up, the inspectors involved were also not blinded to interventions received previously, which could potentially have affected how they approached the inspections. Another limitation is that the covariates, employees per 1000 inhabitants and municipal mergers are also on a municipal level, and not on an individual unit level. This is primarily because more detailed information was not available, and while municipal mergers are by necessity on a municipal level, information on actual

reorganisation in the individual units could, for example, have provided a clearer picture and more precise analyses. We also do not know the baseline compliance for the units in the guidance-through-workshop and control groups, limiting the possibility to estimate and account for changes over time. However, any attempts at establishing these would have interfered with the study design and as such was deemed unfeasible.

Strengths

One of the strengths of the study is that the municipalities were randomly assigned to the different study groups. Based on the principles of randomisation, it could be argued that this ensures that their baseline compliance would have been similar across the groups. Further as they were randomly drawn from a pool of eligible municipalities, they should provide a representative sample. As such we believe the findings can be generalised to similar settings in the health and social care sector and to countries with similar OSH-legislation and regulations. Lastly, the available data allows for both within-group and between-group analyses for the inspection group letting us both assess changes over time in the group and compare it with a control group.

5. Conclusion

The present study found that compliance with regulations increased in the labour inspection group, but this increase was only statistically significant for requirements related to psychosocial factors (i.e. measures pertaining to violence, harassment and factors affecting mental health). Compared with no inspections however, the study found an overall higher level of compliance, and especially requirements related to ergonomic and psychosocial factors. Similar results were not seen for guidance workshops. Thus, while the guidance-through-workshop group did not exhibit significantly higher compliance, labour inspections did improve compliance with OSH-regulations. Future research should investigate how labour inspections can be more effective in improving compliance and how to develop guidance as a tool for improving compliance.

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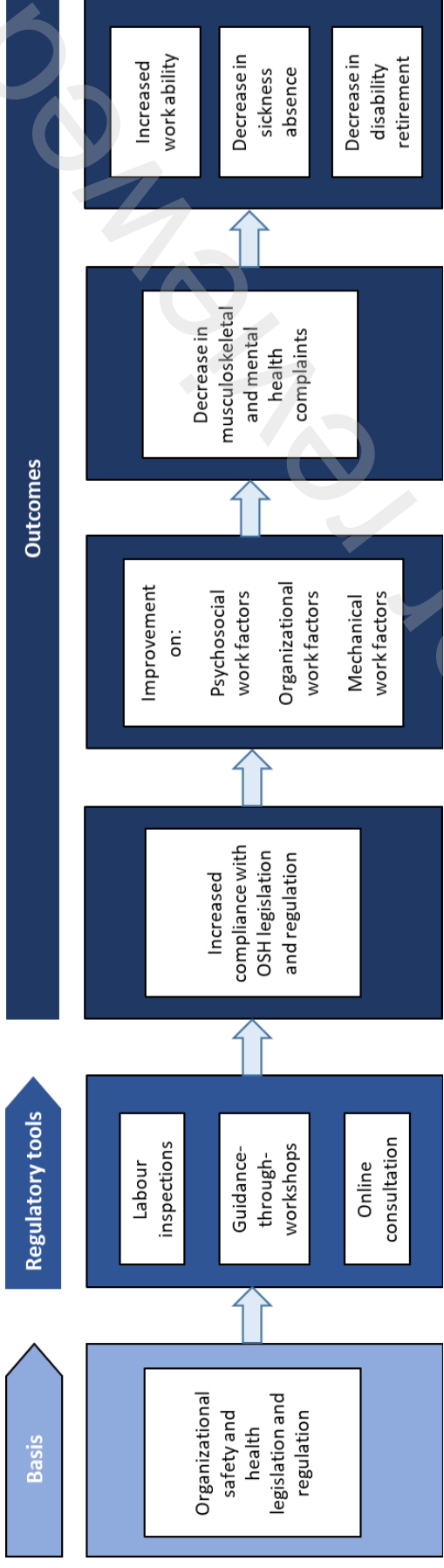
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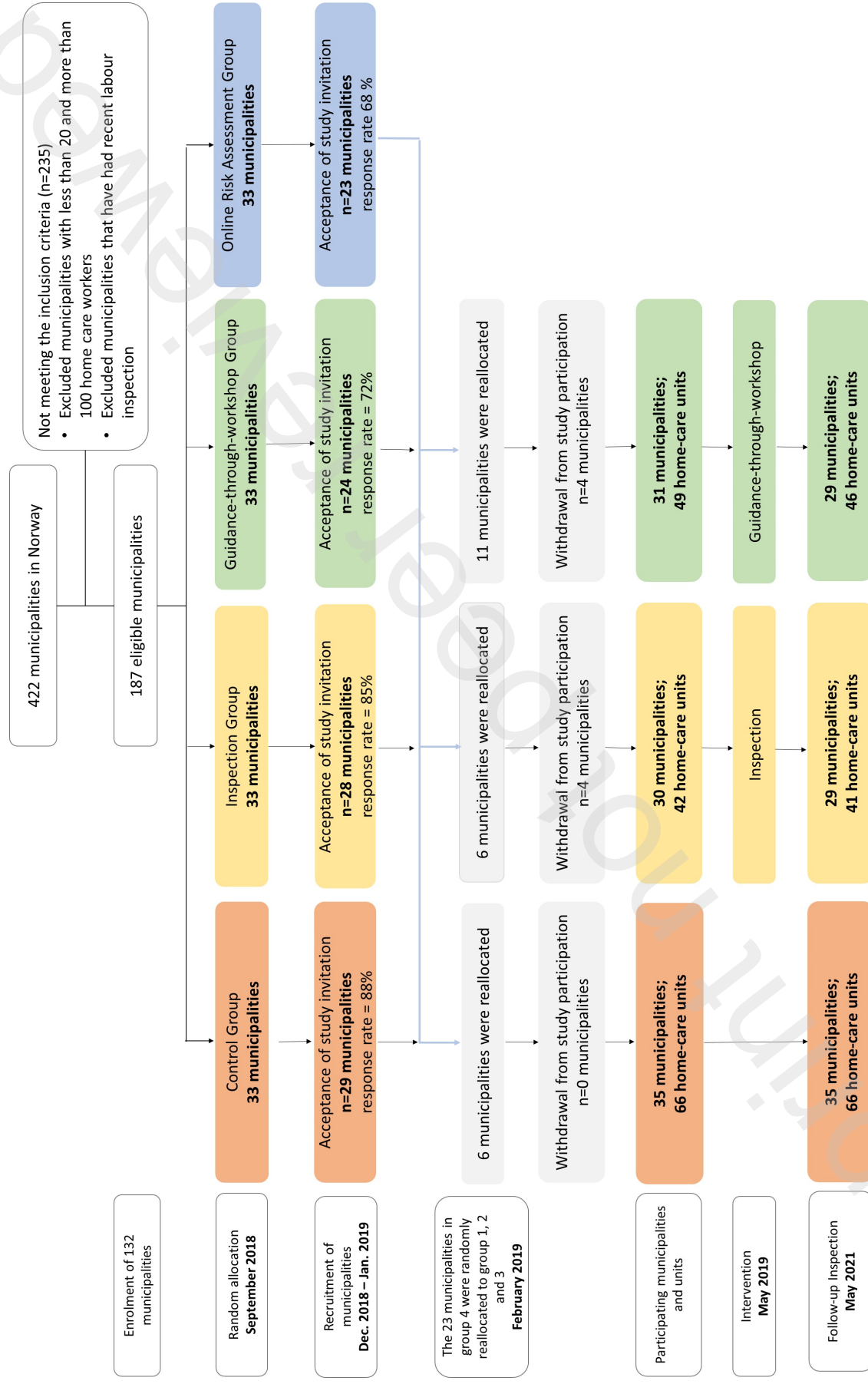
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Vedlegg 4 – Effekter på arbeidsmiljøfaktorer

Effects of the Labour Inspectorate Authority's regulatory tools on psychosocial and biomechanical work factors in Norwegian home care services: a cluster randomised controlled trial

*Bjørnar Finnanger Garshol , Stein Knardahl, Jan Shahid
Emberland, Øivind Skare, Håkon A. Johannessen*



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Original research

Effects of the Labour Inspectorate Authority's regulatory tools on psychosocial and biomechanical work factors in Norwegian home care services: a cluster randomised controlled trial

Bjørnar Finnanger Garshol ,¹ Stein Knardahl,² Jan Shahid Emberland,¹ Øivind Skare,³ Håkon A Johannessen¹

¹Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway

²Research Director, National Institute of Occupational Health, Oslo, Norway

³Department of Occupational Medicine and Epidemiology, National Institute of Occupational Health, Oslo, Norway

Correspondence to

Dr Bjørnar Finnanger Garshol, Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo 0304, Norway; bjga@stami.no

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ABSTRACT

Objectives This study aimed to determine the effects of the Labour Inspectorate Authority's (LIA's) regulatory tools on psychosocial and biomechanical work factors in the Norwegian municipal home care services.

Methods A cluster-randomised controlled trial conducted in the home care services with employee questionnaire data on work factors at baseline, and 6 and 12 months after the interventions. In total, 96 eligible municipalities were randomly assigned to either the control group or one of two interventions: (1) labour inspection visits, based on the LIA's standard inspections; and (2) guidance-through-workshops, where the participating services highlighted issues and trained labour inspectors provided guidance based on existing labour laws and regulations.

Results No favourable intervention effect was observed for the inspection intervention. No effects were observed for most of the variables in the guidance intervention, although an effect was observed for the following psychosocial factors: decision control, control over work intensity and empowering leadership. However, after adjusting for multiple testing, none of the observed effects were statistically significant.

Conclusion Labour inspections did not affect psychosocial and biomechanical work factors in the home care services. A favourable effect of the guidance intervention on psychosocial work factors was observed. However, this was not evident after adjusting for multiple testing. Further research is needed to elaborate on how labour inspections and other regulatory tools can impact psychosocial and biomechanical work factors.

Trial registration number NCT03855163.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Labour inspections increase compliance with existing regulations and decrease workplace injuries. However, little is known about the effects of inspection and other regulatory measures' effect on psychosocial and biomechanical work factors.

WHAT THIS STUDY ADDS

⇒ Labour inspections showed no effect on psychosocial and biomechanical work factors, while guidance workshops showed an initial favourable effect on psychosocial factors, with an increase in decision control, control over work intensity and empowering leadership. However, these effects were not significant after adjusting for multiple testing.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results suggest a need for designing inspection protocols and guidance-through-workshop sessions that more carefully emphasise psychosocial and biomechanical work exposures. Additionally, while one-time guidance sessions may be adequate, further studies should examine whether a more longitudinal approach with follow-up visits would be more optimal. Finally, it is advisable to consider whether existing inspection checklists appropriately examine a wide range of specific work exposures.

BACKGROUND

The influences of biomechanical and psychosocial work factors on employee health, risk of sickness absence and disability retirement have been firmly established.^{1–4} In Norway, musculoskeletal and mental disorders are a major cause of years lived with disability,⁵ with 40% of the cases involving lower back pain⁶ and 25% of the cases involving mental distress⁷ among employees being attributable to psychosocial and biomechanical work factors.

Musculoskeletal pain and mental distress are prevalent in health and social care services, particularly in the home care services.^{8–10} Studies show that home care staff perceive strenuous work tasks, a changing and uncontrollable physical and psychosocial work environment, and organisational challenges as the main risks to their occupational health.¹¹ These services also face increasing demands due to current demographic developments, with a growing elderly population.¹² Additionally, the services are increasingly facing restructuring due to a shift in focus from care in institutions to care at home, for example, due to



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the government pursuing the concept of ageing in place.¹³ The challenges in the sector, together with increasing and changing demands, necessitate an increasing focus on how to improve working conditions for employees in the home care services. Previous studies have focused on influencing the work environment in home care services through accident prevention,¹⁴ and interventions involving organisational change, education and training, digitalisation or scheduling.¹⁵ Interventions based on the enforcement of occupational safety and health (OSH) regulations in home care settings has so far garnered little attention.

Enforcement of OSH regulations is viewed as essential to ensuring the safety and health of employees,^{16 17} and labour inspection is a common enforcement tool. Previous research has found that labour inspections can improve compliance with OSH regulations and have the potential to reduce occupational injuries.^{18–21} However, existing research has predominantly focused on construction and industrial workplaces,²⁰ and to a lesser degree on health and social care services. The need for more research on the effect of labour inspections on psychosocial work factors has been particularly highlighted,¹⁸ given the influence of these factors on employee health.

Therefore, the aim of this study is to determine the effect of the Labour Inspectorate Authority's (LIA's) labour inspections and guidance-through-workshops on psychosocial and biomechanical work factors in Norwegian home care services. Based on previous research on the effect of regulatory tools on compliance and injuries, we hypothesise a favourable effect of inspections and workshops on psychosocial and biomechanical work factors among employees in the home care services.

DESIGN AND METHODS

This study is a cluster-randomised controlled trial including home care service workers from a probability sample of municipalities in Norway. We chose a cluster design because the work environments of home care services are inherently clusters. The study is part of a larger project, and a full description can be found in the published protocol.²² In addition, we conducted a process evaluation.²³ This evaluated, using questionnaires, whether the interventions had been conducted as planned. Further, it evaluated how the participants perceived the utility of the interventions and whether it enhanced their knowledge of OSH management. Finally, it investigated whether these perceptions were associated with intentions to implement changes to the work environment.

Recruitment and participants

Recruitment began by identifying eligible clusters, which were municipalities with more than 20 and less than 100 care workers. This range was chosen to reduce intracluster variability and thus reduce the needed sample size.²² Ineligible municipalities were municipalities that had recently, in 2017–2018, had labour inspections. Based on sample size calculations (see protocol²²), 132 of the 187 eligible municipalities were randomly assigned to one of four trial arms. The project lead conducted the randomisation using random numbers assigned to each municipality, followed by sorting, and allocating the first 33 to the first arm, the next 33 to the second arm, etc. Eligible municipalities were informed about the study, both through letters and email and were invited to participate. Municipalities that elected to participate were asked to provide a contact person from the municipality's home care services. All employees were eligible for participation and contact persons were requested to provide an employee overview with contact information. This was

subsequently used to invite employees to participate in the study through email and text messages.

Originally, three intervention arms were planned, but due to fewer recruited municipalities ($n=104$) than expected those in the third intervention arm (online risk assessment) were randomly reallocated to the two remaining interventions and the control group using the same method as the original randomisation. As 8 municipalities dropped out of the study before the interventions, we were left with 96 municipalities. Thus, 35 municipalities with 1771 potential participants were allocated to the control group, 30 municipalities with 1034 potential participants to the inspection intervention group and 31 municipalities with 1180 potential participants to the guidance-through-workshop group.

Of these, 673 participants in the control group, 517 in the inspection group and 479 in the guidance group participated at baseline. Six months post interventions, the numbers were 363, 285 and 269 for the 3 groups, respectively, while at 12 months, the numbers were 220, 185 and 172, respectively. The dropout rates were 67.3%, 64.2% and 64.1% for the control, inspection and guidance groups, respectively. Figure 1, adapted from the study protocol,²² presents a flowchart of the interventions and data collection process for this study.

Interventions

This study encompasses two interventions, labour inspection and guidance-through-workshop and one control group. The interventions were implemented in the assigned municipalities, that is, at the cluster level.

Inspection intervention

The LIA's standard labour inspections constituted the inspection intervention. The participating workplaces received written information about impending inspections 3 weeks prior to the inspections. Two trained inspectors visited the offices of each participating home care unit. The individual home care service clients and their homes were not included in the inspections. Using a standardised checklist addressing psychosocial and biomechanical work exposures, they observed workplace compliance with the requirements of the Working Environment Act and the Internal Control Regulation. In addition, the inspectors also provided information and advice on how to comply with labour regulations. After the inspection, the inspectors prepared a report on the work environment at each of the participating services, which identified relevant work factors, any cases of non-compliance, and how the organisations should follow up these cases of non-compliance.

Guidance-through-workshop intervention

The guidance-through-workshop intervention consisted of one-time workshops hosted by the LIA to which they invited leaders and representatives of employees at the allocated services to participate. Based on geographical regions, five to seven home care services were assigned to joint workshops. Before attending the workshop, each of the participating services received information on the relevant topics, that is, work environment and employee health, and were also asked to prepare a presentation of relevant issues related to these topics at their workplace. Based on the issues presented at the workshop, the two attending trained labour inspectors would provide guidance to the home care services. This primarily consisted of information and advice based on OSH legislation and regulations.

Control group

The control group had 'care as usual', meaning that no interventions from the LIA were implemented in the services allocated

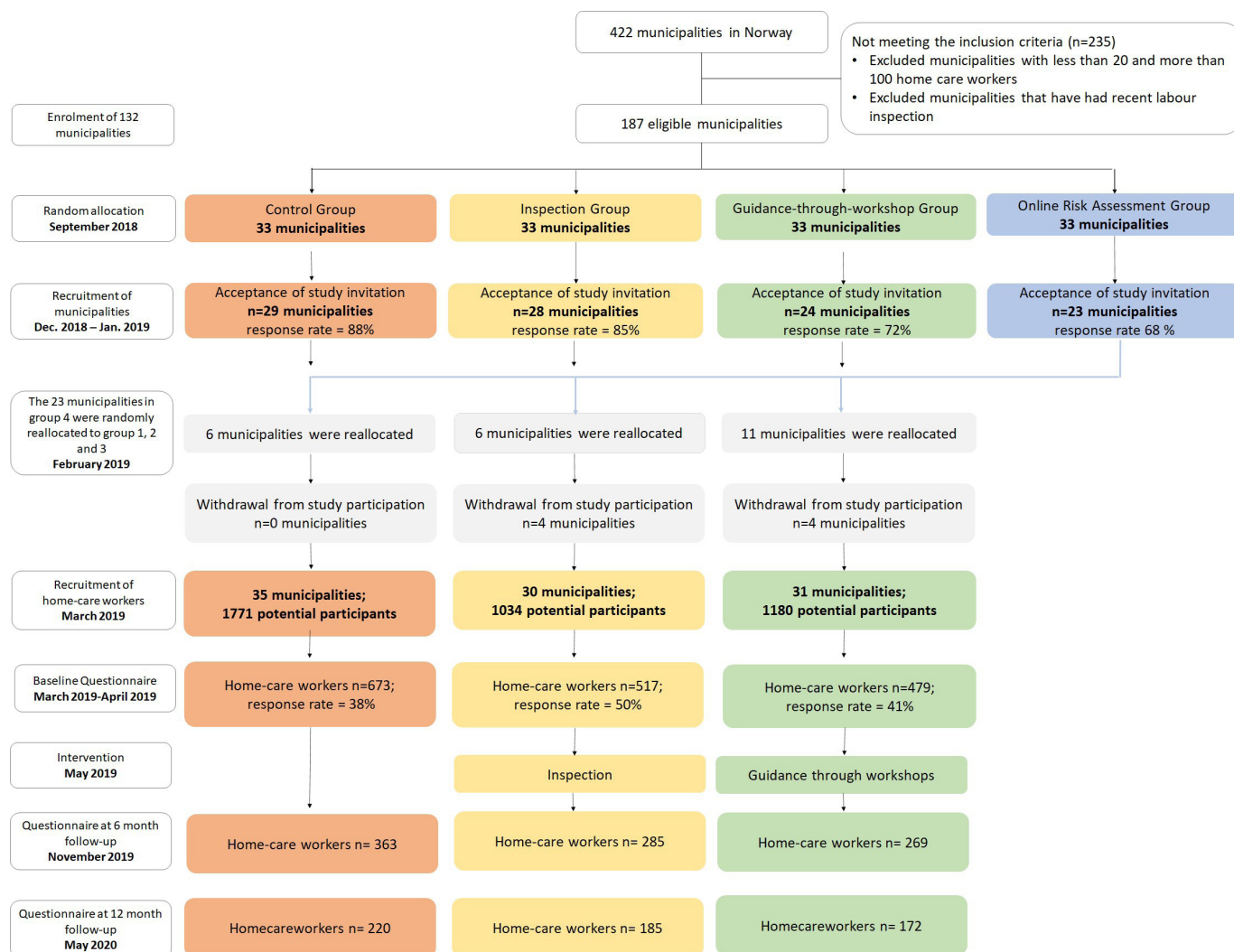


Figure 1 Flowchart illustrating cluster allocation, intervention implementation and data collection, adapted from Indregard *et al.*²²

to this group. The control group completed the same questionnaires as the intervention groups and at the same intervals and periods.

Data collection

We collected data through a proprietary web-based questionnaire developed by the National Institute of Occupational Health in Norway, which was administered to individual participants. The questionnaire could be completed in multiple sessions and accessed through a unique code, which was assigned to each participant in advance. Optionally, the participants could fill out a paper version of the questionnaire and return it by mail (prepaid). Data collection was conducted at baseline prior to the intervention implementation, and at 6 months and 12 months post intervention for all three groups.

Measures

The self-report questionnaire measured psychosocial and biomechanical work factors. Additionally, demographic characteristics, such as age, gender, education level, type of employment and percentage of full-time equivalent employment (FTE), were recorded. Further, job titles were also recorded based on the International Standard Classification of Occupations 2008, which were condensed into six categories: (1) nurses, (2) nurses'

aides, (3) other healthcare professionals, (4) other care staff, (5) leaders and (6) others.

Psychosocial work factors

We measured psychosocial work factors using scales from the General Questionnaire for Psychological and Social Factors at Work (QPS^{Nordic}), which is a comprehensive instrument based on theories of work motivation, job satisfaction, job stress, well-being and health.²⁴ The QPS^{Nordic} has good psychometric properties and high validity and reliability.^{24 25}

In this study, 14 factors were measured with scales from the QPS^{Nordic}, namely: quantitative demands, decision demands, learning demands, role clarity, role conflict, decision control, control over work intensity, positive challenges at work, fair leadership, empowering leadership, support from immediate superior, support from coworkers, focus on human resources and predictability in the coming month. Each scale comprises three to five items. Each item was rated from 1 to 5, where 1=very seldom or never, 2=seldom, 3=sometimes, 4=often and 5=very often or always. The scales were based on the average of the items on each scale.

Additionally, we included five items, developed by Statistics Norway,²⁶ to measure experiences of adverse social behaviour over the last 6 months, at baseline over the last 12 months.

Table 1 Characteristics of study participants at baseline, split into the inspection, guidance-through-workshop and control groups

	Inspection (n=517)	Guidance-through-workshop (n=479)	Control (n=673)
Gender (%*)			
Male	22 (4.26)	22 (4.59)	28 (4.16)
Female	495 (95.74)	457 (95.41)	645 (95.84)
Age (SD)	46.12 (11.62)	44.66 (12.22)	45.30 (12.05)
Marital status (%*)			
Unmarried	70 (13.67)	64 (13.56)	98 (14.89)
Married/cohabiting	398 (77.73)	362 (76.69)	508 (77.20)
Widow/widower	12 (2.34)	7 (1.48)	7 (1.06)
Divorced/separated	32 (6.25)	39 (8.26)	45 (6.84)
Type of employment (%*)			
Permanent	482 (94.14)	434 (92.74)	619 (93.50)
Temporary	16 (3.13)	16 (3.42)	18 (2.72)
Substitute/on-call	11 (2.15)	16 (3.42)	23 (3.47)
Other	3 (0.59)	2 (0.43)	2 (0.30)
Percentage employment† (SD)	79.01 (22.09)	78.25 (22.58)‡	81.22 (21.54)
Job title (%)			
Nurse	190 (37.18)	154 (32.15)	229 (35.18)
Nursing assistant	230 (45.01)	226 (47.18)	283 (43.47)
Other health professions	10 (1.96)	9 (1.88)	14 (2.15)
Other care staff	64 (12.52)	75 (15.66)	105 (16.13)
Leader	13 (2.54)	13 (2.71)	15 (2.30)
Other	4 (0.78)	2 (0.42)	5 (0.77)
Leader responsibilities (%*)			
Top tier leader	89 (17.69)	92 (19.74)	106 (16.31)
Middle tier leader	44 (8.75)	37 (7.94)	48 (7.38)
No leadership responsibilities	370 (73.56)	337 (72.32)	496 (76.31)

*Valid percentages.

†Percentage employment is the percentage of a full-time equivalent position.

‡Significantly different from controls, $p \leq 0.05$.

These were (1) bullying by coworkers, (2) bullying by superior, (3) violence, (4) threats and (5) unwanted sexual attention. Each item was rated from 1=never to 5=yes, on a daily basis.

Biomechanical work factors

To measure biomechanical work factors, we included five items, also developed by Statistics Norway.²⁶ These items assessed the time spent at work (1) squatting/kneeling, (2) standing, (3) leaning forward without support, (4) awkward lifting and (5) heavy lifting. Items 1, 2 and 3 were rated from 1=never to 6=almost all the time, while items 4 and 5 were rated from 1=never to 5=at least 20 times a day.

We adapted four items from Smedley *et al*²⁷ to measure biomechanical work factors known to be especially relevant for home care settings. These were how often in a shift one would; (1) manually transfer clients/patients between a bed and a chair; (2) manually move clients/patients around on a bed, chair or wheel-chair; (3) perform physically demanding tasks without the use of aids; and (4) perform physically demanding tasks without the use of aids, despite them being available. These were rated from 1=never to 5=at least 20 times a day. We also included one item on perceived physical intensity while at work, rated from 1 (not at all) to 10 (extremely heavy) based on Borg.²⁸ Lastly, we included one item measuring allocation of physically demanding work: 'To what degree is physically demanding work appropriately allocated among the staff?'. This was rated from 1=small degree to 5=very large degree.

Statistical analyses

Statistical analyses were performed using STATA V.16 (Stata Corp, College Station, Texas, USA). Logistic regression was used to assess attrition bias based on baseline demographics, whereas t-tests were conducted to compare responders and non-responders. T-tests were also used to compare the two intervention groups separately with the control group at baseline. Changes in the outcome variables were analysed separately using linear mixed models. Time, time×group and the percentage of FTE were included as independent variables. The percentage of FTE was included due to differences in baseline between the guidance group and the control group, and we considered the variable to be intrinsically linked with the exposure. To account for clustering, participants nested within municipalities were included as random effects. The analyses were adjusted for the outcome variable at baseline as recommended for randomised controlled trials.²⁹ To adjust for multiple testing, we used the Benjamini-Hochberg test³⁰ to provide adjusted p values. The level of significance was set to 0.05.

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki.³¹ All participants provided informed, written consent and were informed about their right to withdraw from the study at any time. The study was assessed by the regional committees for medical and health research ethics, and the Norwegian Centre for Data Research approved data handling and storage (566128). All self-reported data were

Table 2 Baseline mean values for all groups and linear mixed models for the effect of the interventions on psychosocial and organisational work factors at 6 and 12 months

	Baseline				6 months				12 months			
	Inspection		Guidance		Inspection		Guidance		Inspection		Guidance	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Coef.	95% CI	Coef.	95% CI	Coef.	95% CI	Coef.	95% CI
Quantitative demands† (1–5)	2.96 (0.76)	2.97 (0.73)	3.08 (0.78)	3.08 (0.78)	0.05	–0.06 to 0.17	–0.02	–0.14 to 0.08	0.11	–0.02 to 0.24	–0.01	–0.13 to 0.13
Decision demands† (1–5)	3.57 (0.65)	3.58 (0.65)	3.62 (0.64)	3.62 (0.64)	0.01	–0.08 to 0.09	–0.02	–0.11 to 0.06	–0.06	–0.17 to 0.04	–0.02	–0.13 to 0.08
Learning demands† (1–5)	2.52 (0.58)	2.52 (0.60)	2.54 (0.59)	2.54 (0.59)	0.04	–0.03 to 0.11	–0.01	–0.09 to 0.06	0.06	–0.03 to 0.16	–0.01	–0.10 to 0.09
Role clarity‡ (1–5)	4.37 (0.60)	4.28 (0.63)	4.27 (0.70)	4.27 (0.70)	0.01	–0.07 to 0.10	0.06	–0.02 to 0.14	–0.05	–0.16 to 0.06	0.03	–0.07 to 0.14
Role conflict† (1–5)	2.64 (0.79)	2.58 (0.79)	2.68 (0.85)	2.68 (0.85)	–0.01	–0.13 to 0.11	–0.07	–0.19 to 0.05	0.10	–0.04 to 0.25	0.07	–0.07 to 0.22
Decision control‡ (1–5)	2.79 (0.73)	2.75 (0.67)	2.80 (0.70)	2.80 (0.70)	–0.07	–0.16 to 0.01	0.08	–0.01 to 0.17	0.01	–0.10 to 0.11	0.16	0.04 to 0.27
Control over work intensity‡ (1–5)	2.29 (0.85)	2.23 (0.76)	2.36 (0.87)	2.36 (0.87)	0.01	–0.09 to 0.10	0.14	0.03 to 0.24	–0.01	–0.14 to 0.10	0.16	0.04 to 0.29
Positive challenges at work‡ (1–5)	4.20 (0.66)	4.20 (0.60)	4.19 (0.63)	4.19 (0.63)	0.01	–0.07 to 0.10	0.04	–0.04 to 0.13	–0.03	–0.14 to 0.08	0.03	–0.07 to 0.15
Fair leadership‡ (1–5)	4.00 (0.85)	4.11 (0.79)	3.99 (0.83)	3.99 (0.83)	–0.05	–0.19 to 0.08	0.11	–0.02 to 0.25	–0.05	–0.22 to 0.11	0.07	–0.09 to 0.24
Empowering leadership‡ (1–5)	3.22 (1.05)	3.27 (1.00)	3.18 (1.01)	3.18 (1.01)	–0.01	–0.18 to 0.15	0.10	–0.06 to 0.26	–0.05	–0.25 to 0.14	0.23	0.03 to 0.43
Support from immediate superior† (1–5)	3.81 (1.02)	3.89 (0.97)	3.71 (1.02)	3.71 (1.02)	–0.06	–0.22 to 0.10	0.08	–0.08 to 0.24	–0.13	–0.32 to 0.06	0.16	–0.03 to 0.36
Support from coworkers† (1–5)	4.27 (0.80)	4.24 (0.80)	4.17 (0.82)	4.17 (0.82)	–0.01	–0.11 to 0.10	–0.01	–0.11 to 0.10	–0.05	–0.18 to 0.08	0.10	–0.03 to 0.24
Focus on human resources‡ (1–5)	2.95 (0.98)	3.12 (0.91)	2.97 (0.96)	2.97 (0.96)	0.01	–0.14 to 0.17	0.02	–0.13 to 0.17	–0.13	–0.31 to 0.05	0.02	–0.16 to 0.21
Predictability in the coming month‡ (1–5)	3.49 (0.97)	3.50 (0.90)	3.47 (0.95)	3.47 (0.95)	0.12	–0.02 to 0.27	0.02	–0.12 to 0.17	0.01	–0.17 to 0.18	–0.05	–0.20 to 0.12

*Intraclass correlation (ICC) for the municipal cluster.

†A lower score is considered advantageous.

‡A higher score is considered advantageous.

Table 3 Baseline mean values for all groups and linear mixed models for the effect of the interventions on adverse social behaviour at 6 and 12 months

	Baseline			6 months			12 months		
	Inspection		Control	Inspection		Guidance	Inspection		Guidance
	Mean (SD)	Mean (SD)		Coef.	95% CI		Coef.	95% CI	
Bullying—coworkers† (1–5)	1.16 (0.50)	1.21 (0.55)	1.22 (0.58)	0.05	–0.01 to 0.13	0.02	0.09	–0.01 to 0.19	–0.01
Bullying—superior† (1–5)	1.11 (0.45)	1.12 (0.45)	1.12 (0.42)	–0.01	–0.07 to 0.04	–0.02	0.05	–0.02 to 0.13	–0.01
Violence† (1–5)	1.17 (0.50)	1.17 (0.51)	1.15 (0.45)	0.01	–0.07 to 0.09	0.03	0.01	–0.09 to 0.10	0.01
Threat† (1–5)	1.14 (0.43)	1.17 (0.49)	1.14 (0.41)	–0.05	–0.11 to 0.01	–0.03	–0.04	–0.12 to 0.03	–0.04
Unwanted sexual attention† (1–5)	1.32 (0.68)	1.41 (0.72)	1.38 (0.74)	0.01	–0.10 to 0.12	0.05	0.06	–0.07 to 0.19	0.08
* Intraclass correlation (ICC) for the municipal cluster.									
† A lower score is considered advantageous.									
									ICC*
									–0.10 to 0.08
									–0.09 to 0.06
									–0.05 to 0.11
									–0.12 to 0.03
									–0.04 to 0.22

stored electronically and kept separate from any identifying information. The participating services were not offered any incentives or compensation, but individual participants could win a 15 000 Norwegian krone gift certificate.

RESULTS

Table 1 presents the background characteristics of each group at baseline. There were no statistically significant group differences in age, gender, marital status, educational background, type of employment, job titles or leadership responsibilities. However, there was a difference in the percentage of FTE between the guidance-through-workshop and the control groups. We observed some statistically significant differences between those who dropped out of the study and those who remained. Those who were older (OR: 1.01, $p < 0.001$), had more education (OR: 1.18, $p = 0.05$) and a higher percentage of FTE (OR: 1.007, $p = 0.002$) had higher odds of remaining in the study. In addition, 'other care staff' had lower odds of remaining in the study at 12 months (OR: 0.59, $p = 0.003$). Those remaining at 12 months were on average 2.3 years older, had 0.06 levels higher education and 3.59% more employment than those who stopped responding. No other differences were observed and the between-group composition remained similar to that at baseline.

We found no significant effects of the inspection intervention on the psychosocial factors compared with the control group (**table 2**). For the guidance-through-workshop group, 13 of the 14 factors showed some development in a potentially positive direction. There were increases in decision control and empowering leadership at 12 months and control over work intensity at 6 and 12 months compared with the control group. However, after adjusting for multiple testing, none of the variables were statistically significant.

We found no statistically significant effects of the interventions on adverse social behaviour (**table 3**).

Regarding biomechanical factors, we found that the inspection group spent more time squatting or kneeling at 6 months than the control group (**table 4**). This effect was not present at 12 months, and after adjusting for multiple testing, it was not statistically significant at either time point. We found no statistically significant effects of the interventions on any of the other variables.

DISCUSSION

This study aimed to determine the effect of labour inspections and guidance-through-workshops conducted by the Labour Inspection Authority on psychosocial and biomechanical work factors. We found small, potentially positive, changes in 13 of the 14 psychosocial factors in the guidance-through-workshop intervention, with significant effects on the factor control over work intensity for all follow-ups, and for decision control and empowering leadership at the 12-month follow-up. However, these were not statistically significant after adjusting for multiple testing. For all other variables, we found no significant effects of the interventions.

We observed no substantial effect of the interventions on psychosocial and biomechanical work factors even though the study process evaluation indicated that most aspects of the implementation of the interventions went as planned.²³ Additionally, participants who responded to the process evaluation rated the utility of the interventions as high and reported enhanced knowledge after attending. As such, the findings are similar to those of Weissbrodt *et al*³² who found that inspections mostly led to increased knowledge of and ability in psychosocial OSH

Table 4 Baseline mean values for all groups and linear mixed models for the effect of the interventions on biomechanical work factors at 6 and 12 months

	Baseline				6 months				12 months			
	Inspection		Guidance		Inspection		Guidance		Inspection		Guidance	
	Mean (SD)	Mean (SD)	Mean (SD)	Control	Mean (SD)	95% CI	Coef.	95% CI	Mean (SD)	95% CI	Coef.	95% CI
Time spent—squatting or kneeling† (1–6)	2.67 (1.04)	2.83 (1.06)	2.85 (1.17)		0.17	0.02 to 0.32	0.09	–0.05 to 0.23	–0.02	–0.19 to 0.15	0.02	–0.14 to 0.20
Time spent—walking or in an upright position† (1–6)	4.64 (1.23)	4.59 (1.20)	4.49 (1.35)		0.06	–0.12 to 0.25	–0.16	–0.35 to 0.02	–0.01	–0.24 to 0.21	–0.15	–0.38 to 0.07
Time spent—leaning forward without support† (1–6)	3.12 (1.23)	3.08 (1.27)	3.09 (1.32)		–0.01	–0.18 to 0.17	–0.07	–0.25 to 0.10	0.01	–0.21 to 0.22	–0.01	–0.23 to 0.19
Lifting in an uncomfortable position† (1–5)	2.06 (0.71)	2.10 (0.72)	2.03 (0.75)		0.06	–0.03 to 0.14	0.02	–0.06 to 0.11	0.07	–0.03 to 0.19	0.11	–0.01 to 0.22
Lifting more than 10 kg† (1–5)	1.97 (0.76)	2.02 (0.81)	1.92 (0.77)		0.04	–0.06 to 0.15	0.01	–0.10 to 0.11	0.03	–0.10 to 0.16	0.13	–0.01 to 0.27
Manually moving patients/clients† (1–5)	2.09 (0.75)	2.04 (0.73)	2.02 (0.74)		–0.01	–0.10 to 0.09	–0.09	–0.19 to 0.01	0.01	–0.10 to 0.14	0.03	–0.09 to 0.16
Lifting/supporting patients/clients† (1–5)	2.15 (0.79)	2.11 (0.73)	2.08 (0.75)		0.03	–0.06 to 0.13	0.01	–0.08 to 0.11	0.02	–0.10 to 0.14	–0.06	–0.18 to 0.06
Physical exertions without aids† (1–5)	1.81 (0.69)	1.78 (0.68)	1.75 (0.67)		0.03	–0.08 to 0.14	0.04	–0.06 to 0.15	–0.01	–0.14 to 0.11	–0.03	–0.16 to 0.09
Physical exertions despite available aids† (1–5)	1.55 (0.61)	1.55 (0.61)	1.55 (0.69)		0.07	–0.02 to 0.17	0.06	–0.03 to 0.15	0.01	–0.10 to 0.13	0.06	–0.05 to 0.18
Perceived physical intensity/demand at work† (0–10)	3.71 (1.93)	3.91 (2.15)	3.86 (2.19)		0.19	–0.07 to 0.45	–0.01	–0.27 to 0.25	0.26	–0.05 to 0.57	0.08	–0.23 to 0.39
Appropriate allocation of physically demanding work† (1–5)	2.83 (1.09)	2.81 (1.10)	2.79 (1.08)		0.01	–0.18 to 0.20	–0.03	–0.23 to 0.15	–0.07	–0.31 to 0.15	–0.07	–0.31 to 0.16

* Intraclass correlation (ICC) for the municipal cluster.

† A lower score is considered advantageous.

‡ A higher score is considered advantageous.

management; however, this did not manifest into improvements in working conditions or employee participation.

Some accidents and injuries are caused by breaches of rules and inadequate barrier functions related to physical hazards, for example, a lack of railing, which inspections and checklists might easily uncover. However, the inherent complexity of addressing psychosocial risk factors could explain the lack of any observed effects of the interventions. Jespersen *et al*³³ argued that psychosocial risk factors are characterised by unclear cause–effect relationships and can have unclear solutions. As such, inspections and workshops might just be part of the solution. They could perhaps contribute more substantively with a longitudinal perspective, for example, through follow-up inspections or guidance-through-workshops, or in conjunction with other interventions. It could also be argued that these tools do not adequately address specific psychosocial work factors in their current form.

Another potential explanation, linked with this complexity, could be different barriers to managing psychosocial work factors that the interventions might not overcome. One suggested barrier is small organisation size,³⁴ as this might affect the resources available for managing psychosocial work factors.³⁵ Larger organisations (more than 100 employees) have been linked with better outcomes after labour inspections than smaller organisations.³² The services in our sample had between 20 and 100 care workers on staff and as such might have limited resources to systematically improve psychosocial factors. Another potential barrier is restructuring or organisational changes.³⁶ Several of the municipalities in this study merged with other municipalities as a part of municipal reform during the study period. As all participating services in this study were municipal services, this may have led to organisational changes and potentially caused a shift in attention from working on psychosocial factors to handling these organisational changes. Finally, the setting itself might have been a barrier, as implementing changes in the work environment might be challenging across different homes being served. Home care services are less well-defined settings than, for example, nursing homes, and have a greater spread, both geographically and in different home environments encountered.¹⁵

The relatively short follow-up period of 12 months may also have been insufficient to observe substantive changes in psychosocial and biomechanical work factors. Previous research on the impact of enforcement tools on work-related injuries²¹ suggests that they have an effect in the long term (>3 years) but not in the short term (≤ 1 year). It is not known whether the effects of enforcement on psychosocial and biomechanical work factors follow a similar trajectory; however, this might explain the observed lack of substantial changes. Lastly, the intervention was administered only once, and it could be argued that repeated interventions might have led to an increased effect. However, such repeated interventions would have taxed the resources of the LIA and the available research on inspections suggest that repeated inspections would not necessarily have resulted in improved compliance²¹ and thus potentially would not influence the different work factors either.

Strengths and limitations

The cluster-randomised controlled trial design is a major strength of the present study allowing us to limit potential confounding factors and to make causal inferences about the effects of the interventions. Further, we have based our data collection on validated, standardised measures, which should reduce measurement error.²⁴ The study had a rather large

attrition rate, which might have influenced the findings. This could somewhat be explained by both the high turnover rate (10.9%) and high sickness absence (11%) among nurses in the Norwegian home care sector.³⁷ There were some statistically significant differences between those who continued to respond and those who stopped. Those who stopped responding were generally younger, had a lower level of education, had a lower FTE-percentage and were more often in the 'other healthcare staff' category. However, the actual differences were quite small, the group distributions remained similar to baseline and no new differences were found between the groups at follow-up. This suggests that they are missing at random. Linear mixed models, used in this study, are considered one suitable way of addressing this.³⁸ Lastly, as this study is cluster randomised at a municipal level, we cannot guarantee that there has not been any intervention contamination across municipalities that might have influenced the results. More than 95% of the participants in this study were women, which reflects the gender balance among employees in the home care services,¹⁵ and as such indicates that the findings are generalisable across settings with similar gender distributions in the health and care services. Additionally, while there are differences in home care provisions between countries, the findings could also be applicable to countries with similar legal requirements regarding psychosocial work environments, such as the EU.³⁹

Implications for practice and future research

The lack of substantial effects suggests that there is a need to evaluate and potentially revise existing practice. The initial positive effects of the guidance-through-workshop intervention, although not statistically significant, could indicate a potential new avenue worth exploring. The factors decision control, control over work intensity and empowering leadership could potentially be related to each other, as a key factor of empowering leadership is facilitating and supporting employee autonomy.⁴⁰ This conceptual congruence could also indicate that the initial findings were more than randomly significant due to multiple testing. Thus, further exploring the potential of providing guidance-through-workshops, together with investigating how inspections could influence psychosocial and biomechanical work factors, are possible future paths of research.

CONCLUSION

The present study found no substantial effects of labour inspections on psychosocial and biomechanical work factors. Guidance-through-workshops produced a positive effect on psychosocial work factors, but these effects were not statistically significant when adjusting for multiple testing. Given the lack of observed effect, further research is needed to elucidate on labour inspections and other regulatory tools can enable effective monitoring and influence psychosocial and biomechanical work factors.

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Contributors BFG conducted the analyses, participated in data interpretation, wrote the manuscript. HAJ is project lead and guarantor, and drafted the first study design. SK, JE, OS and HAJ participated in designing the study and participated in the analyses and data interpretation. JE and HAJ collected the data. All authors read, revised and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study was conducted in accordance with the principles of the Declaration of Helsinki. This study involves human participants. The study was assessed by the Regional Committees for Medical and Health Research Ethics (REC Southeast) (2018/2003/ REK Sør-Øst C). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data will be available 3 years after study completion. Data access request will be reviewed by NSD - Norwegian Centre for Research Data. URL: <https://nsd.no/nsd/english/index.html>.

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ORCID iD

Bjørnar Finnanger Garshol <http://orcid.org/0000-0003-3201-6608>

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Vedlegg 5 – Effekter på selvrapporterte helseplager og legemeldt sykefravær

Effects of the Labor Inspection Authority's regulatory tools on physician-certified sick leave and employee health in Norwegian home-care services – a cluster randomized controlled trial

*Bjørnar Finnanger Garshol , Stein Knardahl, Jan Shahid
Emberland, Øivind Skare, Håkon A. Johannessen*



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Effects of the Labor Inspection Authority's regulatory tools on physician-certified sick leave and employee health in Norwegian home-care services - a cluster randomized controlled trial

by [Finnanger Garshol B](#), [Knardahl S](#), [Emberland JS](#), [Skare Ø](#), [Johannessen HA](#)

This cluster randomised controlled trial found no effect of labour inspections and guidance-through-workshops on degree of physician-certified sick leave due to musculoskeletal or psychological diagnoses or on employee self-reported health in the home-care services. This suggests a need for future research to address how such tools can more adequately address risk factors and if more specific regulations are needed.

Affiliation: Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway. bjga@stami.no

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Effects of the Labor Inspection Authority's regulatory tools on physician-certified sick leave and employee health in Norwegian home-care services – a cluster randomized controlled trial

by Bjørnar Finnanger Garshol, PhD,¹ Stein Knardahl, PhD,² Jan Shahid Emberland, PhD,¹ Øivind Skare, PhD,³ Håkon A Johannessen, PhD¹

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Objective This study aimed to determine the effects of the Labor Inspection Authority's regulatory tools on physician-certified sick leave and self-reported health outcomes among employees in municipal home-care services in Norway.

Methods We conducted a cluster-randomized controlled trial in the home-care service sector, and 96 eligible municipalities were randomly assigned to one of three groups: (i) labor inspection visits, based on the Labor Inspection Authority's standard inspections; (ii) guidance-through-workshops, where participants from home-care services met with labor inspectors to receive information and discuss relevant topics; and (iii) the control group. Data on employee self-reported health (N=1669) were collected at baseline and 6 and 12 months after the interventions. Additionally, registry data (N=1202) on diagnosis specific physician-certified sick leave were collected for 18 months after the interventions.

Results We found no statistically significant effects of either intervention on self-reported health outcomes. There was, for both interventions, a pattern of decrease in days and periods of physician-certified sick leave due to musculoskeletal diagnoses and increase in days and periods of physician-certified sick leave due to psychological diagnoses, but these were not statistically significant.

Conclusion Labor inspections and guidance-through-workshops had no statistically significant effect on self-reported health and physician-certified sick leave. The results should be interpreted with caution given the low response rate and subsequent attrition, and in the context of the COVID-19 pandemic. Future studies, in various industries, should further elucidate whether regulatory tools influence employee health and sick leave due to musculoskeletal and mental disorders.

Key terms labor inspection; occupational health; occupational safety; OSH enforcement; OSH intervention; self-reported health; sickness absence.

Work-related ill-health and sickness absence incur large personal and societal costs (1). Risk factors in the work environment, such as mechanical and psychosocial factors, have been linked to musculoskeletal complaints (2, 3), mental distress (4, 5), and subsequent sickness absence (6–9). In Norway, an estimated 40% of lower back pain cases can be attributed to mechanical and psychosocial work factors (10), while 25% of mental distress cases may be attributed to psychosocial factors

(11). Some sectors have a higher-than-average prevalence of sickness absence, such as the home-care services sector, where nurses have a sickness absence rate of 11% in Norway, compared to the national average of 5.8% (12). There is a high prevalence of musculoskeletal and mental disorders among home-care employees (13, 14), with the work environment being characterized by both job strain (15), such as high work intensity and emotional demands (16) and strenuous work tasks (17),

¹ Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway.

² National Institute of Occupational Health, Oslo, Norway.

³ Department of Occupational Medicine and Epidemiology, National Institute of Occupational Health, Oslo, Norway.

Correspondence to: Bjørnar Finnanger Garshol, Department of Work Psychology and Physiology, National Institute of Occupational Health, Oslo, Norway. [E-mail: bjga@stami.no]

for example awkward postures and lifting/supporting patients. The sector has also been facing increasing demands due to an increase in the elderly population together with increased restructuring to focus on providing care at home instead of in long-term care institutions, both of which could affect working conditions at the services (18).

The enforcement of occupational safety and health (OSH) laws and regulations is essential to protect employee health and ensure a good working environment (19, 20). In Norway, the Working Environment Act and Internal Control Regulation set standards to which organizations are obliged to adhere. These legislative and regulatory measures are enforced by the Norwegian Labor Inspection Authority (NLIA), with labor inspections being their main regulatory tool. The NLIA also provides guidance to organizations on how to understand relevant laws and regulations and on potential risk factors and their health impact, both in conjunction with the inspections themselves and as a separate activity through seminars and workshops.

Previous research on the effects of regulatory measures on OSH noted that labor inspections increase compliance with regulations and reduces the incidence of injuries (21–23). However, most research has been conducted in the manufacturing and construction sectors, and there is little knowledge of potential effects in the healthcare sectors (21, 22). Furthermore, limited research has been conducted on the effect of regulatory measures on psychological and musculoskeletal disorders and sickness absence (22).

Consequently, this study aimed to determine the effects of labor inspections and guidance workshops on self-reported health complaints and physician-certified sick leave due to musculoskeletal and psychological diagnoses of employees in home-care services. Based on previous studies on the effects on compliance and injuries, we assumed that regulatory tools could influence both physician-certified sick leave and self-reported health.

Methods

Design

The present study was a cluster-randomized controlled trial based on a probability sample of home-care service workers in Norway. A cluster-randomized design was chosen as the work environment of home-care services are inherently clusters. The study consisted of two intervention groups, labor inspections and guidance workshops, and one control group. This study is part of a larger project – the Effects of the Labor Inspection

Authority's Regulatory Tools on Work Environment and Health in the Norwegian Home-care Services project (EAVH project) – Clinical Trials ID: NCT0355163 (Registered 26 February 2019), and a full description of the project can be found in the published protocol (24).

Recruitment and participants

In January 2019, Norway had 422 municipalities with home-care services varying in size from 3–>4000 employees (24). For this study, eligible municipalities were those where home-care services employed >20–<100 care workers. This range was chosen to reduce the intra-cluster variability, thereby reducing the required sample size. Additionally, a majority of the home-care services in Norway at the time fell within this range (24). Ineligible municipalities were those that fell outside this scope or had recently undergone labor inspections, that is in 2017–2018. Based on sample size calculations (24), 132 of the 187 eligible municipalities were randomly assigned to one of the four original study groups. The project lead conducted randomization using random numbers assigned to each municipality, sorting, and then assigning the first 33 to one group, the next 33 to another, and so on. We then informed the municipalities about the planned study through letters and email and invited them to participate. Participating municipalities were asked to provide a contact person from the municipality's home-care services, who provided overviews of the current employees, including contact information, such as phone numbers and email addresses. This information was subsequently used to invite all the employees to participate in the study.

Overall, 104 of the 132 randomly assigned municipalities were recruited before the planned implementation of the interventions. Originally three intervention groups were planned (24), but – due to fewer recruited municipalities than expected – those in the last intervention group (online risk assessment) were randomly reallocated to the remaining two interventions and the control group [see Finnanger Garshol et al (25) for further details]. In total, 96 municipalities participated in the study, and these had 3985 employees in their home-care services. Out of these 3985 potential participants, there were 673 respondents from 35 municipalities in the control group at baseline, 517 from 30 municipalities in the inspection intervention group and 479 from 31 municipalities in the guidance intervention group. In total, we had 1669 respondents at baseline, giving a response rate of 41.9%. Of these, 1202 respondents consented to the collection of registry data: 478, 368, and 356 from the control, inspection, and guidance groups, respectively. There were no drop-out in the registry data, while the overall drop-out rate among those who responded at baseline was 65.2% over the

course of the study. Those who stopped responding were younger, had less education, had a lower percentage of full-time equivalent employment, and were more often listed as “other care staff” (25). Figure 1, adapted from the project protocol (24), provides an overview of the study recruitment and the flow of participants including endpoint for registry data.

Interventions

This study included two interventions, labor inspections and guidance workshops, and a control group. Both interventions were implemented between May and October 2019.

Labor inspections

The inspection intervention was structured according to the NLIA’s standardized inspection routines. Participating workplaces in the municipality received notice and information on impending inspections three weeks in advance. The inspections were carried out by trained inspectors at the home-care service offices. Individual care recipients’ homes were not included in the inspections. A standardized checklist, operationalizing relevant legislation (the Internal Control Regulation and the Working Environment Act) was used during the inspections. The checklist was used to check compliance with the legislation and focused on exposures related to the psychosocial, organizational, and mechanical work

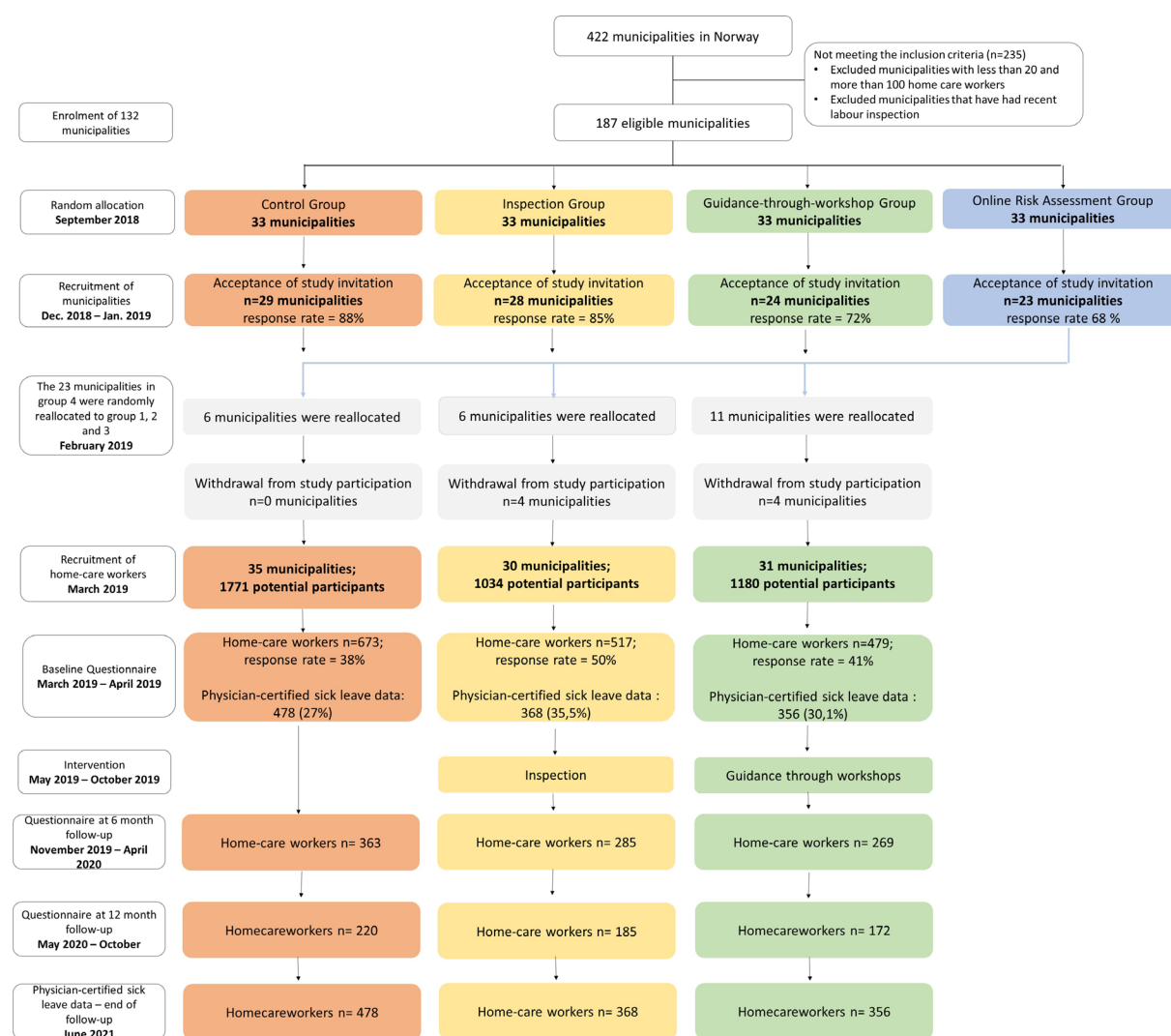


Figure 1. Flowchart illustrating the process of cluster allocation, intervention implementation and data collection for the project, including time points for implementation and the endpoint for registry data.

environment. In addition, inspectors also provided information and guidance on how to comply with labor regulations. Post-inspection, reports were made specifying areas of non-compliance at each home-care service, and the actions they should take to avoid sanctions and fines.

Guidance-through-workshop

Based on geographical location, 5–7 home-care services were assigned to one-time workshops, which two trained labor inspectors from the NLIA led. The manager, safety representative, and employee representatives from each participating home-care service were invited to the workshop and informed that the topic was ‘work environment and employee health’. These representatives were also asked in advance to prepare presentations on specific challenges employees in their own working environments face. The attending inspectors were instructed to provide advice to the participants on these concerns, based on relevant OSH legislation and regulations.

Control group

The control group received ‘care as usual’, meaning that no inspections or guidance-workshops were undertaken. The control group completed the same work environment and health questionnaires as the inspection and guidance groups.

Data collection

Data were collected using a web-based questionnaire developed by the National Institute of Occupational Health (STAMI) in Norway. It could be completed in multiple sessions and each participant received a unique sign-in code. A paper-based version was provided upon request. We collected data prior to the interventions (baseline), and at 6 and 12 months after the interventions for all three groups.

Participants demographics

We collected demographic information from each participant, such as age, gender, marital status, occupation, level of completed education and their percentage employment, that is the full-time equivalent (FTE) percentage based on what is considered a standard full-time position (about 37.5 hours a week), and occupation based on the Norwegian version of the International Standard Classification of Occupations 2008.

Outcome variables

Subjective general health was assessed using a single-item question, ‘How would you rate your health in gen-

eral?’. Responses were given in the following categories 0=very bad, 1=bad, 2=moderate, 3=good, and 4=very good. We measured one domain of mental health, mental distress, while we focused on musculoskeletal complaints and pain for physical health.

Mental distress, defined as symptoms of anxiety and depression, was measured using the five-item version of the Hopkins Symptom Checklist (HSCL-5) (26). Each item was rated from 1 (not at all) to 4 (extremely) and based on symptoms experienced in the previous week. The HSCL-5 is a reliable and validated instrument that performs similarly to more expansive versions, HSCL-10 and 25 (26).

Musculoskeletal complaints were measured using six items adapted from Steingrimsdottir et al (27). The six separate items asked the participants to rate if they in the last four weeks had been troubled by (i) headaches; (ii) neck pain; (iii) back pain; (iv) pain in the shoulder or upper arm; (v) pain in the lower arm, wrist, or hands; or (vi) pain in the hips, legs, knees, or feet during the last four weeks. Each item had the following response categories: 1=not troubled, 2=a little troubled, 3=intensely troubled and 4=very intensely troubled. In addition, the participants were asked to assess their *general pain intensity in the preceding week* using an 11-point numerical rating scale ranging from 0 (no pain) to 10 (worst possible pain). Such numerical rating scales have previously been shown to be applicable across settings, with higher compliance and ease of use than other unidimensional pain measures (28).

Registry data on physician-certified sick leave were obtained for the period 1 January 2018 to 30 June 2021 from the Norwegian Labor and Welfare Administration. This included the start and end date for all physician-certified sick leaves for the period, along with the accompanying diagnoses based on the International Classification of Primary Care 2 (ICPC-2). These diagnoses were recoded into different categories: (i) all musculoskeletal and psychological diagnoses (L and P-codes), (ii) all musculoskeletal diagnoses (L-codes), and (iii) all psychological diagnoses (P-codes). These were chosen as diagnoses of interest as they are potentially caused by psychosocial and mechanical risk factors in the work environment (2–9). Using these categories, we created variables for the total number of days of sick leave, where we counted and added together all days of sick leave due to the diagnoses of interest for 18 months post-interventions. We also created variables for number of sick leave periods, that is the total number of sick leaves due to the diagnoses of interest for 18 months post-interventions. Corresponding days and sick leaves due to L and/or P diagnoses in the 12 months preceding the interventions were used as a measure of baseline sickness absence. The 18 months post-intervention and 12 months pre-intervention periods were calculated for

each individual based on when the intervention or guidance workshop had been conducted for their service or when the baseline questionnaire had been disseminated for the control group.

Statistical analyses

All analyses were performed using STATA (version 16.1, Stata Corp, College Station, TX, USA). T-tests were conducted to compare the demographic variables of the two intervention groups with those of the control-group at baseline. Changes in self-reported health outcomes were analyzed separately for each outcome using linear mixed models with participants nested within the municipalities as random effects. The models included time, time \times group and employment percentage as independent variables. The time variable was based on the different rounds of data collection, that is first round as time=1, etc. The FTE was included as there was a difference between the guidance and control group at baseline. The variable was viewed as intrinsically linked with exposure as it is a measure of how much time an employee spends at work and thus is exposed to the work environment. Tests of the sick leave data showed overdispersion, meaning an assumption of a Poisson distribution was not appropriate. Thus, we used mixed negative binomial regression to analyze physician-certified sick leave, with municipalities included as random effects. All participants were analyzed based on intention-to-treat. The analyses were adjusted for outcome variables at baseline as recommended for randomized controlled trials (29). Further, baseline adjustment was also used to address a group difference at baseline on certified sick leave due to musculoskeletal and psychological diagnoses. To account for multiple testing of self-reported measures, the Benjamini-Hochberg test was used to provide adjusted P-values (30). The level of significance was set at $P < 0.05$.

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki (31). All participants provided written informed consent and were informed of their right to withdraw from the study at any time. While the participating services received no incentives or compensation for participation, individual participants could win a 15 000 Norwegian krone gift certificate. The study was assessed by the Regional Committees for Medical and Health Research Ethics, and the handling of personal data and data storage was approved by the Norwegian Centre for Data Research (Nr: 566128). The project stored all self-reported data electronically and the data were kept separate from any identifying information.

Results

There were no statistically significant group differences on the demographics age, gender, marital status, educational background, type of employment or leadership responsibilities (table 1). However, there was a difference in mean percentage employment, as the guidance-groups mean percentage employment was 3.0 percentage points lower than that of the control group. Of the 1669 respondents, 467 did not consent to the collection of registry data. There was no statistically significant difference in baseline self-reported health between those who consented and those who did not. Those who did not consent were on average 2.4 years younger ($P < 0.001$), had 0.1 years less education ($P = 0.03$) and 2.8 percentage points less FTE employment ($P = 0.02$) than those who consented. Among the participants who consented ($N = 1202$), there were no statistically significant demographic between-group differences, except for, as the main sample, a difference in mean percentage employment. There was a statistically significant group difference at baseline on physician-certified sick leave due to musculoskeletal and psychological diagnoses, with a higher proportion of participants with sick leave in the control (27.6%) versus inspection (18.2%) and guidance (21.1%) groups (table 2).

There were no statistically significant effects of either intervention on the self-reported employee health outcomes (table 3), except for an initial negative effect of the inspection intervention on subjective general health at 12 months prior to adjusting for multiple testing. After adjusting the P-values using the Benjamini-Hochberg test, this effect was no longer observed.

For physician-certified sick leave (table 4), there was a pattern of fewer sick leave days and periods due to musculoskeletal diagnoses and more sick leave days and periods due to psychological diagnoses after the interventions for both inspection and guidance workshops. However, none of these were statistically significant.

Discussion

This study aimed to determine the effects of labor inspections and a guidance workshop intervention on self-reported health complaints and physician-certified sick leave due to musculoskeletal and psychological diagnoses of employees in home-care services. While there was a pattern of decrease in sickness absences due to musculoskeletal diagnoses and an increase in sickness absences due to psychological diagnoses in the intervention groups, we found no statistically significant effect of either interventions on physician-certified sick leave, or any of the self-reported health measures.

Table 1. Characteristics of study participants. [SD=standard deviation.]

	Inspection (N= 517)		Guidance-through-workshop (N= 479)		Control (N= 673)	
	N (%)	Mean (SD)	N (%)	Mean (SD)	N (%)	Mean (SD)
Gender						
Male	22 (4.3)		22 (4.6)		28 (4.2)	
Female	495 (95.7)		457 (95.4)		645 (95.8)	
Age		46.1 (11.6)		44.7 (12.2)		45.3 (12.1)
Marital status						
Unmarried	70 (13.7)		64 (13.5)		98 (14.9)	
Married/ cohabiting	398 (77.7)		362 (76.7)		508 (77.2)	
Widow/widower	12 (2.3)		7 (1.5)		7 (1.1)	
Divorced/ separated	32 (6.3)		39 (8.3)		45 (6.8)	
Education level						
Primary school	25 (5.1)		16 (3.5)		18 (2.8)	
High school	241 (48.8)		239 (51.9)		312 (48.7)	
University/college ≤3 years	209 (42.3)		190 (41.3)		289 (45.1)	
University/college >3 years	19 (3.8)		15 (3.3)		22 (3.4)	
Type of employment						
Permanent	482 (94.1)		434 (92.7)		619 (93.5)	
Temporary	16 (3.1)		16 (3.4)		18 (2.7)	
Substitute/on-call	11 (2.2)		16 (3.4)		23 (3.5)	
Other	3 (0.6)		2 (0.4)		2 (0.3)	
Percentage of full-time equivalent employment		79.0 (22.1)		78.3 (22.6) ^a		81.2 (21.5)
Leader responsibilities						
Top tier leader	89 (17.7)		92 (19.7)		106 (16.3)	
Middle tier leader	44 (8.8)		37 (7.9)		48 (7.4)	
No leadership responsibilities	370 (73.6)		337 (72.3)		496 (76.3)	
Consented to use of registry data on physician-certified sick leave	368 (71.2)		356 (74.3)		478 (71.0)	

^a Significantly different from controls, P≤0.05**Table 2.** Sick leave data for the three different groups pre-intervention and post-intervention. [SD=standard deviation.]

	Inspection (N=368)			Guidance (N=356)			Control (N=478)		
	N (%)	Δ%	Mean (SD)	N (%)	Δ%	Mean (SD)	N (%)	Δ%	Mean (SD)
Participants with one or more physician-certified sick leave periods pre-intervention ^b									
Musculoskeletal and psychological diagnoses	67 (18.2) ^a			75 (21.1) ^a			132 (27.6)		
Musculoskeletal diagnoses	46 (12.5) ^a			60 (16.9)			99 (20.7)		
Psychological diagnoses	28 (7.6)			20 (5.6)			41 (8.6)		
Participants with one or more physician-certified sick leave periods post-intervention ^c									
Musculoskeletal and psychological diagnoses	94 (25.5) ^a			109 (30.6)			154 (32.2)		
Musculoskeletal diagnoses	72 (19.6)			82 (23.0)			118 (24.7)		
Psychological diagnoses	33 (9.0)			36 (10.1)			46 (9.6)		
Overall change in percentage-points from pre- to post-intervention for musculoskeletal and psychological diagnoses		7.3			9.6			4.6	
Physician-certified sick leave periods pre-intervention ^a									
Musculoskeletal and psychological diagnoses			0.27 (0.7) ^a			0.29 (0.6) ^a			0.38 (0.7)
Musculoskeletal diagnoses			0.18 (0.6) ^a			0.21 (0.5)			0.28 (0.7)
Psychological diagnoses			0.09 (0.4)			0.07 (0.3)			0.10 (0.3)
Physician-certified sick leave periods post-intervention ^c									
Musculoskeletal and psychological diagnoses			0.45 (1.0)			0.48 (0.9)			0.47 (0.8)
Musculoskeletal diagnoses			0.31 (0.7)			0.33 (0.7)			0.35 (0.7)
Psychological diagnoses			0.14 (0.6)			0.14 (0.5)			0.11 (0.4)
Physician-certified sick leave days pre-intervention ^b									
Musculoskeletal and psychological diagnoses			11.90 (43.6) ^a			16.08 (64.6) ^a			26.22 (74.0)
Musculoskeletal diagnoses			9.05 (41.7) ^a			12.25 (55.4) ^a			19.82 (66.5)
Psychological diagnoses			2.86 (13.8)			4.82 (34.5)			6.39 (35.3)
Physician-certified sick leave days post-intervention ^c									
Musculoskeletal and psychological diagnoses			30.75 (82.1)			32.11 (84.1)			34.52 (86.2)
Musculoskeletal diagnoses			20.58 (67.1)			21.84 (68.6)			23.57 (75.2)
Psychological diagnoses			10.17 (50.6)			10.27 (51.2)			10.94 (46.8)

^a Difference from controls, P<0.05.^b 12-month period pre-intervention.^c 18-month period post-intervention..

Table 3. Linear mixed models with baseline measures comparing the interventions groups with the control group to assess their effect on health outcomes at 6- and 12-months post-interventions with baseline measures for all three groups. [ICC=interclass correlation coefficient; SD=standard deviation; Coef=coefficient; CI=confidence intervals.]

	Baseline			First follow-up				Second follow-up				ICC ^a
	Inspection	Guidance	Control	Inspection		Guidance		Inspection		Guidance		
	Mean (SD)	Mean (SD)	Mean (SD)	Coef.	95% CI	Coef.	95% CI	Coef.	95% CI	Coef.	95% CI	
General health (0–4) ^b	2.09 (0.82)	2.10 (0.81)	2.09 (0.82)	-0.06	-0.18–0.05	-0.10	-0.22–0.01	-0.15	-0.29–0.01	-0.12	-0.26–0.02	0.019
Mental distress (1–4)	1.35 (0.51)	1.38 (0.51)	1.43 (0.54)	-0.07	-0.15–0.01	-0.07	-0.15–0.01	0.03	-0.06–0.12	-0.02	-0.12–0.07	<0.001
General pain (0–10)	3.18 (2.35)	3.28 (2.41)	3.30 (2.34)	-0.01	-0.36–0.34	-0.14	-0.49–0.20	-0.20	-0.62–0.22	-0.01	-0.42–0.42	0.021
Headache (1–4)	1.83 (0.88)	1.89 (0.81)	1.85 (0.85)	0.04	-0.08–0.16	-0.01	-0.13–0.11	-0.02	-0.16–0.12	0.09	-0.05–0.24	0.011
Neck pain (1–4)	1.90 (0.86)	1.87 (0.85)	1.95 (0.91)	0.05	-0.06–0.17	-0.04	-0.17–0.07	-0.06	-0.21–0.09	-0.07	-0.23–0.08	<0.001
Pain in shoulder and upper arm (1–4)	1.89 (0.88)	1.94 (0.89)	1.97 (0.95)	0.05	-0.07–0.18	-0.01	-0.13–0.12	-0.12	-0.28–0.03	-0.14	-0.31–0.01	<0.001
Back pain (1–4)	1.98 (0.92)	1.98 (0.84)	2.02 (0.89)	-0.02	-0.15–0.11	-0.12	-0.25–0.01	-0.09	-0.25–0.06	0.02	-0.13–0.18	0.009
Pain in hands, wrist or lower arm (1–4)	1.56 (0.81)	1.54 (0.81)	1.64 (0.88)	0.07	-0.05–0.20	0.05	-0.07–0.17	-0.01	-0.15–0.15	-0.02	-0.18–0.13	0.015
Pain in lower extremities (1–4)	1.95 (0.92)	1.93 (0.90)	1.85 (0.90)	0.01	-0.11–0.14	-0.10	-0.23–0.03	-0.03	-0.20–0.12	0.10	-0.05–0.27	<0.001

^a The municipal cluster – values below 0.001 shown as <0.001.^b Higher rating indicates better self-reported health.**Table 4.** Mixed negative binomial regression analysing the effect of the interventions on total number of days of sick leave and total number of sick leave periods for selected diagnoses groups. [IRR=incidence rate ratio; CI=confidence intervals]

	Total number of days of sick leave		Total number of sick leave periods	
	IRR	95% CI	IRR	95% CI
Musculoskeletal and psychological diagnoses ^a				
Inspection	0.89	0.50–1.59	0.93	0.72–1.21
Guidance-through-workshop	0.98	0.54–1.76	1.05	0.81–1.36
Musculoskeletal diagnoses ^a				
Inspection	0.82	0.42–1.60	0.86	0.63–1.16
Guidance-through-workshop	0.94	0.47–1.86	0.95	0.70–1.29
Psychological diagnoses ^a				
Inspection	1.08	0.35–3.31	1.13	0.68–1.85
Guidance-through-workshop	1.16	0.36–3.69	1.32	0.80–2.18

^a Adjusted for outcome baseline values and percentage of full-time equivalent employment.

The EAVH project hypothesized that inspection and guidance would increase compliance with OSH legislation and regulations, which in turn would lead to improved psychosocial and ergonomic working condition and prevent employee ill-health and sickness absence. A previous study in the EAVH project found no effect of either inspection or guidance on a wide array of psychosocial and mechanical work factors (25), several of which have been linked to mental and musculoskeletal health (2–4, 8, 9). Given this lack of effect on work factors, one would expect limited potential of the two interventions to influence employee health and rates of sickness absence. Work factors other than those covered in Finnanger Garshol et al (25) could potentially influence sickness absence and employee health, and the interventions could have influenced how employers followed-up employee sickness absences. As such, unobserved factors could potentially explain some of the patterns seen regarding changes in physician certified

sick leaves with a decrease in musculoskeletal-related sick leave and an increase in psychology-related sick leave. However, with self-reported health measures for mental distress and musculoskeletal complaints showing no similarly clear patterns, and with the patterns themselves not being statistically significant, it is difficult to make any inferences on potential causes for these patterns.

Organizational interventions are complex to develop and implement and challenging to evaluate (32). Two important factors for a successful intervention are: (i) the target audience being aware that there are issues that should be addressed and (ii) the content of the intervention being perceived as effective in addressing these issues (33, 34). The process evaluation of the EAVH project found that both interventions were implemented according to the protocol and that participants reported that the two interventions were both useful and educational (35). In addition, when asked whether they had plans to implement or had implemented changes in the work environment after the interventions, managers in the inspection intervention group were more likely to report having implemented or having plans to implement changes than managers in the control group (35). This indicates that the participants perceived that they had problems that needed to be rectified, and they found that the content of the interventions could be helpful in addressing these problems. As such, there is no evidence suggesting that the lack of substantial effects stems from a failure in the implementation of the interventions. However, we have little information on exactly what types of changes were implemented after the interventions and how outside circumstances affected the implementation of changes. As such we have no information on how the advent of COVID-19 impacted the study. Other studies have reported increased workload and working hours in the general healthcare services dur-

ing the pandemic (36). In the home-care services, staff reported increased psychosocial strain during COVID-19, while managers reporting having less time for measures to improve employee wellbeing because of the pandemic (37). This suggests that COVID-19 might have attenuated the effects of the interventions both through increased load on staff and less time for managers to implement changes to the work environment.

The potential complexity of addressing work factors, health and sickness absence may also explain the lack of observable effects. The causes of ill-health and sickness absence are multifactorial, and while work factors account for a significant proportion (8, 9), many cases are attributable to causes and events outside of work (38). The causes may also vary within and between different work environments, with different work factors taking primacy. This is further illustrated by workplace interventions targeting musculoskeletal and psychological disorders exhibiting a large degree of heterogeneity regarding intervention components, settings, and population (39). Given this potential complexity, one-time inspections or single guidance workshops may not have had an adequate impact on the workplaces to influence employee health and the rate of sickness absence. More involved interventions such as labor inspections with subsequent follow-up guidance sessions or follow-up inspections may have had more of an impact. Alternatively, guidance workshops with several sessions over time to provide more guidance, feedback, and follow-up. However, all inspections and guidance by the NLIA are based on and limited by legislation, and the current rules and regulations may not be clear or defined enough. Weissbrodt & Giaque (40) highlighted that research within the field of labor inspections and psychosocial risk recommends better regulation and more specific legal requirements. This could potentially better inform enterprises of their duties, facilitate labor inspections, and in turn lead to more substantial changes in the work environment.

The present findings of the EAVH project are similar to those of Weissbrodt et al (41) who found that inspections primarily led to increased awareness of and competence in psychosocial issues and, to a lesser extent, any implementation of specific measures. Furthermore, they observed no effect on general working conditions. As such, based on the available research, the effects of regulatory tools are evident in more tangible areas of OSH, notably in reducing injuries (21, 22), while for psychosocial factors, which are more intangible, the effects of regulatory tools are unclear. Common measures to prevent accidents and injuries, such as implementing physical barriers, for example guardrails and protective clothing, exemplify this tangibility. Such measures, or the lack thereof, are more easily observed during inspections. Measures to prevent unsafe behav-

iors or psychosocial risk factors often includes relational or organizational components, such as addressing role conflict, changes in decision latitude or the distribution of job tasks, which are less readily observable, more complex, and require closer inspection and monitoring (42). Furthermore, while the standards and limits for physical and chemical exposures are set numbers, there are no such limits for psychosocial work factors. While such limits might be unfeasible in practice, legislation and regulations could enshrine some OHS requirements, such as requiring plans to prevent specific psychosocial risk factors, for example role conflict or high job demands.

Strengths and limitations

The main strength of this study is its cluster randomized controlled design, which allows for inferences of cause-and-effect relationships. The use of registry data on certified sick leave ensured no recall bias and no loss of information due to dropout for this outcome. We based our data collection on standardized, validated measures to reduce measurement error. One limitation is the potential for self-selection bias in the study, as we have very limited information on those who declined to participate. Another limitation is the lower number of respondents compared to our initial estimates and goal from the study protocol (24), together with subsequent attrition. One potential reason for participant attrition could be the high levels of sickness absences and turnover in general in the home-care sector (12). The lower response rate and subsequent attrition could have introduced biases in the data, and those who stopped responding were generally younger, with less education and a lower mean employment percentage, and were more often in the “other healthcare staff” category. However, the differences were small, and the between-group distribution remained similar to that at baseline throughout the study period (25). Similar differences were observed among those who did not consent to the use of registry data. However, among those who consented, similarly to the main sample, there were no demographic between-group differences except for the employment percentage. The relatively low number of sickness absence cases due to the diagnoses of interest, that is musculoskeletal and psychological diagnoses, in the study population precluded any meaningful stratified analyses or analyses on separate diagnoses, indicating that only the category-level analyses were feasible. The participants were predominantly women; however, this reflects the current gender distribution in home-care services (17). We believe that these findings can be generalized to similar settings in the health and social care sectors, particularly in countries with similar legislation and regulations.

Implications for practice and future research

The results suggest a need to further develop the content of regulatory tools to better address risk factors to occupational health in practice, for example through clearer and more defined regulations. The findings are in accordance with a previously noted lack of effect of regulatory tools on psychosocial and mechanical work factors (25), further suggesting a need for future studies on how regulatory tools can influence the work environment and prevent ill-health and subsequent sickness absence. Future research should also aim to further elucidate the effects of regulatory tools, for example using other methods and in different sectors.

Concluding remarks

The present study found no statistically significant effects of labor inspections and guidance-through-workshops on self-reported health outcomes and physician-certified sick leave due to musculoskeletal or psychological diagnoses. The results should be interpreted with caution given the low study response rate and subsequent attrition on self-report measures, and in the context of the COVID-19 pandemic. Future studies, in various industries, should further elucidate whether regulatory tools influence employee health and sick leave due to musculoskeletal and mental disorders. Attention should also be given to how such regulatory tools and their content can be further developed to prevent sickness absence and employee ill health.

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Collaborators

The EAVH project is a collaboration between the NLIA and STAMI. NLIA was responsible for providing the interventions and STAMI was responsible for the trial design, randomization, data collection, statistical analysis, data interpretation and drafting of the present manuscript.

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Competing interests

None declared.

Patient consent for publication

Not required.

Ethics approval

The study was assessed by the Regional Committees for Medical and Health Research Ethics (REC Southeast) (2018/2003/ REK Sør-Øst C), and data handling and storage was approved by the Norwegian Centre for Data Research (566128). The study was conducted in accordance with the World Medical Declaration of Helsinki.

Trial Registration: Clinical Trials - NCT03855163

Data availability

Data will be available three years after project completion. Data access request will be reviewed by NSD - Norwegian Centre for Research Data/Sikt - Norwegian Agency for Shared Services in Education and Research.

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