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Copen-SCALE: Scaling up an effective intervention to childcare institutions in Copenhagen

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Registration date 04/01/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 21/12/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Globally, the childcare sector is facing a workforce shortage. Denmark, in particular, is experiencing a surge in demand for childcare professionals, a trend expected to intensify, with a projected increase of over 50,000 children aged 0-5 by 2030. Maintaining the status quo would necessitate an additional 6,500 trained childcare workers by 2030. Furthermore, Danish childcare workers face challenges such as high levels of musculoskeletal pain (38%), compromised mental well-being, and up to 14 days of annual sickness absence. Consequently, there is a pressing need to ensure the well-being of childcare workers and enhance their capacity to care for children over an extended period. Physical and psychosocial work environments play a pivotal role in sustaining a resilient workforce. Hence, large-scale initiatives that prioritize the health of childcare workers and address both physical and psychosocial aspects, are crucial for retaining existing professionals and attracting new talent in the field. This study builds on research focused on improving childcare workers' musculoskeletal health by addressing ergonomics and fostering children’s self-reliance and motor skills. The Copen-SCALE intervention (see the pilot study of the intervention here: https://www.isrctn.com/ISRCTN79194493) introduces additional dimensions, including educating workers on preventing and managing pain and incorporating more health-promoting physical activity into their daily routines. The intervention will be delivered by working environment consultants from the Copenhagen municipality following previous delivery methods. The Copen-SCALE evaluation involves four separate studies to evaluate different aspects of the scale-up of the intervention in the Copenhagen Municipality. The first two studies, an effectiveness evaluation and an economic evaluation, will be conducted utilizing an incomplete stepped-wedge controlled trial with the primary outcome of pain-related sickness absence. The next study establishes the type II hybrid design, and is an implementation evaluation focusing on the following outcomes: 1) acceptability, (2) adoption, (3) appropriateness, (4) cost, (5) feasibility, (6) fidelity, (7) penetration, and (8) sustainability. The final study is an evaluation of the required adaptations to the intervention to enable the scale-up. This evaluation will consider changes at the interventional and institutional levels guided by the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS). Therefore, this evaluation of Copen-SCALE has four aims, which are to assess the impact, cost-effectiveness and implementation of the Copen-SCALE intervention on

the health and working environment of participating childcare workers and to assess adaptations required to the intervention, at the intervention level and at the institution level, to enable the scale-up.

Who can participate?
Childcare workers aged 18 to 70 years old employed in the participating childcare institutions within Copenhagen Municipality during the intervention period.

What does the study involve?
Participating childcare institutions will be included in the study and participate in the intervention that lasts 6-8 months during working hours and is delivered by a work environment consultant. The intervention includes four elements: 1) ergonomics, 2) children's self-reliance and motor skills, 3) education in prevention and handling pain, and 4) health-promoting physical activity at work.
The participants will be asked to answer questionnaires before and after the intervention to address factors related to the work environment, health, and the intervention. A subpopulation will be invited to participate in interviews.

What are the possible benefits and risks of participating?
There are incentives for participation in the intervention provided by the municipality that is implementing the intervention. Participating in the evaluation will contribute to improving the working environment of childcare workers in Denmark. Participation in the evaluation only involves answering questionnaires so the risks of participating are limited.

Where is the study run from?
The evaluation is run by The National Research Centre for the Working Environment while the Work Environment Consultancy of Copenhagen Municipality conducts the delivery of the intervention. It takes place in up to 350 childcare institutions in the municipality of Copenhagen, Denmark.

When is the study starting and how long is it expected to run for?
January 2022 to December 2027

Who is funding the study?
The National Research Centre for the Working Environment

Who is the main contact?
Charlotte Diana Nørregaard Rasmussen, cnr@nfa.dk

Study website
https://nfa.dk/sites/sundhedsmiljo/index.html

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Copen-SCALE: Scaling up an effective intervention to childcare institutions in Copenhagen – a stepped wedge type II hybrid effectiveness-implementation trial

Study objectives

This study has two hypotheses:
1. Implementation of a workplace intervention in childcare institutions will reduce pain-related sickness absence among childcare workers.
2. The intervention will be implemented with high fidelity

Ethics approval required
Ethics approval not required

Ethics approval(s)
The National Research Centre for the Working Environment has an institutional agreement with the Danish Data Protection Agency about procedures to treat confidential data (journal number 2023-10/751), e.g. by securing data at a protected drive with limited access and making all individual data anonymous. The Danish National Committee on Biomedical Research Ethics (The local ethical committee of Frederiksberg and Copenhagen) has evaluated a description of the study and concluded that, according to Danish law as defined in Committee Act § 2 and § 1, the intervention described should not be further reported to the local ethics committee (study no. F-23049692).

Study design
Type II hybrid effectiveness-implementation incomplete stepped-wedge controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Workplace

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Workplace – Childcare institutions

Interventions
This study is an evaluation of an intervention being implemented by working environment consultants from Copenhagen municipality in childcare institutions (i.e. the intervention is not delivered by the research team). All childcare workers who are employed are eligible in the participating childcare institutions in Copenhagen municipality. A recommended tool was used, the Optimal Design with Empirical Information (OD+), for effectively planning and powering incomplete stepped-wedge control trials. Considering a power of 80%, an alpha level of 0.05, and a reliability of 0.70, the required sample size for our study was determined to be 74

childcare institutions. Given, that we have 350 childcare institutions that are eligible for participation, we believe that we will be able to fulfil the targeted number in our sample size calculation.

The primary aim of the intervention is to reduce pain-related sickness absence in childcare workers by addressing four elements of the intervention. These four elements are ergonomics, children's self-reliance and motor skills, education in pain prevention and handling, and health-promoting physical activity. The intervention will be delivered over a 6-8 month period in each participating institution. This study will evaluate the effectiveness of the intervention, the cost-effectiveness of the intervention, the implementation of the intervention, and the adaptions required to enable implementation.

Intervention Type
Other

Primary outcome measure
Pain-related sickness absence within the last three months measured using a questionnaire at baseline and follow-up (approx. 6-8 months after the intervention start). Participants will be asked to answer the following categories: 0 days, 1-5 days, 6-10 days, 11-15 days and above 15 days.

Evaluation of implementation
The primary outcome for implementation will be the fidelity of the intervention. Fidelity will be measured as:
1. Adherence, defined as the proportion of program components that were delivered compared to the number prescribed in the intervention protocol, measured using a short questionnaire survey for the consultants after completing each intervention activity
2. Exposure, defined as the number of sessions, measured using the consultant's intervention logs registered throughout the study period
3. Quality of delivery measured using the following questions for the consultants after completing each intervention activity:
3.1. "Regarding today, to which extent have you contributed to… [To a very large extent (100) /to a large extent (100)/somewhat (50)/to a small extent (0)/to a very small extent (0)]
...the participants' commitment and motivation?
..ensuring the employees' participation in the activity?
..adapting the activity to the needs of the participants?
..maintaining the participants' attention?
3.2. Suppose that your performance, at its best, is equal to 10 points. How would you rate your performance today? [0–10 (0=not capable to perform; 10=best performance) (0–4 were scored 0, 5–7 were scored 50, 8–10 were scored 100)]
4. Participant responsiveness measured using the following question for the consultants after completing each intervention activity:
4.1. To which extent are the participants committed and motivated? [To a very large extent (100) /to a large extent (100)/somewhat (50)/to a small extent (0)/to a very small extent (0)]

Secondary outcome measures
The following secondary outcome measures will be assessed at baseline and follow-up (approx. 6-8 months):
1. Frequency of pain in any body region (except the head) within the last three months measured using a questionnaire
2. Worst pain in neck/shoulder and lower back within the last three months measured using a

Numeric Pain Rating Scale (NPRS) from 0-10
3. Pain duration within the last seven days measured using a modified version of the Nordic Musculoskeletal Questionnaire (NMQ)
4. Average pain intensity in neck/shoulder and lower back within the last seven days measured using an NPRS from 0-10 (NMQ)
5. Pain-related work interference measured using a modified version of the NMQ
6. Pain-related health literacy levels measured using a modified version of the Health Literacy Questionnaire (HLQ)
7. Fear-avoidance beliefs measured using two questions from the Örebro Musculoskeletal Pain Questionnaire (OMPQ)
8. Perceived physical exertion at work measured using the BORG-10 Rating of Perceived Exertion (RPE) scale
9. Meaning in work measured using a question from the Danish Psychosocial Questionnaire.

Evaluation of cost-effectiveness
A cost-effectiveness evaluation will be made with the following outcomes:
1. Sickness absence will be collected from workplace registers. Data will be collected from one year before the intervention (2023) until the last childcare institution has finished the intervention (in 2027).
2. Productivity costs will be measured using a modified version of the iMTA Productivity Cost Questionnaire (iPCQ) at baseline and follow-up. Costs will be collected during the implementation of the intervention and will include:
2.1. Staff time: Employees' and managers' participation in intervention activities, measured using registration of participation in activities that are not directly part of daily work (e.g. a workshop /meeting for planning the activities)
2.2. Employees' and managers' costs will subsequently be valued based on their average yearly gross salaries, including overhead costs measured using intervention activity time recorded in hours and personnel records
2.3. Consultants' time: The time spent on implementing the intervention by the consultants will be registered. Their costs will be based on their usual consultant fees using costs recorded and provided by the consultants
2.4. Consumables: Materials (print-outs and posters etc.) as well as fruit/snacks/coffee at meetings will be recorded be measured using invoices.

Secondary outcomes for implementation are acceptability, appropriateness, feasibility, adoption, penetration and sustainability:
1. Acceptability, appropriateness and feasibility measured using semi-structured interviews guided by the Theoretical Framework of Acceptability (TFA) with selected participants during follow-up
2. Adoption and recruitment logs will be reviewed to measure the characteristics and number of institutions that actively participated in contrast to those that were eligible for participation. The pertinent characteristics, encompassing type (public/private) and size (employee count, unit count), will be extracted from municipal registers.
3. Penetration and Sustainability will be measured using purposive sampling qualitative methods to ensure representation from both low- and high-performing childcare institutions, including interviews with a representative cohort of childcare workers and managers conducted after the implementation of the Copen-SCALE intervention (approx. 6-12 months after ended intervention)

Evaluation of adaptation
Adaptations to the intervention at the institutional level measured using FRAME-IS framework document analysis, focus groups with consultants, and observations at random participating institutions during the intervention period and/or at follow-up

Overall study start date
02/01/2022

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. All employees directly involved in childcare at the participating institutions
2. Consent to participate in the scientific evaluation

Participant type(s)
Employee

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
The study aims to include all childcare workers in 74 participating childcare institutions in Copenhagen municipality. Although there are 350 eligible childcare institutions, the target sample size for the study is set at 74 institutions based on the power analysis and statistical parameters outlined.

Key exclusion criteria
Non-permanent employees.

Date of first enrolment
08/01/2024

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
Denmark

Study participating centre
The National Research Centre for the Working Environment
Lersø Parkallé 105
Copenhagen
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Study participating centre
Arbejdsmiljø København
Enghavevej 82
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Sponsor information

Organisation
National Research Centre for the Working Environment

Sponsor details
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Sponsor type
Research organisation

Website
http://nfa.dk/

ROR
https://ror.org/03f61zm76

Funder(s)

Funder type
Research organisation

Funder Name
National Research Centre for the Working Environment

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. All of the individual participant data collected during the trial, after deidentification will be available at the Danish National Archives after the trial ends (somewhere in 2028) as the researchers are required to provide all of their data to the archive – but as an agreement with the Children and Youth Administration Copenhagen Municipality (collaborators in the study) they will not be sharing the IPD anywhere unnecessary as their law department requested them not to.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available