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Adaptation and feasibility of the Copen-scale intervention among childcare workers – a pilot study

Submission date
18/10/2023

Recruitment status
No longer recruiting

Registration date
26/10/2023

Overall study status
Completed

Last Edited
19/10/2023

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Globally, the childcare industry faces workforce shortages. In Denmark, there is a high demand for childcare workers, and it is expected to escalate due to a projected increase of over 50,000 children aged 0-5 by 2030. If everything remains the same, this requires additional 6,500 trained childcare workers by 2030. Moreover, Danish childcare workers report high levels of musculoskeletal pain (38%), compromised mental well-being, and as much as 14 days of annual sickness absence. Consequently, there is a compelling need to ensure the vitality of childcare workers, enhancing their ability to care for children for more years. The physical and psychosocial work environment is key for sustaining a robust workforce. Thus, large-scale interventions promoting childcare workers' health - through good physical and psychosocial work environment - are essential, both for fostering workforce retention, and for attracting new entrants to childcare.

In 2018-2019 the researchers conducted an intervention (called TOY) in 16 childcare institutions in Copenhagen, aiming to enhance childcare workers' ability to promote self-reliance and learning among nursery children, particularly in physically challenging situations. The intervention had high feasibility and demonstrated a significant reduction in pain-related sickness absence among the childcare workers. Moreover, the intervention had low implementation costs, and the return on investment of the intervention was 63%, indicating a monetary benefit for the childcare institutions. These findings support that the TOY intervention is sufficiently cost-effective for scale-up to childcare institutions in Denmark.

The original TOY intervention involved addressing two elements of the working environment to improve musculoskeletal health, these being ergonomics and children’s self-reliance and motor skills. Copen-SCALE builds upon the original TOY intervention with the addition of dimensions focusing on educating workers about how to prevent and handle pain, as well as incorporating more health-promoting physical activity in their daily work routine. The intervention will be delivered by working environment consultants from Copenhagen municipality, which is the same method of delivery as TOY.

However, before scaling up the intervention to all 350 childcare institutions in Copenhagen, this study will evaluate the fidelity and feasibility of the intervention, as well as the adaptations required to the intervention to enable implementation.

Who can participate?
Childcare workers employed in the four 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 take part 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 addressing factors related to work environment, health and the intervention. A sub-population will be invited for interviews.

What are the possible benefits and risks of participating?
Participation in the evaluation only involves answering questionnaires so the risks of participating are limited. 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.

Where is the study run from?
The National Research Centre for the Working Environment (Denmark)

When is the study starting and how long is it expected to run for?
June 2023 to July 2024

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

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Adaptation and scaling-up an effective intervention to childcare institutions in Copenhagen – a pilot study of the Copen-SCALE intervention

Study objectives
It is feasible to adapt and implement an evidence-based intervention to childcare institutions in Copenhagen

Ethics approval required
Ethics approval not required

Ethics approval(s)
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 (ref number: H-23049692).

Study design
Non-randomized quasi-experimental pilot study

Primary study design

Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of pain-related sickness absence in childcare workers

Interventions
This study is an evaluation of an intervention being implemented by working environment consultants at Copenhagen municipality (ie. an intervention not delivered by the research team). The intervention's primary aim is to reduce pain-related sickness absence in childcare workers by addressing four elements. These four elements are 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 intervention will be delivered over a 6-8 month period in each institution. This study will evaluate the fidelity and feasibility of the intervention, as well as the adaptions required to the intervention to enable implementation. Moreover, the researchers will evaluate the feasibility of the evaluation design (e.g. the content of the questionnaires, delivery methods and response rates). There is no control group for the pilot study.

Intervention Type
Behavioural

Primary outcome(s)
Fidelity of the intervention, measured as:
1. Adherence: proportion of program components that were delivered compared to the number prescribed in the intervention protocol. This will be assessed through a short questionnaire survey for the consultants after completing each intervention activity.
2. Exposure: number of sessions. This will be registered throughout the study period in the consultant's intervention logs.
3. Quality of delivery measured by 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 by the following question for the consultants after completing each intervention activity:
"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)]"

Key secondary outcome(s))
1. Feasibility of the intervention will be measured with questions based on the validated instrument Feasibility of Intervention measures (FIM) through questionnaires and semi-structured interviews with the participants during follow-up.
2. Participants' acceptability of the intervention will be assessed using a validated questionnaire

Acceptability of Intervention Measure (AIM), and semi-structured interviews of selected participants during follow-up. The interview guide will be based on the Theoretical Framework of Acceptability (TFA), which includes a generic TFA-based questionnaire.
3. Adaptation of the intervention documented using the FRAME-IS framework. Adaptations to the intervention will be assessed through the use of document analysis, focus groups with consultants and observations at participating workplaces. These data will be collected throughout the study period.

Completion date
31/07/2024

Eligibility

Key inclusion criteria
All employees directly involved in childcare from the recruited institutions who consent to participate in the scientific evaluation

Participant type(s)
Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
26/10/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Denmark

Study participating centre
The National Research Centre for the Working Environment
Lersø Parkalle 105
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Sponsor information

Organisation
National Research Center for the Working Environment

Funder(s)

Funder type
Government

Funder Name
National Research Centre for the Working Environment

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Charlotte Rasmussen (cnr@nfa.dk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes