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Goldilocks Work Principle – Childcare

Submission date 25/12/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 31/12/2019	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 22/01/2025	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 31/03/2021:
Background and study aims
Current preventive approaches in occupational practice and research mainly focus on reducing the risk of work-related sickness and absenteeism by reducing high physical work demands. However, this approach has shown inadequate in solving some of the main current challenges in working life and occupational health, such as musculoskeletal disorders and social inequality in health. In order to address these challenges, some interventions have aimed at improving health of workers by offering physical exercise at the workplace. However, these initiatives have had difficulty reaching the employees most in need, and in being sustainable. One main reason is that such initiatives require the workers to spend time away from productive work.
As an alternative, we propose the Goldilocks Work Principle aiming to design productive work in a way that promotes health without negatively affecting work productivity (doi: 10.5271/sjweh.3754). In a proof of concept study we showed that the Goldilocks-games contained in the present intervention have good potential to create meaningful changes in physical activity for childcare workers (doi: 10.3390/ijerph17207419). However, the effectiveness of the Goldilocks Work Principle has not yet been tested in workplace settings. Thus, the objective of this study is to implement and evaluate Goldilocks-games with an aim to promote health among childcare workers without compromising work productivity.

Who can participate?
Childcare workers employed in the participating childcare institutions during the intervention period.

What does the study involve?
The participants will be asked to answer questionnaires addressing factors related to work and health, to participate in health measurements, and to wear accelerometers and a heart rate monitor for several days. Further, the participants will take part in three consultant visits where they learn how to play different Goldilocks-games and afterwards implement the games in their regular work. An intervention implementing the Goldilocks-games will last for 8 weeks. Participants will receive the intervention either immediately following baseline assessments or after an 8 week wait-list period, decided by randomisation at institutional level.

What are the possible benefits and risks of participating?
This study will potentially benefit participants by organising their productive work in a way that

promotes their health by performing core work tasks with more HIPA compared to usual work. Still, participation may result in potentially harmful effects from performing HIPA, like musculoskeletal pain, minor injuries, stress, increased need for recovery, sickness absence and reduced work productivity. All of these possible side effects will be evaluated.

Where is the study run from?
The study is run from The National Research Centre for the Working Environment and the Work Environment Consultancy of Copenhagen Municipality. It takes place in 12-16 childcare institutions in Denmark.

When is the study starting and how long is it expected to run for?
The study involves an intervention lasting for 8 weeks, with the wait list control group waiting 8 weeks before being offered the intervention. The intervention period will start in April 2021 and is expected to be completed by end of 2021.

Who is funding the study?
The Danish Work Environment Research Fund, grant number 20185100177.

Who is the main contact?
Andreas Holtermann, aho@nfa.dk

Previous plain English summary:
Background and study aims
Currently, occupational health has mainly focused on reducing work-related harm and injury and the risk of work-related sickness and absenteeism, for instance by reducing high physical work demands. However, this approach is not able to adequately address some of the main current challenges in working life and occupational health, for example, musculoskeletal (bone, joint and muscle) disorders and social inequality in health and physical capacity. Some initiatives have attempted to improve health and physical capacity of workers by offering physical exercise at the workplace. However, these initiatives have had difficulty reaching the employees in most need and in being sustained over time. One major reason for this is that the initiatives require time away from performing productive work and are therefore additional to the work required. The Goldilocks work principle aims to design productive work in a way that promotes health and physical capacity without reducing work productivity. However, the effectiveness of Goldilocks work principle has not yet been tested in workplace settings. The aim of this study is to develop, implement, and evaluate Goldilocks-games, a way of working in childcare that follows the Goldilocks work principle, to promote physical capacity and health among childcare workers, without compromising work productivity.

Who can participate?
Childcare workers employed in the participating childcare institutions during the intervention period.

What does the study involve?
The participants will be asked to answer questionnaires about work and health-related factors, participate in health and physical capacity measurements, and to wear accelerometers and a heart rate monitor for several days. Further, the participants will take part in developing and implementing the Goldilocks games during productive work with the aim of promoting health and physical capacity. Participants will receive the same intervention either immediately following baseline assessments or after a 10-week wait-list period, decided by randomisation at the level of the childcare facility.

What are the possible benefits and risks of participating?
This study will potentially benefit participants by organising their productive work in a way that promotes their physical capacity and health without compromising their work productivity. Still, participation may result in potentially harmful effects from performing moderate to vigorous physical activity, like musculoskeletal pain, work injuries, work stress, increased need for recovery, sickness absence and reduced work productivity, which will be evaluated.

Where is the study run from?
The National Research Centre for the Working Environment (Denmark) and the Work Environment Consultancy of Copenhagen Municipality (Denmark)

When is the study starting and how long is it expected to run for?
January 2019 to December 2021

Who is funding the study?
The Danish Work Environment Research Fund

Who is the main contact?
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Study website
http://nfa.dk/GoldilocksWork

Contact information

Type(s)
Scientific

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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
Can childcare work be designed to promote high-intensity physical activity for improved health? - A randomised controlled trial

Study objectives
Current study hypothesis as of 31/03/2021:
An organisational intervention in childcare institutions that introduces daily, playful physical activities (termed ‘Goldilocks-games’) where the childcare workers play together with the children will:
1. Increase time spent in high-intensity physical activity (HIPA) during childcare work, and
2. Improve health among childcare workers.

Previous study hypothesis:
A participatory organisational intervention in childcare institutions that introduces daily, playful physical activities (termed 'Goldilocks games') together with the children will:
1. Increase work time with health-enhancing moderate to vigorous physical activity (MVPA) during childcare work
2. Improve cardiorespiratory fitness and health among childcare workers

Ethics approval required
Old ethics approval format

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 2015-41-4232), 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 (Ref number: H-18041423)

Study design
Cluster-randomized wait-list-controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)

Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Physical activity of childcare workers in the workplace

Interventions
Current interventions as of 31/03/2021:
The original intervention (doi: 10.1186/s12889-020-8291-y) was developed before COVID-19. Due to the pandemic, the institutions had to adhere to new guidelines from the Danish Health Authority, including more stringent hygiene standards and physical distance measures. Thus, we tailored the project and the intervention to these new guidelines and daily practice at the workplaces. The main changes of the project and the intervention are; the workshops for the childcare workers are replaced with outdoor consultant visits in smaller groups of childcare workers; the pre and post cardiorespiratory fitness test were no longer possible to perform while still adhering to the guidelines from Danish health Authority and was therefore excluded from the protocol (and cardiorespiratory fitness excluded from the title and aim of the intervention), the duration of the intervention-period was reduced from 10 weeks to 8 weeks. The new and revised intervention is described below;

The intervention aims to increase childcare workers' productive work time spent in HIPA, thus improving their health. Participating childcare institutions will be randomised to either an intervention or a wait-list control (i.e. usual practice) arm of the trial. This randomisation will be conducted upon enrolment of each participating childcare institution into the study. The randomisation sequence has been developed using the statistical software "R". Due to the nature of the trial, blinding of participants and researchers conducting the study will not be possible. However, allocation concealment will be maintained throughout the study, and all researchers involved in the recruitment and enrolment of participating childcare institutions will be blinded to the method used to develop the randomisation sequence. Participating childcare institutions will be informed of their allocation to intervention or wait-list control group before the baseline data collection. Randomisation is done prior to the baseline measurement to secure logistics and support feasibility of participating in the intervention.

The intervention group will receive an 8 week intervention delivered by a work environment consultant after the baseline measurements followed by follow-up measurements; during the follow 8 weeks they are encouraged to keep playing the Goldilocks-games without receiving any further support from the project group. The wait-list control group will continue usual practice for 8 weeks after the baseline measurements, and after the follow-up measurements they will receive the 8 week intervention.

A participatory approach was used in preparatory developmental work to design Goldilocks-games (doi: 10.3390/ijerph17207419) to ensure they are relevant for the childcare and feasible to perform at childcare institutions. The Goldilocks-games were developed on the basis of i) a

continuous dialog with stakeholders in childcare (e.g. employer organisations and unions, practitioners in childcare, work environment consultants), ii) observations of childcare work, and iii) dialogue with managers and childcare workers.

For the implementation of Goldilocks-games in the trial, the manager, a union representative, and an occupational health and safety representative (collectively referred to as the TRIO) from the participating childcare institutions will have a meeting with two members of the project group. The visit will outline the Goldilocks Work Principle for the institutions and aim to facilitate planning and management support to the implementation and evaluation of the intervention. The TRIO is responsible for outlining the pedagogical focus, rostering and practical planning at their institutions. Involving the TRIO at an early stage will enhance the likelihood of organisational buy-in and the possibility for introducing organisational changes.

At each individual childcare institution, the intervention will be initiated by a consultant visit (Consultant visit 1) during a regular work day. At Consultant visit 1, the work environment consultant will spend half an hour with each of the classes in the institution instructing children and childcare workers in how to play Goldilocks-games. Moreover, the childcare workers will be instructed in how to record whether the Goldilocks-games were conducted as planned during the week or not.

At weeks three and five during the intervention, the work environment consultant will conduct further two half an hour consultant visits with each class of children and childcare workers within the institution. The aims will be to i) teach the classes additional Goldilocks-games ii) support childcare workers' commitment to playing the Goldilocks-games, and iii) collect information on whether the Goldilocks-games were played or not.

Previous interventions:
The intervention aims to increase childcare workers' productive work time spent in MVPA, and thus their cardiorespiratory fitness and health. Participating childcare institutions will be randomised to either intervention or usual practice (i.e. wait-list control) arms of the trial. This randomisation will be conducted upon enrolment of each participating childcare institution into the study. The randomisation sequence has been developed using the statistical software "R". Due to the nature of the trial, blinding of participants and those conducting the study will not be possible. However, allocation concealment will be maintained throughout the study, and all researchers involved in the recruitment and enrolment of participating childcare institutions will be blinded to the method used to develop the randomisation sequence. Participating childcare institutions will be informed of their allocation to intervention or usual practice group before the baseline data collection. The reason for randomising prior to the baseline measurement is due to the logistics and feasibility of participating in the intervention.

The participating childcare institutions will be randomly assigned to either the intervention group, which will receive the 10-week intervention immediately after the baseline measurements followed by 10 weeks without further support, or the wait-list control group, which will continue usual practice for 10 weeks while the intervention group receives the intervention and then completes pre-intervention measurements and receives the 10-week intervention.

During the first period, only the intervention group will be offered the intervention, whilst the wait-list control group will be offered already existing ergonomics consultancy and guidance, and advice on musculoskeletal pain management by consultants at the municipality. During the second period, the usual practice group will be offered the intervention, while the intervention group is expected to continue the organisational changes from the intervention without

receiving any further intervention delivery. Local municipal work environment consultants (occupational therapists and physiotherapists) will deliver the intervention.

Intervention: The intervention will apply a participatory approach to ensure that the intervention is relevant for, tailored to, closely integrated with pedagogical teaching aims, and feasible for the childcare institutions to implement. The intervention content (Goldilocks-games) has been created on the basis of a continuous dialogue with stakeholders related to childcare (e. g. employer organisations and unions, practitioners in childcare, work environment consultants), observations of childcare work, and dialogue with managers and employees in childcare institutions. Furthermore, the manager, a union representative, and an occupational health and safety representative (collectively referred to as the Trio) from the participating childcare institutions will have a meeting with the work environment consultants. The visit will outline the Goldilocks work principle for the institutions and aim to facilitate planning and management support to the implementation and evaluation of the intervention. The Trio will then be involved in planning and tailoring the intervention process to their own childcare institution. Thus, the Trio is responsible for outlining the pedagogical focus, and rostering and practical planning at their institutions. Involving the Trio at an early stage will enhance the likelihood of organisational buy-in and the possibility for introducing organisational changes.

At each individual childcare institution, the intervention will be initiated by a 2.5-h workshop (Workshop 1) during a regular staff meeting. At Workshop 1, the work environment consultants will inform the participating Trio and childcare workers about the overall concept of the Goldilocks work principle, facilitate the participants to develop tailored Goldilocks-games compliant with their pedagogical teaching goals, and finally facilitate development of specific action plans allocating responsibilities for implementation of the Goldilocks-games in their daily routines and schedules. Information regarding whether the Goldilocks-games were conducted as planned will be collected.

After 3-4 weeks of the intervention period, the work environment consultants will conduct a 1.5-h follow-up workshop (Workshop 2) with the participants at each individual childcare institution. The aims will be to evaluate the implementation of the Goldilocks-games, facilitate sustainability of well-functioning Goldilocks-games, and modify those Goldilocks-games that are not working as intended. Moreover, in order to facilitate implementation of the Goldilocks-games, the work environment consultants will make a consultation visit at the childcare institution 2 weeks following Workshop 1 and a consultation phone call with a member of the Trio 2 weeks after Workshop 2.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 31/03/2021:
Change between baseline and 8 weeks follow-up in relative work time spent in HIPA measured by heart rate (i.e. ≥60% of heart rate reserve).

Previous primary outcome measure:
Work time spent in moderate to vigorous physical activity measured by heart rate (i.e. ≥60% of heart rate reserve) or accelerometers (i.e. fast walking (≥130 steps/ minute), running and stair climbing) between baseline and 10 weeks follow-up

Secondary outcome measures

Current secondary outcome measures as of 31/03/2021:
1. Change between baseline and 8 weeks follow-up in sleeping resting heart rate, measured by heart rate monitors
2. Change between baseline and 8 weeks follow-up in self-perceived pain, exhaustion and energy measured using single item questions
3. Change between baseline and 8 weeks follow-up in need for recovery measured by questionnaire
4. Change between baseline and 8 weeks follow-up in self-perceived productivity measured using questionnaire
5. Incremental change in cost-effectiveness (ratio of incremental change in cost and change in work time spent in HIPA) and return on investment (indicated by return-on-investment ratio) during 8 weeks intervention from an employers´ perspective.

Health-related outcomes will be determined for all participants at baseline and 8 weeks follow-up. Outcomes include height, weight, fat percentage and resting blood pressure. Physical behaviours and heart rate will be assessed by accelerometers and heart rate monitors worn over several working days. Moreover, at baseline and 8 weeks, participants will receive an electronic questionnaire, with questions concerning health status, musculoskeletal pain, fatigue, work environment, expectations and satisfaction with the intervention.
For cost-effectiveness analysis, we will collect information on cost of intervention activities and cost associated with health-related productivity loss. Intervention cost will include:
- Staff time: Participation of childcare workers will be assessed based on registration of attendance.
- Work environments consultant time: Hours spent on preparation and delivery of the consultant visits will be retrieved from the work environment consultants delivering the consultant visits.
- Consumables: Information on the cost of materials (e.g. print-outs and materials used in the Goldilocks-games) will be collected via invoices.
- Overhead (e.g. telephone bills and electronics usage): 20 % of the intervention cost will be added to the total intervention cost.
Cost related to health-related productivity loss will include cost related to presenteeism and sickness absence - the two indicators of health - related productivity loss, measured using a questionnaire.
Cost-effectiveness ratio will be calculated by dividing the corrected cost difference by the corrected effect difference. The cost-effectiveness of the intervention would be judge based on the incremental cost-effectiveness ratio plane (doi 10.1016/j.jacc.2008.09.018).
For return-on-investment (ROI), the cost will be defined as the mean difference in intervention costs between the intervention and control group. Benefits will be defined as the mean difference in the health-related productivity loss costs (presenteeism and sickness absence) between intervention and control group.
Net benefit (subtracting intervention cost form total benefit)>0, benefit-cost ratio (comparing cost with the EUR value of the interventions benefits) >1 and ROI>0% will indicated a positive financial gain for childcare institutions.

Previous secondary outcome measures:
1. Indirectly measured cardiorespiratory fitness assessed using Ekblom-Bak submaximal cycle ergometer test between baseline and 10 weeks follow-up
2. Resting heart rate during sleep measured by heart rate monitors between baseline and 10 weeks follow-up
3. Need for recovery measured by questionnaire (Need for Recovery-battery) at baseline, 10 weeks and 20 weeks follow-up
4. Self-perceived productivity measured using questionnaire at baseline, 10 weeks and 20 weeks follow-up

All individual level assessments will be completed by all participants at baseline, 10 weeks and 20 weeks follow-up. Participants will receive an electronic questionnaire, which they can fill out during working hours. Assessments of health-related outcomes will include height, weight, waist circumference and resting blood pressure. Assessments of cardiorespiratory fitness measures include cardiorespiratory fitness (using Ekblom-Bak submaximal cycle ergometer test). Physical activities and heart rate will be assessed by accelerometers and heart rate monitors worn over several working days.

Overall study start date
01/01/2019

Completion date
31/12/2022

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)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Number of participants was estimated based on a statistical power analysis addressing the primary outcome in a clustered parallel group design with before- and after-measurements. The power calculation was based on data from a larger sample (N=167) of childcare workers in Copenhagen in a previous trial (ISRCTN10928313). In this sample, work time spent in HIPA was, on average, 1.24 min/day with a standard deviation (SD) between subjects of 2.90 min/day. This data was processed according to the principles of compositional data analysis (CoDA), expressing work time spent at HRR ≥60% (i.e. HIPA) relative to time spent at HRR <60% in terms of isometric log-ratios. Expressed as an isometric log-ratio, the average relative work time spent in HIPA was -4.35 (SD 1.10). Based on these transformed data, we will need an estimated total of 132 participants (corresponding to approximately 14 childcare institution clusters shared between the intervention and wait-list groups) to be able to detect (at $p < 0.05$) a 5min/day increase in relative work time spent at HRR ≥60% with a power of 0.80, an estimated intra-cluster correlation coefficient (ICC) of 0.05, a fixed cluster size of 10, and an assumed drop-out rate of 30%.

Total final enrolment
141

Key exclusion criteria

1. Pregnant
2. Allergy to tape or tape adhesive
3. Not able to speak or understand Danish
4. Work position ending during the intervention period

Date of first enrolment
12/04/2021

Date of final enrolment
04/07/2022

Locations

Countries of recruitment
Denmark

Study participating centre
The National Research Centre for the Working Environment
Lersø Parkallé 105
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2100

Study participating centre
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Sponsor type
Research organisation

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ROR
https://ror.org/03f61zm76

Funder(s)

Funder type
Government

Funder Name
Danish Work Environment Research Fund

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed scientific journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/01/2020	No	Yes
Protocol article	protocol	17/02/2020	24/02/2020	Yes	No
Other publications	Cross-sectional study collecting baseline data	27/11/2021	07/07/2022	Yes	No
Basic results			22/01/2025	No	No