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Working on Informal Care: supporting working caregivers in combining work and informal care

Submission date
21/11/2022

Recruitment status
No longer recruiting

Registration date
21/11/2022

Overall study status
Completed

Last Edited
29/01/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
The role of informal carers is becoming increasingly important due to demographic, social and political developments. Informal carers who combine the care of a loved one with a paid job often deal with an extra challenge or load, because they have to combine several roles and tasks (work, private life, care). The support of working informal carers is essential so that they can maintain the care in good health and also remain active in the labor process. This study investigates whether a workplace conversation method called " the participatory approach" - aimed at joint-problem solving bottlenecks in combining work, private life and informal care - has a positive impact on the work-life-informal care balance of working carers and their ability to successfully combine work and informal care.

Who can participate?
All employees within the participating organizations who provide informal care to a family member, friend or neighbor are able participate (no minimum amount of caregiving hours required).

What does the study involve?
All participating working carers will be asked to complete a questionnaire on their work - life - informal care balance at three time points (at the start of the study, and after 4 and 7 months). Other outcomes of interest are distress, and the perceived burden of combining work and informal care for caregivers, as well as social support at work. Employees in the intervention group will follow the participatory approach. The intervention consists of at least three face-to-face meetings over a period of 3-4 months. In these meetings, a stepwise process is followed to identify and solve problems related to the combination of work and informal care in multiple life domains (work, home, informal care situation). This process is guided by an independent occupational health professional, who is in the role of process leader. After receiving the intervention, a subset of the participants (employees and supervisors) will be interviewed to hear their experiences with the intervention (process evaluation). Participants in the control group will not be provided with the participatory approach intervention. They can (continue to) use any and all existing support forms for working carers already provided within and outside the organizations.

What are the possible benefits and risks of participating?
Participants in the intervention group can benefit from the participatory approach, as work-life-informal care balance is expected to improve. Furthermore, potential benefits at the employer and societal level include lower sickness absence and reduced health care. No risks are associated with the intervention.

Where is the study run from?
The study is run from the Dutch National Institute for Public Health and the Environment; Center for Nutrition, Prevention and Health Care Services.

When is the study starting and how long is it expected to run for?
September 2021 to June 2024

Who is funding the study?
This research is funded by the Strategic Program RIVM (Dutch National Institute for Public Health and the Environment), grant number S/040001/02.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
S/040001/02/SM

Study information

Scientific Title

Working on Informal Care: process and effect evaluation of a workplace participatory approach to support working carers in combining work and informal care

Acronym
WIC

Study objectives
In this study, we investigate the implementation process and effectiveness of a Participatory approach aimed at supporting caregiving employees in successfully combining work and informal care. We hypothesize that the Working on Informal Care (WIC) Participatory approach is more effective in improving work-life-informal care balance of caregiving employees (primary outcome), than providing usual support for working carers within organizations. Furthermore, we hypothesize that the intervention will have a positive impact on distress, and the perceived burden of combining work and informal care for caregivers, as well as social support at work and the use of support services (secondary outcomes).

Ethics approval required
Ethics approval not required

Ethics approval(s)
The Centre for Clinical Expertise of the Dutch National Institute of Public Health and the Environment reviewed the study protocol (VPZ-515) and designated that it did not fall under the scope of the Medical Research involving Human Subjects Act and was therefore exempt from further ethical review.

Primary study design
Interventional

Study design
Interventional individual-level randomized controlled trial with two arms

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of work-life-informal care disbalance among working informal carers

Interventions
Current interventions as of 17/10/2023:

The WIC participatory approach is a stepwise process led by occupational professionals or company social workers who facilitate the participants (i.e. caregiving employees and their supervisors) through a structured process of identifying and prioritizing problems in combining work and informal care, designing strategies to address these issues, implementing these strategies and a post-implementation evaluation.
A randomized controlled trial using parallel groups (i.e. intervention group vs control group) will be carried out in the participating organizations in the Netherlands (among which two municipal organizations, an institute for higher education and a governmental organization). The randomization will be at the individual level and participants (i.e. caregiving employees) will be randomly allocated to either the intervention group or the control group.
1. Intervention group – Participants in this group will receive the WIC participatory approach,

which is a stepwise approach guided by process leaders. These process leaders (occupational professionals or company social workers) have been trained to facilitate the participatory approach with help of the 'Working on Informal Care' intervention toolkit. The intervention consist of at least three face-to-face meetings (held within a period of 4 months) between the caregiving employee, the facilitator and supervisor, aimed at jointly solving problems in combining work and informal care.
2. Control group – Participants in the control condition will receive the usual care /support provided for caregiving employees within the participating organizations. So, they will not receive the WIC participatory approach during the study period including no access to the intervention toolkit.
Both participants in the intervention group and control group are allowed to (continue) to use any and all existing support forms for working carers provided within and outside the organizations (e.g. care leave, individual arrangements between employees and their supervisor oncerning informal care).

The researcher who will analyze the data will be blinded and therefore not be aware of group allocation. The blinded researcher will only have access to a coded datafile from which group allocation cannot be derived.

Data collection for outcomes in the intervention group and control group will take place at three time points: at baseline, immediately post-intervention (end of PA cycle, at 4 months), and at 7-months follow-up.
Data collection for process outcomes will take place after participants have completed the PA intervention (at 4 months), and will thus only involve those in the intervention group.

The sample size needed for the proposed study was calculated based on the primary outcome negative interference between work and homelife, measured with the SWING questionnaire (Geurts et al, 2005)). An independent statistician calculated the necessary population size for reaching 80% power at type-I error rate alpha=0.05, from the power plots obtained by extensive simulations. We obtained the expected outcome values at the baseline from the values reported by Janssen et al. (2022), which is a cluster randomized trial investigating a workplace health intervention on teachers' mental health. However, the reported mean and standard deviations at the baseline in this trial were different between the intervention (1.01; n=36, SD=0.55) and control group (0.87; n=21, SD=0.87). Such differences often occur when the randomization plan does not work as expected, therefore we used the group size weighted average of the reported intervention and control means, and the bias-corrected group size weighted average of the reported within-group variances to obtain a single mean and standard deviation of the outcome at baseline, equal to 0.985 and 0.4905, respectively. Considering a moderate Cohen's d effect size of 0.5 for the intervention, which is also in line with the effect reported by Janssen et al. 2022, we simulated baseline and follow-up outcome values for the intervention and control groups using bivariate normal distributions with the assumed baseline and follow-up means, assuming a correlation of 0.6 between the baseline and follow-up values of each individual. We simulated 500 populations with incremental sample sizes. The power at each sample size was calculated as the fraction of significant ANCOVA tests (alpha=0.05) of the intervention effect at the follow-up, adjusted for the outcome values at the baseline. We determined the required sample size for a parallel arm individually randomized controlled trial to be 50 individuals in the intervention and control groups, resulting in 100 total individuals. Assuming a loss-to-follow-up of 20% after 7 months, 125 workers needed to be included at baseline.

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Previous interventions:

The WIC participatory approach is a stepwise process led by occupational health professionals (OHPs) who facilitate the participants (i.e. caregiving employees and their supervisors) through a structured process of identifying and prioritizing problems in combining work and informal care, designing strategies to address these issues, implementing these strategies and a post-implementation evaluation.
A randomized controlled trial using parallel groups (i.e. intervention group vs control group) will be carried out in the participating organizations in the Netherlands (among which at least 2 municipal organizations and a care organization). The randomization will be at the individual level and participants (i.e. caregiving employees) will be randomly allocated to either the intervention group or the control group.
1. Intervention group – Participants in this group will receive the WIC participatory approach, which is a stepwise approach guided by OHPs. These OHPs have been trained to facilitate the participatory approach with help of the 'Working on Informal Care' intervention toolkit. The intervention consist of at least three face-to-face meetings (held within a period of 4 months) between the caregiving employee, the facilitator and supervisor, aimed at jointly solving problems in combining work and informal care.
2. Control group – Participants in the control condition will receive the usual care /support provided for caregiving employees within the participating organizations. So, they will not receive the WIC participatory approach during the study period including no access to the intervention toolkit.

Both participants in the intervention group and control group are allowed to (continue) to use any and all existing support forms for working carers provided within and outside the organizations (e.g. care leave, individual arrangements between employees and their supervisor concerning informal care).

The researcher who will analyze the data will be blinded and therefore not be aware of group allocation. The blinded researcher will only have access to a coded datafile from which group allocation cannot be derived.

Data collection for outcomes in the intervention group and control group will take place at three time points: at baseline, immediately post-intervention (end of PA cycle, at 4 months), and at 7-months follow-up.
Data collection for process outcomes will take place after participants have completed the PA intervention (at 4 months), and will thus only involve those in the intervention group.

The sample size needed for the proposed study was calculated based the primary outcome, negative interference between work and homelife, measured by the SWING questionnaire (Geurts et al, 2005). To calculate the sample size needed to achieve 80% power at the significance level alpha=0.05, we conducted intensive simulations based on the average survey scores and standard deviations reported by Janssen et al. (2022; Effects of mindfulness-based stress reduction and an organizational health intervention on Dutch teachers' mental health). We set the mean and standard deviation values at T0 to 0.87(sd=0.38) for the control group, and to 1.01(sd=0.55) for the intervention group. Based on data from Janssen et al. (2022), we considered the mean survey score to be 0.89 with a standard deviation of 0.42 at T1 for the control group. For the intervention group, we assumed a mean score of 0.75 with a standard deviation of 0.5 at T1, which we assumed to be a meaningful intervention effect. Using the obtained power curves from the ANCOVA analysis of 500 simulations per scenario, we calculated the needed sample size to be 100 (50 individuals per control/treatment group) with a baseline /follow-up correlation r^2=0.6 (corresponding to high correlation). Assuming a loss-to-follow-up of 20% after 7 months, 120 workers will need to be included at baseline (60 per group).

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome is work-life-informal care disbalance, measured by two negative interference scales of the of the Survey Work-home Interference Nijmegen (SWING; Geurts et al. 2005), which is a valid and reliable instrument. Measurement will be at baseline, 4 months and 7 months follow-up.
1. Negative interference of the combination of work and informal care on the personal/home life of working carers, will be measured by an adapted version of the SWING work-to-home interference scale. Following Boezeman et al. (2018), the SWING work-to-home interference scale will be transformed into a work/care-to-social and personal life interference scale by replacing the word 'work' with 'combining work and care' in the items and by broadening the scale item content to social life.
2. Negative interference of informal care on work, measured with the adapted negative home-work interference scale of the SWING questionnaire (Geurts et al, 2005). Following Boezeman et al. (2018) we replace the word 'home' with 'care situation' in the scale items.

Key secondary outcome(s)
Current secondary outcome measures as of 17/10/2023:

Secondary outcomes will be measures at baseline, 4 months and 7 months:
1. Distress, measured with the 16-item distress scale of the 4DSQ questionnaire (Terluin et al, 2006).
2. Social support from supervisors and colleagues, measured using 7 items adapted from the Dutch National Monitor Work and Informal Care (Nationale Werk & Mantelzorg monitor, 2021).
3. Perceived burden of combining work and informal care and role overload, measured by 2 items adapted from the EDIZ-plus questionnaire (de Boer et al, 2012).

Covariates, measured at baseline:
1. Socio-demographic variables, including gender, age, and educational level will be recorded with factual questions.
2. Caregiving situation will be recorded with factual questions, e.g. amount of caregiving hours, number of care recipients and caregiving tasks.
3. Work-related factors will be measured, including weekly working hours and occupational group. Also, physical and psychosocial risk factors, including job demands, support from others, and autonomy will be measured, by means of Job Content Questionnaire (Karasek, 1998), and the ResQ-Care questionnaire (Wuttke, 2021).
4. General health and impairments, will be recorded by means of 1 item in the RAND-36 questionnaire (Van der Zee, 1996) and 2 items in the Dutch Informal Care Study questionnaire (SCP, 2019).

Previous secondary outcome measures:

Secondary outcomes will be measures at baseline, 4 months and 7 months:
1. Distress, measured with the 16-item distress scale of the 4DSQ questionnaire (Terluin et al, 2006).
2. Social support from supervisors and colleagues, measured using 7 items adapted from the Dutch National Monitor Work and Informal Care (Nationale Werk & Mantelzorg monitor, 2021).

3. Use of support services, inside and outside of work. Measured by 2 items adapted from the Dutch National Monitor Work and Informal Care (Nationale Werk & Mantelzorg monitor, 2021).
4. Perceived burden of combining work and informal care, measured by 2 items adapted from the EDIZ-plus questionnaire (de Boer et al, 2012).

Covariates, measured at baseline:
1. Socio-demographic variables, including gender, age, and educational level will be recorded with factual questions.
2. Caregiving situation will be recorded with factual questions, e.g. amount of caregiving hours, number of care recipients and caregiving tasks.
3. Work-related factors will be measured, including weekly working hours and occupational group. Also, physical and psychosocial risk factors, including job demands, support from others, and autonomy will be measured, by means of Job Content Questionnaire (Karasek, 1998), and the ResQ-Care questionnaire (Wuttke, 2021).
4. General health and impairments, will be recorded by means of 1 item in the RAND-36 questionnaire (Van der Zee, 1996) and 2 items in the Dutch Informal Care Study questionnaire (SCP, 2019).

Completion date
15/06/2024

Eligibility

Key inclusion criteria
1. Working at least 20 hrs per week at participating organization;
2. Providing informal care to someone within their social environment (no minimum hrs of informal care required);
3. Having given informed consent.

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
125

Key exclusion criteria
1. Working for less than 20 hours at the participating organization;
2. A contract that ends before the follow-up measurement at 7 months;
3. Currently on sick leave for more than two weeks consecutively;
4. Not proficient in Dutch language;
5. Not mentally capable to fill in a valid questionnaire;

6. Going on pregnancy or parent leave before follow-up measurement at 7 months;
7. Currently in legal conflict with their employer.

Date of first enrolment
09/05/2022

Date of final enrolment
16/10/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Two municipal organizations within the sector Public services (>7.500 employees)
Netherlands
-

Study participating centre
One institute for higher education (>2.500 employees)
Netherlands
-

Study participating centre
One governmental organization (>6.000 employees)
Netherlands
-

Sponsor information

Organisation
National Institute for Public Health and the Environment

ROR
https://ror.org/01cesdt21

Funder(s)

Funder type
Government

Funder Name
Rijksinstituut voor Volksgezondheid en Milieu

Alternative Name(s)
Netherlands National Institute for Public Health and the Environment, RIVM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

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?
Results article	Results of the process evaluation	09/01/2025	20/01/2025	Yes	No
Results article	Effects of the workplace participatory approach	22/01/2025	29/01/2025	Yes	No