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Stepped Care focused on return to work for employees with psychological distress

Submission date 02/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/10/2023	**Overall study status** Ongoing	
Last Edited 04/09/2025	**Condition category** Other	

Plain English summary of protocol
Background and study aims
Psychological complaints are common, are associated with absenteeism and are the most common reason for disability. Early interventions aimed at return to work for employees with psychological complaints are needed. In this study a step-by-step approach (Stepped Care) will be evaluated on time to lasting return to work for employees with psychological distress.

Who can participate?
Employees with psychological distress and absenteeism between 2 and 8 weeks are eligible for inclusion.

What does the study involve?
First, a low-intensive E-health intervention is offered early in the absenteeism process and only in case of persistent absenteeism a high-intensity intervention in the form of a Participatory Approach will follow. Measurements in the form of questionnaires will take place at four moments, divided over 12 months.

What are the possible benefits and risks of participating?
The Stepped Care approach will be offered on top of usual care, so the participant will be offered extra guidance. By participating the participant will also contribute to (scientific) knowledge about the process of absenteeism and return to work for employees with psychological distress. The risks of participating is that it will cost time and energy from the participants to follow the interventions and filling in of the questionnaires.

Where is the study run from?
National Institute for Public Health and the Environment (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to January 2026

Who is funding the study?
This research was funded by the Netherlands Organization for Health Research and Development. (ZonMw), grant number 50-55900-98-203 / 10320052010005. The funder was not involved in the determination of the study.

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10320052010005

Study information

Scientific Title
Return to work for Employees with distress: a STepped cARe Treatment

Acronym
RESTART

Study objectives
Faster sustainable return to work for employees who receive the stepped care approach compared to care-as-usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/10/2023, Medical Ethics Review Committee of Amsterdam University Medical Centers (Van Der Boechorststraat 7, Amsterdam, 1081 BT, Netherlands; +31 20-4445585; metc@amsterdamumc.nl), ref: 2023.0474

Study design
Single-blind interventional randomized controlled trial with a 2 x 2 factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Workplace

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Return to work for sick-listed employees with psychological distress

Interventions
The stepped care approach consists of two elements, a low-intensive e-Health and a high-intensive participatory approach (PA) in the workplace. Participants will be randomized into four groups based on intention-to-treat. All participants will receive usual care. On top of that they either receive both e-Health and PA, only e-Health, only PA, or nothing (only usual care, i.e. the control group).

The e-Health will be administered through an app (online) of which the duration is 6 weeks. The participatory approach consists of three meetings that are guided by a trained return-to-work (RTW) coordinator. The first meeting will be between the RTW-coordinator and employee, the second between the RTW-coordinator and the supervisor, and the third meeting will be between the employee and supervisor, guided by the RTW-coordinator. The end product will be a return-to-work plan, which the RTW-coordinator will plan an evaluation for. Duration of the period in which the three meetings will take place will be around three weeks, the evaluation will take place approximately after three months.

There will be four measurement moments for all participants: at baseline (t0), after the e-Health (t6 weeks) after the PA (t6months) and a follow up at 12 months (t12 months).

Randomization:
A computer-based randomization list, generated by an independent researcher, will be used to allocate participants, based on their participant-ID, to one of the four groups. Before the statistical analyses are performed the condition-IDs are recoded by an independent researcher, which allows the primary researcher to be blinded for the allocation and the RCT to be single-blind.

Intervention Type
Behavioural

Primary outcome measure
Time to lasting return to work (Lasting RTW is defined as RTW to the employee's previous position, or another position with equal earnings, for a minimum of four consecutive weeks). Lasting RTW is measured using self-report of the employee on the measurement moments and absenteeism records.

Secondary outcome measures
1. (Severity of) stress-related symptoms, measured using the four-dimensional symptoms questionnaire at the 4 measurement moments over 12 months.
2. Total sick-leave days measured by self-report and absenteeism record at the 4 measurement moments over 12 months.
3. Self-efficacy measured using the Work Self-Efficacy questionnaire at the 4 measurement moments over 12 months.
4. Self-reported health measured with the Patient Reported Outcomes Measurement Information System (PROMIS) questionnaire at the 4 measurement moments over 12 months.

Overall study start date
17/01/2022

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Employees with absence duration of 2-8 weeks
2. Employees with psychological distress as measured with a distress screener

Participant type(s)
Employee

Age group
Adult

Lower age limit
18 Years

Upper age limit
67 Years

Sex
Both

Target number of participants
170

Total final enrolment
39

Key exclusion criteria
1. Severe psychiatric disorder (suicidal risk, schizophrenia, bipolar disorder)
2. Under treatment for chronic or terminal illnesses that preclude their ability to resume work in the near future (e.g. chemotherapy, cardiac surgery)
3. Labour dispute with employer involving legal action
4. Working less than 12 hours according to contract
5. Pregnancy
6. No proficiency in the Dutch language
7. No access to internet

Date of first enrolment
11/04/2024

Date of final enrolment
18/07/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Zorg van de Zaak Netwerk
Postbus 30514
Utrecht
Netherlands
3503 AH

Sponsor information

Organisation
National Institute for Public Health and the Environment

Sponsor details
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Sponsor type
Research organisation

Website
https://www.rivm.nl/en/

ROR
https://ror.org/01cesdt21

Funder(s)

Funder type
Government

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication of at least five papers in a high-impact peer-reviewed journal. The papers will at least cover the protocol, the main and secondary outcomes and process evaluations of the intervention.

Intention to publish date
01/02/2026

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be available upon request from Hanneke Lettinga, hanneke.lettinga@rivm.nl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)			04/10/2023	No	No
Protocol article		22/08/2024	23/08/2024	Yes	No
Other publications	Qualitative study	16/05/2025	19/05/2025	Yes	No