

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

Submission date 02/10/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/09/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

67 years

Sex

All

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

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

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 article		22/08/2024	23/08/2024	Yes	No
Other publications	Qualitative study	16/05/2025	19/05/2025	Yes	No
Protocol (preprint)			04/10/2023	No	No