

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

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<b>Registration date</b> 05/10/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/09/2025	<b>Condition category</b> 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?

Hanneke Lettinga, [hanneke.lettinga@rivm.nl](mailto:hanneke.lettinga@rivm.nl)

Karin Proper, [karin.proper@rivm.nl](mailto:karin.proper@rivm.nl)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Karin Proper

### ORCID ID

<https://orcid.org/0000-0001-7016-1625>

### Contact details

RIVM  
Volksgezondheid en Zorg  
Postbus 1  
Bilthoven  
Netherlands  
3720 BA  
+31 30 2743340  
[karin.proper@rivm.nl](mailto:karin.proper@rivm.nl)

### Type(s)

Public, Scientific

### Contact name

Miss Hanneke Lettinga

### ORCID ID

<https://orcid.org/0000-0003-2569-980X>

### Contact details

RIVM  
Volksgezondheid en Zorg  
Postbus 1  
Bilthoven  
Netherlands  
3720 BA  
+31 629661007  
[hanneke.lettinga@rivm.nl](mailto:hanneke.lettinga@rivm.nl)

## 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](mailto:hanneke.lettinga@rivm.nl)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		22/08/2024	23/08/2024	Yes	No
<a href="#">Other publications</a>	Qualitative study	16/05/2025	19/05/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol (preprint)</a>			04/10/2023	No	No