# Helping people with rheumatoid arthritis to stop smoking - a multicentre study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/08/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/10/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
23/10/2025	<b>-</b>	[X] Record updated in last year

## Plain English summary of protocol

Background and study aims

Rheumatoid arthritis (RA) is a chronic autoinflammatory disease that accompanies affected patients for many years. The exact causes of RA are not yet fully understood. However, it is known that certain factors influence the disease, such as smoking. We now aim to examine whether a specific counselling technique (quick verbal smoking intervention) can support smoking cessation and how this may affect disease control (disease activity, quality of life, antirheumatic medication).

## Who can participate?

Outpatients and inpatients (age 18 years or above) with RA from St. Elisabeth-Hospital Meerbusch-Lank or from University Hospital Düsseldorf, who had smoked at least five conventional cigarettes per day during the week prior to participation.

## What does the study involve?

The study will last about 48 weeks and include three clinic visits: at baseline, after 12 weeks, and after 48 weeks. These visits will take place during the patients' regular appointments, so no extra travel or cost is required. At each visit, patients will be asked to complete a questionnaire (about 15 minutes), and exhaled carbon monoxide will be measured with a short breath test that takes only a few seconds. At the baseline visit, a brief counselling session of up to five minutes will also be conducted after the physician's appointment.

## What are the possible benefits and risks of participating?

If patients succeed in reducing or quitting cigarette consumption, positive effects on disease activity and a reduction in rheumatic symptoms can be expected. Participation in the study does not involve any additional costs or travel for patients, as both the counselling sessions and the completion of questionnaires will take place during their regular appointments. No known risks or burdens are expected.

Where is the study run from?

The study is run from St. Elisabeth-Hospital Meerbusch-Lank (Germany)

When is the study starting and how long is it expected to run for? June 2024 to April 2026.

Who is funding the study? Investigator initiated and funded

Who is the main contact? Prof. Dr med. Stefan Vordenbäumen, stefan vordenbaeumen@rrz-meerbusch.de

## Contact information

## Type(s)

Public, Scientific, Principal investigator

#### Contact name

Prof Stefan Vordenbäumen

## Contact details

Hauptstraße 74-76 Meerbusch Germany 40668 +49 2150917187 stefan.vordenbaeumen@rrz-meerbusch.de

## Type(s)

Scientific

#### Contact name

Dr Martin Kleefisch

#### Contact details

Hauptstraße 74-76 Meerbusch Germany 40668 +49 2150 917 187 martin.kleefisch@rrz-meerbusch.de

## Type(s)

Scientific

#### Contact name

Mrs Theresa Jütten

#### Contact details

Hauptstraße 74-76 Meerbusch-Lank Germany 40668

## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

V02QuiSIRA062024

# Study information

#### Scientific Title

A multicentre randomized controlled trial of a brief smoking cessation intervention in patients with rheumatoide arthritis compared to usual care: effects on smoking behaviour and disease activity (QuiSIRA - Quick Smoking Intervention in active smoking Rheumatoid Arthritis patients)

## **Acronym**

QuiSIRA

## **Study objectives**

It will be examined whether a quick verbal smoking intervention leads to higher smoking cessation rates among patients with rheumatoid arthritis and improves disease control (disease activity, quality of life, antirheumatic medication).

Working hypothesis: The quick verbal smoking intervention is superior to providing information alone about the relationship between smoking and rheumatoid arthritis with regard to smoking cessation rates.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 26/06/2024, Ethics Committee of the Medical Faculty, Heinrich Heine University Düsseldorf (Moorenstraße 5, Düsseldorf, 40225, Germany; +49 2118119591; Ethikkommission@med.uni-duesseldorf.de), ref: 2024-2806

## Study design

Multicenter interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Quality of life, Treatment, Efficacy

## Health condition(s) or problem(s) studied

Rheumatoid arthritis and nicotine consumption

#### **Interventions**

To assess whether a quick smoking intervention can support smoking cessation in patients with rheumatoid arthritis, participants will be randomly assigned to one of two groups. In the intervention group, a quick smoking intervention using motivational interviewing will be applied in combination with information on the relationship between smoking and RA (usual care). In the control group, only usual care will be provided.

Each participant will be in the study for approximately one year.

- Baseline visit: participants complete a questionnaire (~15 minutes) and a short interview (~5-10 minutes).
- Follow-up visits at 12+- 6 weeks and 48 +-6 weeks: only the questionnaire is completed (each ~15 minutes).
- Follow-up visits are aligned with the patients' routine appointments at the rheumatology outpatient clinic.

#### Recruitment and randomisation:

Patients were approached during their outpatient clinic visits or during an inpatient stay and asked about their interest in the study. Randomisation was performed by assigning patients alternately to the study groups.

## **Intervention Type**

Behavioural

## Primary outcome(s)

Non-smoking rate at 12 (+/-6) weeks (seven-day point prevalence abstinence) measured by questionnaires

## Key secondary outcome(s))

- 1. Disease activity measured using DAS28 CRP at week 12 and week 48
- 2. Flare rate defined as increase or initiation of  $\geq 5$  mg daily prednisone or change of medication or new medication at week 12 and week 48
- 3. Health-related quality of life measured by VR 12-questionnaire at week 12 and week 48
- 4. Antirheumatic medication at week 12 and week 48 measured by questionnaires
- 5. Nicotine dependence measured by Fagerström-questionnaire at week 12 and week 48
- 6. Number of abstinence attempts measured by questionnaires at week 12 and week 48
- 7. Carbon monoxide measured by Micro+Tm Smokerlyzer at week 12 and week 48
- 8. Lifestyle information measured by MEDAS-questionnaire and physical activity assessment at week 12 and week 48
- 9. Number of cigarettes smoked per day at week 12 and week 48 measured by questionnaires 10. Seeking of additional support since week 0 (e.g. hypnosis, acupuncture, smoking cessation counselling) measured by questionnaires

## Completion date

06/04/2026

# **Eligibility**

Key inclusion criteria

- 1. Diagnosis of RA according to ACR/EULAR criteria, no overlap syndromes except for secondary Sjögren Syndrom allowed
- 2. Outpatients/inpatients (age >18 years) from St. Elisabeth-Hospital Meerbusch-Lank and from University Hospital Düsseldorf
- 3. Active cigarette smoking patients (at least five conventional cigarettes per day in the last week)
- 4. Sufficient proficiency in German language (at least C1) as judged by the intervenor

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

## Lower age limit

18 years

#### Sex

All

### Total final enrolment

124

## Key exclusion criteria

- 1. Occasional smokers (less than five conventional cigarettes per day in the last week)
- 2. Use of vaporizers only
- 3. Use of tabacco heaters only
- 4. Prior structured smoking intervention:
- 5. Prior structured quick smoking intervention (to the best of the patient's knowledge)
- 6. Prior alternative smoking intervention treatments such as hypnosis or acupuncture
- 7. Nicotine replacement therapy at the moment (nicotine-containing patches, chewing gum, lozenges, sprays, inhalers)
- 8. Medication for smoking cessation at the moment (Bupropion, Cytisin, Vareniclin)

## Date of first enrolment

26/06/2024

## Date of final enrolment

11/06/2025

## Locations

## Countries of recruitment

Germany

## Study participating centre

## St. Elisabeth-Hospital Meerbusch-Lank

Hauptstraße 74-76 Meerbusch Germany 40668

Study participating centre Universitätsklinikum Düsseldorf

Moorenstraße 5 Düsseldorf Germany 40225

# Sponsor information

## Organisation

St. Elisabeth-Hospital Meerbusch-Lank

# Funder(s)

## Funder type

Other

### **Funder Name**

Investigator initiated and funded

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/ or analysed during the current study will be available upon request from (Prof. Dr. med. Stefan Vordenbäumen, stefan.vordenbaeumen@rrz-meerbusch.de)

## IPD sharing plan summary

Available on request

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet

Participant information sheet 11/11/2025 11/11/2025 No