ISRCTN17343801 https://doi.org/10.1186/ISRCTN17343801

# Effect of a mobile application on disease activity control in inflammatory arthritis

**Submission date**
02/02/2024

**Recruitment status**
No longer recruiting

**Registration date**
21/02/2024

**Overall study status**
Completed

**Last Edited**
05/12/2024

**Condition category**
Musculoskeletal Diseases

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

**Plain English summary of protocol**
Background and study aims
Mobile applications (apps) are a major resource for information on lifestyle and general health. A healthy lifestyle is associated with improved outcomes in inflammatory arthritis. Within the MeRLiN study (Meerbuscher Lebensqualitätsstudie zu Rheuma, Lebensstil und Impfungen), the researchers therefore assessed whether targeted lifestyle counselling via an app could improve disease activity in arthritis patients. The aim of this study is to assess whether disease activity in inflammatory arthritis is improved by lifestyle counselling via an app.

Who can participate?
Patients aged over 18 years with inflammatory arthritis (such as rheumatoid arthritis, psoriatic arthritis, spondylarthritis)

What does the study involve?
Patients are alternatingly randomly allocated to either report health-related quality of life only, or to additionally receive 12 weeks of individualized lifestyle counselling via the app about a healthy Mediterranean diet, sports and physical activity, mental health, and non-smoking.

What are the possible benefits and risks of participating?
Participants may benefit from improved disease control in addition to standard of care. There are no foreseen risks.

Where is the study run from?
St Elisabeth Hospital Meerbusch-Lank (Germany)

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

Who is funding the study?
The German Society for Rheumatology (Germany)

Who is the main contact?
Dr Türker Kurt, tuerker.kurt@rrz-meerbusch.de

# Contact information

### Type(s)
Principal Investigator

### Contact name
Prof Stefan Vordenbäumen

### ORCID ID
http://orcid.org/0000-0001-5725-5483

### Contact details
Hauptstr. 74-76
Meerbusch
Germany
40668
+49 (0)2150/9170
stefan.vordenbaeumen@rrz-meerbusch.de

### Type(s)
Public, Scientific

### Contact name
Dr Türker Kurt

### ORCID ID
http://orcid.org/0000-0002-5801-630X

### Contact details
Hauptstr. 74-76
Meerbusch
Germany
40668
+49 (0)2150/9170
tuerker.kurt@rrz-meerbusch.de

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
Effect of a mobile application on disease activity control in inflammatory arthritis: a randomized controlled pilot study from the "MEerbuscher Lebensqualitätsstudie zu Rheuma, Lebensstil und ImpfungeN" (MERLIN)

### Acronym
MERLIN

### Study objectives
Mobile application with lifestyle counseling improves disease activity control in inflammatory arthritis.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 10/06/2021, Ethics committee of the Medical Faculty of Heinrich-Heine-University Düsseldorf (Ethikkommission an der Med. Fakultät der HHU, Moorenstr. 5, Düsseldorf, 40225, Germany; +49 (0)21181-19591; ethikkomission@med.uni-duesseldorf.de), ref: 2021-1408

### Study design
Multicenter interventional double-blinded randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Home, Hospital

### Study type(s)
Quality of life, Treatment

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

### Health condition(s) or problem(s) studied
Inflammatory arthritis: rheumatoid arthritis, psoriatic arthritis, spondyloarthritis

### Interventions
Patients were alternatingly randomized to either report health-related quality of life (HRQoL) only, or to additionally receive 12 weeks of individualized lifestyle counselling via the app pertaining to a healthy Mediterranean diet, sports and physical activity, mental health, and non-smoking.

### Intervention Type
Behavioural

### Primary outcome measure
Low disease activity or remission, categorized according to disease-specific instruments: Rheumatoid Arthritis Disease Activity Index (RADAI) for rheumatoid arthritis, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) for axial spondyloarthritis and Disease Activity Index in Psoriatic Arthritis (DAPSA) for PsoA at baseline and 12 weeks.

### Secondary outcome measures
1. Adherence to a healthy Mediterranean diet measured using the Mediterranean Diet Adherence Screener (MEDAS) at weeks 0 and 12
2. Health-related quality of life measured with the Short-Form Health Survey (SF-36) at weeks 0 and 12
3. Weight (in kg) measured using a scale at weeks 0 and 12
4. Self-estimated time doing sports per week (in h) measured using a questionnaire via mobile phone application at weeks 0 and 12
5. Exercise per week measured using BSA (Bewegungs- und Sportaktivität Fragebogen = Movement and sports activity questionnaire) via mobile phone application at weeks 0 and 12
6. Mental health status measured using the Patient Health Questionnaire 5 (PHQ-5) questionnaire via mobile phone application at weeks 0 and 12
7. Rheumatoid arthritis disease activity measured using the compound Disease Activity Score-28 (DAS-28) during patient visit in a subgroup of rheumatoid arthritis (RA) patients at weeks 0 and 12

### Overall study start date
22/01/2021

### Completion date
31/05/2024

## Eligibility

### Key inclusion criteria
1. Patients with inflammatory arthritis:
1.1. Rheumatoid arthritis according to the 2010 American College of Rheumatology (ACR) /European Alliance of Associations for Rheumatology (EULAR) criteria
1.2. Psoriatic arthritis according to Classification Criteria for Psoriatic Arthritis (CASPAR) criteria
1.3. Spondylarthritis according to Ankylosing Spondylitis Disease Activity Score (ASDAS) criteria
2. Age >18 years
3. Written consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

**Upper age limit**
99 Years

**Sex**
Both

**Target number of participants**
150

**Total final enrolment**
170

**Key exclusion criteria**
1. Patients without written consent
2. Age <18 years
3. Unable to use mobile phone/not in possession of mobile phone

**Date of first enrolment**
01/06/2022

**Date of final enrolment**
31/05/2023

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**St Elisabeth Hospital Meerbusch-Lank**
Hauptstr. 74-76
Meerbusch
Germany
40668

**Study participating centre**
**Krankenhaus Porz am Rhein**
Urbacher Weg 19
Cologne
Germany
51149

# Sponsor information

**Organisation**
The German Society for Rheumatology

**Sponsor details**
Wilhelmine-Gemberg-Weg 6, Aufgang C
Berlin
Germany
10179
+49 (0)30 24 04 84 70
info@dgrh.de

**Sponsor type**
Other

**Website**
https://dgrh.de

# Funder(s)

**Funder type**
Other

**Funder Name**
The German Society for Rheumatology

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**
01/08/2024

**Individual participant data (IPD) sharing plan**
The statistical analysis report generated and analyzed during the current study is available upon reasonable request from Dr Türker Kurt (tuerker.kurt@rrz-meerbusch.de) after the publication of the data, excluding data potentially permitting patient identification such as date of birth or date of visits, thereby precluding the necessity for participants' consent in accordance with ethical restrictions. Legal restrictions may apply concerning patent law aspects, which will be checked following requests.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 14/05/2024 | 20/08/2024 | Yes | No |