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
https://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
https://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

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

Primary study design
Interventional

Study design
Multicenter interventional double-blinded randomized controlled trial

Study type(s)
Quality of life, Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

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

Funder(s)

Funder type
Other

Funder Name
The German Society for Rheumatology

Results and Publications

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