

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

Submission date 02/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/02/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/12/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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 alternately 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

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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; ethikkommission@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 alternately 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

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Sponsor information

Organisation

The German Society for Rheumatology

Sponsor details

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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