# Patients' satisfaction with a digital solution aiming for the monitoring and support of patients with immune-mediated rheumatologic diseases

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
15/06/2021		[X] Protocol		
Registration date 21/08/2021	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 12/09/2024	Condition category  Musculoskeletal Diseases	Individual participant data		

#### Plain English summary of protocol

Background and study aims

Supporting rheumatology patients undergoing immunological treatments is of great relevance. Mobile health technologies (mHealth) have the potential to bring actionable insights to clinicians following up on those patients whose health status often changes in between clinical visits. These patients are also in need of personalized education to better cope with the disease and improve both their physical and mental health. The aim of this study is to explore the feasibility of using a mobile health solution to support the personalized care of patients with a rheumatologic disease that requires immunological treatment.

#### Who can participate?

Patients aged over 18 years with immune-mediated inflammatory diseases, such as spondyloarthritis and rheumatoid arthritis, who are treated with biologic disease-modifying anti-rheumatic drugs (bDMARDs) or specific targeted synthetic DMARDs (tsDMARDs)

#### What does the study involve?

Participants will be informed about the study and after checking eligibility criteria and signing informed consent they will be able to participate. They will receive a mobile application to access health education and behavioral change support, including access to questionnaires (psychometrics) that will support clinicians to provide them with more personalized care.

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

The main benefit is that participants will have access to personalized educational and behavioral support. In addition, their health status will be better monitored by their clinicians which eventually can lead to the improvement of the provision of care. The educational and behavioral content of the mobile solution focuses on the low-risk type of advice (e.g. stress management) and is not intended to substitute for advice from clinicians. Only clinicians involved in the provision of care will be able to identify the patients, thus minimizing any privacy risks.

Where is the study run from?
La Paz and Infanta Leonor University Hospitals (Spain)

When is the study starting and how long is it expected to run for? March 2020 to June 2022

Who is funding the study?

Abbvie via an independent grant awarded to the Sociedad Española of Rheumatology (Spain)

Who is the main contact? Chamaida Plasencia-Rodriguez chamiplaro@gmail.com

# Contact information

#### Type(s)

Scientific

#### Contact name

Mrs Chamaida Plasencia Rodríguez

#### **ORCID ID**

https://orcid.org/0000-0003-3503-9047

#### **Contact details**

Servicio de Reumatología Hospital Universitario La Paz Paseo de la Castellana, 261 Madrid Spain 28046 +34 (0)607914606 chamaida.plasencia@ser.es

# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

HULP-PI-4519

# Study information

#### Scientific Title

Feasibility study of digital solutions to support and follow-up of patients with immune-mediated rheumatological diseases

#### Acronym

DigiReuma

#### **Study objectives**

The purpose of this observational study is to measure the impact of the use of a digital solution on the quality of care perceived by patients.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 27/01/2021, Comité de Ética de la Investigación del Hospital Universitario La Paz (Paseo de La Castellana 261, Hospital General, 8ª planta, Madrid, Spain; +34 (0)91 727 74 13; ceic. hulp@salud.madrid.org), ref: HULP-PI-4519

#### Study design

Prospective observational multicenter study

#### Primary study design

Observational

#### Study type(s)

Other

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

Rheumatoid arthritis, axial spondyloarthritis

#### **Interventions**

Participants will be informed about the study and after checking eligibility criteria and signing informed consent they will be able to participate. They will receive a mobile application to access health education and behavioral change support, including access to questionnaires (psychometrics) to support clinicians in providing them with more personalized care.

Total duration of observation: 6 months
Total duration of follow-up: 6 months

#### Intervention Type

Behavioural

#### Primary outcome(s)

- 1. Impact of the mobile solution on patients' satisfaction, measured using an ad-hoc questionnaire at 6 months
- 2. Engagement at an aggregated level measured continuously via users' login frequency from recruitment until drop-out or the end of the follow-up

#### Key secondary outcome(s))

- 1. Quality of life measured by Health Assessment Questionnaire (HAQ) at baseline, 1, 2, 3, 4, 5 and 6 months
- 2. Disease activity measured by Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at baseline, 1, 2, 3, 4, 5 and 6 months

#### Completion date

20/06/2022

# **Eligibility**

#### Key inclusion criteria

- 1. Over 18 years of age
- 2. Have a smartphone or tablet-type cell phone
- 3. Accepting participation in the study and signing the informed consent form
- 4. Patients under follow-up for at least 1 year in the Complex Therapies Unit of the Rheumatology service with a diagnosis of rheumatoid arthritis, spondyloarthritis, or psoriatic arthritis

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Total final enrolment

56

#### Key exclusion criteria

- 1. Not owning a mobile device compatible with the mHealth solution
- 2. Not being able to participate in the program without assistance

#### Date of first enrolment

30/06/2021

#### Date of final enrolment

30/07/2021

# Locations

#### Countries of recruitment

Spain

#### Study participating centre

#### Hospital Universitario La Paz

Servicio de Reumatología Hospital Universitario La Paz Paseo de la Castellana, 261 Madrid Spain 28046

# Study participating centre Hospital Universitario Infanta Leonor

Sección de Reumatología Hospital Universitario Infanta Leonor Avenida de la Gran Vía del Este, 80. Distrito Municipal de Villa de Vallecas Madrid Spain 28031

# Sponsor information

#### Organisation

Sociedad Española de Reumatología

#### **ROR**

https://ror.org/01fm69p79

# Funder(s)

# Funder type

Industry

#### **Funder Name**

AbbVie

#### Alternative Name(s)

AbbVie Inc., AbbVie U.S., AbbVie US, Allergan

#### **Funding Body Type**

Government organisation

# **Funding Body Subtype**

For-profit companies (industry)

#### Location

United States of America

# **Results and Publications**

## Individual participant data (IPD) sharing plan

In principle, the data will be held at a local database that will be used for the analysis, and it will be kept for safety reasons. The data underlying this article will be provided by the Digireuma Committee under licence / by permission. Data will be shared on request to the corresponding author Chamaida Plasencia-Rodríguez (chamaida.plasencia@ser.es) with the permission of the Digireuma Committee.

## IPD sharing plan summary

Not expected to be made available

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/12/2022	06/09/2023	Yes	No
Results article		25/09/2023	12/09/2024	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file			20/07/2021	No	No