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

Submission date
15/06/2021

Recruitment status
No longer recruiting

Registration date
21/08/2021

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
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

Secondary outcome measures
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

Overall study start date
02/03/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
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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

Sponsor details
C/ Marqués del Duero, 5, 1º
Madrid
Spain
28001
+34 (0)915 767 799
prensa.es@abbvie.com

Sponsor type

Research organisation

Website
https://www.ser.es/

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

Publication and dissemination plan
The researchers will disseminate their research through conventional academic outlets such as ACM, and IEEE sponsored conferences, and health informatics journals.

Intention to publish date
01/03/2022

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?
Protocol file			20/07/2021	No	No
Results article		07/12/2022	06/09/2023	Yes	No
Results article		25/09/2023	12/09/2024	Yes	No