

D2.1 / Initial report on user research & co-creation process

Editor	Contractual delivery date	Actual delivery date
Patty de Groot (EMC)	June 2023	July 2023
Deliverable type	Dissemination level	Version - date
R – Document, report	PU – Public	1.0 – 29/07/2023



Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency. Neither the European Union nor the European Health and Digital Executive Agency can be held responsible for them.

Deliverable 2.1

Project acronym	iPROLEPSIS
Project full title	Psoriatic arthritis inflammation explained through multi-source data analysis guiding a novel personalised digital care ecosystem
Grant Agreement ID	101095697
Deliverable number	D2.1
Deliverable title	Deliverable title in sentence case
Work package	WP2 – Knowledge mining, foundations and participatory design
Deliverable type	R
Dissemination level	PU – Public
Version - date	v1.0 - 29/07/2023
Contractual delivery date	June 2023
Actual delivery date	July 2023
Lead partner	EMC
Editor	Patty de Groot (EMC)
Contributors	Jolanda Luime (EMC), Patty de Groog (EMC), Despoina Petsani (AUTH), Konstantina Tsimpita (AUTH), Sofia Dias (FMH), Andreas Raptopoulos (WCS), Kosmas Dimitropoulos (CERTH), Dimitrios Konstantinidis (CERTH), Ilias Papastratis (CERTH), Gerogios Apostolidis (AUTH), Vasilis Charisis (AUTH), Leontios Hadjileontiadis (AUTH), Laura Coates (UOXF), Ilja Tchetverikov (CICERO), Maria Mytilinaiou (AUTH), Catia Gonçalves (SPR), Ana Maria Rodrigues (SPR).
Reviewed by	Laura Coates (UOXF) Ana Maria Rodrigues (SPR)
Approved by	Leontios Hadjileontiadis (AUTH, Project Coordinator)
Keywords	User Research, User Requirements, Focus groups, Survey

Document history

Version	Date	Contributors	Action / status
0.1	27/03/2023	EMC	Document structure ToC ready
0.2	08/05/2023	ALL	Received literature on User Requirements.
0.3	20/06/2023	CICERO, SPR, AUTH, UOXF	Received descriptions of the healthcare systems.
0.4	14/07/2023	EMC AUTH	Ready for internal review
0.5	16-07-2023	UOXF	Reviewed by Laura Coates (UOXF)
0.5	18-07-2023	SPR	Reviewed by Ana Maria Rodrigues (SPR)
0.6	20-07-2023	EMC	Document revised
0.7	29-07-2023	AUTH	Revised and approved by the Project Coordinator
1.0	31-07-2023	AUTH	Submitted to the EC by the Project Coordinator

Contents

List of figures.....	8
List of tables.....	9
List of abbreviations.....	10
Executive summary.....	11
1 Introduction.....	13
1.1 Document scope.....	13
1.2 Document structure.....	13
2 Background Knowledge.....	14
2.1 Context.....	14
2.1.1 PsA care in Greece.....	14
2.1.2 PsA care in Portugal.....	16
2.1.3 PsA care in the United Kingdom.....	18
2.1.4 PsA care in the Netherlands.....	19
2.1.5 The European Guidelines for remote care in RMDs.....	21
2.1.6 Take Away Messages.....	21
2.2 iPROLEPSIS DHTs User Requirements.....	23
2.2.1 MiPROLEPSIS patient App.....	23
2.2.2 BiAURA.....	24
2.2.3 Recommendation systems.....	25
2.2.4 MiPROLEPSIS HCP Dashboard.....	27
2.2.5 Serious Gaming Suite.....	27
3 User Research & Co-Creation Method.....	30
3.1 General Approach.....	32
3.1.1 The process.....	32
3.1.2 The parties involved in the development process.....	35
3.2 Focus Groups Method.....	36
3.2.1 Set-up.....	36
3.2.2 Analysis.....	36
3.3 Survey.....	37
4 User Research & Co-Creation Results.....	37
4.1 Progress.....	37
4.1.1 Ethical Approvals.....	37
4.1.2 Conducted Research.....	37
4.2 Focus Group Results.....	39
4.2.1 Theme 1 – Disease Activity.....	40
4.2.2 Theme 2 – Coping.....	42

4.2.2.1	Behavioural adaptations.....	42
4.2.2.2	Mental adaptations.....	43
4.2.2.3	Intervention	43
4.2.2.4	Prevention.....	43
4.2.3	Theme 3 – Care Experience	44
4.2.3.1	Needs.....	44
4.2.3.2	Tele-Consultations	45
4.2.4	Theme 4 – Digital Biomarkers.....	47
4.2.4.1	Benefits	47
4.2.4.2	Drawbacks	47
4.2.4.3	Terms	48
4.2.4.4	Preference Differences	48
4.2.5	Patient Experience Map	50
4.2.5.1	Curve of Disease Activity	50
4.2.5.2	Curve of Emotional Wellbeing.....	51
4.2.6	Personas	54
4.2.6.1	Persona 1 – Innovator.....	55
4.2.6.2	Persona 2 - Early Adopter.....	56
4.2.6.3	Persona 3 - Early Majority.....	56
4.2.6.4	Persona 4 - Late Majority.....	57
4.2.6.5	Persona 5 – Laggard.....	57
4.3	Survey Results	59
4.3.1	Section 1 – Demographics and Technological Experience.....	59
4.3.2	Section 2 – miPROLEPSIS app.....	61
4.3.2.1	Content.....	61
4.3.2.2	Appearance.....	63
4.3.3	Section 3 – biAURA app.....	65
4.3.4	Section 4 – Personalised Gaming Suite (PGS).....	66
4.4	Triangulation.....	69
4.4.1	Features of disease activity and Pros and Cons of technology to assess it.....	69
4.4.2	Active User Input.....	70
4.4.3	Notifications and Data Sharing.....	71
4.4.4	Requirements from triangulation process.....	71
5	Defining User Requirements.....	72
5.1	MiPROLEPSIS patient app.....	73
5.2	BiAURA	74
5.3	Recommendation Systems.....	74

5.4	MiPROLEPSIS HCP Dashboard	75
5.5	Serious Gaming Suite.....	76
6	Next steps.....	77
7	Conclusions	79
	References.....	80
	Appendix I Focus Group Script English Version	84
	Appendix II iPROLEPSIS Patient Survey	86
	Appendix III Focus Group Code Book	110

List of figures

Figure 1 The PsA Healthcare Touchpoints in Greece.....	15
Figure 2 The psoriatic arthritis Healthcare Touchpoints in Portugal.	17
Figure 3 The psoriatic arthritis Healthcare Touchpoints in the United Kingdom.	19
Figure 4 The psoriatic arthritis Healthcare Touchpoints in the Netherlands.	20
Figure 5 Product Development Processes identified of relevance to the iPROLEPSIS project. A. The CAPTAIN Framework (Tessarolo, 2022). B. The Design Thinking Method ⁷	31
Figure 6 iPROLEPSIS User Research & Co-Creation approach. It is based on Design Thinking & The CAPTAIN Framework.	33
Figure 7 Word Tree map based on the symptoms expressed by participants of all focus groups. The numbers and the size of the blocks indicate how many participants mentioned this complaint at least once.....	Error! Bookmark not defined.
Figure 8 Word Tree Map based on items that were mentioned by participants in the various focus groups. The numbers and size of the blocks indicate in how many focus groups these measures were suggested.....	49
Figure 9 Patient Experience Map. The level of disease activity is indicated in purple. The level of emotional wellbeing in pink. Letters indicate specific fluctuations which are described in the text.	50
Figure 10 Visualisation of the innovation diffusion curve by E.M. Rogers and the Chasm Theory by G.A. Moore. The image was retrieved from the weagree.com website.	55
Figure 11 Various overviews of the answers to the question “Which items do you think are most indicative of your PsA flare-ups? So how important is it for us to measure them?” The size of the blocks and the colours indicate the expressed attitudes.	61
Figure 12 Various overviews of the answers to the question “How would you feel about the devices (smartphone and/or smartwatch) continuously measuring your ...”. The size of the blocks and the colours indicate the expressed attitudes.....	62
Figure 13 Attitude towards the receipt of various kinds of notification by the miPROLEPSIS app on a 5-point scale. Dark blue = strong like, grey = strong dislike.....	63
Figure 14 Respondents want to receive short questions on the following items, indicated in number of times an item was checked from the list.	63
Figure 15 Graph showing the inclusion of audio such as relaxing sounds, classical music or story telling in the bedtime routines per country. Size of the bars indicate percentages of the 183 respondents with a bedtime routine.	66
Figure 16 Graph showing the amount of boxed checked per item to the question: “In which of the following areas do you see potential benefits for a serious game suite to help you improve or sustain your self-management skills?.”.....	67
Figure 17 Graph showing the amount of boxed checked per item to the question: “What genre/type of game would you like to play?”.....	68
Figure 18 Graph showing the amount of boxed checked per item to the question: “Which types of in-game awards would serve as motivation for you to continue playing the game?.”.....	68
Figure 19 Graph showing the amount of boxed checked per item to the question: “Which types of graphics and main characters would you prefer to see in the game?”	69
Figure 20 iPROLEPSIS Digital Health Ecosystem Roadmap.	78

List of tables

Table 1 The different parties involved in the development process.	35
Table 2 Dissemination overview.....	38
Table 3 Numbers of participation.....	39
Table 4 Demographics Focus Groups.....	39
Table 5 Illustrative quotations corresponding to Theme 1.....	41
Table 6 Illustrative quotations corresponding to Theme 2.....	44
Table 7 Illustrative quotations corresponding to Theme 3.....	46
Table 8 Illustrative quotations corresponding to Theme 4.....	49
Table 9 Illustrative quotations corresponding to the Patient Experience Map.....	52
Table 10 Demographics of Survey Participants	59
Table 11 Technological experience of Survey Participants.....	60
Table 12 Rating of different visualisation types by respondents.	64
Table 13 Rating of screen layouts by respondents.	64
Table 14 Rating of colour use by respondents.....	65
Table 15 Interest in the PGS by age group.	67
Table 16 User Requirements miPROLEPSIS patient app.....	73
Table 17 User Requirements biAURA.....	74
Table 18 User Requirements Recommendations.....	74
Table 19 User Requirements miPROLEPSIS HCP Dashboard	75
Table 20 User Requirements Serous Gaming Suite	76

List of abbreviations

PsA	Psoriatic Arthritis
PsO	Psoriasis
RA	Rheumatoid Arthritis
HCP	Healthcare Practitioner
GP	General Practitioner
DHT	Digital Health Tool
DMARDs	Disease-Modifying Antirheumatic Drugs
sDMARDs	Synthetic Disease-Modifying Antirheumatic Drugs
bDMARDs	Biological Disease-Modifying Antirheumatic Drugs
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs,
EIA	Early Inflammatory Arthritis
PROMS	Patient-Reported Outcome Measures
PIFU	Patient-Initiated Follow-Up
PGS	Personalised Gaming Suite
FG	Focus Group
UR	User Requirement
IDC	Innovation Diffusion Curve
EULAR	European Alliance of Associations for Rheumatology

Executive summary

Deliverable 2.1 is the first deliverable of WP2 'Knowledge mining, foundations and participatory design'. It is part of Task 2.2 'User research and co-creation process'. In D2.1, the co-creation approach is mapped out. This approach is a combination of Lean, Scrum and Design Thinking, where in Design Sprints various Digital Health Tools shall be developed. Furthermore, D2.1 presents the first steps taken in user research. This deliverable concludes the Empathising phase of the design approach, providing information on Psoriatic Arthritis (PsA) patients and their needs. Two applied methods elicit PsA patients' views on their disease and digital biomarkers, i.e., focus groups and a survey. All were performed in the four participating countries: The Netherlands (NL), The United Kingdom (UK), Greece (GR), and Portugal (PT). Additionally, the scientific literature was reviewed on existing user requirements and the features of each PsA-related health care system applied in the four participating countries were described.

In the PsA focus groups, participants discussed disease activity and symptom fluctuations. They mentioned experiencing a range of symptoms with varying severity and never being completely symptom-free. Fluctuations in disease activity were described, with sudden or gradual flare-ups. Over time, participants learned to monitor their symptoms and identified various triggers, including weather changes, physical overexertion, stress, and lifestyle factors, like alcohol, smoking, sleep, and diet (specific food triggers mentioned were sugar, caffeine, fat, E-numbers, red meat, gluten, and sour fruits).

Coping with PsA involved a process of trial and error, with patients needing to understand their bodies and develop appropriate coping mechanisms. Behavioural adaptations, including changes in activity patterns, rest, social activities, and eating habits, were employed during flare-ups. Mental adaptations involved dealing with grief, residual symptoms, and insecurities. Interventions, such as medication and alternative therapies (e.g., physical therapy, acupuncture, Cannabidiol oil), were used to regain control during flare-ups, and preventive measures focused on dietary restrictions, physical activities, emotional control and stress reduction. These coping strategies often require sacrifices and adjustments in various aspects of PsA patients' lives, such as career switches and home adaptations.

Participants expressed a willingness to try digital biomarkers but had varying attitudes and preferences. They recognized potential benefits in personal and macro-level learning, but some patients also raised concerns about personal gain, trust in technology, and potential psychological impacts. Clear value propositions, data validity, and usability were important considerations for participants. Overall, there were not many privacy concerns as participants trusted that if the Digital Health Tools (DHTs) were adopted by the hospitals they would comply with data security regulations.

A survey was conducted to identify user requirements for the DHTs of iPROLEPSIS (i.e., miPROLEPSIS app, biAURA app, Recommendation systems, miPROLEPSIS HCP Dashboard, and Serious Gaming Suite) among a broader sample of PsA patients in the participating countries. A total of 299 participants provided responses, with a median age of 56 yrs (IQR 49-63 yrs), a balanced gender distribution and a range of educational levels, with a tendency towards medium to higher levels of education. Smartphone ownership was high across all countries (88%-96%), followed by tablets (19%-72%) and smartwatches/activity trackers (37%-56%). Participants reported daily Internet usage, both at home and outside. Overall, participants showed relatively high technological literacy and device usage. The data indicate a tech-savvy demographic willing to adopt new technologies, including apps for

monitoring PsA. Those already owning devices are more open to trying new apps, but many without smartwatches expressed a future interest in acquiring one.

Within the survey and the focus groups preferences varied regarding the level of intrusiveness and tracking features of the iPROLEPSIS DHTs. Approximately two-thirds of the patients saw potential benefit in incorporating gaming into their disease management. Preferences for game design varied among patients who were interested in serious games, with a specific need for age-appropriate, enjoyable, and stress/anxiety management games.

In conclusion, a detailed compilation of patients' needs was elicited in the first six months of the project. The development of digital biomarkers is considered important, but challenges lie ahead in catering to all needs. The heterogeneity of PsA poses challenges for DHT design, as it must accommodate a wide range of symptom expressions and age groups. A core goal is to incorporate patients' insights into their disease activity and provide support during the trial-and-error process, considering the prominence of uncertainty and grief cycles in their experiences. Identifying preference differences in DHT features and appearance highlights the necessity to address tensions and achieve consensus in co-creation and development sprints; a methodology that is adopted and followed by the iPROLEPSIS.

1 Introduction

User research and co-creation play vital roles in transforming healthcare by putting the needs and experiences of Psoriatic Arthritis (PsA) patients and healthcare practitioners (HCPs) at the centre of innovation and development processes. These practices enable a deep understanding of the diverse perspectives, challenges, and aspirations of the people who directly engage with healthcare systems, ultimately leading to the creation of more effective, patient-centric solutions.

In the past, healthcare design and decision-making were often driven by expert opinions and assumptions about what users needed and wanted. However, this approach failed to capture the complexities and nuances of individual experiences, resulting in solutions that were disconnected from the real-life needs of patients and providers. Recognizing this limitation, iPROLEPSIS embeds User Research and Co-Creation at the core of its research process. This process employs a variety of qualitative and quantitative research methods, such as interviews, observations, surveys, and usability testing to gather data that inform the development and refinement of healthcare solutions.

1.1 Document scope

Deliverable 2.1 is the first deliverable of WP2 'Knowledge mining, foundations and participatory design'. It is part of Task 2.2. 'User research and co-creation process' and contains a threefold of intentions:

1. Describe the design approach consisting of user research and co-creation that is adopted for the development of the iPROLEPSIS DHTs.
2. Describe the results of the Empathising phase of the adopted design approach. Within this phase of the design process, focus groups and surveys were conducted to elicit the experiences and needs of PsA patients when it comes to the management of their disease. Additionally, these methods were used to get a feel of the initial attitudes of PsA patients toward the concept of the intended DHTs.
3. Report the initial User Requirements derived from literature and the Empathising phase of the design approach that will be used for the DHT development.

1.2 Document structure

D2.1 provides an overview of the methods and outputs of the conducted user research. Apart from this introductory Section 1, the rest of the document is structured in additional five sections as follows:

- **Section 2:** provides a brief overview of the context in which iPROLEPSIS lies and existing knowledge on user requirements for each DHT;
- **Section 3:** provides an extensive description of the methodology that it is adopted for participatory design of the DHTs;
- **Section 4:** provides the results obtained from the focus groups and surveys conducted among PsA patients from the United Kingdom (UK), Greece (GR), Portugal (PT), and the Netherlands (NL);
- **Section 5:** provides the first set of user requirements per DHT deducted from the literature, focus groups and surveys; and
- **Section 6:** discusses the next actions for the co-creation process.

2 Background Knowledge

2.1 Context

Section 2.1 provides a context evaluation of the healthcare systems involved in the iPROLEPSIS project. Within this evaluation, each healthcare system surrounding the care for PsA patients has been mapped. Evaluation of the various healthcare systems is important, since a comprehensive understanding of the workflow, circumstances and people involved is needed to create solutions that are not only technologically advanced, but which are also tailored to meet the unique challenges of the healthcare ecosystems (Skivington, 2021).

Each PsA-related healthcare system of GR, PT, UK, and NL is separately described below.

2.1.1 PsA care in Greece

In Greece, screening and monitoring of patients with PsA is carried out by rheumatology specialists. Patients can be referred for diagnostic or therapeutic purposes to both the public hospital and the private rheumatology practice.

Figure 1 illustrates how the healthcare services for PsA patients are organised in Greece. The diagram is divided into several sections from 'before diagnosis' to periods of 'stable disease'. **Before Diagnosis.** Once a person starts to develop PsA symptoms, s/he can book an appointment with a medical specialist directly. Since the Greek system is not General Practitioner (GP)-based, someone who experiences complaints needs to figure out by themselves which medical specialist to visit. It is also possible that a dermatologist refers a psoriasis (PsO) patient to the rheumatologist. A patient can choose either for public or private care services. In the public sector, especially in the bigger cities of the country, there is usually a long waiting list that could reach up to two months for the appointment with a rheumatologist. In the private sector, an appointment can be scheduled within a week. **Diagnosis.** At the patients' initial rheumatology appointment, the rheumatologist will prescribe blood tests, X-rays and/or MRI, according to the patients' symptoms. The patient will book a follow-up appointment to review the results of the tests. At the follow-up appointment the patient receives the diagnosis of PsA, and the rheumatologist begins treatment with Medication 1. **Active Disease.** When a patient is started on a new medication, the drug is prescribed for two months. After this period, the patient visits the rheumatologist for a clinical examination and blood tests to test for drug side effects and to have an initial impression about the disease activity of the patient. After these two months, the patient comes in for follow-up appointments every three months. **Stable Disease.** Once stable and free of drug side effects, the patient will schedule a follow-up appointment every six months. If the disease flares or if the disease manifests in a new location of the body, the appointments will go back to the state of active disease.

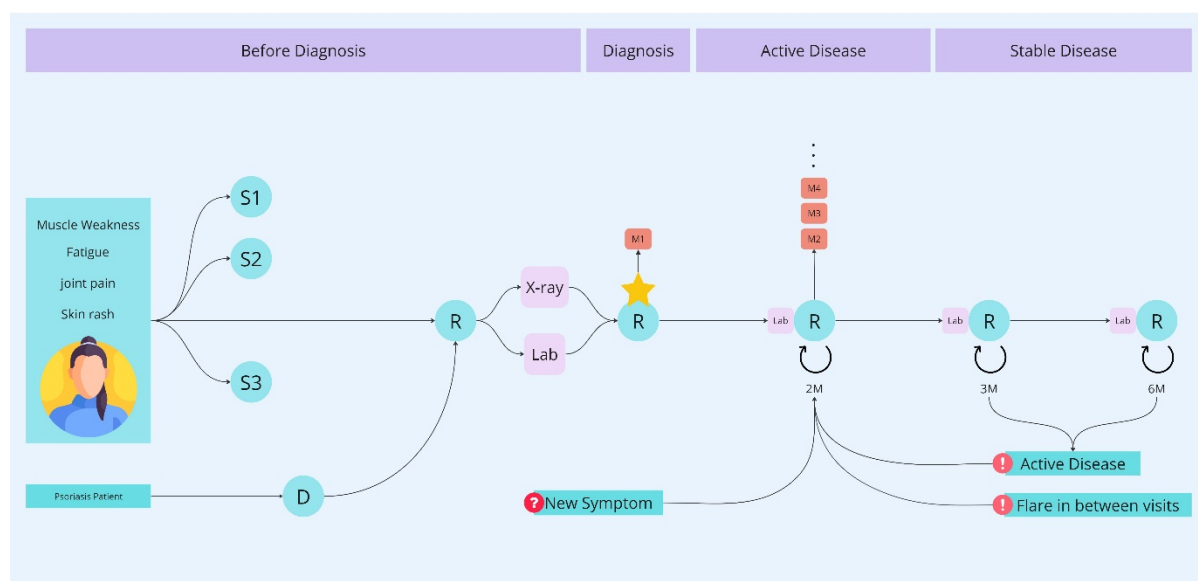


Figure 1 The PsA Healthcare Touchpoints in Greece.

Abbreviations indicate the following: **D** – appointment Dermatologist; **R** – appointment Rheumatologist; **S1-S2** – appointment any other medical specialist; **M1-M4** – new medication prescribed.

Health insurance is organised by a single fund, i.e., the National Organisation for the Provision of Health Services (EOPYY). The EOPYY purchases health services provided by the National Health System for the public. EOPYY also contracts with private providers, mainly to deliver primary and outpatient care and diagnostic services. On this basis, insured patients will receive either free services from public providers or pay for services from private providers. In 2016, the Greek state extended coverage of services to uninsured patients. Thus, uninsured patients with PsA have access for free to a package of services, which includes primary care, diagnostic tests, outpatient and inpatient care, but only in public institutions. Access to all biological treatments is free of charge for all patients. However, for all other treatments, those insured in the health insurance fund scheme contribute to the cost of the medicines (25% of their value), while the uninsured receive their treatment free of charge. Synthetic Disease Modifying Antirheumatic Drugs (sDMARDs) can be found in all pharmacies across cities but biological Disease Modifying Antirheumatic Drugs (bDMARDs) are available only in public pharmacies located in specific areas of the city. Patients must obtain their drugs by themselves.

The COVID-19 pandemic had a significant impact on the health and mortality of the population in Greece. Due to numerous cancellations of appointments in public facilities, patients with rheumatological diseases were forced to make telephone appointments with doctors in public facilities. On the other hand, due to the challenges in the health sector resulting from the pandemic, the government launched a digital transformation policy for the health sector. Thus, patients during and after the pandemic gained access to various platforms with health data and electronic records, with a major achievement being the ability to obtain prescriptions for medicines and laboratory tests without being physically present in a health facility.

The use of teleconsultation and telemedicine was mainly expanded during the Covid-19 pandemic to facilitate access to care in remote and under-covered areas. Now, after Covid-19, the top priority of the National Health System is, on the one hand, the development and organisation of primary health care, and on the other hand, the further development of digital health services.

2.1.2 PsA care in Portugal

The Portuguese health system is composed of three concomitant systems: the National Health Service (Serviço Nacional de Saúde – SNS), special public and private healthcare insurance schemes for certain professions (health subsystems), and private healthcare insurers. SNS is the main healthcare provider in the country, covering 100% of the population. It is publicly funded and tendentiously free of charge for users. Just like in Greece, there are barriers in the access to hospital specialized public services. Therefore, many patients seek appointments with rheumatologists in the private sector.

In Portugal, screening and monitoring of patients with PsA is performed mostly by Rheumatologists, although in some areas the internal medicine counsellor still takes that role. Patients are firstly seen by the GP and then referred to the Rheumatologist or to the internal medicine doctor. **Figure 2** illustrates how the healthcare services for PsA patients are organised in Portugal. The diagram is divided into several sections from ‘before diagnosis’ to periods of ‘stable disease’.

Before Diagnosis. Since 2015, SNS has a reference network for rheumatic and musculoskeletal diseases, including PsA. When a person starts to experience the initial symptoms of PsA, they usually visit their GP or other medical specialists (S). It is also possible that patients come in through the hospital emergency services (U). The GP/S/U all have authority to order X-rays and/or blood tests. According to the guidelines, patients identified by primary healthcare services are referenced to rheumatology appointments at tertiary healthcare centres. Moreover, there are a few tertiary centres, which are considered reference sites for PsA, that provide multidisciplinary clinical appointments with a rheumatologist and a dermatologist. In the past, patients were also referenced to autoimmune diseases clinical appointments by internal medicine doctors; this is still occurring in certain areas/centres.

Diagnosis. In the private sector, patients with PsA are screened and monitored by rheumatologists only. Some private hospitals also have multidisciplinary teams with a rheumatologist and dermatologist. at the initial rheumatology appointment diagnostic tests are ordered and the patient schedules a follow-up appointment to receive the diagnosis. At the follow-up appointment the rheumatologist begins treatment with medication 1.

Active Disease. Patients visit their rheumatologist every 3 months. During these appointments a clinical examination takes place and if necessary, the medication will be altered. Patients with more severe cases of PsA can be referred to centres with multidisciplinary teams that include dermatologists and rheumatologists.

Stable Disease. As the PsA stabilises the frequency of appointments can be changed from every three months to every six months. However, patients under bDMARDs continue to visit their rheumatologist every three months. Only hospital doctors (Rheumatologists, Internal Medicine, Gastroenterologists and Dermatologists) are authorised to prescribe these drugs and the bDMARDs are dispensed by the hospital pharmacy. If during an appointment active disease is identified, the time between appointments will be set back to every three months. Patients are told they can contact their rheumatology team when their disease flares. This team is composed of rheumatologists and may include rheumatology nurses and/or dermatologists in some centres.

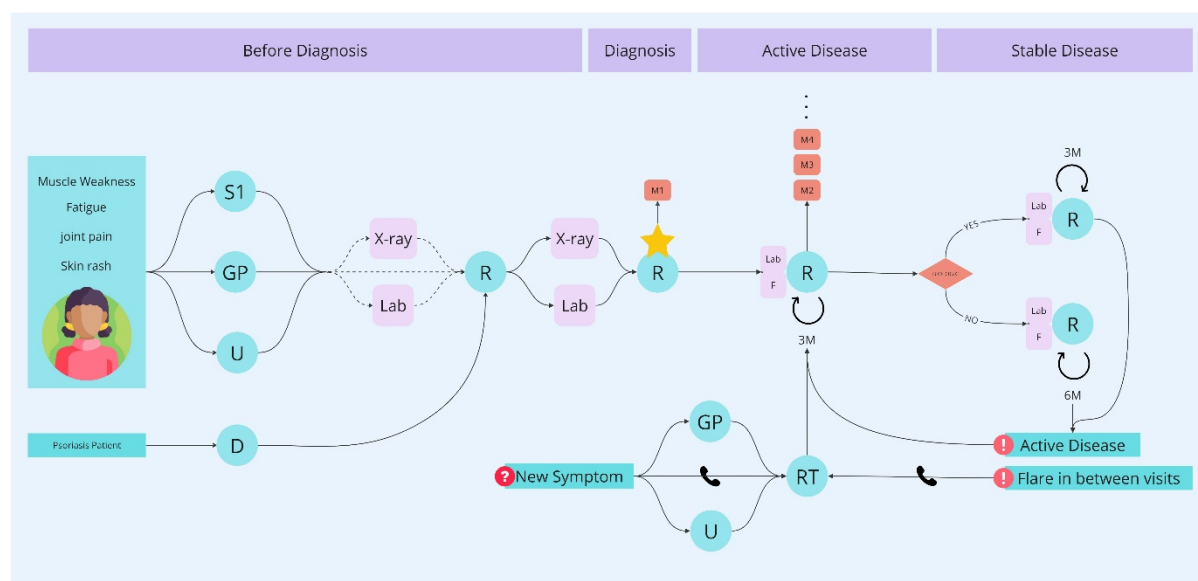


Figure 2 The psoriatic arthritis Healthcare Touchpoints in Portugal.

Abbreviations indicate the following: **GP** – appointment General Practitioner; **U** – visit to the Hospital Emergency Services; **D** – appointment Dermatologist; **R** – appointment Rheumatologist; **S1-S2** – appointment any other medical specialist; **RT** – interaction with the Rheumatology Team. This team is composed of rheumatologists and may include rheumatology nurses and/or dermatologists in some centres; **F** – patient fill out PROMS; **M1-M4** – new medication prescribed.

Since July 2022, all hospital clinical appointments are free of charge in the public sector. For patients followed both in the public and private sectors, the costs of methotrexate, Leflunomide and biotechnological treatments are fully covered by the government budget. Biotechnological drugs are exclusively dispensed by public hospital pharmacies.

The COVID-19 pandemic had a significant impact on the healthcare system, leading to the cancellation of multiple healthcare appointments and to lower demand. A survey conducted between June and August 2020 demonstrated that approximately 60% of the respondents identified at least one unmet healthcare need, mainly due to the cancellation of appointments by healthcare providers. Moreover, individuals with worse health status registered the highest number of unmet healthcare needs (Lourenço, 2022). The adoption of TM by Portuguese institutions has been growing, leveraged by the telehealth governance model and public reimbursement mechanisms, proving particularly relevant during the pandemic (Miranda, 2023). During the pandemic, remote clinical appointments duplicated in primary healthcare services and increased by 36% in hospitals between March and July 2020 in comparison to the same period in 2019 (Lourenço, 2022).

National priorities for the decade are summarised in the National Healthcare Plan 2021-2030 (DGS/Ministério da Saúde, 2022). Rheumatic and musculoskeletal diseases were not considered a strategic priority. Universal digital coverage is a strategic area in the National Healthcare Plan 2021-2030. The Portuguese Health Ministry developed a platform, RSE Live, that allows doctors to schedule and conduct remote appointments with patients. This platform can be utilised by all public healthcare providers. All private sector hospitals have telehealth platforms available; the choice of appointment modality (face-to-face vs. remote) lies with the patient. A phone app (SNS24) that enables patients to access digital prescriptions issued both in the public and private sectors is also available. However, monitored patients are still few. Low digital literacy among patients and providers, lack of care integration and resource scarcity represent barriers hampering pilot TM initiatives' scale-up (Miranda, 2023).

2.1.3 PsA care in the United Kingdom

PsA care in the United Kingdom (UK) is led by rheumatologists in secondary care hospitals. This is all provided through the NHS. Care is often on a “shared-care” basis, where rheumatologists advise on treatment, but GPs support with ongoing prescription of medications. Contrary to the organisation of care in Portugal or Greece, care in the UK consists of nearly all public practices and for most of the public no private practices are in place. Patients can self-fund to see a rheumatologist for a diagnosis (for an earlier appointment), but patients requiring Disease-modifying antirheumatic drugs (DMARD) therapy would then be referred back to the NHS system for ongoing prescription and monitoring.

Figure 3 illustrates how the healthcare services for PsA patients are organised in the UK. The diagram is divided into several sections from ‘before diagnosis’ to periods of ‘stable disease’.

Before Diagnosis. As someone develops PsA in the UK, s/he will contact her/his GP to discuss complaints of unknown origin. The GP will assess and may order blood tests and/or X-rays. Based on their suspicions, the patient is referred to the early inflammatory arthritis (EIA) or PsA clinic for a rheumatology review.

Diagnosis. Same as in GR and PT the rheumatologist will order the required diagnostic tests, such as additional blood tests, X-rays, Ultrasound or MRI. At the follow-up visit, the rheumatologist starts treatment with Medication 1. This drug is prescribed for the next three months, and blood monitoring is ordered.

Active Disease. The patient visits the GP for blood monitoring and the rheumatologist for physical check-ups. During these appointments the rheumatologist coordinates with the patient which drug is prescribed on which dose.

Stable Disease. After medications are stable, shared care with the GP is initiated. In this situation rheumatologists are responsible for advising on drug and dose, etc. GPs provide monthly prescriptions and execute the blood monitoring. If a new kind of medication is prescribed, the same rules apply where the rheumatologist takes care of the prescription until the medication is stable; then, they move to shared care with the GP. The guidelines state that a patient should first be reviewed every six months. If treatment is going well, the period can be extended to 12 months. However, currently there is a crisis in appointments and these guidelines cannot be met. Therefore, currently the time between appointments highly varies, but, in general, the frequency of appointments goes up when the disease is more active. The NHS has moved to patient-initiated care where patients fill out Patient-reported outcome measures (PROMS) yearly. These PROMS are used to prioritise appointments. In case a patient experiences a flare-up of her/his disease, s/he can contact the rheumatology nurse or her/his GP; they decide the course of action from there or schedule an appointment with the rheumatologist to alter medication. Once a patient is put on biologics, the full care transfers to the rheumatologist. When the medication use of biologics is stable patients visit their rheumatologist every six-to-twelve months. The rheumatologist performs blood monitoring and prescribes the medication for the next period. A healthcare delivery company delivers the medication to the patients’ home every three months.

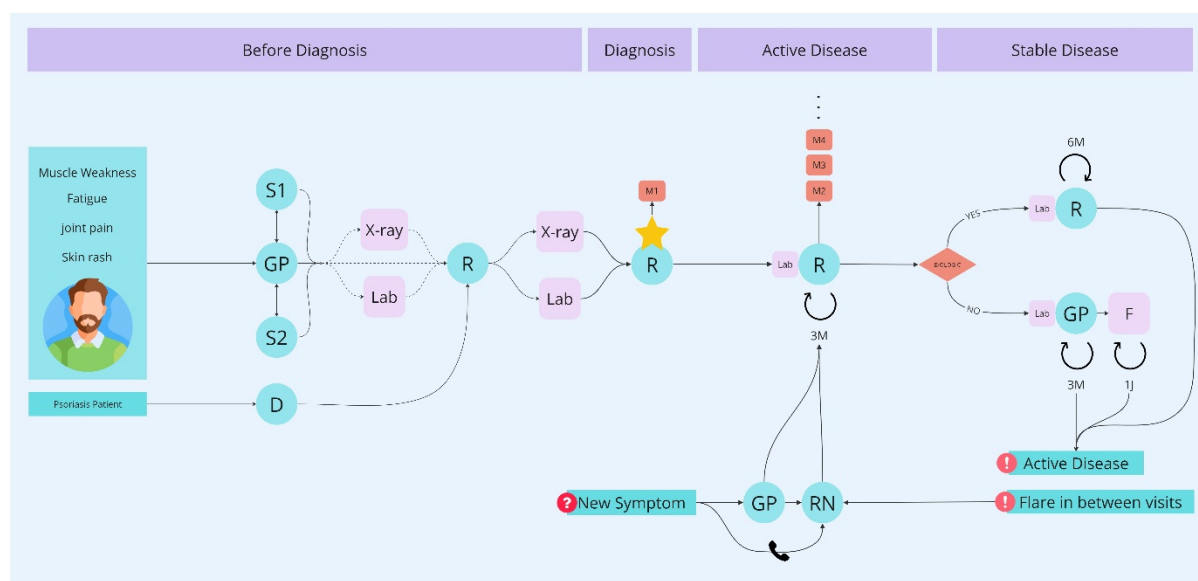


Figure 3 The psoriatic arthritis Healthcare Touchpoints in the United Kingdom.

Abbreviations indicate the following: **GP** – appointment General Practitioner; **S1-S2** – appointment any other medical specialist; **D** – appointment Dermatologist; **R** – appointment Rheumatologist; **RN** – interaction with Rheumatology Nurse; **F** – patient fill out PROMS; **M1-M4** – new medication prescribed.

Treatment is free at the point of use to all patients in the NHS. Patients may pay a prescription charge for outpatient treatment. This is set at £9.65 (approx. €11.24), although patients can pay for annual cover. There is no cost for hospital or GP visits.

The COVID-19 pandemic had a significant impact on the healthcare system with a number of appointments cancelled or reconfigured to remote appointments. Now, following these changes, appointments can be either in person (face-to-face in clinic) or remote (telephone or secure video platforms, in some centres remote electronic patient questionnaires and asynchronous review). The proportional use of in-person or remote appointments significantly varies, depending on provider, hospital and patient. It is likely that patients coming to face-to-face clinics will have a higher change of active disease (with stable, well patients being offered remote follow up).

National priorities and directions are summarised in the NHS Long Term plan. This includes an increasing use of patient-initiated follow-up (PIFU) where follow up may be variable depending on patient requests.

2.1.4 PsA care in the Netherlands.

In the Netherlands, the care for patients with PsA is organised through the rheumatological practices at the secondary care hospitals. There are also some dedicated secondary care centres for rheumatology. All rheumatological care is publicly organised and no private practices are in place.

Figure 4 illustrates how the healthcare services for PsA patients are organised in the Netherlands. The diagram is divided into several sections from ‘before diagnosis’ to periods of ‘stable disease’. **Before Diagnosis.** To obtain a first appointment at the rheumatology clinic a patient needs to be referred by a GP. If a patient has been referred to another medical specialist first (S) s/he can also make a referral to a rheumatologist. **Diagnosis.** Equivalent to Greece, Portugal and the UK, a patient comes in for an initial visit and the rheumatologist runs some diagnostic tests and when the patient comes for follow-up, s/he will receive the diagnosis. At the diagnostic appointment, the rheumatologist will start treatment by prescribing

Medication 1 and will send the patient to the rheumatology nurse for further information about what PsA entails, how to cope with symptoms and explanation about the prescribed drug. **Active Disease.** During active disease patients visit their rheumatologist every three months. The rheumatologists will assess the disease activity and when needed can change the medication dosage or the type of drug. If a patient changes from type of drug or manner of administration the patient will get an appointment with the rheumatology nurse for additional explanation. **Stable Disease.** Once the medication stabilises and the disease activity had decreased to acceptable levels, the time between appointments is increased. First from three to six months then to nine and then to twelve months. If the disease is stable enough and patients agree, appointments can become alternating with phone consultations. If during a consultation active disease is identified, the time between consultations will be decreased again to see if the disease becomes less active. Patients are told that they can always call the hospital in between visits when their disease flares. They will get in touch with the rheumatology nurse, who determines if the patient needs to come in. Sometimes patients experience new symptoms that they do not always directly identify as PsA complaints. In this case they could either make an appointment with their GP or they will call their rheumatology nurse to ask. The GP or rheumatology nurse can then schedule an appointment with the rheumatologist. The role of the rheumatology nurses is also to help patients that have a hard time understanding their disease or have some more social economic problems that needs certain additional attention. They can have regular consultations with the rheumatology nurse only. If something is up, they ask the rheumatologist to have a look on the spot.

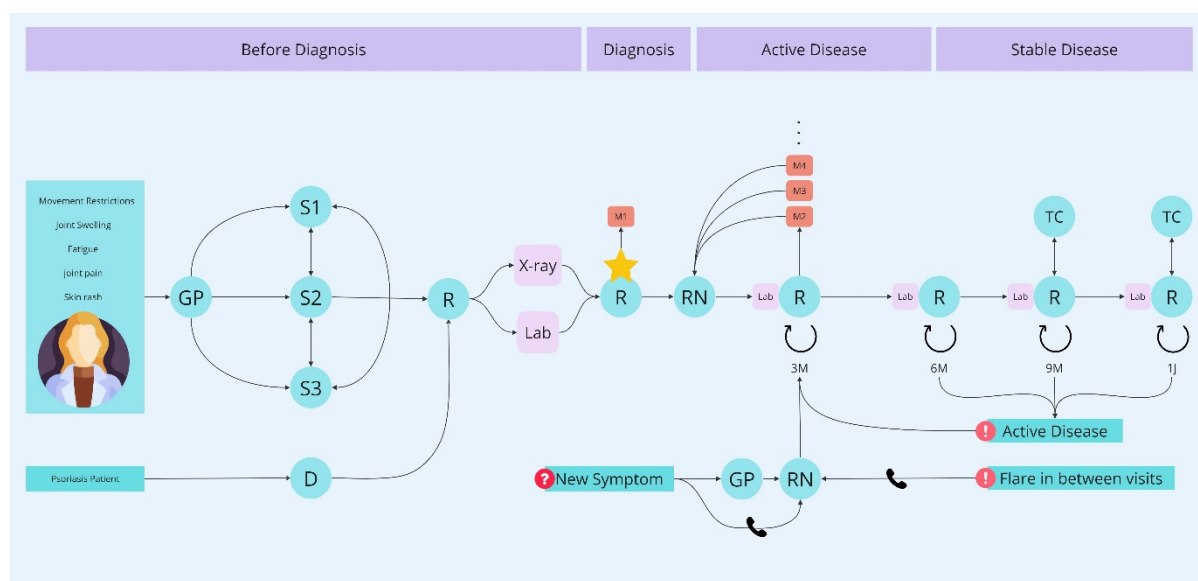


Figure 4 The psoriatic arthritis Healthcare Touchpoints in the Netherlands.

Abbreviations indicate the following: **GP** – appointment General Practitioner; **S1-S3** – appointment any other medical specialist; **D** – appointment Dermatologist; **R** – appointment Rheumatologist; **RN** – interaction with Rheumatology Nurse; **TC** – Telephone Consultation; **M1-M4** – new medication prescribed.

All expenses for consulting a physician in a primary care setting are covered by medical insurance. The costs for secondary care providers are also covered by medical insurance, however, patients must contribute with a maximum yearly rate (2023: € 385) (Dutch Government, n.d.).

Counter to the role of the GP in the UK, there are no shared care practices in the treatment of rheumatological diseases between primary and secondary care in the Netherlands.

Rheumatologists are responsible for diagnosis, initial care, long-term care and prescription of medication for patients with PsA. The sDMARDs often used in the treatment of PsA can be obtained at the local pharmacy of the patients. However, the more expensive bDMARDs can only be obtained at the pharmacy of the local secondary care hospital or affiliated pharmacy. Medication costs are covered by medical insurance; the rules for own contribution to medication costs as well, within the same yearly maximum rate.

In the past couple of years, a shift towards telemedicine has taken place. Mainly a shift in teleconsultations and video-consultations was seen throughout the field of rheumatology. This transition was shifted in to gear by COVID-19, where 80% of the total number of rheumatological outpatient visits were performed exclusively via telephone with in-person visits only on indication (Bos et al., 2021). In this study, survey insights of 75 rheumatologists in May 2020 on usage, acceptance, facilitators and barriers of telemedicine were collected. The research found that the top three facilitators for telemedicine were less travel time for patients, ease of use of the system, and shorter waiting period for patients. The top three barriers were impossibility to perform physical examination, difficulty estimating how the patient is doing, and difficulty in reaching patients. On average, respondents were content with current tele-health solutions, although some felt insecure mainly because of the inability to perform physical examination and missing nonverbal communication with their patients (Bos et al., 2021). The use of telehealth and digital health solutions is now promoted and encouraged by healthcare insurers and the government (Dutch Government, 2022). It has become a part of the efficiency benchmark with minimum of teleconsultations for the average rheumatological practice being set to about 30% (2023).

2.1.5 The European Guidelines for remote care in RMDs

On a larger scale, the European Alliance of Associations for Rheumatology (EULAR) provides recommendations for the way the care for rheumatology patients is organised. The EULAR is an organisation that represents people with arthritis/rheumatism, health professionals in rheumatology and scientific societies of rheumatology of all European nations. They improve and implement standards of care for people with rheumatic and musculoskeletal conditions. The EULAR sets-up task forces aimed at elaborating recommendations in the field of rheumatology. Occasionally, the EULAR publishes recommendations and points to consider in scientific journals. In 2022, the EULAR published 'Points to consider for remote care in rheumatic and musculoskeletal diseases' (de Thurah, 2022). Four overarching principles and nine points to consider were formulated. These points stress that the use of telehealth should be tailored to patients' needs and preferences and that healthcare teams should have adequate equipment and training in telecommunication skills. If these conditions are met, telehealth can be used in screening for rheumatological diseases as preassessment in the referral process, for disease monitoring and regulation of medication dosages and in some non-pharmacological interventions. Furthermore, people with a rheumatic condition should be offered training in using telehealth so that barriers can be resolved whenever possible (de Thurah, 2022).

2.1.6 Take Away Messages

Within the field of rheumatology there is support for the development and implementation of DHT. The care for PsA patients has been disrupted in all four of iPROLEPSIS participating countries, where some were more affected than others. As was highlighted by the EULAR points to consider, it is important that technologies developed fit with the needs and preferences of patients and are functional and usable for the healthcare professionals. This also means that the technologies to be developed need to fit within the healthcare systems of the different countries.

By reviewing the different care systems surrounding the PsA patients in the different countries we can identify several major differences and similarities.

Differences

- In NL and the UK, patients receive government funded care in public facilities. In PT the majority of patients receive government funded care in public facilities; however, some patients who can afford it choose private care. In GR, patients can choose between private and public care, where patients who can afford it choose private care to avoid long waiting lists.
- In GR, GPs are not directly involved in the care system. Patients can come to medical specialists on their own merit. The UK, PT and NL systems include GPs in their care pathways. In PT and NL, the GPs' responsibility is only the referral of patients, whereas in the UK system GPs and rheumatologists share the care responsibilities.
- Only the NL system systematically adopts the specific role of the rheumatology nurses. Rheumatology nurses exist also in UK and PT, yet most of the time they are busy and overwhelmed (UK) and not available in all hospitals (PT). In NL, the rheumatology nurses undertake specific tasks regarding triage of patients calling to the clinic, providing additional explanation on medication or symptom management and helping patients who need additional attention about disease management or other specific circumstances such as financial aids, family management, etc.
- The Portuguese and the UK system make a distinction in the CarePath for patients with or without biologic use. In Portugal this only affects the time between consultations, where in the UK this means that all care responsibilities move towards the rheumatologist.
- The UK is the only system that enforces patient-initiated care with the directions of the NHS. They have implemented yearly PROMS for stable patients that help prioritise appointments.
- The manner in which patients can get medication and have to pay for it varies. In Greece, low-level medication can be bought without prescriptions. Other higher-level medications can be obtained only with prescriptions in certain pharmacies. In the Netherlands and Portugal, a prescription is needed for the medication. Patients can obtain low level medication at local pharmacies, but high-level medication can only be obtained from hospital pharmacies. In the UK, all medications also need a prescription, but the prescriptions can be renewed by the GP. Patients can get their low-level medication at pharmacies and their high-level medication (only prescribed by rheumatologists) is delivered at home every three months.

Similarities

- The UK, GR and PT all experience long waiting lists for rheumatology appointments. In these countries, patients who can afford it thus choose to get care in the private sector. The UK has set up an EIA clinic that is meant to see patients within three weeks, however currently their waiting list is seven-to-eleven weeks.
- All countries have the same diagnostic process where the rheumatologists run diagnostic tests and initiate treatment at the next visit.
- All countries use blood monitoring to check inflammatory markers and drug side effects.
- All countries adjust the time between visits based on the level of disease activity and the type of medication that is used.
- All countries have a system in place that allows the patients to contact the rheumatology clinic in times of flare.

2.2 iPROLEPSIS DHTs User Requirements

Within iPROLEPSIS, several DHTs will be developed with the aim to early detect the transition to PsA in PsO patients, to predict flares to allow for early intervention, and to generate personalised recommendations and personalised interventions that help manage the disease. The different DHTs to be developed are: the miPROLEPSIS patient app; the miPROLEPSIS healthcare practitioner dashboard; the biAURA biaural sounds app; the personalised recommendation system; and the Personalised Gaming Suite (PGS).

Each purposed DHT is briefly described below; then, for each technology, current knowledge on user requirements is presented.

2.2.1 MiPROLEPSIS patient App

According to Description of Actions (DoA), the miPROLESIS patient application should provide the following functionalities:

1. Operate as data capturing tool, collecting data from wearables, external APIs (e.g., weather data), user generated inputs (e.g., questionnaires), and embedded smartphone sensors (e.g., accelerometer, keyboard etc.).
2. Receive feedback regarding various lifestyle aspects. In specific, this may concern:
 - a. Nutrition, physical activity, sleep and mood
 - b. Suggested plans related with the aforementioned lifestyle/wellbeing aspects, along with evidence-based hints.
 - c. Risk prevention advice (e.g., alerts for proactively avoiding environmental stressors and activities that increase mechanical stress).
 - d. Aspects more specific to the disease management, like stress, fatigue, pain, as well as medication reminder.
 - e. Overall quality of life (as validated by the EQ-5D-5L questionnaires)
3. Incorporate a number of engagement hooks (e.g., motivational goals and achievement) enhancing the willingness of the patient to keep being in the loop.
4. Provide personalized configurations in order to better address patient's needs.
5. Be available in both iOS and Android as well as provide multilingual support.

To this end, additional features that build trust, guarantee the security and ensuring privacy of (sensitive) data are considered a prerequisite. Thus, aspects like privacy by design, open, transparent and timely communications, accessibility of privacy policy, data security and clear accountability should be taken into account¹.

In terms of UI design basic rules used in the development of such applications should be considered. These include²: (1) the provision of simple navigation, (2) making large touch areas, (3) reduction of clutter, (4) display of readable text, (5) use of touch controls, (6) use of simple forms, (7) consideration of the thumb position and (8) ensuring a consistent experience. To these elements, aspects like the platform characteristics, the minimization of user inputs, the ability to enhance familiarity and predictability, as well as accessibility and the minimized push notification burden should be considered³.

The majority of the aforementioned features are considered typical for such applications. Indeed, most of the existing (in the market) applications for well-being support and management provide such functionalities to their users. The main differentiating factor in the

¹ https://www.applicationprivacy.org/wp-content/uploads/2011/01/Mobile-App-Packet_Final.pdf [Last visited on: 30/06/2023]

² <https://uxdesign.cc/8-rules-of-mobile-design-1b8d9936c241> [Last visited on 05/07/2023]

³ <https://relevant.software/blog/mobile-app-ui-design-guide/> [Last visited on 05/07/2023]

iPROLEPSIS project, is the pivoting process that will incorporate new functionalities related with the management of PsA and combine the other lifestyle aspects. Typical examples of such applications (following a B2B2C model) are, Woliba, Wellness 360, Virgin Pulse, Limeade, Wellable, CoreHealth⁴ etc.

2.2.2 BiAURA

Patients with PsA and other inflammatory autoimmune diseases, e.g., psoriasis, are possible to experience some type of sleep disorder. This argument is supported by a few works in the literature even though the exact causal relationship between sleep deficiency and immune dysregulation remains unresolved (Irwin, 2019) (Garbarino, 2021) (Ibarra-Coronado, 2015). Hence, technology-based applications that promote sleep quality can have significant impact to patients with PsA.

The sleep intervention approach of the iPROLEPSIS project aims at eliciting neural entrainment driven by binaural beats. The latter is an auditory illusion that occurs when two sounds with adjacent frequencies are conveyed to each ear separately. The auditory illusion is the impression of hearing one frequency, i.e., the binaural beat, which is the same as the difference of the two adjacent frequencies. What happens during neural entrainment is the synchronization of the brain neural activity with the binaural beat. Hence, for sleep related applications, the binaural beats should be of low frequency (<4Hz) because in this frequency band, i.e., delta waves, the brain neural activity operates during sleep.

A mobile application, the biAURA app, will allow the patient to start listening some sound compositions designed to induce binaural beating and the sound will play until the patient falls asleep. The onset of restful sleep will be automatically detected in near real-time fashion processing motion and heart rate data streams from a smartwatch. An additional feature that can be incorporated in the biAURA app is the “structured awakening”. This function starts a sound designed to “wake up the brain” a few minutes before the morning alarm specified by the patient. Apart from the use of biAURA app for sleep quality regulation, it will also be considered as a tool for pain management in a daily use via a voluntary use by the user. This equips the biAURA app with a dual functionality, i.e., to improve the sleep quality and readiness for the next day and to provide alternative means for pain soothing during PsA flare-ups.

It should be noted that it has been shown that the effect of neural entrainment using binaural beating depends on how long the user listens (Garcia-Argibay, 2019). Specifically, they are more effective with longer periods of listening, up to two hours. Hence, apart from the sound design and the timing of the intervention which are the main challenges of the research and development, a crucial parameter for the success of sleep improvement using the biAURA app is user engagement.

The available mobile health (mHealth) applications for sleep offer a wide range of services, i.a, sleep tracking, alarm clocks, education, and sound recording during sleep. A review by Shin et al. (2017) suggested that mHealth interventions for sleep decrease sleep disorders and improve sleep quality. Nevertheless, user engagement is not satisfactory as shown in the literature. Krebs et al. (2015) presented that about half of the respondents who download such mHealth applications stop using them due to poor user experience, i.e., high data entry burden, loss of interest, and hidden costs. Moreover, another work by McCurdie et al. (2012)

⁴ <https://woliba.io/>, <https://www.wellness360.co/>, <https://www.virginpulse.com/>, <https://www.limeade.com/>, <https://www.wellable.co/>, <https://corehealth.global/> - Source Capterra [Last visited on: 11/07/2023]

showed that it is possible to abandon an application that fails to establish immediate engagement due to lack of participatory practices during designing process.

The design of an engaging application requires a thorough understanding of the needs and preferences of end-users to produce relevant functional and non-functional requirements. Moreover, it is imperative for such type of applications to accurately specify the context of the technology (e.g., do the end-users wear their watch during sleeping or do they sleep with their phone by the bed?). Existing knowledge from the literature is limited, yet provides useful insights into end-users' needs, preferences, and contexts.

A work by Aji et al. (2019) explored user needs and preferences for mHealth applications that aim at sleep improvement using a mixed-method approach. The latter incorporated the triangulation of the data from three research methods, i.e., focus groups, an online survey, and an analysis of app reviews. The outcome of this work was that the app features that positively affect engagement are sleep diaries, alarms, and personalisation. The latter consists of personalised sleep feedback, sleep advice based on the collected data, and content according to their conditions, e.g., insomnia, narcolepsy, etc. It is also highlighted that didactic information, poorly designed features, i.e., bad aesthetics and complex functionality, and software bugs have a negative impact on user engagement.

Furthermore, a recent scoping review by Mahmud et al. (2022), investigated the main functionalities of mHealth sleep applications and the methodology towards sleep improvement. Also, the work identified the barriers to using such applications among end-users. The review identified that the most common functions of the applications are evaluating and tracking sleep as well as providing alarms and sleep diaries. Specifically, for sleep evaluation and tracking wearable device technology plays a significant role. Regarding the identified limitations, the most significant one is the accuracy to monitor sleep, especially in patients with insomnia and fragmented sleep problems. Moreover, a couple of common concerns consist of privacy issues and the dependence on battery life when wearable devices are used in the application.

In summary, there is a plethora of mHealth applications for sleep available but there are few which show a satisfactory performance in a wide range of end-user categories. The main characteristic of that a successful mHealth sleep app is the robustness in sleep tracking which supports informative sleep monitoring feedback, i.e., sleep diary. Secondly, personalisation is important especially when application aims at dealing with significant sleep problems, such as chronic insomnia. Finally, it is worth noting that the existence of the alarm feature is dominant in available mHealth sleep application. This highlights the importance of the awakening, apart from aiding sleep onset.

2.2.3 Recommendation systems

Maintaining a well-balanced and nutritious diet is of paramount importance for the human health, especially now that food globalization and lifestyle changes significantly challenge people's ability to adhere to healthy diets (Dernini, 2015). Following a well-balanced diet and avoiding excessive caloric intake can prevent obesity, a prominent disease that according to WHO has nearly tripled since 1975⁵. This is very alarming since obesity is a risk factor leading to noncommunicable diseases (NCDs), such as cardiovascular diseases and diabetes, that are responsible for 74% of all deaths worldwide and they can be effectively prevented through interventions on diet. However, it is known to be quite challenging for a common person to keep track of personal food requirements because of the massive diversity of dietary components and items. To this end, personalised food recommendation systems have

⁵ <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight> [Last visited on 26/07/2023]

emerged in the last few years to assist users to adapt to and maintain a healthy diet (Theodoridis, 2019; Stefanidis, 2022). These systems usually propose specific meals or develop entire meal plans that allow users to receive a well-balanced amount of nutrients and calories.

However, personalised diet and physical activity recommendation systems based on artificial intelligence (AI) face barriers, such as data privacy, security, and accuracy. Access to sensitive user data, including health and dietary information, is essential (Tran et al., 2018). Yet, safeguarding this data presents a challenge that developers must tackle. Moreover, the system's effectiveness hinges on the accuracy of user-provided data; inaccurate or incomplete user profile data can lead to incorrect recommendations and jeopardize user trust (Verma et al., 2018). Therefore, user engagement and trust are vital. Users must trust the system's recommendations and maintain consistent engagement for the system to show effectiveness. This trust-building can be challenging given the personal and sensitive nature of health and nutrition. However, certain facilitators can foster the success of a personalised diet and physical activity AI recommendation system. User-centred design is one such facilitator. By designing the system with a user-focused approach, it becomes more likely to meet user needs and ensures ease of use. Consequently, this boosts user engagement and fosters trust in the system.

Considering the unique nutritional needs of each user, a key requirement is that a recommendation system should take into account characteristics, such as age, gender, height, weight, physical activity level, lifestyle and medical condition (Kesari, 2022). In addition, other factors, such as culture and ethnicity as well as dietary restrictions, such as vegetarian or vegan meal preference, gluten sensitivity, lactose intolerance and food allergies should also be considered for a successful food and physical activity recommendation system that can keep users engaged and satisfied (Ordovas, 2018). An ideal food recommendation system should be able to self-adaptively achieve a trade-off between user's food preferences and personalised nutrition/health requirements so that the recommendations are both desirable and relevant to user's health (Min, 2019). Finally, of great importance is the variability of generated meal plans (Stefanidis, 2022). Users can more easily adhere to a diet that presents a huge variety in meals per week since consuming repetitive meals can be frustrating and lead to loss of interest from the user side.

Additionally, it is crucial for diet and physical activity recommendation systems to collaborate with health professionals, such as dietitians, nutritionists and physicians in order to maintain a high level of credibility and to ensure users that the system recommendations are validated by experts in the field, thus further facilitating the adherence of users to the recommended diet and physical activity plans (Trang Tran, 2018). For a recommendation system to be able to cope with complex nutritional rules, while satisfying the health requirements and personal preferences of users, and simultaneously offering a satisfactory meal variability in the generated meal plans, a large pool of available meals is required, and thus special attention should be paid in this direction. In the framework of the EU-funded Horizon H2020 PROTEIN project (<https://protein-h2020.eu/>), a lot of work has been made on the development of a personalised AI food and physical activity recommendation system, enhanced with nutritional rules from experts, ontologies and a pool of expert-validated meals, showcasing the importance of combining experts' knowledge and artificial intelligence for the development of a highly accurate recommendation system that can provide nutritional and physical activity advice to users.

Regarding the health of PsA and PsO patients, psoriasis is an inflammatory condition with strong genetic ties and a variety of aspects of autoimmunity that are also influenced by environment and lifestyle, including nutrition and physical activity. To this end, users require

from a food recommendation system to suggest specific diets that will reduce the inflammation symptoms and improve the overall life quality of the users. More specifically, obese and overweight users will benefit from low-calorie diets to decrease their weight and benefit for reduced symptoms (Ford, 2018). A food recommendation system should also avoid proposing meals rich in saturated fat that increase inflammation and instead recommend diets rich in vegetables and fruits, which improve metabolic and immunological function.

When designing for the P90 user, i.e., those who fall in the 90th percentile in terms of usage or requirements, it is important to consider their unique needs. This could include users with specific dietary restrictions, complex health conditions, or high levels of physical activity. The system should be flexible enough to accommodate a wide range of dietary needs and preferences (Kesari, 2022). P90 users may require more detailed customization options to accurately reflect their unique dietary needs. They may also benefit from advanced features, such as detailed nutritional analysis, integration with fitness tracking devices, or the ability to track specific nutrients (Greiwe, 2020). Furthermore, P90 users may require more robust support and educational resources to understand and effectively use the system. While it is important to design for the P90 user, it is also crucial not to alienate the rest of the user base. Striking a balance between catering to advanced users and keeping the system accessible and useful for all users is key to success.

2.2.4 MiPROLEPSIS HCP Dashboard

The miPROLEPSIS HCP environment is a dashboard that aggregates the information collected by the miPROLEPSIS patient applications. Such applications should⁶:

1. Provide quick and easy access to patients' history and other relevant information to provide quality of care.
2. Provide quick measures to patient outcomes, supporting accurate interventions.
3. Enable patient prioritization facilitating regular patient check-ups.

In order to achieve the aforementioned requirements, such dashboards should include features for identifying positive and negative trends, interpreting performance metrics and measuring inefficiencies. These should respect the following design principles⁷ (Rabiei, 2022): (1) simplicity and focus, (2) hierarchy and data flow, (3) clear and understandable visualizations combined with consistent colouring and formatting, (4) responsiveness, (5) incorporation of interactive elements, and (6) employment of data security and privacy measures.

According to the iPROLEPSIS DoA, such a dashboard aims to cover exactly these needs: (1) allowing HCPs to track their patient status, (2) view projections, and (3) associate the collected measurements with patients' responses to treatment plans, enabling the optimization of care. Finally, by being the main point of interaction between the system and as the miPROLEPSIS HCP dashboard integrates the foreseen system intelligence, the ability to trace a result back to its original data must be provided, ensuring transparency and explainability to the users.

2.2.5 Serious Gaming Suite

The treatment of PsA requires a combination of pharmacological and non-pharmacological interventions. While approaches such as physical therapy and psychosocial interventions can be beneficial, ensuring long-term adherence to the prescribed treatment plan poses a challenge, as non-adherence can have negative consequences for patients (Rongen-van Dartel et al., 2015; Campbell et al., 2017). Serious games offer promising potential as non-

⁶ <https://fuselabcreative.com/healthcare-dashboard-design-best-practices/> [Last visited on 05/07/2023]

⁷ <https://www.syntrixconsulting.com/blog/10-best-practices-in-healthcare-dashboards-design> [Last visited on 11/07/2023]

pharmacological treatments for PsA by providing engaging and interactive experiences that support various aspects of PsA management. Also referred to as educational or applied games, serious games offer learners the opportunity to engage in situations that may be impractical or unsafe in the real world. These games are believed to have positive effects on the development of various skills (Susi et al., 2007).

From a theoretical game design perspective, high-quality serious games must effectively blend the serious and game elements. They should provide systematic support to players in achieving the primary goal associated with the serious aspect of the game, while also eliciting and maintaining a captivating player experience that emphasizes the game aspect. Integrating both components is essential for a cohesive and harmonious overall experience (Caserman et al., 2020). Moreover, the Mechanics-Dynamics-Aesthetics (MDA) game design framework formalizes the components of game consumption. Mechanics involve the representation and algorithms that define how the game is constructed. Dynamics encompass the player's experience and interaction with the game mechanics during gameplay. Aesthetics relate to the desired emotional responses evoked from participants, contributing to their enjoyment of the game. When developing serious games, the MDA framework can be extended (eMDA) to focus on modelling cognitive and emotional processes, ensuring that the game experience takes precedence over the underlying purpose, such as improving mental health or learning outcomes. Within the MDA game design perspective, it is crucial to consider aspects that promote quality in both the serious and game parts of serious games while maintaining a balance (Dias et al., 2023). These aspects, outlined in the extended MDA (eMDA) framework include (Caserman et al., 2020):

1. Quality aspects in the **serious part** of the game:
 - Clearly defined characterizing goal that supports the player in achieving it (e.g., enhancing learning, training).
 - Development of appropriate methods without errors in the subject matter and provision of feedback for player progress assessment.
 - Evaluation of the achievement of the characterizing goal through measurable effects and benefits.
2. Quality aspects in the **game part** of the game:
 - Establishing a positive experience and engagement by maintaining game flow, ensuring varied gameplay, and balancing skills and challenges.
 - Dynamic adaptation of game difficulty and complexity, fostering emotional connection and instinct arousal, and providing a sense of control to the user.
 - Including appropriate graphics, sound, and interface design that support the game tasks and cater to the target audience.
3. Quality aspects in the **balance between serious and game parts**:
 - Integrating the serious part within the gameplay to ensure the characterizing goal cannot be avoided.
 - Adopting a co-creation approach involving all stakeholders (e.g., game designers, domain experts, users).
 - Selecting suitable interaction technology for the target group, including intuitive game mechanics and natural mapping between technology and gameplay, while avoiding adverse effects, technical issues, and ensuring ease of maintenance.

By considering these quality aspects in both the serious and game parts and maintaining a balance between them, the design and development of effective Serious Games are enhanced.

Furthermore, user requirements play a vital role in determining the effectiveness, usability, and overall user experience of serious games. They serve as guiding principles throughout the design process, ensuring that the game aligns with the intended learning objectives, is user-friendly, and provides an engaging experience. Taking user requirements into account enables the development of high-quality serious games that effectively educate, train, and engage users in a meaningful way.

Additionally, various aspects have been identified as important for the adoption of serious games, as well as for stimulating people to play and adhere to the game. These aspects encompass factors such as user motivation, perceived relevance and usefulness, ease of use, accessibility, social interaction, feedback mechanisms, and incentives. Considering and addressing these aspects during the design and implementation of serious games can increase their appeal, engagement, and long-term usage by the target audience. Below are presented some key aspects that are known to be significant:

- **Usability and accessibility.** Serious games need to be user-friendly, intuitive, and accessible. Easy navigation, clear instructions, and intuitive interfaces contribute to a positive user experience and increase adoption. Additionally, ensuring accessibility for users with disabilities or specific needs is crucial for inclusive adoption (Yanez-Gomez et al., 2017; Salvador-Ullauri et al., 2020; Aguado-Delgado et al., 2020).
- **Engaging gameplay.** Engaging gameplay is vital for capturing and sustaining user interest. Serious games should incorporate elements such as MDA components, challenging tasks, interactive features, clear goals, attractive storyline, adaptable to gender and age, and meaningful feedback to make the game experience enjoyable and motivating. Gamification techniques, such as rewards, achievements, and progress tracking, can also enhance engagement and encourage adherence (Schwarz et al., 2020).
- **Relevance and meaningful content.** The content of serious games should be relevant and meaningful to the target audience. Users are more likely to adopt and adhere to a game that addresses their specific needs, interests, and goals. The content should align with the educational or training objectives, providing practical knowledge and skills that users can apply in real-life contexts (Adams, 2010).
- **Social interaction and collaboration.** Integrating social interaction and collaboration features in serious games can enhance adoption and adherence. Multiplayer modes, leaderboards, cooperative gameplay, and online communities create opportunities for users to interact, compete, and collaborate with others, fostering engagement and motivation (Oksanen, Hämäläinen, 2014).
- **Personalisation and adaptation.** Personalization and adaptation aspects are important for tailoring the game experience to individual users. Serious games that can adapt to the user's skill level and progress provide a more personalized and meaningful experience, leading to increased adoption and adherence (Streicher & Smeddinck, 2016)
- **User feedback and support.** Providing positive feedback, rewards, and recognition for user achievements within the game can boost motivation and adherence. Additionally, offering adequate user support, such as tutorials, help features, and responsive user service, can address user concerns, improve usability, and foster long-term engagement. (Erhel & Jamet, 2013; Bharathi et al., 2016; Johnson et al., 2017)

In summary, understanding and addressing these aspects can contribute to the successful adoption and adherence of serious games. In other words, by considering usability, relevance, engagement, personalization, social interaction, designers and developers can create compelling experiences that motivate users to play and adhere to the serious games.

Although not specifically designed for PsA, a multicenter randomized controlled trial was conducted to examine the effect of a serious puzzle game targeting implicit attitudes toward medication on adherence to DMARDs in patients with rheumatoid arthritis (RA) (Pouls et al., 2022). The intervention group played the serious puzzle game at their discretion for 3 months, while the control group received usual care. Data on game play and various questionnaires were collected. The primary outcome, DMARD implementation adherence, did not differ significantly between the intervention and control groups after 3 months. Secondary outcomes, including beliefs about medication and clinical outcomes, also did not show significant differences. The serious game was played frequently, suggesting it can be an effective channel for reaching patients, but it did not demonstrate an effect on adherence to DMARDs or clinical outcomes in patients with RA. Another study introduced a comprehensive application designed for the rehabilitation of patients diagnosed with first and second stage RA (Vargas et al. 2021). The application consists of modules for doctors and kinetherapists, along with a game module tailored to match the symptoms of each stage of RA. Its purpose is to facilitate hand rehabilitation in RA patients through the utilization of digital technology and multimodal interaction. The application underwent testing by a group of seven students, revealing that mental stress, finger and wrist fatigue, and physical exertion were generally insignificant in most cases.

From a technological perspective, serious games can also be enhanced through the integration of diverse sensor devices and technologies, such as those used for movement therapy/rehabilitation, hand and grip measurement, VR gloves, among others. For instance, ArthriKin is an application designed to monitor RA patient exercises and provide real-time feedback and corrections. It utilizes the Microsoft Kinect device to track body posture during daily exercises (Dorado et al., 2019). Another application focuses on supporting occupational hand therapy by estimating joint movement angles and using a neural network to determine 3D hand positions (Cejnog et al., 2019). In an experimental study, virtual reality combined with Leap Motion technology was found to significantly improve dexterity, flexion, extension, and ulnar deviation in patients with wrist and hand stiffness (Dabholkar & Shah, 2020).

Taking into consideration the aforementioned theoretical frameworks and current applications, iPROLEPSIS aims to introduce, for the first time, the development of an AI-adaptive personalized suite of serious games (AI-PGS) with the purpose of preventing inflammation in PsA patients. This innovative suite will provide support for various essential health aspects such as fitness, diet, mood, motor skills, and breathing. Some games within the suite will eventually incorporate biofeedback and sensorimotor art-based approaches to alleviate and manage stress, fatigue, and pain. This comprehensive approach intends to integrate novel technologies and personalized interventions to enhance the well-being of individuals with PsA.

Moreover, the AI-PGS design will follow a participatory approach, in accordance with the game design and co-creation principles, where HCPs, researchers, designer/developers, and PsA patients will be involved from the early stages of the game design.

3 User Research & Co-Creation Method

The iPROLEPSIS development process will follow a user-centered development process. It is based on the CAPTAIN Framework (**Figure 5A**) as was provided by the iPROLEPSIS Management Team. The CAPTAIN Framework is extensively described by Tessarolo et al. (2022). In short, the CAPTAIN Framework is a hybrid development approach, leveraging the concepts of Lean StartUp, SCRUM Agile and Design Thinking. The CAPTAIN development process is organized in following iterative cycles referred to as 'Sprints'. Each sprint has a

planned duration of about 12 weeks and consists of interdependent steps that might overlap and pursue clear goals and objectives.

The first concept that is adopted by the CAPTAIN framework is the **Lean StartUp Methodology**. It provides insights on when to change the direction of a product and when to persevere, reducing the waste of effort and time. The lean approach was adopted to deliver a functional prototype frequently enough to the stakeholder community. Hereby you can collect feedback timely and readjust the technology as needed. Secondly, the concept of **SCRUM** is integrated in the CAPTAIN framework. Scrum is a management framework that describes a set of meetings, tools and roles for efficient project delivery. It helps in organizing work across technical partners to collaborate towards delivering high value. SCRUM allows teams to self-manage, learn from experience and adapt to change. Lastly, **Design Thinking (Figure 5B)** is adopted at the first steps of implementation of the CAPTAIN framework. Design Thinking is a hands-on, user-centric approach to problem solving. This iterative approach is defined by the design thinking process and comprises 6 distinct phases⁸:



Figure 5 Product Development Processes identified of relevance to the iPROLEPSIS project. **A.** The CAPTAIN Framework (Tessarolo, 2022). **B.** The Design Thinking Method⁷.

1. **Empathise:** Conduct research to develop knowledge about what your users do, say, think, and feel. E.g., interviews, observations, surveys, grey literature, etc. The goal is to gather enough observations that you can truly begin to empathise with your users and their perspectives.
2. **Define:** Combine all your research and observe where your users' problems exist. In pinpointing your users' needs, begin to highlight opportunities for innovation.
3. **Ideate:** Brainstorm a range of crazy, creative ideas that address the unmet user needs identified in the define phase. Give yourself and your team total freedom; no idea is too farfetched, and quantity supersedes quality.
4. **Prototype:** Build real, tactile representations for a subset of your ideas. The goal of this phase is to understand what components of your ideas work, and which do not. In this phase you begin to weigh the impact vs. feasibility of your ideas through feedback on your prototypes.
5. **Test:** Put your prototype in front of real customers and verify that it achieves your goals.
6. **Implement:** Put the vision into effect. Ensure that your solution is materialized and touches the lives of your end users.

⁸ <https://www.nngroup.com/articles/design-thinking/> [Last visited on 17/03/2023]

3.1 General Approach

As described above within iPROLEPSIS the Captain Framework is followed with an increased emphasis on Design Thinking. The full development process that emerged from combining these approaches is indicated in **Figure 6**. Different groups of people are involved in each step of the process. Within this section the process and the participating parties are described. Basically, the process is divided in an Emphasising phase, of which the results are described in this deliverable, a Development phase that applies co-creation with all stakeholders in sprints, and finally User Testing to ensure that in native languages the digital health tools are properly understood and easy to use.

3.1.1 The process

The development process visualised in **Figure 6** is described here, step by step.

Step 1. Empathise

Focus Groups (FGs): Group interviews were guided by semi-structured scripts. FGs are conducted and analysed in native languages. More information about the set-up of the FGs is described in Section 0

Surveys: Meant to elicit more specific user needs and attitudes towards the application of digital biomarkers for PsA patients. To obtain a broader perspective of the opinion of the PsA patient population. More information about the survey can be found in Section 3.3.

The focus group and survey findings were used to create a **Patient Experience Map** and five different **Personas**. The goal of the patient experience map is to indicate where our DHTs might be able to help with improving their Emotional Wellbeing. Personas were created because they present information in the form of relatable individuals that are more memorable than mere numbers. Hereby, they improve the user-centred design process.

The following steps will be conducted in two separate trajectories. One development trajectory is set up for the miPROLEPSIS app development and one development trajectory is followed for the development of the Personalised Serious Gaming Suite. For each development trajectory, one patient co-creation group and one HCP co-creation group will be set up, leading to four co-creation groups in total.

Step 2. Co-Creation Session 1

The first co-creation session is meant to initiate the design sprints in the development process. The co-creation sessions will be performed with English speaking participants from the four countries with clinical partners.

Step 3. Define

Evaluate the knowledge that is obtained and decide upon development steps, requirements and content for the next design sprint.

Step 4. SCRUM Prototype Development

Technical team shall build the prototype as decided upon in the Define step. Scrumming will be applied to achieve the goal.

Step 5. Technical Testing

Technical team will test the prototype to make sure all functions work as they should, and no bugs are present.

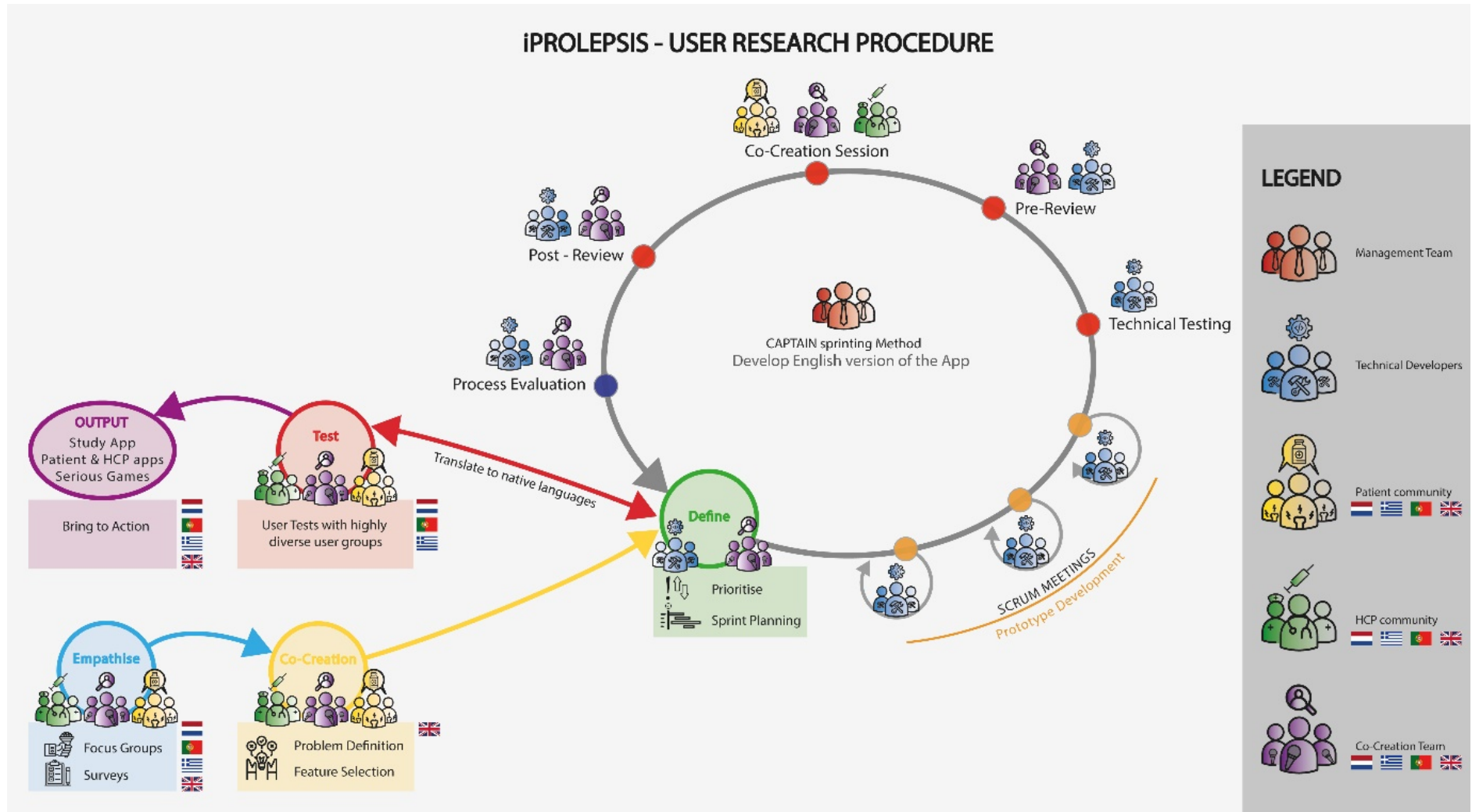


Figure 6 iPROLEPSIS User Research & Co-Creation approach, based on Design Thinking & The CAPTAIN Framework.



Funded by the
European Union

Step 6. Pre-Review

Technical team & Co-creation team will set an intent for upcoming co-creation session and will work out the best way to obtain the information and feedback needed.

Step 7. next Co-Creation Session

The co-creation team will conduct the workshops/feedback sessions with the patient or HCP co-creation group depending on the prototype developed. The co-creation sessions will be performed with English speaking participants from the four countries with clinical partners.

Step 8. Post-Review

Technical team & Co-creation team analysis of the results from the co-creation sessions.

Step 9. Process Evaluation

Technical team & Co-creation team review of the development process and examine if any steps/methods should be changed to improve the next loop.

GATE 1: Iterate Step 3-9 until satisfaction about the Digital Health Tools is achieved.

Step 10. User Testing

Once the DHTs are deemed satisfactory in English they will be translated to Greek, Portuguese and Dutch. User Tests will be set up to make sure that the DHTs are also understandable to the test participants, thus participants outside of the co-creation group. The exact amount of User Tests to be performed depends on the results of the tests. However, at least one session should be performed for each:

- PDPID App User Test in each country
- miPROLEPSIS Patient app User Tests in each country
- miPROLEPSIS HCP dashboard User Tests in each country
- Personalised Serious Gaming Suite Patient User Tests in each country

GATE 2: User Test results in native languages should be satisfactory before starting implementation of the DHTs.

Step 11. Implementation

Once the user tests confirm that the DHTs are ready for implementation they will be provided to the population. Users' satisfaction and acceptability will be assessed. DHTs that are developed for implementation:






- PDPID study app
- miPROLEPSIS patient app
- miPROLEPSIS HCP dashboard
- Recommendation system
- biAURA app
- Personalised Serious Gaming Suite (PGS)



3.1.2 The parties involved in the development process

Table 1 shows the different parties that are involve in the development process.

Table 1 The different parties involved in the development process.

Symbol	Name	Description
	Management Team	Team of people that will have oversight over the entire development process.
	Technical Developers	Teams that perform the technical development work of the Digital Health Tools (DHT). There will be 3 different teams: <ul style="list-style-type: none"> <input type="checkbox"/> App developers <input type="checkbox"/> Serious Game developers <input type="checkbox"/> Intervention developers
	Co-Creation Team	Team of people (1 person in each country) that will co-ordinate and manage the execution of the Design Thinking process including; conduction & analysis of interviews, surveys, co-creation sessions and user evaluations.
	Patient Community	Teams of patients that are involved in the participatory design process. There will be several teams: <ol style="list-style-type: none"> A. Focus group (FG) participants: From each country patients will participate in the empathise phase. Focus groups will be conducted in their native language. B. Co-creation group: From each country patient partners shall participate in the co-creation steps. These patients need to speak & read English as that will be the language applied during the development process. C. Test participants: From each country patients will participate in user-tests once the DHT are translated to their native language. It is important that these communities contain as much variation in types of people as possible.
	HCP Community	Teams of Healthcare Professionals (HCPs) that are involved in the participatory design process. There will be several teams: <ol style="list-style-type: none"> A. Focus group participants: From each country HCPs will participate in the empathise phase. 1-2 Focus groups will be conducted in their native language. B. Co-creation group: From each country HCP partners shall participate in the co-creation steps. The language applied during the development process will be English. C. Test participants: From each country HCPs will participate in user-tests once the DHT are translated to their native language.

3.2 Focus Groups Method

3.2.1 Set-up

Focus groups have become increasingly popular in health research for exploring what individuals believe or feel, as well as why they behave in the way they do (Rabiee, 2004).

The aim of the focus groups was to obtain the patients' insights on disease activity, disease management and care needs; and to empathise with their attitude towards digital biomarkers as to obtain future directions for digital biomarker development.

The focus groups were performed in four countries in their native languages. Purposive sampling was applied in the recruitment process. Patients were invited from several hospitals for this study by their rheumatologist if they were diagnosed with PsA over a year ago. In the first year after diagnosis patients have had plural encounters with their rheumatologists and should have established some self-management strategies. During focus groups men and women from different ages were together in the discussion.

A qualitative research approach was adopted. Semi-structured focus group discussions, based on the Common-Sense Model of Self-Regulation (Leventhal, 2016) were conducted through 60–90-minute video conferences. Interviews were moderated by one researcher per country and various observers, following the same interview guidelines. At the start of the focus groups, some general rules were explained to create a safe and confidential environment for the focus group. The main questions related to the following topics; their personal experience with their disease activity; their disease management and coping mechanisms; their care needs and preferences and their attitude towards digital biomarkers. Member checks on the script were performed by our patient partners. The English version of the interview script is attached in Appendix I Focus Group Script English Version.

All interviews were audio-recorded and transcribed to verbatim using automatic speech recognition software (Amberscript⁹/Happy Scribe¹⁰/Microsoft Office¹¹) and manual editing.

3.2.2 Analysis

Data was analysed with the Atlas.ti¹² qualitative data management software. An iterative structured abductive coding process was adopted to move from individual codes to constructs (Boeije, 2009; Thompson, 2022). For initial coding the following sensitising concepts were used:

- Disease Activity
- Coping Strategies
- Care Experiences
- Attitude & Beliefs about Digital Biomarkers

Translation is one source of threat to the accuracy of cross-cultural, cross-language qualitative research, reducing its validity (Pinto da Costa, 2021). Therefore, untranslated data was analysed, with coding in English. The first version of the codebook was established from the Dutch Focus groups and was then evaluated and adjusted on its use for the Greek, English and Portuguese focus groups. English transcripts were coded by all coders to assess the agreement and application of the codes by different researchers.

⁹ <https://www.amberscript.com/en/>

¹⁰ <https://www.happyscribe.com/>

¹¹ <https://support.microsoft.com/en-us/office/transcribe-your-recordings-7fc2efec-245e-45f0-b053-2a97531ecf57>

¹² <https://atlasti.com/>

3.3 Survey

To obtain more specific input from a broader population of PsA patients a survey was created. The survey consists of 5 sections dedicated to:

- **Section 1:** Demographics & Technological experience
- **Section 2:** miPROLEPSIS patient app - Content and Appearance.
- **Section 3:** BiAURA app – preferences
- **Section 4:** Personalised SeriousGaming Suite – Content and Appearance

The English version of the survey can be found in Appendix II iPROLEPSIS Patient Survey.

The aim was to collect responses from 100 patients per country. Descriptive statistics were used to analyse the user preferences of the participants. Some of the results have been used for triangulation with the focus group findings.

4 User Research & Co-Creation Results

4.1 Progress

4.1.1 Ethical Approvals

To conduct the user research some decisions were made about the ethical approvals.

- ✓ Ethical approval for conducting FGs was needed for GR and PT, was waived in the NL and not requested in the UK due to its time extensive procedure. For the UK it was decided to talk with patient advocates so that ethical approval was not required. This however meant that their results can be analysed, but no direct quotations can be used in publications.
- ✓ Ethical approval was not requested for the survey. Data collection was anonymous no personal details were collected and no sensitive questions were asked.
- ✓ Co-creation sessions will be conducted with patient partners of the project; thus, no ethical approval is required. However, the Ethical Approval will be obtained for the user tests in native languages.

4.1.2 Conducted Research

Focus groups and a user survey were conducted in each of the participating countries up to Month 6 of the project. The user survey was disseminated through channels in **Table 2**. The participation numbers reached during this process are indicated in **Table 3**.

Table 2 Dissemination overview

Country	Channels	Reach
UK	<ul style="list-style-type: none"> □ Patient Associations: <ul style="list-style-type: none"> ○ Psoriasis Association ○ PAPAA □ Facebook groups: <ul style="list-style-type: none"> ○ PsA Support UK 	4000 members
PT	<ul style="list-style-type: none"> □ Sociedade Portuguesa de Reumatologia <ul style="list-style-type: none"> ○ Linked-In ○ Facebook □ PsO Portugal (psoriasis patient association) <ul style="list-style-type: none"> ○ Facebook ○ Instagram ○ Email to associates □ Liga Portuguesa Contra as Doenças Reumáticas (rheumatic disease patient association) <ul style="list-style-type: none"> ○ Facebook ○ Instagram 	2372 followers 14000 followers 12000 followers 1187 followers 948 receivers 14000 followers 239 followers
GR	<ul style="list-style-type: none"> □ Hellenic league against rheumatism (ELEANA) <ul style="list-style-type: none"> ○ Facebook □ Branches of ELEANA across Greece □ Psoriasis patient support association "kalypso" <ul style="list-style-type: none"> ○ Facebook □ E-mail list of patients with PSA from outpatient clinic of Hippocraton Hospital □ E- mail list from private clinics 	12000 members 11 branches
NL	<ul style="list-style-type: none"> □ DEPAR cohort Newsletter email □ Focus group participants & patient partners □ Patient Associations: <ul style="list-style-type: none"> ○ ReumaZorgNederland Website & Newsletter ○ ReumaNederland Website ○ Psoriasis Patiënten Nederland □ Facebook groups: <ul style="list-style-type: none"> ○ Groep van Artritis Psoriatica ○ Lotgenoten contact leven met Reuma ○ Leven met Reuma en Artrose 	502 receivers 32 receivers 498 members 532 members 1100 members
General	<ul style="list-style-type: none"> □ iPROLEPSIS Linked-In post □ iPROLEPSIS Twitter post □ iPROLEPSIS Facebook post □ IPROLEPSIS Website 	

Table 3 Numbers of participation

Research Activity	Country	# Patients involved	
Patient FGs	UK	5	39
	PT	5	
	GR	7	
	NL	22	
Patient Survey	UK	89	299
	PT	48	
	GR	31	
	NL	131	
Total # of patients involved		338	

4.2 Focus Group Results

This section presents the key outcomes derived from the Patients' focus groups. In total 9 focus groups and 1 one-on-one interview were conducted in the 4 different countries. The demographics are described in **Table 4**. Of the 39 PsA patients 50% of the participants were Dutch, the mean age of the participants was 51 yrs [min:29, max:78 yrs] old and 51% of the participants were female. This is in line with the prevalence of the disease which is highest among patients 30–60 years of age and affects men and women equally (Fitzgerald, 2021). The mean time since diagnosis was 13 years [min:1, max:44 yrs].

Table 4 Demographics Focus Groups

	UK	NL	PT	GR	Overall
Focus groups (N)	2	4	2 1 Interview 1-1	2	10 1 interview 1-1
Participants (N)	5	22	5	7	39
Age (years, mean +sd)	55 ± 14	52 ± 11	46 ± 10	47 ± 13	51 ± 12
Gender (%♀)	60	55	60	28	50
Time Since Diagnosis (years, mean, sd)	23 ± 16	9 ± 9	13 ± 7	19 ± 9	13 ± 12

By means of thematic analysis and abductive coding a codebook was developed. This codebook can be found in Appendix III Focus Group Code Book. By applying these codes to the original transcripts 4 different themes were identified by the 6 coders: PG (NL), JL (NL), DP (GR), KT (GR), MR (PT). The identified themes are discussed below. **Table 5** to **Table 8** provide overviews of the established (sub)themes with corresponding illustrative quotations.

4.2.1 Theme 1 – Disease Activity

Patients experience a wide range of symptoms with varying severity over time. According to most patients, they are never completely symptom free and always having some residual complaints. If patients are in an acceptable symptom state, they mention that life simply becomes easier. Pain and fatigue are reduced to acceptable levels, people feel more energised, movements become more supple, and they are capable and more eager to engage in various activities such as low impact sports or social events. They do not notice these improvements immediately but notice at the end of the day *“Oh, I have been doing well today”*. But even in low disease, patients cope with residual disease activity, such as pain or fatigue on a daily basis.

Disease activity highly fluctuates; one day they can do everything and then in a fortnight their disease is acting up again. For some patients these fluctuations are rapid, for others these flare ups are more gradual over days. During a flare up patients mentioned the following symptoms as indicated in **Figure 7**.

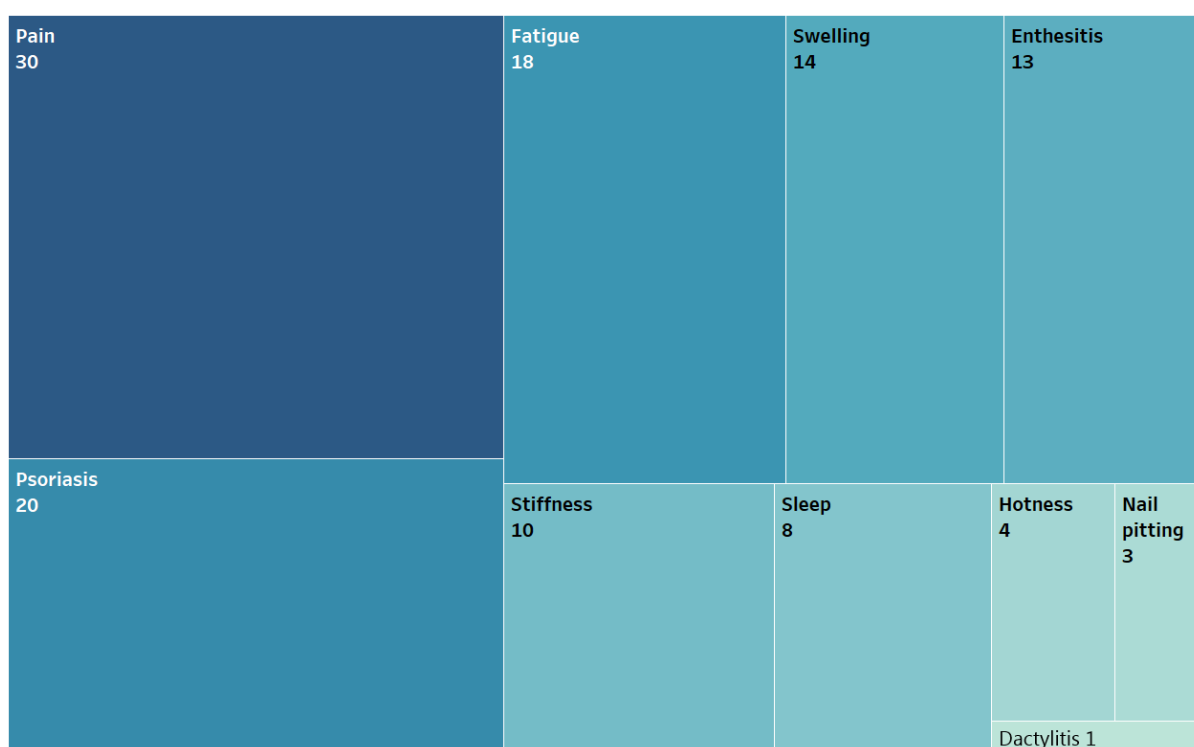


Figure 7 Word Tree map based on the symptoms expressed by participants of all focus groups. The numbers and the size of the blocks indicate how many participants mentioned this complaint at least once.

Pain, fatigue, swelling are symptoms that are mentioned limiting the patients’ ability to execute daily functions. They experience difficulties getting down the stairs, getting a good night’s sleep; tossing and turning in bed, loss of grip strength, changes in the way they move such as limping, waddling or walking slower. Being limited in your abilities causes negative emotions to play up indicated by patients as ‘frustration’ or ‘sadness’. These mood changes are often what gives the increases in symptoms away to the people in their inner circle and may affect their social relationships.

Participants learn from closely monitor the symptoms in their own bodies. Over time they identify potential triggers for inflammation. Weather changes were often indicated as the cause of symptom increase as everyone recognised this phenomenon in their own disease. However, the weather conditions that were identified as best were highly personal.

Environmental conditions indicated of influence are temperature, humidity, air quality and hay season. For this reason, patients indicate that their complaints change along with the seasonal changes. Other triggers of which patients were all in agreement that they have significant effect are physical overexertion (mechanical stress) and stress (mental or psychological). Furthermore, patients agree that lifestyle factors may play a part as well. Lifestyle triggers that were mentioned were alcohol use, smoking, not enough sleep and food intake. With regard to food intake sugar, caffeine, fat, E-numbers, red meat, gluten and sour fruits were indicated as potential triggers by one or more patients.

Table 5 Illustrative quotations corresponding to Theme 1

Theme 1 – Disease Activity	
Sub-theme	Quotation
Low Disease Activity	<i>"That I become more energetic, that I move more. I still think to myself: 'Yeah, I'm not doing especially well or anything.' But those around me notice that I seem fitter, so to speak. Then you think back: 'Ah yes, maybe so, maybe so.' It's not 100 percent, so that makes it a bit complicated."</i>
	<i>"Not a day goes by that I don't have stiff fingers, but I do try to do everything I want to do and that's not always easy. But okay, we manage."</i>
	<i>"I'm never absent of pain but you manage pain differently. It's strange if I'm not in pain I'm wondering why I'm not in pain, if that makes sense."</i>
High Disease Activity	<i>"My indicator is my skin. Because way before the joints will start to flare up, I'll notice a rash, a new rash on my arm or in a crease somewhere, and I'm like, oh, okay, I didn't even notice there. It didn't even itch and then give it a week and then the joint pain will be there or there'll be more significant psoriasis rashes. So, yeah, for me, the indicators are more the skin just seems to be that much quicker to respond."</i>
	<i>"For me, 100% as the morning stiffness. So, if I'm just going to have a quick sort of burnout quickly flare, there's just going to be a problem for a couple of weeks. I don't get all the morning stiffness. I just deal with the pain, and I can work with pain. I've dealt with that most of my life. But when I get up and I fill up and hit by a truck every single morning, I know that that's going to be a real slow, long Burnham one."</i>
Effect of Symptoms	<i>"The frustration is created because you get those restrictions imposed again from what your body can or can't do. I think they do notice that from time to time at home. And then not directly because I am complaining about what is bothering me but in the way of how you are present."</i>
	<i>"With me particularly, my sleep is always very disturbed. Even when I'm not in a lot of pain, I'm quite uncomfortable all the time, so I'm always tossing and turning. Well, I know if I'm having a bit of a flare because my sleep pattern gets really bad."</i>
	<i>"I didn't realise I did this, but when my legs and my feet are aching and I therefore get really tired from walking, I can't walk in a straight line apparently. I'm sort of walking alongside my husband and I start drifting into him and just nudging him and bumping into him, and he knows it's because I'm tired"</i>
Triggers	<i>"I have actually denied for quite some time that it is also determined by the weather. When it's humid or when it gets colder. Towards the end of the year, I'm usually back at the physical therapist and then towards spring, I can pick up some things and get going again."</i>
	<i>"I have good days and not so good days. But I have also noticed that when I am very sad or my emotions are high, then I also get more complaints. I get joint pain right away."</i>

	<i>"I was stressed, and it just hit me, then it came out, which was probably already in there, the PsA."</i>
--	--

4.2.2 Theme 2 – Coping

After receiving the diagnosis PsA patients indicated that this disease is marked by trial and error. They have to get to know their body and the manifestations of their disease. They need to develop the appropriate coping mechanisms that are in line with their personality and learn how to deal with uncertainties and limitations. It is all about finding balance in life which is hard and even after a long time with the disease. Over time, they still make occasional mistakes. Moreover, patients keep coming across new activities they are incapable of, resulting in life marked by loss and adjustment. They need to learn how to accept their new selves with the disease and its' limitations.

4.2.2.1 Behavioural adaptations

From the transcripts it emerged that during times of exacerbation participants make several behavioural adaptations, as listed below:

Changed activity patterns.

- **Time spent in bed.** participants rise earlier than normal because they wake early from pain and stiffness or because they need additional time to prepare for the day. It was also stated that during very intense flares participants become unable to get out of bed and will stay there the entire day. Participants also have the intention to go to bed earlier, but state that this is easier said than done.
- **Transportation.** participants allow themselves to take, for example, public transportation or the car instead of walking. Others indicate that they will work from home removing the travel time they normally would have.
- **Resting time.** participants limit the number of activities for the day and increase their resting time such as relaxing on the couch.
- **Social Activities.** participants engage in fewer social activities. Because they need rest and because of feelings of shame. The shame can be caused by the visibility of the complaints, but one patient also mentioned not attending a wedding since he could not fit into his proper shoes. Participants also indicated to turn inwards reducing their motivation to engage in social activities.

Physical activity (PA).

- **Decreased PA.** unable to participate in any kind of sport or change high impact for low impact sports; reduced walking distance, unable to carry loads; benchmarking the distance that can be walked or cycled, and the changed manners of transportation; unable to perform certain activities and therefore omitting them.
- **Shortened intervals between activity and rest.** participants stated to take more short breaks during their activities.
- **Execute movements differently.** participants compensate for the loss of function from the affected limb. Hereby, movements will defer from the movements during times of low disease activity.

Eating Habits. In general participants indicated that during times of flare their appetite remains normal. However, one patient mentioned turning to food ordering due to the inability to get to the supermarket. Another admitted to being an emotional eater affecting her food intake during a flare.

4.2.2.2 Mental adaptations

Besides making changes in their behaviour patients also have to adjust to the mental impact the disease has on them. From the focus groups there are several mental adaptations that need to be developed over time. In short, patients need to learn how to deal with grief, how to deal with residual symptoms and how to deal with insecurities. These subthemes are illustrated in **Table 6** and further explained in the patient experience map in Section 0.

4.2.2.3 Intervention

During times of flare patients apply different kinds of intervention to get the disease back under control. These interventions envelop medication intake like prednisone injections and pain killers, visiting physical therapists for exercises and alternative therapies like taking cannabis oil, meditation or acupuncture. It was mentioned that during mild flare ups, it can be helpful to power through the pain and pry your own body loose with some movements. It takes a lot of dedication to do so, because it hurts, but it will be helpful for the rest of the day.

4.2.2.4 Prevention

Participants also indicated that they adopt changes in life for the purpose of keeping their disease under control. These changes can be of different categories, such as:

Dietary restrictions. Eating only unprocessed food, avoiding certain E-numbers and limiting caffeine, alcohol, fat, sugar, etc. intake.

Physical activities. Avoidance of certain activities (e.g., cycling, running), changing sports from high impact to low impact and benchmarking the duration, but also trying to remain active as much as possible within the ranges that are dictated by the disease. Furthermore, activities are scheduled carefully since big (social) events can take a large toll. Therefore, resting time beforehand and afterwards must be factored in.

Emotional control. Working actively to get more grip on their emotions, as being emotional tends to negatively affect the intensity of a flare up.

Stress avoidance. Trying to reduce stress in life as much as possible.

Alternative therapies. Participants perceive medication as junk but are aware they are not able to go without it. Still, they keep looking for alternative therapies that may help them get more control over their disease. Alternative therapies with the aim to prevent flare ups are; the Wim Hof method, Meditation, autogenic training and self-management training.

In general, actions that are taken to prevent flare-ups often come with sacrifices that need to be made in the personal lives of patients and their surrounding people. Participants brought up how they had to let go of career paths or promotions because of stress or physical workload. In some cases, participants also adjusted their home surroundings, finding for example a new home without stairs or a car with automatic drive.

Table 6 Illustrative quotations corresponding to Theme 2

Theme 2 – Coping	
Sub-theme	Quotation
Trial & Error	<i>“I think the difficulty too, with the flare up, is what do you try? I mean, there isn’t a great deal of advice out there and PsA is not well known.”</i>
Behavioural Changes	<i>“I’ll have to get up an hour earlier for work. I’ll have to have a long, hot bath. I’ll have to do all the walking before work. Whereas if it’s just like a regular mini flare, I don’t know what you want to call it, I can power through those, they’re just pain.”</i>
	<i>“In terms of behaviour changing, is that option to do I then because I work in a school that’s near a tube station in London, so it’s about a 15 minute walk there and I normally do that, but on the days where I know this is just stiff and it’s not happening, I’m always going to give myself permission to get the bus because it’s just a little bit easier.”</i>
	<i>“It’s like I almost benchmark myself, if that makes sense. So, I won’t go do that thing in case I can’t walk as far as I used to, or I won’t go to the gym because I’m going to compare to what I used to be able to do. So, you end up just saying no to everything.”</i>
Mental Changes	<i>“Well, because it’s like a light switch. The minute I go into a flare, I start going inward and I have to try and overcome that.”</i>
	<i>“I just have to learn to deal with it. Then I just have to accept that it is what it is and enjoy the things I can do. Well, that’s quite a difficult process.”</i>
	<i>“I used to do a lot of sports and then muscle soreness is kind of a reward of, ‘hey, you’re doing something right.’” And that feeling now needs to have a different mindset.”</i>
Interventions	<i>“The GP did actually recommend acupuncture, so I booked it to see if it helps. Because the GP said it’s supposed to be very good for painful jaws.”</i>
	<i>“I use cannabis oil a lot when I feel really bad.”</i>
	<i>“Then maybe if it’s really bad, I’ll take some painkillers but obviously I’m on drugs to stop the inflammation anyway.”</i>
Prevention	<i>“It usually has something to do with E numbers and I know pretty much what products contain them. For example, in coffee you can put syrup from hazelnut or something, I know certain brands that I just have to stay away from. Because then it goes wrong.”</i>
	<i>“I spent such a fortune on complementary and alternative stuff. I was determined and I don’t drink, and I did all the right stuff and don’t eat the tomatoes and don’t eat this. And I didn’t listen to the experts, and it was a colossal mistake. I think it can be complementary, but it shouldn’t be a substitute. It’s not an alternative”</i>

4.2.3 Theme 3 – Care Experience

In general, patients express that they are satisfied with the care that they receive. Depending on their disease activity the frequency of consultations is altered as fits with their needs. In the UK one topic of discussion was the move towards patient-initiated care which causes anxiety because of long waiting lists limiting the access to care. Patients were afraid of not being able to schedule check-up appointments.

4.2.3.1 Needs

Patients visit their rheumatologist for routine consultations with various aims. Most of them look for affirmation. Affirmation that the complaints they are experience are indeed due to their PsA; affirmation that adverse drug reactions are not taking place, so they continue their

medication safely; and affirmation that there is no unnoticed active disease going on. Moreover, for many it is an obligatory moment of self-reflection, where they can take a pause to evaluate their disease evolution over the past couple of months. Together with their rheumatologist they make the necessary tweaks to medication or get additional information on treatments or complaints. Additionally, patients want to know what to expect for the future regarding disease activity and daily functioning and to remain up to date with new therapies or treatment options. Lastly, patients express a need for advice with respect to alternative therapies and lifestyle adjustments that can help them further increase their disease activity and perhaps let them taper their medication further. This latter need is currently unmet most of the times.

Participants only call in to the rheumatology clinic in between visits when they experience symptoms that significantly impact their quality of life or if they become anxious of permanent damage. In most cases, they already know what intervention will be prescribed. Some patients learned this the hard way since they were hospitalised previously due to exacerbations. But many of the flare ups that patients are experiencing are not shared with the rheumatologists immediately. They either await their appointment or try to self-manage their symptoms by using over the counter painkillers, nonsteroidal anti-inflammatory drugs, (NSAIDs), and adjust their physical load.

During the consultations, participants want to be treated with respect. They like their doctors to understand what they are coping with, and they need to be taken seriously. Most patients expressed that the patient-doctor relationship involves mutual interaction and when you find a doctor you trust, you are halfway through on the right track. One Portuguese patient stated that in order to move the focus from medication to quality of life, she had sought care in the private instead of the public sector.

4.2.3.2 Tele-Consultations

Attitudes towards the use of teleconsultations differed between participants, but not much between countries. Participants all experienced remote consultations during the COVID-19 time and based their opinion on these experiences. Only one Portuguese participant indicated that his/her clinic did not offer telephone consultations.

The main benefit of teleconsultations mentioned is that it saves time. This benefit was mostly expressed by participants that have had the disease for a longer period, claim to be confident in monitoring their own disease activity, established functional coping mechanisms, and are able to verbally express their complaints. For them, routine consultations are not always as useful as they would spend their consultation time simply chatting with their rheumatologist. In Greece, there is also a possibility to e-mail your medical specialist. Participants liked this form of interaction since they experienced that doctors have more available time to thoroughly read and respond to emails than to phone calls.

The downside of teleconsultations is the missed opportunity to be in physical contact. Some participants indicate that teleconsultations do not work for them. Some crave personal interaction, some state that during phone conversations they do not express the full extent of their complaints (they downplay their symptoms). These patients indicate that it is a necessity for the rheumatologist to observe them, just walking down the hall and do physical examination of the joints.

During the focus groups some conditions for tele-consultations were expressed. First, the Portuguese patients expressed that remote consultations could be a convenient option, but only for specific things such as clarification of minor doubts, test results, routine follow-up when in low disease activity, and renewing medication prescriptions. Participants from other countries agreed that these consultations only work if your condition is stable, there is a high

level of trust between you and your rheumatologist and if anything is up you should be able to schedule an appointment quickly. Especially the latter is indicated as a main barrier for remote consultations in the UK and Portugal. In the Netherlands a participant also indicated that if we were to move to remote consultations that the fact that you need to pick up your medication at the hospital anyways is inconvenient. The latter is due to the health insurance policy in the Netherlands that requires expensive medication to be provide by the hospital rather than the pharmacy.

Table 7 Illustrative quotations corresponding to Theme 3

Theme 3 – Care Experience		
Sub theme	Quotation	
Needs	Understanding	<i>“The doctor always wants to focus on what hurts where and how bad is the rash and how has it changed. So, for me, the importance of my appointments is for them to understand what the impact of my disease is on me. I want them to know what my acceptable sort of desired outcomes are because they never ask. And it really bothers me. There is no point asking me how much it hurts if you don't know what I'm trying to achieve.”</i>
		<i>I feel that sometimes physical therapist and GPs just don't get it very well. Then I think: “yes, I can feel what is happening in my body.” And then you go for a visit and they say: “no, no, that can't be it, that has nothing to do with the rheumatism. It's just overexertion.” I really do get tired of it.</i>
	Affirmation	<i>“I think it's probably like stability. Has anything changed? Is it still the same and everything's okay and the mark is still within range and it's always a bit high, but I think it's that sort of stability and predictability”</i>
	Reflection	<i>“More checking to see if it's going well and if there is something else I should do. I can imagine that at a certain point, in terms of medication, it is also good to start tapering, because in the end it is not useful to continue with this forever.”</i>
		<i>“It's usually whatever I usually go armed with. I need to talk about this or this that's bothering me at the moment because every six months is usually something that's really bothering you at the time. And I find the problem is with six months, you don't feel like it's a serious if something starts playing up, you don't feel like it's serious enough to just contact them and say, I need to be seen now.”</i>
	Future Directions	<i>“At the beginning, I was like: ‘What can I expect. Can I expect things to improve, or not? Is this what it is?’ You have to learn how to deal with that. So that I discussed thoroughly with my rheumatologist, which I find important.”</i>
Advice	<i>“Advice is primarily focused on medication. It makes sense because that is how our healthcare system works. However, what I am looking for is; what else can I do to make sure my body functions better?”</i>	
Tele-consultations	Trust	<i>“My doctors know me. They know me personally. They know me well, how I react to stuff. if I go in and talk about the aches and pains and things and this going wrong and that going wrong, I'm not in a good place. That's one of the reasons why I think video consultations or phone consultations only work if you have real trust.”</i>

	Benefits	<i>"In COVID-19 time everything went by phone and I was actually fine with that too. Now coincidentally tomorrow I'm going to the hospital again. But anyway, then I am going to ask if next time it can be done by phone again. If I don't have any complaints that saves a lot of time, from both sides."</i>
	Drawbacks	<i>"I have the idea that when you consult per phone, as we did during COVID times, I say too quickly: "no, no, it is going well." Whilst if I were sitting in front of him, he would have noticed that I am not."</i>
		<i>"I find it insufficient. Insufficient because, at a time when the disease starts to become more active, we can hardly get an appointment"</i>

4.2.4 Theme 4 – Digital Biomarkers

The last theme identified from the focus groups is that of digital biomarkers. The participants showed a willingness to experiment with smartphone apps or wearables for activity tracking, although some of them were unfamiliar with these devices. The attitudes of the participants ranged from curious to sceptic. Findings from this Theme were used to create Personas in Section 4.2.6. With the participants potential benefits and drawbacks of digital biomarkers were discussed.

4.2.4.1 Benefits

Learning on a personal level. As was previously addressed under the Theme Coping, patients are forced to learn about their disease by trial and error. Participants stated that by means of digital biomarkers they may be able to learn from experience more easily as the digital biomarker would provide personal insights. This can also help them to identify potential triggers and adequately respond to changes in disease activity and so reduce the impact of a flare.

Learning on a macro level. By conducting research and collecting many sources of data we could learn more about PsA in general. Hereby participants can help future generations to receive early diagnosis, tailored monitoring and tailored treatments

4.2.4.2 Drawbacks

No personal gain. The participants that indicated that digital biomarkers would not be of added value to them feel they have a good understanding of their body and have already found the appropriate coping mechanisms. They do not expect a digital biomarker to provide any further insights they haven't already obtained.

Low trust in technology. Some participants did not believe that technology could ever capture the full extent of their disease. They fear that by the implementation of these digital biomarkers, they would have to defend their complaints to their healthcare professionals even more.

Psychological impact. Participants warned of possible psychological side effects from the implementation of digital biomarkers. They gave several implications. First, gaining too much insight into what is negatively affected by your PsA may be very depressing. Participants already experience quite some grief and would not want to add to that. Moreover, a participant indicated probably becoming scared of getting a flare if the data indicated changes. This expectation to feel worse again may negatively affect emotional wellbeing compared to the situation when unaware of what is going to happen. Hereby, measuring everything can also add to stress where patients indicated to be susceptible to the digital biomarker starting to control their life.

4.2.4.3 Terms

Purpose. Patients emphasised that the intention of digital biomarkers should not solely be to replace hospital visits. Participants are willing to collect and share their data if there is a clear value proposition. This means the data should be used to improve care either for them personally or for other PsA patients.

Validity. Patients' belief it is imperative there is a strong relation between the data, the findings and PsA. There is value proposition if the algorithms accurately detect flares or present relevant features to measure disease activity better. Patients do not want to receive false positive detected flares, but also do not want to defend themselves if their experience deviates from the processed data. For this reason, some patients expressed concerns in sharing the data with their healthcare practitioners, fearing the power this information might have on treatment decisions.

Privacy. Overall, there were not many privacy concerns. Mostly, participants trusted that if a digital biomarker is provided by the hospital, it will comply with all rules and regulations that are in place for data security. However, patients are aware that the data collected can easily be used in malicious ways causing some reservations towards the concept.

Usability. It was stressed that the measurement tool should fit into the lives of the patients. They like passive unobtrusive data collection, for example not turning on a device each time they go for a walk or take always their phone with them. The digital biomarker results should be easy and interpretable by the patients.

4.2.4.4 Preference Differences

Intrusiveness. Patients had different preferences regarding the level of intrusiveness of the digital biomarkers in relation to disease management. On the one hand, there were patients that would like to receive warnings of flare and warnings of overexertion. They believed that these reminders could help them with settings boundaries and remind them to take rest. On the other hand, there were patients that did not want to be reminded of their disease on a daily basis. Although some patients stated that they would like to receive weekly or monthly overviews.

Tracking. Patients mentioned various disease features they would like to track as shown in **Figure 8**. Most of them would like to monitor pain levels, energy levels, sleep and physical activity. But also temperature of the joint, swelling and skin manifestations were mentioned. The assess impact of other triggers they would like to monitor the impact of weather and stress, for example.

Own input. Patients differed in their views on the use of questionnaires. In general, participants felt that inserting their own experience is needed to make sure that the algorithm knows this. This is commonly done by using questionnaires, yet one should be aware that there are also patients that strongly dislike questionnaires and won't fill them out. If we were to implement this, these questions need to be short-multiple-choice questions that only takes very little time to fill out.

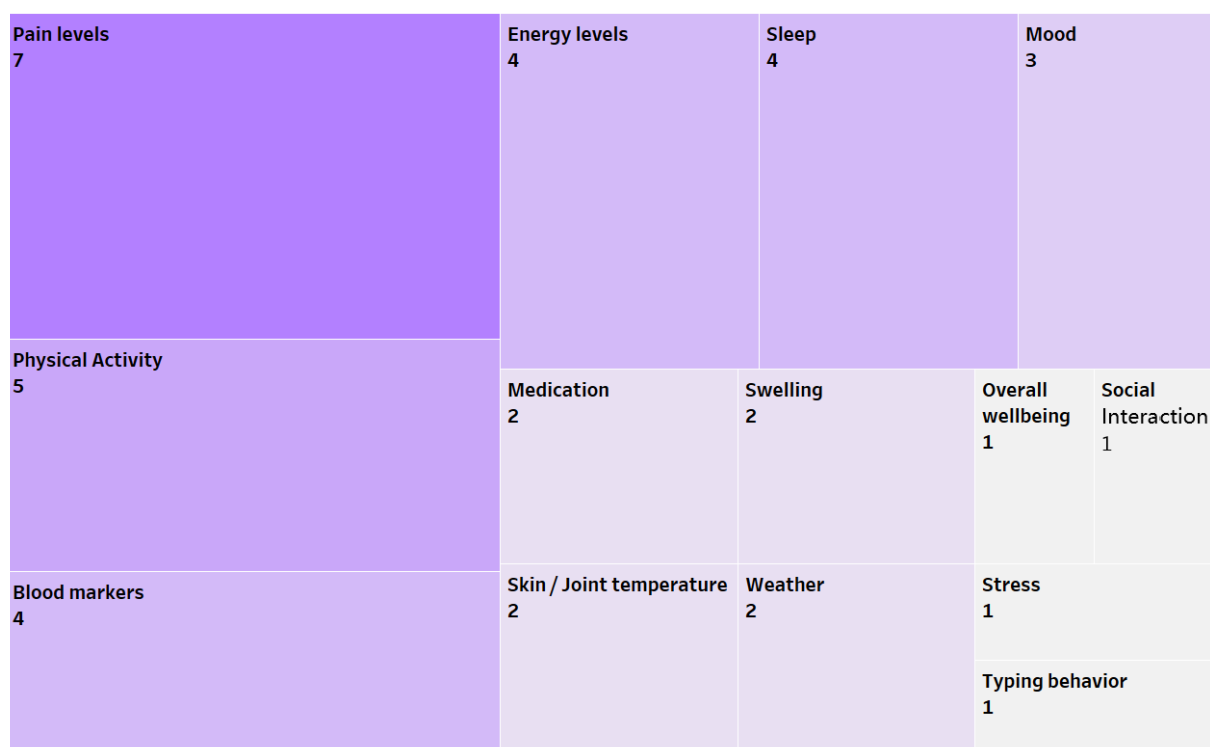


Figure 8 Word Tree Map based on items that were mentioned by participants in the various focus groups. The numbers and size of the blocks indicate in how many focus groups these measures were suggested.

Table 8 Illustrative quotations corresponding to Theme 4

Theme 4 – Digital Biomarkers	
Sub-theme	Quotation
Benefits	<i>“Then you can probably judge for yourself; ‘in what situation does that happen? Can I do something with that?’.”</i>
	<i>“We are talking still at the micro level, so in the sense of what does it mean to me this app. Conversely, it can, of course, also be done on a macro level. For scientific evidence in that sense. I think that can be very interesting.”</i>
Drawbacks	<i>“On the other hand, I think, “after 18 years I know how it works.” I know when I have more symptoms and I know when I need to take it easy. So, I don’t know if that’s going to add anything valuable for me.”</i>
	<i>“I’d be a bit concerned about psychologically. I mean, think, oh, I’m going to be bad, I’m going to be bad.”</i>
	<i>“I’m all for the data, I’m all for both parties having access to it, I’m all for having it form and part of treatment decisions, but it can’t be the be all and end all like blood tests currently are. I go and have a blood test. I see your blood test looks fine. All bets are off on any changes. So that’s my big fear, is what it doesn’t show.”</i>
	<i>“I also don’t like the idea that when I have a quiet week, I immediately have the rheumatologist on the phone saying, “gee, what’s the matter? Has your PsA flared up again?” Then I would think, “yeah, I just don’t feel like doing anything for a week. That’s okay for once.”</i>
Conditions	<i>“It would also help a lot to understand the evolution of the disease, and what could also cause a crisis, because there are situations that sometimes trigger a crisis, and it would also help us, the patients, to understand what we could change, what we could do, to minimize the pain, and also the doctor to have a record of these situations.”</i>
	<i>“Digital health platforms have the potential to be very useful, but it is also important to ensure the quality of the information available. I have tried a few platforms related to my condition, and my experience has been mixed. Some have been very helpful,</i>

	<p><i>with features such as symptom tracking, disease education and a supportive community. However, others have been less reliable and have not provided relevant or accurate information.</i></p> <p><i>"I don't even want to think about being measured every day. Do I then have to put on or turn on a device or something like that every day? Will it be something like that? I would find that very annoying."</i></p>
Preferences	<p><i>"Yes, a kind of alarm system so to speak. If through that data it becomes clear that you are overexerting yourself you get some kind of warning: "hey, It's not inflammation yet, but you're doing too much. Be careful, because if you continue it's going to inflame."</i></p> <p><i>"I would like to see information about daily symptoms, such as pain, joint stiffness and fatigue. It would also be useful to have a record of daily activities, such as exercise and sleep quality."</i></p> <p><i>"It's confronting you know. It's really confronting because in the questionnaires they really ask; how do you walk up a staircase, indicate from zero to ten, and then I think, "oh, man." This and that doesn't work either."</i></p>

4.2.5 Patient Experience Map

PsA has a great impact on the life of those affected. Emotional wellbeing is highly related to the experienced disease activity fluctuating over time. In the Patient Experience map (Figure 9), we used the quotes from the focus group on Emotion, Mental Adaptations and Disease Activity and related this to the different stages of disease identified in the Healthcare Touchpoint Diagrams in Section 2.1. The quotes underlying these curves are indicated in Table 1.

The goal of this figure is to empathise with our end users and indicate where our Digital Health Solutions might be able to help with improving their Emotional Wellbeing. The curves shown are very general curves based on the commonalities patients describe during the different stages of disease. It needs to be stressed that all PsA patients are unique, and their experience depends on disease activity, their personal lives, time they need to adjust and their personalities.

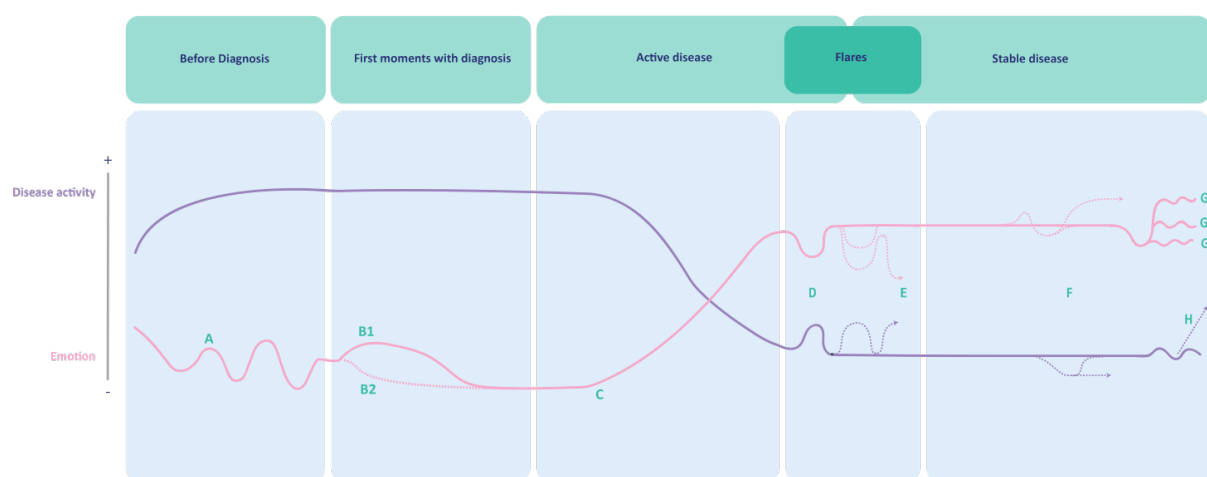


Figure 9 Patient Experience Map. The level of disease activity is indicated in purple. The level of emotional wellbeing in pink. Letters indicate specific fluctuations which are described in the text.

4.2.5.1 Curve of Disease Activity

As shown in figure 9, symptoms are present before diagnosis and emotional wellbeing is already low (point A). It can take quite a while before the PsA is eventually diagnosed by a rheumatologist. The rheumatologist initiates treatment (point B) of which it is known that it can take up to three months before a patient will notice a decrease in disease activity. Finding the

proper medicinal treatment is a process of trial and error, but over time the medication should help decrease the disease activity of the patient. Some patients will be relieved after getting the diagnoses (point B1), while others did not expect that something serious was going on (point B2). The point where medication starts to have effect is indicated in point C. In general, patients will always experience some residual disease activity such as pain and fatigue, as appeared from the focus groups. That means that they almost never return to their health state before diagnosis.

After medication kicks in some patients are stable while others will stay at higher levels of disease activity. Over time everyone will experience exacerbation of disease which can range from small flare ups that will disappear by itself to extreme exacerbations that can end up in hospitalisation. These flare ups are illustrated by the curves at point D and E but can occur at any point in the disease activity curve. After a flare, depending on the extremity of the exacerbation, patients will have added residual disease activity afterwards.

Point F illustrates how patients with stable disease can actively participate in decreasing their disease activity. This is done by applying trial and error, getting to know your own body over time and knowing when to apply which coping mechanisms. Patients can experience periods of remission in which they suffer from barely any disease activity and can live as healthy people. However, the future is uncertain and PsA can start to act up again indicating that the medication they have been taking stopped working. Following point H the patient experiences a large flare up, falling back into the phase of active disease.

4.2.5.2 Curve of Emotional Wellbeing

The curve of emotional wellbeing is almost the inverse of the disease activity curve. When PsA develops, people will start to look for an explanation. The search for a diagnosis can be expedited if individuals are at risk due to family history or a prior psoriasis diagnosis. But it can also be a lengthy process, where patients have consulted multiple medical specialists and have already received various incorrect diagnoses. To patients this process is a roller coaster of emotions where they can feel helpless and disappointed if a diagnosis turns out to be wrong. These emotional variations are indicated at point A.

The diagnosis of PsA greatly impacts on the emotional wellbeing of patients. Often patients are overwhelmed by the information given and shocked having a disease that will never go away. They walk out of the hospital as different people than they used to be; their lives have been turned upside down. Even if patients briefly feel relieved (point B1) as finally an explanation for their complaints was given their emotional wellbeing takes a deep dive, as indicated in point B2.

After facing the diagnosis, the patient starts taking medication. It takes time before the medication takes effect, which contributes to feelings of hopelessness. Once the right treatment is found (point C), patients gradually start to feel better as their disease activity decreases.

At any point in time patients can encounter flare ups. As was already previously discussed in Section 0 increases in disease activity are accompanied by changes in mood and feelings of grief. Each flare is a big confrontation where patients experience, they are not the person they used to be before. These feelings are illustrated in point D. Patients are also tailoring their life to their disease. They need to make sacrifices because they have no other choice which can affect their financial security, their career paths and their personal relations. Needing to let go of these things can negatively affect their Emotional Wellbeing over time as is indicated by point E.

Point F illustrates and improvement in emotional wellbeing that comes with the years. This is for three main reasons. First, patients shall over time discover the coping mechanisms that

work best for them as a person. These adaptations found by trial and error can have a positive influence on their disease activity and give a feeling of control. Secondly, patients develop coping mechanisms that help them deal with periods of flare ups. They discover alternative things they can do during periods of flare that numb their grievances. Third, patients mentally adapt to their residual disease activity. They still experience pain, fatigue and exacerbations, but they know now how to keep it in the background and know how not to worry too much. Based on their ability to do so there can be several outcomes in point G. At this point there can also be a drop in emotional wellbeing. This drop occurs when patients realize that this is as good as it gets and that they will never become the exact person they were before. This significantly impacts the perception of their and can cause feelings of depression.

Table 9 Illustrative quotations corresponding to the Patient Experience Map

Point	Quotes
A	<i>"So literally throughout my entire it took me two years to get diagnosed even though I had the whole pitting of the nails. My joints don't really swell and I don't get the blood test markers. My immune system has always never shown it for one reason or another."</i>
	<i>"It took ten years to diagnose mine, because they identified a different kind of rash. And they kept changing their mind about what it was."</i>
	<i>"The intensity of the pain perplexed me, and despite my efforts to understand it, I couldn't find any answers. I underwent various tests, consulted different doctors including pathologists and orthopaedists, but none of them could provide a definitive diagnosis. Frustrated, I decided to visit a rheumatologist, as my symptoms seemed to align with a potential rheumatic condition. I was admitted to a public hospital for a week of extensive testing. Numerous examinations were conducted which eventually revealed signs of arthritis."</i>
B	<i>"They say "the first year is about treatment, second year is about acceptance." Period. And I find, maybe that's personal, but that had quite an impact, just that way of doing things, because at the end of the day I walked out of that hospital and I think, "yeah and now?"</i>
	<i>"When I received the initial diagnosis, I was in a state where I couldn't engage in physical activity outside of my home. This continued for about a year and a half due to other medical reasons, and unfortunately, the treatment I was undergoing at the time was not yielding positive results. I spent most of my time confined to my bed or the couch, only venturing outdoors for essential activities with assistance. Even then, my mobility was severely limited, and I relied on assistance or a wheelchair for larger distances."</i>
	<i>"Along with the trauma also came depression. I noticed it happened so suddenly. I thought, "Okay, now my life breaks down." You know, there are a lot of things I can't do anymore. "I don't have a life" is how I felt at the beginning. It took me almost six months to get used to it a little bit and process it in my head. "Okay, that's it. And you have to go with it." But I have to say that after the diagnosis, this problem was often very enervating. I became more sensitive and I get sad about something more quickly."</i>
C	<i>"When the pain subsides, you do notice that. And that you can move more, you really do notice that as well. And that you're less tired. Sometimes those around you notice it before I do. I don't know how that works either. (Laughs). But that's more that I don't realize that then."</i>
	<i>"When I am not bothered, I am cheerful and I am excited to do things."</i>
D	<i>For example, you get the shock, hey, everything has changed, your body changed, your life has to change. You have moments, for example, you want to cycle together with your husband, with your friends or with your family and suddenly you think, "you can't." And at those moments I get depressed, I feel.... That hurts for me.</i>
	<i>"A feeling of loss and maybe yes, as a grief cycle, it's ultimately exactly what it is. It's a grief cycle and that live in a series of chapters, the film that you've got multiple versions of yourself. One where you can do all the stuff you want to do, and one where you're off work and stuck at home and you can't do the things you promised. That is a big weight to carry."</i>

	<p><i>And I think it's far more disabling than the disease can be, in my personal experience, anyway</i></p> <p><i>"I just don't know if, because you feel good that everything goes better or if you feel less good that automatically everything goes less well. But I can very much relate to that if you are emotional, then things also go worse. My father had died and my rheumatism jumped up all at once. Yes, what comes first? Which is it, the chicken or the egg?"</i></p> <p><i>"But there is definitely a correlation with me having low mood, depression, whatever. At the same time as a flare. The obvious one is that would come afterwards, because you lose mobility or you're sore in pain. But they can be so close together sometimes, they're sort of indistinguishable."</i></p>
E	<p><i>"I think a lot of the time, the flare up is there at a level all the time. I don't know what the others think, but it's not a flare up that ever goes back to normal. It's there all the time and sometimes it's worse than others, but once it started flaring until it becomes, as they said, acquiescence, like your hands, it never goes away. It doesn't. My experience, it doesn't. It might be at different levels, but it's there."</i></p> <p><i>"It's like surrendering a little time and time again and that just really sucks. Because if I have a good day, then I do a little too much again, so that two days later you have to give in again, which I don't do. So, it piles up."</i></p>
F	<p><i>"However, I believe that I am managing fairly well with the help of the biological agent or simply adapting to the dyskinesia caused by arthritis. Comparing my current phase to the initial period of my diagnosis, I don't believe I'm experiencing the same level of symptoms as I did when I was first diagnosed. While I understand that I have the disease and there are limitations to what I can do, I still maintain functionality. I may have more dyskinesia and experience pain during certain days of the month, especially in winter, but it's not to the extent that it renders me non-functional as it did in the beginning."</i></p> <p><i>"I don't tend to focus because I think I've had to train myself over the years to be a selective worrier because I realized that I was worrying about everything and it wasn't doing me any good, and sometimes I was worrying about things that might not happen."</i></p> <p><i>"I went to a personal trainer last year, for example. I was thinking: " Well, I'm going to improve my fitness."</i></p> <p><i>"I am still very much trying to figure out: what else is there to make my body function better. Nutrition, I think, has a lot of impact on all your symptoms. Alcohol consumption, I think also. Smoking, you name it."</i></p> <p><i>"The consultations were like, what medication am I missing. So, there comes that point in the consultations where it stagnates. And so there came a point where I had to move to a private doctor to get better care and improve the quality of life a little bit."</i></p> <p><i>"If you've always got joints that are continually hurting, you kind of put it to the back of your mind."</i></p>
G	<p><i>"On average, I'm like a fish in the water. Good."</i></p> <p><i>"The periodic outbreaks of the disease have no significant impact on my daily life. I continue to carry out my usual physical activities without any reduction. However, I listen to my body's signals, and when it feels fatigued, I prioritize rest by sleeping more or opting to work from home instead of going out for work. This allows me to adapt and ensure that I take care of myself during those times."</i></p> <p><i>"Yes, it's just bad, but then it's still not as bad as it was in the beginning. So, then you accept that or something."</i></p> <p><i>"I want to do everything. I'm always busy, I have a hard time sitting still, and yes, that's just annoying. I have to constantly adjust my life and I start to dislike that more and more."</i></p>
H	<p><i>"As a kid, I would have big, long periods where I was completely normal. I've done all sorts of things my doctors didn't want me to do. The closer I get to 40, the harder that is to bounce back."</i></p> <p><i>"You don't know how it's going to turn out anyway. It may suddenly become more intense, and you may have a lot of symptoms. It may just stay quieter for a very long time."</i></p> <p><i>"Well, I experienced that with medication it just went away for one, two years. That was a Valhalla, and it was a huge bummer when it came back, and it hasn't really gone away since."</i></p>

4.2.6 Personas

Personas are created for enhancing user understanding and improving the user-centred design of (digital) products. It is a well-known and successful design methods, originally introduced in 1999. They are fictional representations of target users that are created to better understand and address their needs preferences and behaviours. Personas usually encompass aspects such as context and environment, tasks and workflows, skills and knowledge, personal traits, goals, values, motivations but also frustrations. In the context of AI solutions, the following attitudes have been identified as specifically relevant (Holzinger, 2022):

- Trust.** How much trust does the user have in the decisions/output of the AI system?
- Acceptance.** Does the user accept (and follow) the decision of the AI system?
- Assent.** Is the user willing to accept/use the support by the AI system?

The generic benefit of personas arises from summarizing user information into an intuitive representation that can be easily communicated within organizations, teams, departments, and to external stakeholders. In theory, personas offer an engaging description of users' needs and desires, presenting them as relatable individuals that are more memorable than mere numbers (Jansen, 2021).

The persona's created here are based on the findings of the focus groups and are theoretically underlined by the **Innovation Diffusion Curve (IDC)** originally developed by Rogers E. in 1962 (Rogers, 2010). The IDC visualises how new ideas, products or technologies spread and are adopted by people over time. Five adopter types are described to help practitioners and researchers develop strategies to accelerate the diffusion process, address barriers to adoption, and effectively communicate the value and benefits of innovations. The theory was expanded by Moore (1991), indicating that one should address only one group of customers at a time, using each group as a base to inspire the next. The 'chasm' identified is the most difficult transition between early adopters and early majority (Moore, 1991). The IDC expanded with the chasm is shown in **Figure 10**. Based on this model, quotations with the quote 'personal characteristic' were clustered to the five adoption types.

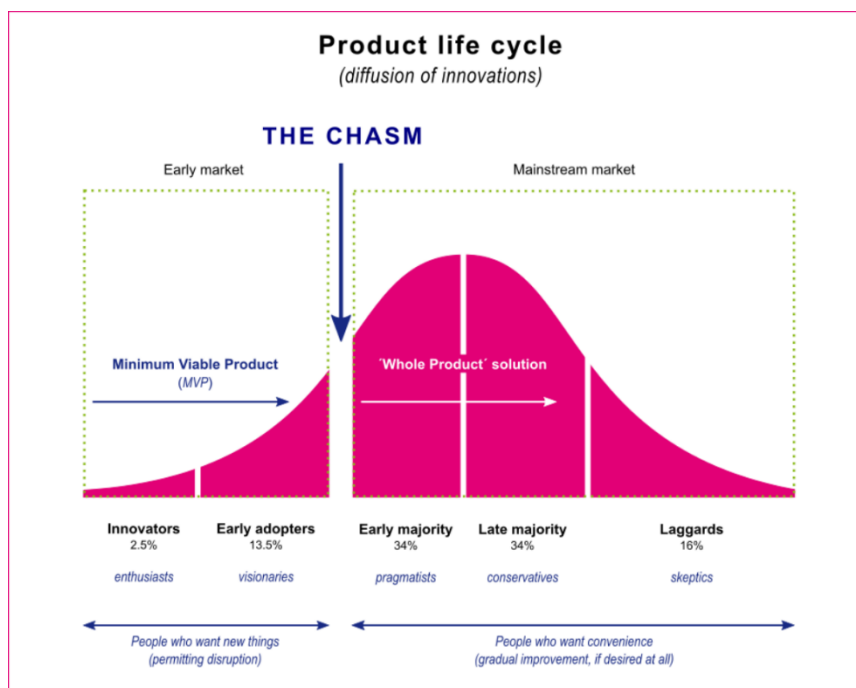


Figure 10 Visualisation of the innovation diffusion curve by Rogers (2010) and the Chasm Theory by Moore (1991). The image was retrieved from the weagree.com website.

4.2.6.1 Persona 1 – Innovator

Sarah Ferreira



32 years old
PsA since 2020
Data Analyst

Digital Skills
●●●●●

Health Literacy
●●●●●

Description

Sarah is a tech-savvy individual who eagerly embraces new technologies and approaches to managing her health. She is an avid data tracker and believes in the power of correlations to understand her condition. She is open to remote consultations and video calls, recognizing their convenience but knows that her disease is still too active. Sarah takes a proactive and curious approach, constantly seeking ways to optimize her body function through factors like nutrition, lifestyle choices, and holistic approaches to managing her symptoms. She sees the potential of measurement technology to provide valuable insights at a personal and collective level, contributing to a deeper understanding of the disease. Privacy is not a concern for her if data is anonymized and used to improve patient care.

Typical Quote

“I experience that this disease is a lot of learning and experiencing. “If I do this, then the next day or next week I'm going to suffer.” I think such measurement technology can provide insight at multiple levels; in the hospital, on with big data, multiple people, analytics. But on a personal level as well. Yes, if I have a party today and I go out and drink a lot of beer, that you can also see in the analysis; “okay, beer actually has a lot of impact.” What impact does eating fat have? What impact does a bad night's sleep have, that that you learn a lot more from that. What would otherwise take maybe ten years to learn it through experience.”

4.2.6.2 Persona 2 - Early Adopter

James Smith



50 years old
PsA Since 1990
Marketing Manager

Digital Skills



Health Literacy



Description

Is willing to embrace new technologies, although he retains some reservations about data privacy. He recognizes the potential benefits of measurement tools and apps and has already tried out various simple health and medication trackers. While James is open to tele-consultations, he also stresses the importance of in-person consultations for maintaining a persona relationship with his rheumatologist. He is curious about the insights that data analysis can provide but prefers not to directly access the data himself. He would collect data for research purposes but not for personal gain. Amir has already suffered from PsA for a long time and feels like he knows his own body well enough and that he developed the appropriate coping mechanisms needed.

Typical Quote

“I don't know. I'm a real technician but increasingly a little bit more reticent about the things that you can all do, by linking things together. I would have been a huge proponent of that maybe 15 years ago. But now I'm a little more cautious and maybe that's because of the abuse of a Google and a I don't know what.... But yes, I think that's kind of it. I do see the indeed, the benefits and the possibilities you say.”

4.2.6.3 Persona 3 - Early Majority

Pieter Westhuijs



58 years old
PsA since 2017
Retired Accountant

Digital Skills



Health Literacy



Description:

Frequently uses his mobile phone in his everyday life but does not carry it around all the time. Therefore, he has reservations about whether a health app would truly enhance her daily life. He questions the purpose of the app and wonders if it would only serve as a tool for gathering data to be processed later. He is open to participating in surveys or questionnaires that could contribute to the medical community's understanding of disease progression, particularly in practical aspects related to psychological well-being and fatigue. While he has limited familiarity with technology, he is willing to learn and believes it is not an insurmountable obstacle. He values the potential benefits of technology but seeks user-friendly and accessible tools that can integrate into his daily routine effectively.

Typical Quote:

“My knowledge of technology remains at a basic level. However, I believe that with some learning, it is not something that is insurmountable. So, at first, I was wondering in what way do you want to measure all that? And if you go by the number of steps, then I have to constantly take my mobile phone with me, which I forget nine times out of ten. Then it makes no sense.”

4.2.6.4 Persona 4 - Late Majority

Katerina Antonopoulou



67 years old
PsA since 2002
Retired Teacher

Digital Skills



Health Literacy



Description:

Is sceptical about using a measurement tool or health app due to her concerns about it taking control of her body and life. In general, she finds rating her disease confronting. She expresses strong reluctance towards being measured every day and finds the idea carrying along a device on a daily basis annoying and disruptive to her life. However, she indicates some willingness to engage with a measurement tool on a less frequent basis, such as once a week. Katerina acknowledges her limited knowledge of modern digital technologies and wonders if she might be too old to fully embrace the idea of using apps and wearable devices. Furthermore, Katarina emphasizes the importance of maintaining contact with healthcare professionals, highlighting her belief that digital tools may create distance whilst direct communication with doctors is essential. She highly values the personal connection and the ability to discuss his concerns and experiences directly with his healthcare providers.

Typical Quote:

“But no, really, I'm absolutely not going to use it, because then I'm sure I am going to do too much. It's going to totally control your body and your life. No horrible, away with all that stuff. It really gives a lot more stress than it brings good things.”

4.2.6.5 Persona 5 – Laggard

Emma Jansen



40 years old
PsA since 2023
Homemaker

Digital Skills



Health Literacy



Description:

Relies on her healthcare providers for most of her medical management. She admits that she tends to be passive in her approach, only taking her prescribed medications and expecting to hear about the rest from her healthcare team. She underestimates the impact of her condition and initially believes it's not as severe as it actually is, highlighting a sense

of naivety. She tends to react to her condition rather than taking a proactive approach. Emma acknowledges her limited digital skills and health literacy, which contribute to challenges in navigating healthcare information and understanding medical terminology.

Typical Quote:

“I do not have to monitor anything. My rheumatologists knows exactly where I am coming from. I do not have to explain anything.’ I hear everything during my consultation, at that time I know everything, but later I quickly forget it, and I always go to checkups alone, and there is writing, but I cannot read that very well quickly’

4.3 Survey Results

4.3.1 Section 1 – Demographics and Technological Experience

A comprehensive survey was conducted among a diverse group of psoriatic arthritis patients across different countries, including the UK, NL, PT, and GR. The survey encompassed demographics, such as age, gender, time since diagnosis, and level of education, as well as technological experience, including device ownership, daily device usage, and internet usage. Demographics are indicated in **Table 10** and **Table 11**.

The survey reflects a diverse age range among the participants, with the majority falling between 25 and 65 years old, suggesting that PsA affects individuals across various stages of adulthood, highlighting the importance of tailored technological solutions that can accommodate different age groups.

Table 10 Demographics of Survey Participants

		UK N = 89	NL N =131	PT N =48	GR N =31	Total N = 299
Age (median, IQR in years)		57 (48-63)	59 (47-65)	55 (46-61)	47 (39-57)	56 (46-63)
Gender (N)		83	58	60	42	65
Time Since Diagnosis (median, IQR in years)		7 (4-18)	4 (2-7)	7 (5-15)	6 (2-13)	6 (2-13)
ISCED Level of Education (N)						
0	< Primary	-	-	-	-	-
1	Primary	-	1	1	-	2
2	Lower secondary	4	23	4	-	31
3	Upper secondary	8	37	14	9	68
4	Post-secondary, Non-tertiary	12	-	4	2	18
5	Short-cycle tertiary	6	5	1	11	23
6	Bachelors	35	45	17	8	105
7	Master's	22	18	6	1	47
8	Doctoral	2	2	1	-	5

Table 11 Technological experience of Survey Participants

	UK N = 89	NL N =131	PT N =48	GR N =31	Total N = 299
Device Ownership (N yes)					
Smartphone	88	127	45	30	290
Tablet	66	94	14	14	188
Smartwatch / Activity tracker	47	48	14	11	120
None	1	1	1	1	4
Daily Device Usage (N)					
Smartphone	85	126	46	30	287
Tablet	37	59	11	6	113
Smartwatch / Activity Tracker	42	43	18	10	113
Computer / Laptop	57	83	43	16	199
Usage of internet (N daily – occasionally)					
Wifi inside the home	88	130	48	31	294
Wifi outside the home	86	122	46	29	284
Personal mobile data	84	115	47	30	276

Based on the provided data, the demographics of technological literacy and device usage across different countries were analysed.

Regarding digital devices, most survey participants across all countries owned a smartphone, with high ownership rates ranging from 88% in the UK to 96% in NL and PT. Tablet ownership was relatively lower, with ownership rates ranging from 19% in PT to 72% in NL. Smartwatch/activity tracker ownership was also moderate, with ownership rates ranging from 37% in GR to 56% in NL.

The vast majority of participants reported using the internet daily, both inside and outside their homes, with high usage rates across all countries. From the answers provided, it seems that technological literacy and device usage are relatively high across all countries surveyed, however, one must keep in mind that the survey was conducted online, and the population of non-technology users could not fill out the questionnaire.

Smartphones are the most widely owned and used devices, followed by tablets and on a smaller percentage of smartwatches/activity trackers. Internet usage is also prevalent, with participants accessing the internet daily. The data provided includes the age range of the participants, with the average age ranging from 47 to 59 years across different countries. While younger age groups generally exhibit higher technological literacy, the participants' ages suggest a relatively tech-savvy demographic overall, indicating that a significant portion of the surveyed population may be open to adopting new technologies, including apps for monitoring their psoriatic arthritis. Participants who already own smartphones, tablets, and smartwatches are more likely to be open to trying new apps for monitoring psoriatic arthritis. Nevertheless, it is noteworthy that many participants who did not currently own a smartwatch expressed a willingness to acquire one in the future. This inclination suggests that the survey responders, which are patients with technological experience, acknowledge the importance of technology in monitoring their health and managing the progression of their disease.

The data were analysed using a chi-square test of independence to examine the relationship between device ownership, daily usage and internet usage and countries involved. The results indicated that there is no significant association between these variables ($p>0.05$), therefore suggesting that there is no strong evidence to support differences in these proportions among the countries.

4.3.2 Section 2 – miPROLEPSIS app

4.3.2.1 Content

Feature Importance. Sleep, pain, state of mind, fatigue, physical activity, mood and stress have all been identified as important indicators of the disease activity of PsA patients. As can be seen from **Figure 11** on some indicators there is more agreement than on others. This counts for fatigue, pain and stress to some extent and for social interactions more heavily as is visualised by the size and colours of the blocks. Time spend on ones' phone is indicated as not indicative for arthritis flare ups and is perceived as unimportant to measure.

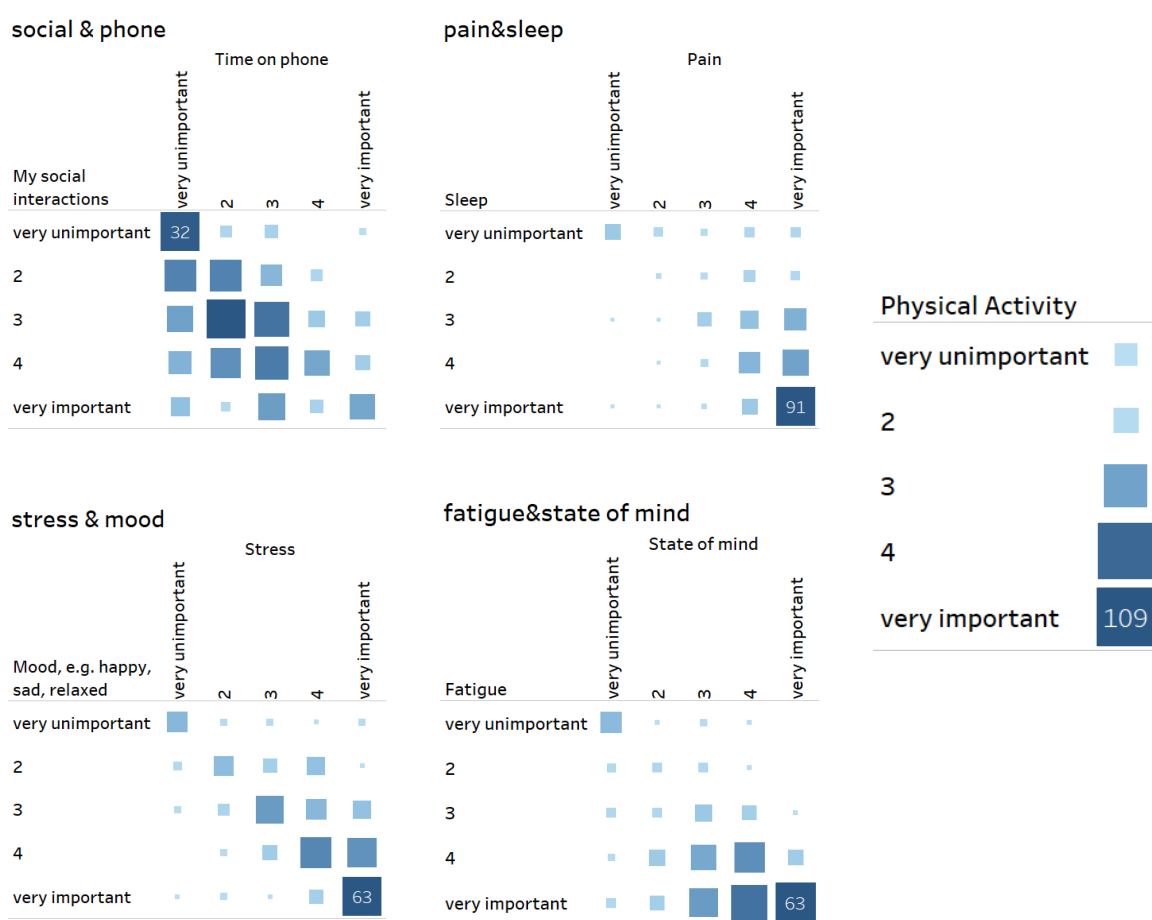


Figure 11 Various overviews of the answers to the question “Which items do you think are most indicative of your PsA flare-ups? So how important is it for us to measure them?” The size of the blocks and the colours indicate the expressed attitudes.

Tracking. Besides knowing which factors are important to measure, the method for measurement should also be considered. **Figure 12** shows to what extent respondents would be open to technology continuously measuring different items. In general respondents comply with one another. They like the measurement of physical activity, stress, sleep and weather and expressing discontent for screentime, keystroke dynamics and voice analysis. There were different levels of invasiveness stated for some measures. Measuring physical activity with GPS tracking was less preferred. Analysing the content of messages typed with keystroke

dynamics was a definite ‘no’ as well as tracking which app someone is using at a certain time of day and voice analysis during phone conversations.

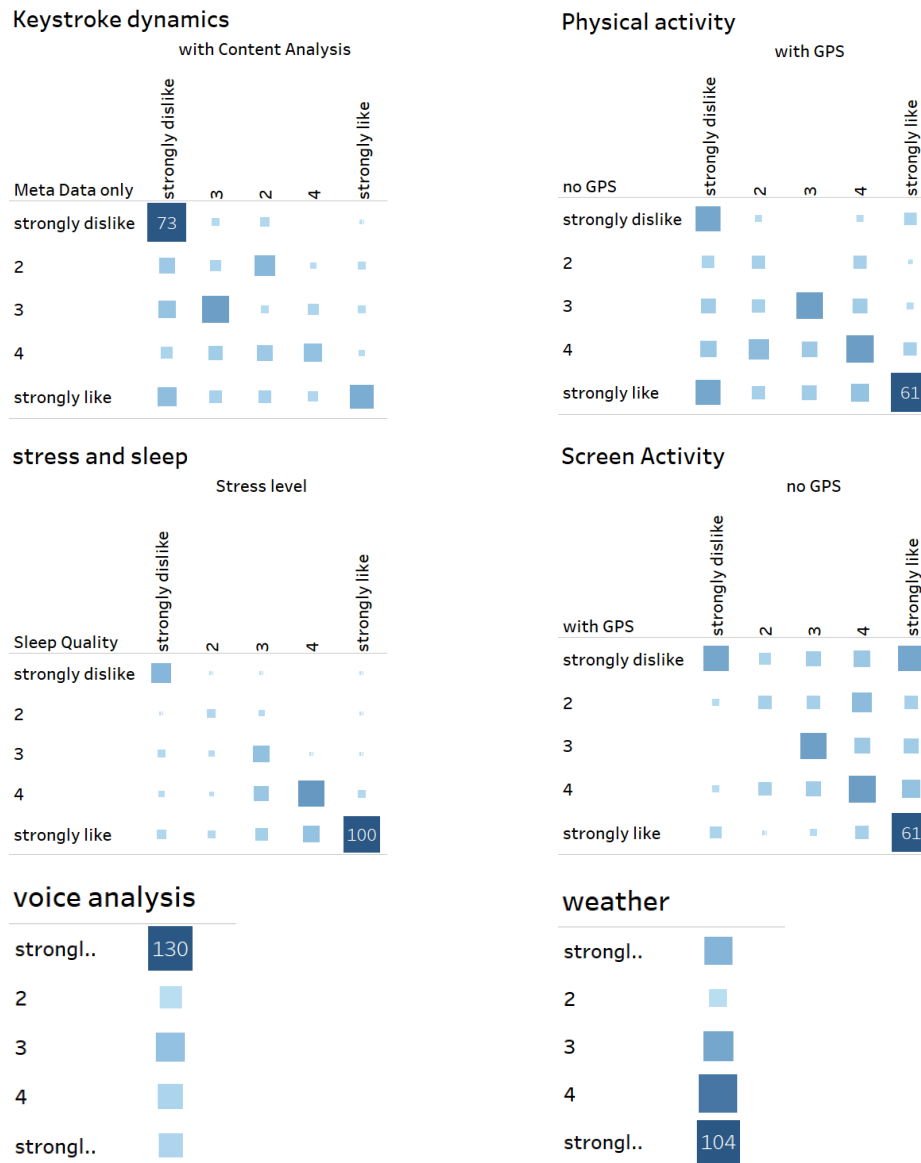


Figure 12 Various overviews of the answers to the question “How would you feel about the devices (smartphone and/or smartwatch) continuously measuring your ...”. The size of the blocks and the colours indicate the expressed attitudes.

Feedback. The receipt of various notifications would be appreciated by the respondents. When it comes to filling out daily questions, 47% of the respondents are positive. They would also be fine with receiving a reminder to fill them out once per day. Besides providing active input to the app, respondents are even more positive against receiving feedback from the app. Most appreciated is receiving a warning that a flare is predicted. This was indicated as 4-5 like by 75% of the respondents. Sharing data summaries with and sending flare detection warnings to assigned monitoring healthcare professionals is a possibility that is appreciated by respectively 62% and 55% of the respondents. These attitudes are indicated in **Figure 13** from strong like on the left (dark blue) to strong dislike on the right (grey).

warnings & reminders

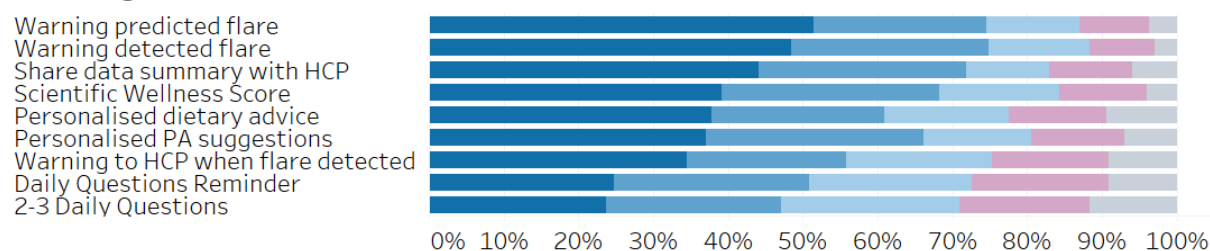


Figure 13 Attitude towards the receipt of various kinds of notification by the miPROLEPSIS app on a 5-point scale. Dark blue = strong like, grey = strong dislike.

Questions. Figure 14 shows the respondents preferences towards questionnaire content. A small 8% of the respondents indicated they did not want to receive any short questions or complaints. So, the majority would like to collect data with short questions, preferably on pain, stiffness and fatigue. Only few respondents filled out the comment section of this question. Mentioning only weather (1x), Liquid intake (1x), alcohol consumption (1x) and menstruation (1x).

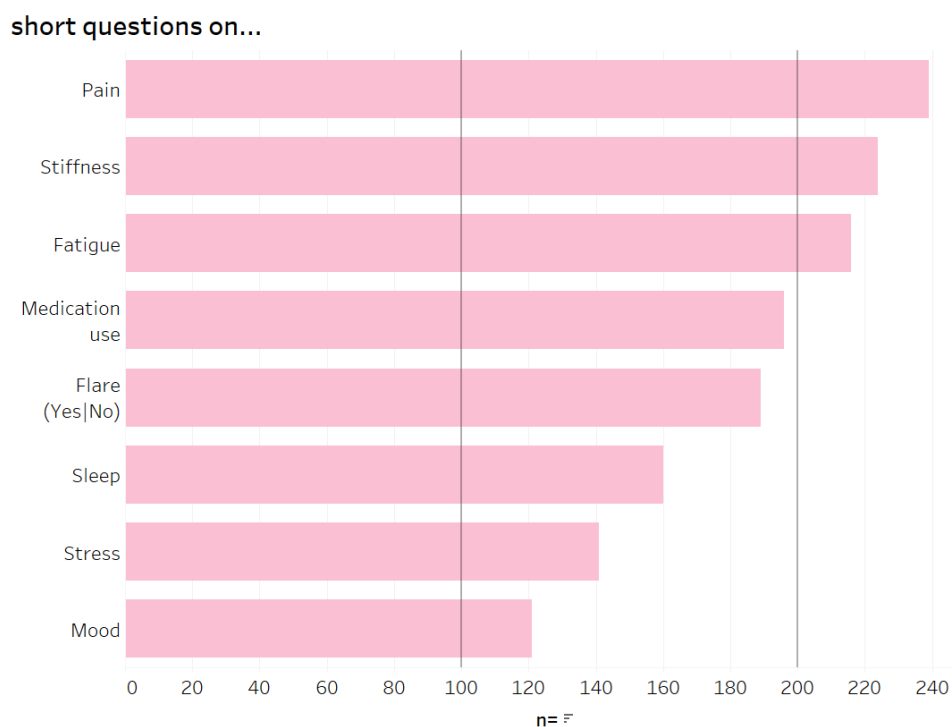


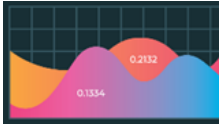
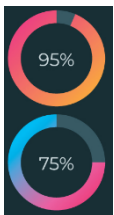
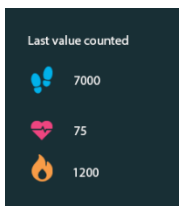

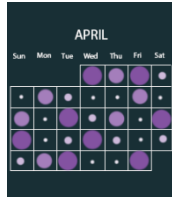
Figure 14 Respondents want to receive short questions on the following items, indicated in number of times an item was checked from the list.

4.3.2.2 Appearance

Data Visualisation. In the comments made on the images in Table 12 it was indicated that the following factors are important for data representation: **Interpretability**. Respondents want to be able to quickly and correctly interpret the results of their data. This is easier if graphs are used that they are already familiar with (**Familiarity**), that apply clear and concise color coding and that combine visual and descriptive information. Furthermore, they would like to have an overview in a split second and then the possibility to take a deep dive further into the data comparing days/weeks/months in a different kind of graph. Within the comments two specific things were mentioned with regard to the psoriatic patient population. 1. Brainfog can interfere with interpretability, emphasizing the need of clean pages and 2. older people have difficulty

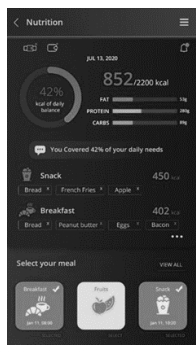
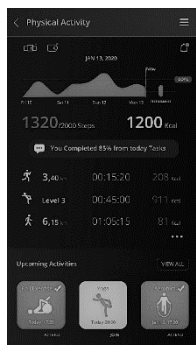
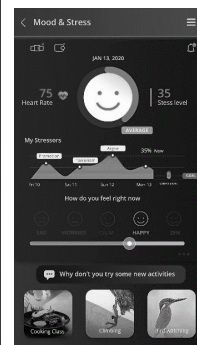

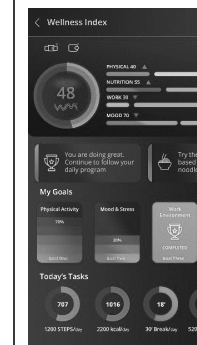
reading small text. Within **Table 12** it is also indicated which data visualisations statistically are preferred.

Table 12 Rating of different visualisation types by respondents.

					
	Item A (%)	Item B (%)	Item C (%)	Item D (%)	Item E (%)
++	44	35	46	8	11
+	28	33	26	49	14
±	11	20	15	28	21
-	6	6	5	23	13
--	11	5	7	22	41

Screens. Opinions on the screens indicated in **Table 13** highly differed. In general, patients state that they like to have a page that provides an overview of all sorts of data, but it easily becomes cluttered, and they lose oversight. The screens need to be simple and organised. Moreover, there is some tension between respondents about the smiley face. By some identified as childish, whilst other thought it provided quick insight.





Table 13 Rating of screen layouts by respondents.

					
	Item A (%)	Item B (%)	Item C (%)	Item D (%)	Item E (%)
++	16	15	16	9	21
+	29	28	24	24	29
±	25	28	28	27	25
-	14	13	17	19	11
--	16	16	16	21	14

Color Use. Through the comments to the images in **Table 14** and as can be seen from the ratings, respondents indicate that they like some color use. Contrast is needed to capture the users' eye to the right points. But not too much color should be used and color should not be used for colors' sake. The colors used need to be functional and they should be distinguishable for people that are visually impaired because of partial blindness, color blindness or uveitis.

The patients that preferred the monochromatic screens mentioned to prefer these because they were calmer to the eye, duller, but also a little more professional.

Table 14 Rating of colour use by respondents.

				
	Item A (%)	Item B (%)	Item C (%)	Item D (%)
++	33	29	4	4
+	30	25	7	10
±	14	18	22	15
-	10	14	33	30
--	12	13	33	41

4.3.3 Section 3 – biAURA app

Of the total number of PSA patients that filled out the survey 61% of the respondents indicated to have some kind of bedtime routine. PT respondents seem to be slightly less likely to have a bedtime routine, whilst the NL and UK respondents are slightly more likely to adhere to a bedtime routine. In GR, the distribution is approximately 50-50. Across gender, education levels or age groups there are no large differences in respondents having a bedtime routine.

Of the 116 respondents that do not follow a bedtime routine 53% would like to try a bedtime routine based on the biAURA intervention. The other 57% would not be interested with the main reasons stated:

- Not wanting to adhere to a bedtime routine
- Considering noise as annoying and wanting to sleep in silence
- The absence of sleeping issues.

One of the respondents who indicated not to be interested in the sleep sounds, mentioned to already use binaural beats on Spotify or the meditation moments app. This respondent admits to its functionality, but has in general no sleeping issues so was still not interested.

About the bedtime routines of the 183 respondents following a bedtime routine, the following can be stated:

Duration. In 72% percent of the cases this routine takes less than half an hour. There is a difference between countries. In PT and GR the ratio is 50-50 between routines taking < 30 minutes and > 30 minutes. The NL and the UK prefer shorter bedtime routines with 75% adhering to <30-minute routines.

Audio. In 31% of the cases listening to audio is part of the bedtime routine at least 1-2 nights per week. Dutch respondents use audio less often (only 14% of the NL responders with a

bedtime routine adopt audio) as opposed to 45-55 % in GR, PT and the UK. Moreover, women are more likely to listen to audio as part of their bedtime routine every night.

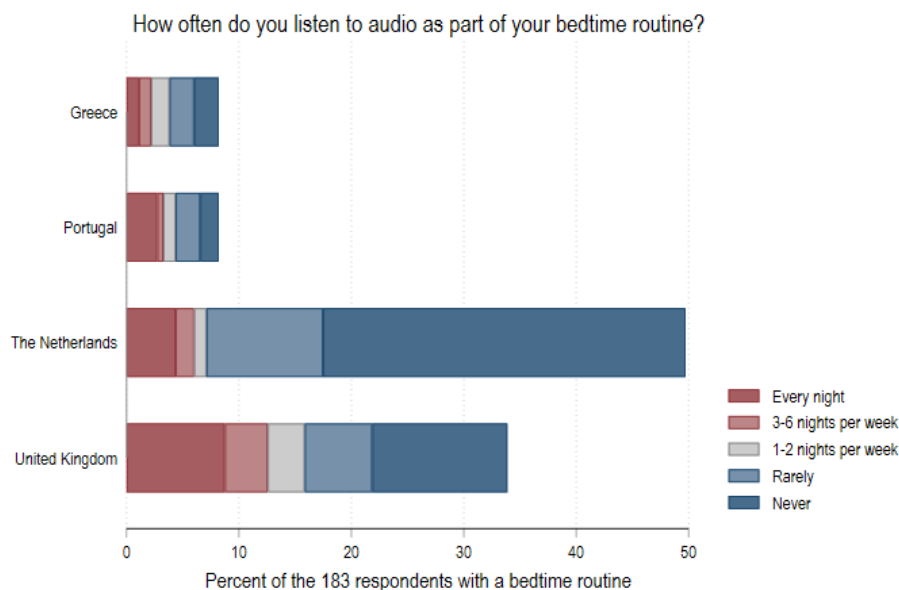


Figure 15 Graph showing the inclusion of audio such as relaxing sounds, classical music or story telling in the bedtime routines per country. Size of the bars indicate percentages of the 183 respondents with a bedtime routine.

Meditation. 9% of the respondents (N=16) use meditation regularly in their bedtime routine, 23% uses meditation sometimes (N=42) and the majority of 68% never resorts to meditation (N=125). None of the GR respondents use meditation, whilst in the UK, NL and PT it is about 30% that uses meditation at least 'sometimes'. Meditation is adopted for 46% by females and only for 12% by males.

4.3.4 Section 4 – Personalised Gaming Suite (PGS)

Based on the introduction of the PGS 65% of the respondents would be interested in serious games that address various aspects of health and well-being.

Of the 99 respondents that indicated not to be interested in the PGS 9% did not need to improve their disease management, 77% do not enjoy playing games and 14% stated not to be interested in other reasons. 15 respondents filled out these other reasons, they stated:

- Preferring to read a book or puzzles on paper
- Only liking to play physical games with others
- Wanting to avoid more screentime or blue light before bed.
- Anxiety of overexertion
- Being shy of being visually monitored

The 65% of interested respondents corresponds to 187 PsA patients and is build up by 80% of the GR respondents, 80% of the PT respondents, 64% of the UK respondents, and 55% of the NL respondents. Females are more interested than males (71% vs 28%) and as respondents become older their interest in the PGS decreases, as can be seen from **Table 15**. Furthermore, respondents in their first year of diagnosis are slightly more interested than respondents after the first year. Where about 70% of respondents in their first year is interested and after the level of interest is reduced to ~64%.

Table 15 Interest in the PGS by age group.

Interested in PGS?	<30 N = 12	31-40 N = 26	41-50 N = 67	51-60 N = 87	61-70 N = 81	>70 N = 26	Total N = 299
Yes (%)	92	77	84	62	54	31	65
No (%)	8	23	16	38	46	70	35
Total (%)	100	100	100	100	100	100	100

The following descriptions are in relation to the number of respondents that indicated to like the idea of the PGS.

Purpose. As can be seen from **Figure 16** respondents were asked to indicate which areas they identify could benefit from a PGS to help improve or sustain their self-management skills. Respondents from the various countries agree that it would be a nice feature if the game would respond to their real-time physiological signals (64% checked the box). Furthermore, the games were indicated as potentially beneficial if they would help with motor skills (62%), pain management (60%), and then diet (47%), and stress/anxiety management (45%). Emotional expression was indicated least potentially beneficial with (28%). Diet was better liked by the PT (74%), motor skills were slightly less liked by the GR (52%) and stress and anxiety were less liked by NL and GR (~33%) and slightly by the UK.

areas to improve with gaming

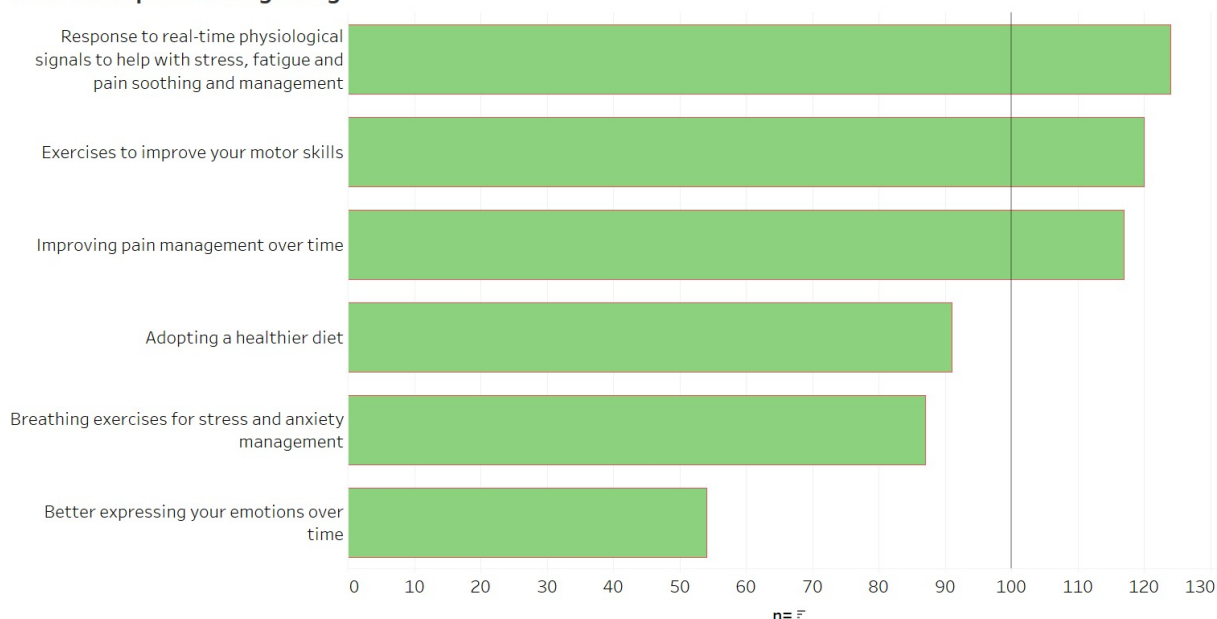


Figure 16 Graph showing the amount of boxed checked per item to the question: “In which of the following areas do you see potential benefits for a serious game suite to help you improve or sustain your self-management skills?.”

Device type. Preference for the device to give access to the PGS is first via smartphone (56% checked the box), second via tablet (21% checked the box), and lastly Computer/laptop (14% checked the box). Only two respondents indicated to prefer playing on the TV. Respondents who preferred the smartphone were less excited about the use of a tablet or computer, but respondents who marked the computer or tablet as a probable device, most often also marked the use of a smartphone.

Interaction Technology. Regarding the technology to be used to control the games, 88% prefer to play the game by means of a touchscreen that tracks finger movements on the screen. The other options hand tracking with camera or a physical keyboard and mouse were less preferred with only 13 and 18%.

Game type. Puzzle games are liked by most (63% checked the box), followed by educational games, traditional games, strategy games, and exercise games (~47%). Rhythm games, simulation games and racing games are least liked (11 – 24%). Preferences are indicated in **Figure 17**.

genre / type of gaming

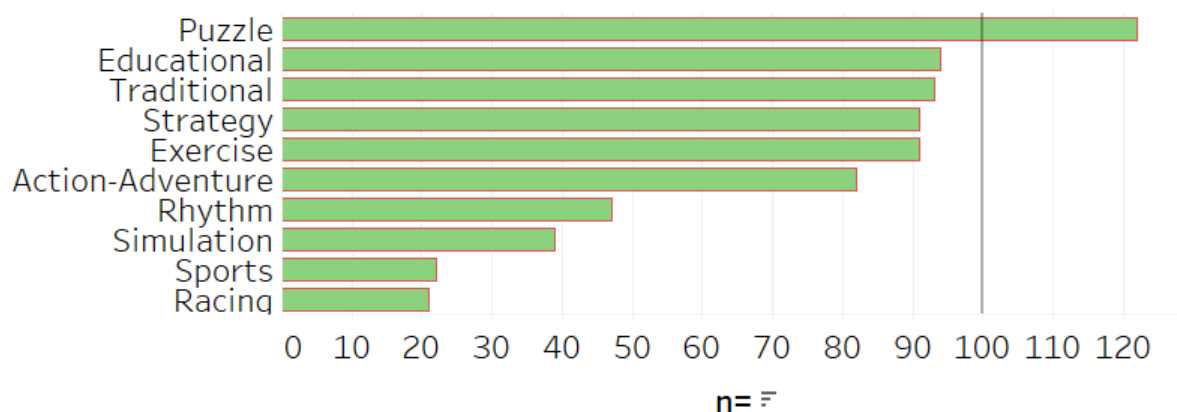


Figure 17 Graph showing the amount of boxes checked per item to the question: “What genre/type of game would you like to play?”

Social Dimension. 69% does not want a social dimension integrated in the serious game. If a social dimension were to be implemented in the game it does not matter whether the game is cooperative or competitive, if the difficulty settings can be determined for each person separately.

Feedback on progression. The mean importance of receiving feedback, motivational messages and suggestions from the gaming suite in terms of monitoring progress is 2.9 ± 1.2 on a scale of 5, indicating a mid tendency to welcome feedback.

In-Game awards. Only 15% does not find in-game awards appealing. As can be seen from **Figure 18**, Scores are most appealing followed by challenges, badges and ratings. Questionnaires are perceived as least appealing.

in-game awards

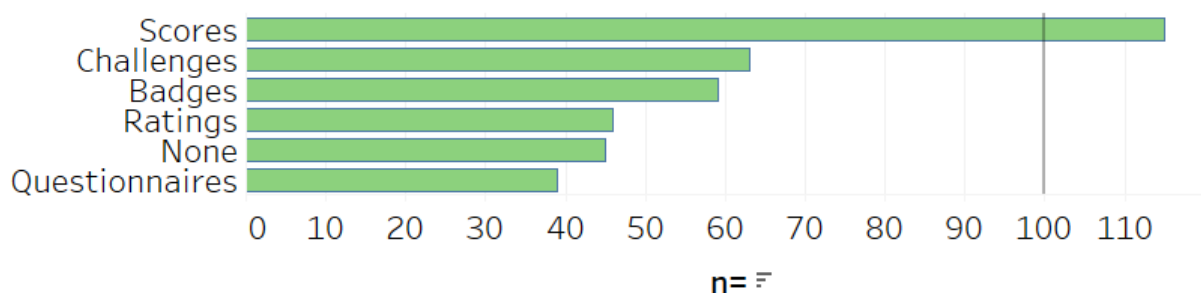


Figure 18 Graph showing the amount of boxes checked per item to the question: “Which types of in-game awards would serve as motivation for you to continue playing the game?”

Levels of Difficulty. Respondents preferred to have different levels of difficulty. About half of them would like to have levels that they need to complete to unlock new levels. The others would like it if the game would adjust its difficulty level based on their performance. Only 3% checked the box to prefer only one level of difficulty.

Characters. Most respondents (50%) indicated no preference towards the graphics and characters of the games. From the ones that did have a preference they leaned towards animations and 3D characters. Results are indicated in **Figure 19**.

preference of main graphics and characters

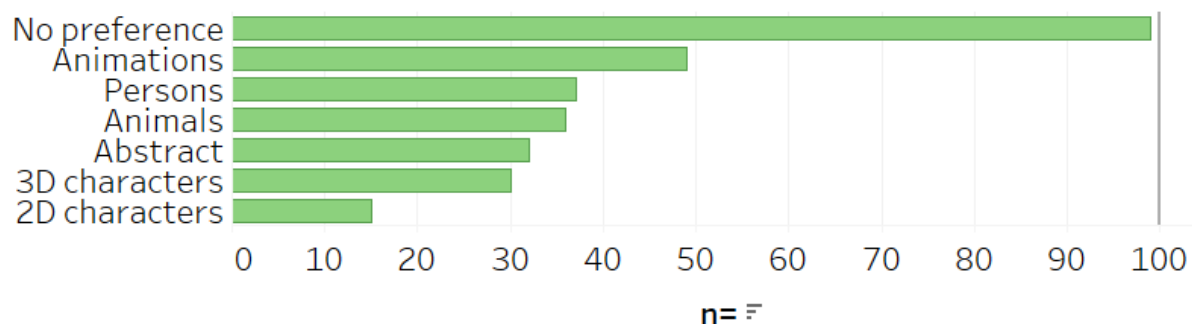


Figure 19 Graph showing the amount of boxed checked per item to the question: "Which types of graphics and main characters would you prefer to see in the game?"

Highlights from the PGS Comment Section.

- No bright sounds and colours, limited use of flashing images (migraines).
- Must be age appropriate, so no children's games for adults.
- Must be built for absolute beginners, since there are users with no experience with computer games.
- It must be fun to play the game.
- They can be helpful for stress and anxiety management.

4.4 Triangulation

This section relates the focus group findings to the outcomes of the survey. Features of disease activity and Pros and Cons of technology to assess it, active user input and feedback are discussed.

4.4.1 Features of disease activity and Pros and Cons of technology to assess it

Throughout the focus groups, many symptoms were reported as indicative of increased disease activity, and most of these complaints were confirmed by the survey. Sleep, Pain, Fatigue, State of mind, Stress, Mood, and Physical Activity were identified as important indicators of disease activity by both the focus groups and the survey. Other complaints mentioned in the focus groups, supported by open comments in question 12 of the survey, include (Morning) Stiffness, Heat from joints, Swelling/Joint Range of Motion, Psoriasis, Functional limitations, and the feeling of being chronically hot or cold. One area of ambiguity is social interactions. Within the focus groups, the level of social interactions was described as fluctuating along with disease activity, with participants mentioning tendencies to "turn inwards", reluctance to discuss oneself, and cancelling activities due to lack of energy. The survey results show some debate regarding the importance of measuring social interactions, with a greater weight leaning towards insignificance in the ratings. Nevertheless, maybe they did not connect this in the same way to their disease activity as people in the focus group did.

Some differences between the focus groups and the survey appeared in keystroke dynamics, screen activity and voice analysis. In general, the people that completed the survey were reluctant to measure these features. They probably did not connect these with their disease activity, as they could not see the direct connection of a specific symptom, for example mood alteration, with changes in pitch of voice, the use of the phone or typing pattern. Nevertheless, this could be anticipated, as they are often unconsciously present. Hence, there must be an understanding and explanation about the features a technology tries to capture and how these are associated with the PsA symptoms that need to be measured; here are some examples:

Keystroke Dynamics. Within the survey, respondents expressed reluctance regarding the measurement of typing behaviour. This reluctance is particularly strong towards content analysis of typed text and somewhat milder towards the analysis of metadata. Clearly this attitude derives from the user's privacy considerations and lack of knowledge about the informative character of keystroke dynamics. In fact, keystroke dynamics is an emerging technology that is gaining popularity in analysing the mental states of individuals, such as fatigue and stress. It is also utilized for measuring cognitive function and has been adopted for various diseases including Alzheimer's, bipolar disorders, Parkinson's, and multiple sclerosis. This technology has the potential to be highly valuable and relatively non-invasive in assessing a patient's mood, level of fatigue, cognitive clarity, mental well-being, and more. Additionally, it can serve as a measure of manual dexterity, which can be affected in PsA patients when experiencing hand-related symptoms.

Screen activity. Within the literature, the measurement of screen activity is utilized in studies investigating sleep disturbance, sedentary behaviour, and concentration. It can enhance the accuracy of other phone and wearable sensors on for example sleep time. The focus groups emphasized the importance of accuracy and reliability of the results for the adoption of DHTs. However, that was discussed in more general terms, not specifically towards screen time. The participants in the survey expressed a dislike, but unclear why respondents have reservations about this measurement. It could be that they did not perceive value as is necessary to evaluate the relevance of these screen activity measurements and strive for an approach that minimizes privacy invasion.

Voice Analysis. The participants in the survey expressed a strong aversion towards voice analysis. Most probably, this attitude was driven by user's privacy considerations. Existing literature explains the connection between speech characteristics and conditions, such as depression, fatigue, and both acute and chronic pain. Utilizing speech measures provides a promising approach to evaluating these frequently encountered, challenging-to-quantify issues in a non-intrusive manner. The feedback gathered from focus groups and the survey emphasized the significance of measuring pain, mental state, stress, mood, and fatigue to attain precise assessments of disease activity.

There is consensus between the focus group and survey findings regarding the symptoms that should be measured and the potential measurement technologies for physical activity, stress, sleep, and weather conditions. Additionally, it is evident that as privacy intrusion intensifies (such as the inclusion of GPS data), resistance towards the technology also grows. This aligns with the outcomes from the focus groups, where participants display a willingness to compromise their privacy for the sake of their health, but they emphasize the importance of guaranteeing the security and protection of their data.

4.4.2 Active User Input

During the focus groups, certain concerns were raised regarding the use of daily questionnaires to monitor the personal experiences of users. Some participants expressed their dislike for filling out daily questions, finding it confrontational and repetitive. However, in the survey, patients were more receptive to being reminded about their condition. The majority

of respondents (80%) expressed a preference for receiving brief questions about their pain, stiffness, and fatigue. Only 8% of participants indicated a desire to avoid any questions about their disease altogether. Additional questions that were deemed valuable included inquiries about medication usage and flare-ups. In general, it is preferred to incorporate some form of manual input into the app. During the co-creation process, it is important to assess the appropriate frequency of these questions, determine their priority, and formulate them in a concise and reliable manner.

4.4.3 Notifications and Data Sharing

In the focus groups, part patients had mixed feelings about notifications on their flare risk and the change of getting a flare. Some of them preferred being notified upfront, while others found the notifications intruding in their daily lives reminding them of being sick which they disliked. From the survey, it was found that most respondents (75%) had a positive attitude towards flare prediction or detection warnings. Reasons for this from the focus groups could be that it would allow them to intervene sooner and then reduce the impact of the flare on their personal lives. Initially, there were concerns about patients' reluctance to share their data, but most findings contradicted this assumption. Patients in the focus groups expressed trust in a hospital-provided system for data safety and security. The survey did not specifically address this issue. However, when asked about sharing data summaries or flare warnings with assigned healthcare professionals, 62% and 55% of respondents, respectively, responded positively. Nonetheless, the focus groups highlighted a few noteworthy points. Firstly, participants emphasized the importance of ensuring the accuracy and patient confirmation of any warnings received by healthcare professionals. They found it intrusive to receive calls from healthcare professionals while on vacation or when there was no significant concern. Secondly, there was a fear expressed regarding the potential influence of data. Sharing data with healthcare professionals could lead to judgments and opinions based on the data, causing participants to feel the need to defend their experiences and increasing anxiety due to discrepancies between the data and their personal accounts. This issue is already prevalent in current healthcare, where patients occasionally experience a sense of not being listened to or understood.

4.4.4 Requirements from triangulation process

By comparing the results from the focus groups and surveys, it can be observed that there is agreement between the two methods regarding the importance of certain indicators. Both the focus groups and surveys highlight the significance of factors like sleep, pain, and fatigue. That is why these aspects have been chosen to be incorporated into the miPROLEPSIS App first. However, there may be some discrepancies on specific indicators, such as the importance of social interactions and time spent on one's phone for PsA flare-ups, which were perceived differently between the two methods. In the upcoming design sprints, there will be additional discussions focused on explaining the necessity and benefits of incorporating these factors into the miPROLEPSIS App.

Respondents also indicate a preference for various notifications. They are positive about filling out daily questions, with 47% showing a positive attitude and being open to receiving a daily reminder. Respondents are even more positive about receiving feedback from the app, with a high appreciation for receiving a warning predicting a flare-up. Sharing data summaries with assigned healthcare professionals and receiving flare detection warnings are also appreciated. Additionally, the preference for short questions on pain, stiffness, and fatigue reinforces the significance of these factors in the questionnaire content.

Triangulating these findings allows for a more comprehensive understanding of the research topic by considering multiple perspectives and identifying common themes or patterns across different data sources.

5 Defining User Requirements

This section lists all User Requirements found from the literature, previous projects, the focus groups and the survey. A table indicating the requirement ID, a description, the source and priority is added for each DHT.

The sources of requirements were identified and presented. The iPROLEPSIS DHTs take as starting point the DoA, which reflects the consortium's expertise and long-term experience with PsA and is supported by literature. These requirements are specified as "DoA". Additional requirements were specified through the thorough search of the literature, as described in Section 2.2. and are presented as "L" followed by the related domain that this was extracted from (e.g., privacy, best practices in the field). These types of requirements can be updated if they seem to be in contrast with the user's perspective as it will be continuously gathered and analysed during the iPROLEPSIS User Research & Co-Creation approach. Other sources of requirements at this stage were the focus groups, surveys and background knowledge of patient journeys, disease activity and emotional wellbeing. These were specified as "iPROLEPSIS users' request".

For the user requirements the MoSCoW approach was applied for prioritisation, in order to primarily comply with the DoA requirements and fulfil as many as possible user aspirations that were not initially foreseen. The MoSCoW approach is a rather simple one, prioritizing the requirements using the words "must have", "should have", "could have", "won't have at this time". The "must have" requirements are obligatory and absolutely necessary. The "should have" requirements are high priority but not obligatory. The "could have" requirements are considered desirable (nice-to-have) but not necessary. The "won't have at this time" or "would like to have" requirements are considered as out-of-scope for this project and can be considered as future requirements (accomplishable after the end of the project). Keeping balance in the features list size is crucial, that will lead to a realistic planning of the developments and integration activities of the project while ensuring that the user requirements are sufficiently covered.

It is important to clarify which features and requirements are the ones that will be included in the iPROLEPSIS DHTs. The requirements result from the triangulation of partner's experience and expertise as depicted in the DoA, the continuous search of the literatures and the user's opinion. The user's perspective is of foremost importance for deciding for a feature and adding or deleting a requirement from the backlog. A feature with strong supermajority (> 80% of the responders) either in favor or against should be considered for inclusion as a "must" or "won't have at this time" to the backlog, accordingly. However, if there is a strong objection from the users but the literature and experts believe that this is an important feature for the system that cannot be changed or removed, the Co-Creation team will be responsible for proposing alternatives based on user's feedback in order to maintain the feature and improve user acceptance. Such requirements will be put back in the backlog for testing in the next Sprint. If there are suggestions that are mentioned by a lower majority of the people (50-80% of the respondents) will be marked as "should have" while even lower mentions (< 50 % of the responders) will be marked as "could have" and will not be tested in the later Sprints. If the "could have" requirements keep coming up during the Sprints, the Co-Creation team will consider changing the priority to "should have".

5.1 MiPROLEPSIS patient app

In **Table 16**, the identified user requirements for the miPROLEPSIS patient app are tabulated.

Table 16 User Requirements miPROLEPSIS patient app

UR.mP.#	Description	Source	Priority
UR.mP.01	A user needs to be able to login to the application	DoA	Must
UR.mP.02	A user needs to be able to edit his/her account details	L [Best application practices]	Must
UR.mP.03	A user needs to be able to delete his/her data	GDPR; iPROLEPSIS users' request	Must
UR.mP.04	A user needs to be able to delete his/her account	GDPR	Must
UR.mP.05	A user needs to agree with the terms of the application before entering app	L [Security practices]	Must
UR.mP.06	Privacy terms need to be available to the users	L [Security practices]	Must
UR.mP.07	A patient needs to be able to connect his/her wearable	DoA; iPROLEPSIS users' request	Must
UR.mP.08	A patient needs to be able to review the measurements monitored through the smartphone or the wearable in several lifestyle areas, such as nutrition, physical activity, sleep, mood etc	DoA; iPROLEPSIS users' request	Must
UR.mP.09	A patient should be allowed to log and track medication intake, disease flares, and any external factors that may impact their symptoms, such as weather or stress levels.	iPROLEPSIS users' request	Should Have
UR.mP.10	A patient needs to be able to receive notifications	DoA	Must
UR.mP.11	A patient needs to be able to customize the frequency and timing of reminders and alerts to match their comfort level and minimize intrusive thoughts or anxiety.	iPROLEPSIS users' request	Must
UR.mP.12	A patient needs to have an explanation of why the app collects information like keystroke dynamics, screen activity and voice analysis	iPROLEPSIS users' request	Must
UR.mP.13	A patient needs to be able to provide feedback to the monitoring healthcare professional	DoA	Must
UR.mP.14	A patient needs to be able to answer questionnaires	DoA; iPROLEPSIS users' request	Must
UR.mP.15	A patient needs to be able to receive recommendations	DoA	Must
UR.mP.16	A patient needs to be able to retrieve statistics on the wellness activities s/he performed in a selected period	Market research (Source Capterra)	Should
UR.mP.17	A patient needs to be able to set up her/his planner of lifestyle activities (nutrition, physical activity, sleep, and mood etc)	Market research (Source Capterra); iPROLEPSIS users' request	Should

UR.mP.18	A patient needs to be motivated and receive motivational advice	DoA; iPROLEPSIS users' request	Must
UP.mP.19	A patient needs to be able to provide user generated inputs	DoA	Must
UP.mP.20	A patient needs to be able to use the smartphone's embedded sensors	DoA; iPROLEPSIS users' request	Must
UP.mP.21	A patient needs to use the application in both Android and iOS platforms	IPROLEPSIS users' request	Must
UP.mP.22	A patient needs to use a multilingual application	IPROLEPSIS users' request	Should
UP.mP.23	A patient needs to have access to a knowledge base	Market research (Source Captterra)	Should
UP.mP.24	A patient should be able to have visualisations and reports summarizing trends between symptoms and activities-external factors	IPROLEPSIS users' request	Should

5.2 BiAURA

In **Table 17**, the identified user requirements for the biAURA app are tabulated.

Table 17 User Requirements for the biAURA app

UR.[BA].#	Description	Source	Priority
UR.BA.01	The biAURA app must allow the users to start the binaural beat sound.	L [Aji et al.]	Must
UR.BA.02	The biAURA app must provide a sleep diary to users.	L [Aji et al.]	Must
UR.BA.03	The biAURA app should provide an alarm to users.	L [Aji et al., Mahmud et al.]	Should
UR.BA.04	The biAURA app should block notifications from other apps during playing the binaural beat sounds.	L [Aji et al.]	Should
UR.BA.05	The battery consumption of the biAURA app should be optimized.	L [Mahmud et al.]	Should

5.3 Recommendation Systems

In **Table 18**, the identified user requirements for the Recommendation Systems are tabulated.

Table 18 User Requirements for the Recommendation Systems

UR.[RS].#	Description	Source	Priority
UR.RS.01	The user must be able to provide information regarding its age and body height and weight to the AI recommendation system for improved dietary advice.	L [Trang Tran, Atas, Felfernig, & Stettinger, 2018]	Must
UR.RS.02	The user must be able to provide its physical activity level / fitness to the AI recommendation	L [Trang Tran, Atas, Felfernig, & Stettinger, 2018]	Must

	system for improved physical activity recommendations.		
UR.RS.03	The user must be able to provide its dietary restrictions (e.g., food intolerances, allergies, etc.) to the AI recommendation system.	L [Stefanidis, et al., 2022]	Must
UR.RS.04	The user must receive personalized daily and weekly meal plans from the AI recommendation system.	L [Stefanidis, et al., 2022]	Must
UR.RS.05	The user must receive personalized physical activity suggestions from the AI recommendation system.	L [Stefanidis, et al., 2022]	Must
UR.RS.06	The user should get information on the calories and nutrients of the meals generated by the AI recommendation system.	PE [EU-funded H2020 PROTEIN project]	Should

5.4 MiPROLEPSIS HCP Dashboard

In **Table 19**, the identified user requirements for the miPROLEPSIS HCP Dashboard are tabulated.

Table 19 User Requirements for the miPROLEPSIS HCP Dashboard

UR.[mH].#	Description	Source	Priority
UR.mH.01	A user needs to be able to login to the application	DoA	Must
UR.mH.02	A user needs to be able to edit his/her account details	L [Best practices]	Must
UR.mH.03	A user needs to be able to delete his/her data	GDPR	Must
UR.mH.04	A user needs to be able to delete his/her account	GDPR	Must
UR.mH.05	A monitoring healthcare professional needs to be able to view patients' summaries over time	L [Best practices]	Must
UR.mH.06	A monitoring healthcare professional needs to be able to get summaries on the parameters measured	L [Best practices]	Must
UR.mH.07	A monitoring healthcare professional needs to be able to view historical data of a selected patient	L [Best practices]	Must
UR.mH.08	A monitoring healthcare professional needs to be able to review the progress of a selected patient	DoA	Must
UR.mH.09	A monitoring healthcare professional needs to be able to receive notifications	DoA	Must
UR.mH.10	A monitoring healthcare professional needs to be able to set plans and review the progress for a specific patient	DoA	Must
UR.mH.11	A monitoring healthcare professional needs to be able to provide user generated inputs (annotations)	Based on previous projects' experience	Could
UR.mH.12	A monitoring healthcare professional needs to be able to create/edit/delete and assign questionnaires to capture patients' feedback	DoA	Must

UR.mH.13	A monitoring healthcare professional needs to be able to receive information on the QoL of a selected patient	DoA	Must
UR.mH.14	A monitoring healthcare professional needs to know when the patients experience a flare	DoA	Must
UR.mH.15	A monitoring professional should be able to make prioritisation among his/her assigned patients	L [Best practices]	Must
UR.mH.16	A monitoring professional needs to be able to trace back to the original data used for the generation of a result	L [Best practices]	Must
UR.mH.17	A user needs to be supported based on organization's hierarchy	L [Best practices]	Could
UR.mH.18	A monitoring professional needs to perform associations	DoA	Must
UR.mH.19	A monitoring professional needs to receive projections on disease evolution	DoA	Must
UP.mH.20	A monitoring professional needs to have access to a knowledge base	Based on previous projects' experience	Should
UP.mH.21	A monitoring professional needs the information presented to be viewable in different screen sizes	L [Best practices]	Could

5.5 Serious Gaming Suite

In **Table 20**, the identified user requirements for the Serious Gaming Suite are tabulated.

Table 20 User Requirements for the Serous Gaming Suite

UR.[SG].#	Description	Source	Priority
UR.SG.01	A patient must be able to register and sign in by creating an account and register within the Serious Gaming Suite. (User registration/sign in)	O [know-how from previous projects]; iPROLEPSIS Users' request	Must
UR.SG.02	A patient should be able to choose from a variety of games targeting different health aspects. (Game selection)	O [know-how from previous projects]	Should
UR.SG.03	A patient should be able to actively participate in the games through physical movements, gestures, or other inputs. (Gameplay interaction)	L [Caserman et al., 2020]	Should
UR.SG.04	The system must provide feedback to patients based on their gameplay performance. (Gameplay feedback)	L [Erhel, & Jamet, 2013; Bharathi et al., 2016; Johnson et al., 2017]; iPROLEPSIS Users' Request	Must
UR.SG.05	The system should track and record patient progress within the games for evaluation and analysis. (Progress Tracking)	L [Caserman et al., 2020]; iPROLEPSIS Users' request	Should

UR.SG.06	The system should offer personalized game scenarios and adapt gameplay and levels of difficulty based on individual patient profile and goals. (Personalization and adaptation)	L [Streicher, & Smeddinck, 2016]; IPROLEPSIS Users' request	Should
UR.SG.07	The games could be accessible on various devices such as smartphones, tablets, and PCs. (Multi-platform support)	O [know-how from previous projects]	Could
UR.SG.08	Patient progress and preferences could be synchronized across devices to ensure a seamless gaming experience. (Data synchronization)	O [know-how from previous projects]	Could
UR.SG.09	The system could allow clinicians to monitor patient progress, provide recommendations, and adjust game interventions if needed. (Clinician interaction)	O [know-how from previous projects]	Could
UR.SG.10	The system could support regular updates, to add new features, and improvements to the suite. (Game updates)	O [know-how from previous projects]	Could

6 Next steps

In this section, a preliminary plan outlining the methods and timeline for patient interaction during the development of the iPROLEPSIS DHTS (specifically the miPROLEPSIS App and Serious Gaming Suite) is presented. It includes approximate months during which the interactions with patients would take place. As iPROLEPSIS follows an iterative User Research & Co-Creation approach, end user groups are contacted in various points in time in order to provide feedback for the iPROLEPSIS DHTs development. In the planning, we have considered five main points of Co-Creation sessions with the users. In each session, an updated increment of the system and different tools for feedback collection will be exploited. The definition of the Sprint goal takes place in the Define phase (**Figure 20**) that includes the Sprint Planning and prioritization. The tools for feedback gathering are decided in the Pre-Review phase, while the open issues and the update of backlog takes place in the Post-Review phase. In order to create the overall patient interaction plan, the potential availability of HCPs was also taken into account, avoiding planning Co-Creation sessions in holiday periods (Christmas, Easter, summer).

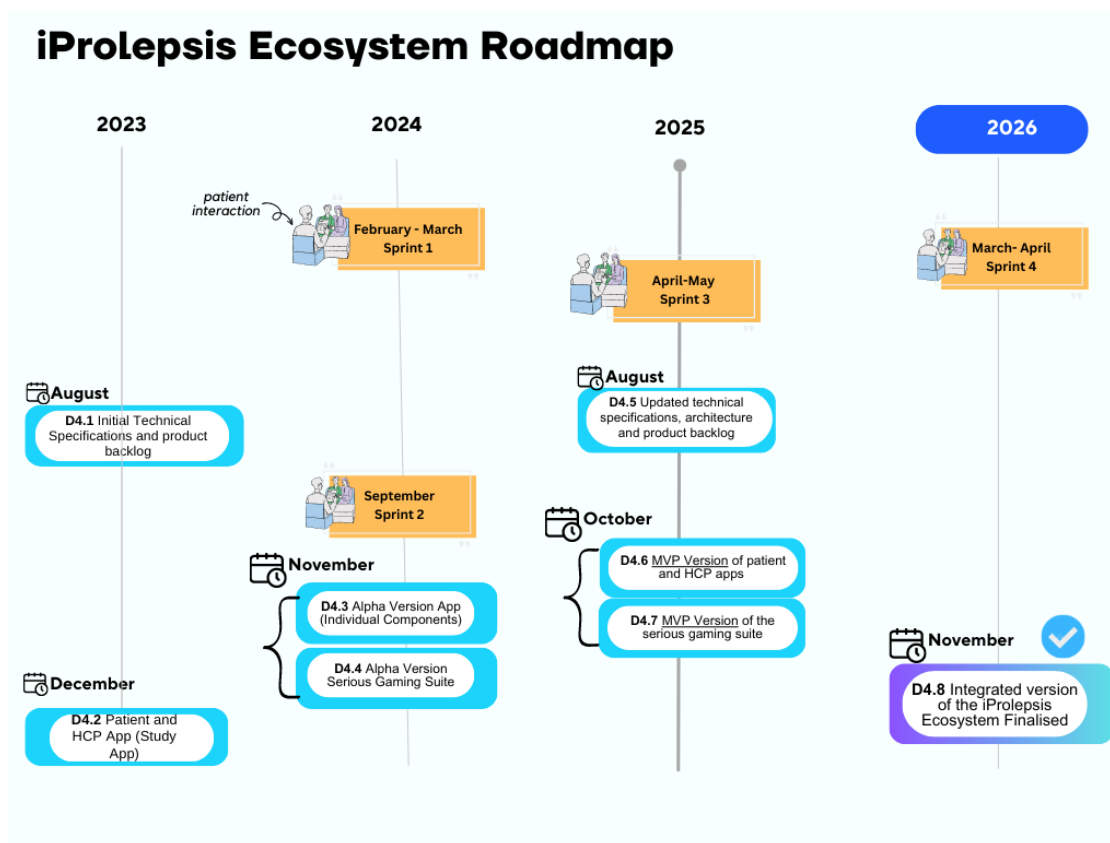


Figure 20 iPROLEPSIS Digital Health Ecosystem Roadmap.

The iterative procedure will start in August 2023 with the development of initial technical specifications, architecture, and product backlog (**D4.1**) that will also consider the current deliverable (**D2.1**) for the first version of product backlog including also the user's perspective.

By December 2023, the miPROLEPSIS PDPID App will be created (**D4.2**), following an iterative prototype development approach based on SCRUM. **Milestone 3** in December 2023, marks the approval of the miPROLEPSIS-PDPID study and the release of the miPROLEPSIS PDPID app.

Sprint 1: From February to March 2024, patients will have their first interaction with the miPROLEPSIS study app by exploring the initial minimum viable products (MVPs) of the app. The feedback that will be gathered will drive further the improvement of the miPROLEPSIS study app.

In September 2024, **Sprint 2** will take place, allowing patients to validate the alpha version of the app and provide feedback based on the results of Sprint 1.

In November 2024, an alpha version of the app with individual components will be available. Also in November 2024, an alpha version of the iPROLEPSIS Serious Gaming Suite (**D4.3/D4.4**), consisting of individual games, will be developed. **Milestone 5** delivered in November 2024 as well, signifies the completion of the alpha version of the iPROLEPSIS Digital Health Tools.

In April-May 2025, patients will engage in **Sprint 3**, which represents their first interaction with the integrated app and gaming suite that are released in November 2024

In August 2025, updated technical specifications, architecture, and product backlog (**D4.5**) will be released, with updated documentation of technical specifications after the alpha version.

In October 2025, the MVP version of the miPROLEPSIS app, integrating various components, will be launched (D4.6). In addition, the MVP version of the iPROLEPSIS serious gaming suite, featuring personalized features, will be introduced (D4.7).

From March to April 2027, the final sprint, **Sprint 5**, will occur. This spring will allow patients to provide their last round of feedback and engage in the project in order to move towards the final version of the iPROLEPSIS Digital Health Ecosystem.

In November 2026 the integrated version of the iPROLEPSIS Digital Health Ecosystem will be completed, incorporating a fully featured patient app, serious gaming suite, and HCPs' dashboard. **Milestone 10** delivered in December 2026 represents the finalization of the integrated iPROLEPSIS Digital Health Ecosystem.

7 Conclusions

The key takeaways from D2.1 are:

- **Complexity.** The iPROLEPSIS project aims to create DHTs tailored for a complex context. It is important to recognize that each country has its own unique approach to organizing care for PsA patients. While some countries may have limited access to care, which could facilitate the integration of Digital Biomarkers, it could also lead to complications if urgent appointments are unavailable. It is crucial to understand that these innovations are disruptive and, for successful adoption, they need to seamlessly align with the various care systems. The diagrams illustrating the Healthcare Touchpoints in each country can assist in evaluating the potential impact of these innovations.
- **Heterogeneity.** PsA is a highly heterogenous disease. There is a wide range of symptom expression which varies between patients, fluctuates in severity and can develop in new locations overtime. Furthermore, PsA can onset from 30 years and older. The disease affects thus both people living an active life with children and careers, as well as a large population of elder people living in retirement. This brings a long many challenges for the design of the DHTs. Several Personas were developed that can help guide the development process of the iPROLEPSIS DHTs.
- **Trial and Error.** From the focus groups it can be concluded that the PsA marks the life of patients with much uncertainty. By means of trial and error they need to sort out what happens in their body and how to act accordingly. This process is difficult and is paired with many grief cycles. Supporting patients going through this process should be one of the core purposes of the iPROLEPSIS Digital Health Ecosystem. A Patient Experience Map was made to indicate this process over time.
- **Preference Differences.** The survey and the focus groups highlighted that preferences regarding the DHTs features and appearance are diverse. More explanations and causal necessities should be provided to the users about the use of visuals, colour use, notifications, and daily questions in the proposed DHTs. It is important that the identified needs for more explanations are addressed in the upcoming co-creation and development sprints, aiming for a consensus between technological requirements and user acceptance.

Findings from the context analysis, literature review, and the empathising phase were translated to specific URs for each DHTs in Section 5. Next steps will be to enter the co-creation phase with two patient partners from each of the participating countries and to work in design sprints to first develop the miPROLEPSIS PDPID app (first (study) version to be launched in December 2023 before the initiation of the PDPID Study (January 2024)).

References

- Adams, S. A. (2010). Use of “serious health games” in health care: a review. *Information Technology in Health Care: Socio-Technical Approaches*, 160-166.
- Aguado-Delgado, J., Gutierrez-Martinez, J. M., Hilera, J. R., de-Marcos, L., & Otón, S. (2020). Accessibility in video games: a systematic review. *Universal Access in the Information Society*, 19, 169-193.
- Aji, M., Gordon, C., Peters, D., Bartlett, D., Calvo, R. A., Naqshbandi, K., & Glozier, N. (2019). Exploring user needs and preferences for mobile apps for sleep disturbance: mixed methods study. *JMIR mental health*, 6(5), e13895.
- Alhazmi, A., & AG Arachchilage, N. (2021). A Serious Game Design Framework for Software Developers to Put GDPR into Practice. In *Proceedings of the 16th International Conference on Availability, Reliability and Security* (pp. 1-6).
- Al Mahmud, A., Wu, J., & Mubin, O. (2022). [In Press] A scoping review of mobile apps for sleep management: user needs and design considerations. *Frontiers in Psychiatry*.
- Boeije, H. R. (2009). Analysis in qualitative research. *Analysis in qualitative research*, 1-240.
- Bharathi, A. K. B. G., Singh, A., Tucker, C. S., & Nembhard, H. B. (2016). Knowledge discovery of game design features by mining user-generated feedback. *Computers in Human Behavior*, 60, 361-371.
- Campbell, N. K., et al. (2017). The duality of economic issues with medication non-adherence in patients with inflammatory arthritis. *Current Rheumatology Reports*, 19(10), 1-10.
- Caserman, P., Hoffmann, K., Müller, P., Schaub, M., Straßburg, K., Wiemeyer, J., ... & Göbel, S. (2020). Quality criteria for serious games: serious part, game part, and balance. *JMIR serious games*, 8(3), e19037.
- Cejnog, L., Cesar, Jr R. M., Campos, T. D., & Elui, V. (2019). Hand range of motion evaluation for Rheumatoid Arthritis patients. *Proceeding in 14th IEEE International Conference on Automatic Face & Gesture Recognition* (pp. 1-5).
- Dabholkar, T. Y., & Shah, S. S. (2020). Effect of Virtual Reality Training Using Leap Motion Controller on Impairments and Disability in Patients with Wrist and Hand Stiffness. *Indian Journal of Public Health Research & Development*, 11(11), 210-219.
- Dernini, S., & Berry, E. M. (2015). Mediterranean diet: from a healthy diet to a sustainable dietary pattern. *Frontiers in nutrition*, 2, 15.
- DGS/Ministério da Saúde. (2022). Plano Nacional de Saúde 2021-2030. Saúde Sustentável: de tod@s para tod@s. Retrieved June 26th from <https://www.sns.gov.pt/noticias/2022/04/08/plano-nacional-de-saude-2021-2030-2/>.
- Dias, S. B., Jelinek, H. F., & Hadjileontiadis, L. J. (2023). Multisensed Emotions as Adaptation Controllers in Human-to-Serious NeuroGames Communication. *IEEE Communications Magazine*.
- Dorado, J., Toro X. D., Santofimia, M. J., Parreño, A., Cantarero, R., Rubio, A., & Lopez, J. C. (2019). A computer-vision-based system for at-home rheumatoid arthritis rehabilitation, Computer Architecture and Networks Group. *International Journal of Distributed Sensor Networks*, 15(9).

- Duh, H. B. L., Chen, V. H. H., & Tan, C. B. (2008). Playing different games on different phones: an empirical study on mobile gaming. In Proceedings of the 10th international conference on Human computer interaction with mobile devices and services (pp. 391-394).
- Dutch Government. (2023, June 26th). Wanneer betaal ik een eigen risico voor mijn zorg? Retrieved June 26th 2023 from: <https://www.rijksoverheid.nl/onderwerpen/zorgverzekering/vraag-en-antwoord/eigen-risico-zorgverzekering#:~:text=eigen%20risico%20betaalt-,U%20betaalt%20een%20eigen%20risico%20als%20u%2018%20jaar%20of,risico%20vastgesteld%20op%20%E2%82%AC%20385>.
- Dutch Government. (2022). The Integrated Care Agreement; Integraal Zorgakkoord: 'Samen werken aan gezonde zorg'. Retrieved June 26th 2023 from: <https://www.rijksoverheid.nl/documenten/rapporten/2022/09/16/integraal-zorgakkoord-samen-werken-aan-gezonde-zorg>
- Erhel, S., & Jamet, E. (2013). Digital game-based learning: Impact of instructions and feedback on motivation and learning effectiveness. *Computers & education*, 67, 156-167.
- FitzGerald, O., Ogdie, A., Chandran, V., Coates, L. C., Kavanaugh, A., Tillett, W., ... & Mease, P. J. (2021). PsA. *Nature reviews Disease primers*, 7(1), 59.
- Ford, A. R., Siegel, M., Bagel, J., Cordero, K. M., Garg, A., Gottlieb, A., ... & Armstrong, A. W. (2018). Dietary recommendations for adults with psoriasis or PsA from the medical board of the national psoriasis foundation: a systematic review. *JAMA dermatology*, 154(8), 934-950.
- Garbarino, S., Lanteri, P., Bragazzi, N. L., Magnavita, N., & Scoditti, E. (2021). Role of sleep deprivation in immune-related disease risk and outcomes. *Communications biology*, 4(1), 1304.
- Garcia-Argibay, M., Santed, M. A., & Reales, J. M. (2019). Efficacy of binaural auditory beats in cognition, anxiety, and pain perception: a meta-analysis. *Psychological research*, 83, 357-372.
- Greiwe, J., & Nyenhuis, S. M. (2020). Wearable technology and how this can be implemented into clinical practice. *Current allergy and asthma reports*, 20, 1-10.
- Holzinger, A., Kargl, M., Kipperer, B., Regitnig, P., Plass, M., & Müller, H. (2022). Personas for artificial intelligence (AI) an open source toolbox. *IEEE Access*, 10, 23732-23747.
- Hunicke, R., LeBlanc, M., & Zubek, R. (2004, July). MDA: A formal approach to game design and game research. In Proceedings of the AAAI Workshop on Challenges in Game AI (Vol. 4, No. 1, p. 1722).
- Ibarra-Coronado, E. G., Pantaleón-Martínez, A. M., Velazquez-Moctezuma, J., Prospéro-García, O., Méndez-Díaz, M., Pérez-Tapia, M., ... & Morales-Montor, J. (2015). The bidirectional relationship between sleep and immunity against infections. *Journal of immunology research*, 2015.
- Irwin, M. R. (2019). Sleep and inflammation: partners in sickness and in health. *Nature Reviews Immunology*, 19(11), 702-715.

- Jansen, B. J., Jung, S. G., Salminen, J., Guan, K. W., & Nielsen, L. (2021). Strengths and weaknesses of persona creation methods: Guidelines and opportunities for digital innovations.
- Johnson, C. I., Bailey, S. K., & Van Buskirk, W. L. (2017). Designing effective feedback messages in serious games and simulations: A research review. *Instructional techniques to facilitate learning and motivation of serious games*, 119-140.
- Kesari, A., & Noel, J. Y. (2022). Nutritional Assessment. In StatPearls [Internet]. StatPearls Publishing.
- Krebs, P., & Duncan, D. T. (2015). Health app use among US mobile phone owners: a national survey. *JMIR mHealth and uHealth*, 3(4), e4924.
- Leventhal, H., Phillips, L. A., & Burns, E. (2016). The Common-Sense Model of Self-Regulation (CSM): a dynamic framework for understanding illness self-management. *Journal of behavioral medicine*, 39, 935-946.
- McCurdie, T., Taneva, S., Casselman, M., Yeung, M., McDaniel, C., Ho, W., & Cafazzo, J. (2012). mHealth consumer apps: the case for user-centered design. *Biomedical instrumentation & technology*, 46(s2), 49-56.
- Min, W., Jiang, S., & Jain, R. (2019). Food recommendation: Framework, existing solutions, and challenges. *IEEE Transactions on Multimedia*, 22(10), 2659-2671.
- Miranda, R., Oliveira, M. D., Baptista, F. M., & Albuquerque, I. (2023). Telemonitoring in Portugal: where do we stand and which way forward?. *Health Policy*, 104761.
- Moore, G.A. (1991). *Crossing the Chasm*. New York: Harper Business.
- Oksanen, K., & Hämäläinen, R. (2014). Game mechanics in the design of a collaborative 3D serious game. *Simulation & Gaming*, 45(2), 255-278.
- Ordovas, J. M., Ferguson, L. R., Tai, E. S., & Mathers, J. C. (2018). Personalised nutrition and health. *Bmj*, 361.
- Pinto da Costa, M. (2021). Conducting cross-cultural, Multi-Lingual and Multi-Country focus groups: guidance for researchers. *International Journal of Qualitative Methods*, 20, 16094069211049929.
- Pouls, B. P., Bekker, C. L., Gundogan, F., Hebing, R. C., van Onzenoort, H. A., van de Ven, L. I., ... & Van den Bemt, B. (2022). Gaming for Adherence to Medication using Ehealth in Rheumatoid arthritis (GAMER) study: a randomised controlled trial. *RMD open*, 8(2), e002616.
- Rabiee, F. (2004). Focus-group interview and data analysis. *Proceedings of the nutrition society*, 63(4), 655-660.
- Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., ... & Moore, L. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *bmj*, 374.
- Rogers, E. M. (2010). *Diffusion of innovations*. Simon and Schuster.
- Rongen-van Dartel, S. A. A., et al. (2015). Effect of aerobic exercise training on fatigue in rheumatoid arthritis: a meta-analysis. *Arthritis care & research*, 67(8), 1054-1062.
- Salvador-Ullauri, L., Acosta-Vargas, P., Gonzalez, M., & Luján-Mora, S. (2020). Combined method for evaluating accessibility in serious games. *Applied Sciences*, 10(18), 6324.

- Schwarz, A. F., Huertas-Delgado, F. J., Cardon, G., & DeSmet, A. (2020). Design features associated with user engagement in digital games for healthy lifestyle promotion in youth: A systematic review of qualitative and quantitative studies. *Games for Health Journal*, 9(3), 150-163.
- Shin, J. C., Kim, J., & Grigsby-Toussaint, D. (2017). Mobile phone interventions for sleep disorders and sleep quality: systematic review. *JMIR mHealth and uHealth*, 5(9), e7244.
- Stefanidis, K., Tsatsou, D., Konstantinidis, D., Gymnopoulos, L., Daras, P., Wilson-Barnes, S., ... Dimitropoulos, K. (2022). PROTEIN AI Advisor: A Knowledge-Based Recommendation Framework Using Expert-Validated Meals for Healthy Diets. *Nutrients*, 14. doi:10.3390/nu14204435
- Streicher, A., & Smeddinck, J. D. (2016). Personalized and adaptive serious games. In *Entertainment Computing and Serious Games: International GI-Dagstuhl Seminar 15283*, Dagstuhl Castle, Germany, July 5-10, 2015, Revised Selected Papers (pp. 332-377). Springer International Publishing.
- Susi, T., Johannesson, M., & Backlund, P. (2007). Serious games: An overview.
- Tessarolo, F., Petsani, D., Conotter, V., Nollo, G., Conti, G., Nikolaidou, M., ... & Konstantinidis, E. I. (2022). Developing ambient assisted living technologies exploiting potential of user-centred co-creation and agile methodology: The CAPTAIN project experience. *Journal of Ambient Intelligence and Humanized Computing*, 1-16.
- Theodoridis, T., Solachidis, V., Dimitropoulos, K., Gymnopoulos, L., & Daras, P. (2019). A survey on AI nutrition recommender systems. *Proceedings of the 12th ACM International Conference on PErvasive technologies related to assistive environments*, (pp. 540–546).
- Thompson, J. (2022). A guide to abductive thematic analysis. *The Qualitative Report*, 27(5), 1410-1421.
- de Thurah, A., Bosch, P., Marques, A., Meissner, Y., Mukhtyar, C. B., Knitza, J., ... & DeJaco, C. (2022). 2022 EULAR points to consider for remote care in rheumatic and musculoskeletal diseases. *Annals of the rheumatic diseases*, 81(8), 1065-1071.
- Trang Tran, T. N., Atas, M., Felfernig, A., & Stettinger, M. (2018). An overview of recommender systems in the healthy food domain. *Journal of Intelligent Information Systems*, 50, 501–526.
- Verma, M., Hontecillas, R., Tubau-Juni, N., Abedi, V., & Bassaganya-Riera, J. (2018). Challenges in Personalized Nutrition and Health. *Frontiers in Nutrition*, 5. doi:10.3389/fnut.2018.00117
- Varga, G., Stoicu-Tivadar, L., & Nicola, S. (2021). Serious gaming and AI supporting treatment in rheumatoid arthritis. In *Public Health and Informatics* (pp. 699-703). IOS Press.
- Yanez-Gomez, R., Cascado-Caballero, D., & Sevillano, J. L. (2017). Academic methods for usability evaluation of serious games: a systematic review. *Multimedia Tools and Applications*, 76, 5755-5784.

Appendix I Focus Group Script English Version

Introduction

[10 minutes]

Welcome

Welcome to this focus group about ‘Patient perspective on disease activity and digital biomarkers for PsA’. We are very grateful for your participation in our research.

Presentation

- Introduce moderator and observer
- What shall happen during this focus group
- Duration of focus group 60 minutes to 1,5 hours.

Rules:

- Participation in the focus group is voluntary.
- All responses are valid—there are no right or wrong answers. Please do not interrupt when someone is talking. Please respect the opinions of others even if you don’t agree.
- Speak as openly as you feel comfortable. It’s all right to abstain from discussing specific topics if you are not comfortable.
- Try to stay on topic; we may need to interrupt so that we can cover all the material.
- Help protect others’ privacy by not discussing details outside the group.
- Please try not to talk at the same time, as then it is hard to keep up with the conversation.
- We would like to capture the conversation on tape. Is that alright with you?

If online explain Zoom/Teams functions

- Mute button
- Raise hand
- Grid view (so all participants can see one another)

Introductory information:

PsA is a chronic disease that requires frequent hospital visits. Our research team wants to see if we can use technology to monitor your disease activity. We are still at the beginning of our development process and are mostly looking for input about where the application of such technology could be useful and what requirements it should meet to be accepted by the target users – which are you.

This group discussion is meant to debate about which information you would like to have about your rheumatic disease, what the future care for PsA should be and how technology could help in achieving these goals.

Introduce Participants:

- Who are you?
- What do you do in daily life?
- How long ago where you diagnosed with PsA?
- What is the first word that comes to mind when you think about PsA?
- Do you agree with the terms of this research? (give consent)

Discussion

[40 minutes]

1. How do you notice that the disease activity of your PsA is low?
 - a. How do you notice your PsA is acting up?
 - b. What is the first thing you notice?
 - c. Sensitizers; pain, sleep, limited range of motion, swelling, mood, activity patterns, strength, ...
 - d. Which symptoms do you find most burdensome?
 - e. What do you worry about and why?
2. If your PsA is flaring, how do you adapt to it?
 - a. AIM: Which symptoms lead to which coping strategy?
 - b. Sensitizers: Resting, Smoking, Painkillers, Sleep, Social behavior, Movement behavior, Specific movements, Mood, etc.
 - c. Why do you apply this specific adaptation?
 - d. When do you choose which strategy?
3. When do you decide to make an appointment at the doctor's office yourself because of a flare?
 - a. Is it possible to get an appointment then soon?
 - b. In your opinion, when is a doctor's visit useful/needed?
 - i. What do you need your rheumatologists for?
 - ii. What do you hope to get out of your appointment?
 - c. Opinion on video calls, telephone consultations, frequency of consultations. Role of consultations
 - d. If you could change the way your care is organized, what would you do differently to improve the disease activity monitoring?
 - i. How would you like to monitor your disease?
 - ii. What do you need regarding your PsA?
4. Do you use your mobile phone or smartwatch to monitor your disease activity?
 - a. If so, what do they use and what for?
 - b. What kind of information would you like to obtain about your PsA?
 - c. If we wanted to measure your disease activity using technology, what should we capture?
 - i. Sensitizers: Fatigue, Sleep, Mood, Pain, Movement, Social activities, etc.
 - d. Would you like monitor your disease in this way?
 - i. What could be benefits of monitoring your disease in this way?
 - ii. What could be drawback of monitoring your disease in this way?

Closing

[10 minutes]

- Shortly summarize what has been discussed.
- Ask each participant if there is anything they would like to add
- Explain what is going to happen with the provided information.
- Explain how they shall receive feedback about the results of this study
- Ask if there are any further questions or comments

Appendix II iPROLEPSIS Patient Survey

Survey Page 1

[X] Survey Page 2

[X] Survey Page 3

Survey Page 4

Survey Page 5

Survey Page 6

Survey Page 7

Survey Page 8

Survey Page 9

[X] Survey Page 10

[X] Survey Page 11

[X] Survey Page 12

Survey Page 13

[X] Survey Page 14

[X] Survey Page 15

[X] Survey Page 16

[X] Survey Page 17

[X] Survey Page 18

[X] Survey Page 19

[X] Survey Page 20

[X] Survey Page 21

[X] Survey Page 22

[X] Survey Page 23

Appendix III Focus Group Code Book

(DA) Disease Activity	Low Disease Activity	What happens when they are doing well & residual complaints.
	Symptoms	Mentioning of PsA specific complaints. E.g. Pain, sleep, fatigue, swelling, skin heat, stiffness.
	Triggers - Own Influence	Things they do themselves that influences their disease activity. E.g. diet, alcohol use, overexertion.
	Triggers - External influences	Things they can not influence, but can trigger their disease. E.g. weather, seasonal changes, climate
	Fluctuations - no triggers mentioned	Mentioning of exacerbations, without a cause. Also mentioning the development of new complaints / expression in new joints.
	Side effects from medication	Misselijk, vermoeidheid
	Mood	Stemming en het effect van je stemming op de ervaring van je ziekte
	Confounders	Co-morbidities, Complaints that come with aging, strained joints, etc.
Coping	Mindset	Attitude in life. How they perceive changes, e.g. glas half full vs glas half empty kind of people.
	Motive	Reasoning on why they make certain decisions. Beliefs that they have about certain actions. Which also might influence their ability to adapt.
	Adaptations: Activities	Changing the activities they perform. Changing their kind of sports, the amount of activities they perform, etc.
	Adaptations: Mental	Letting go, acceptance, thinking in opportunities instead of in limitations.
	Adaptations: Other	
	Emotions	Short waves of feelings they experience. E.g. disappointment, sadness.
	Coping - Impact	Limitations, physically and mentally
	Interventions: Movement	Things they do to prevent worsening of their disease or to make it to the day. E.g. sports, posture training, exercise, physcial therapy, prying loose your joints in the morning.
	Interventions: Medication	Everything they mention with regard to their medication; preferences, switching, playing with dosages, etc.
	Interventions: Other	Everything with regard to alternative treatments. Accupuncture, meditation, Wim Hoff, etc.

Care Experience	Current situation	Frequency of appointments, relation with their rheumatologist, etc. How do they perceive the care they receive now
	Diagnosis Process	how their diagnosis was made
	Needs; consultations	Waarvoor is een consult nodig?
	Needs: gain control without medication	Wat kan ik zelf doen om mijn ziekte te verbeteren?
	Needs: peer contact	Niet het wiel opnieuw uitvinden
	Needs: disbelief / incomprehension / ignorance	from their rheumatology HCP, but also from other people (personal trainers, physical therapists, etc.)
	Needs: Urgency	When to visit the rheumatologist
	Needs: Other	
	eConsults (phone / video call): Positive	The positive sides of eConsults (phone call / video call)
	eConsults (phone / video call): Negative	The negative sides of eConsults (phone call / video call)

Trial & Error	In General	Generic statements about trial & error. E.g. 'it is all experimental'
	Doubts	Doubts whether complaints are of rheumatological origin
	Medication	Tapering medication, switching medication
	Balance	Finding balance in life, activities, and fulfillment
	Other	
Uncertainties		Not knowing what the progression of your disease is going to be. Or when it will flare up. How you will be the next day, the next week, month or year

Digital Biomarkers	Attitudes: data orientation	Quotes that show that some people are very data oriented already. And want to gather as much data about themselves as possible.
	Attitudes: negative	Negative perceptions of Digital Biomarkers & Continuous monitoring.
	Attitudes: positive	Positive perceptions of Digital Biomarkers & Continuous monitoring.
	Attitudes: privacy	Statements about feelings towards privacy issues. 'big brother feeling' vs 'we are already monitoring everything, so no problem'
	Attitudes: other	
	Aim: learning at a macro level	Benefits for the PSA patient population as a whole. Doing it for others.
	Aim: prevention	
	Aim: learning at a personal level	Personal advantages
	Aim: other	
	Usage: Data security / Rights / Privacy	Practical tips and conditions: e.g. data transparency, rights on work phones, guidelines, etc.
	Usage: Invasiveness	frequency of measurement, notifications, reminders, mental load, needing to remember to have your phone with you.
	Usage: alignment with own experiences-feelings	Evidential burden. Needing to defend your feelings because the DB says otherwise.
	Usage: other	
	Measure: Movement	Statements about measuring movement behaviour. Yes, no, how
	Measure: Blood	Statements about the value of blood measurements and how they are obtained now
	Measure: Confounders	Statements made by the participants about potential confounders, e.g. taking pain killers, phone useage, taking a holiday, etc.
	Measure: Pain	Statements about measuring pain. Yes, no, how
	Measure: Sleep	Statements about measuring sleep. Yes, no, how
	Measure: Stress	Statements about measuring stress. Yes, no, how
	Measure: Weather	Statements about measuring Weather. Yes, no, how
	Measure: Energy levels - fatigue	Statements about measuring energy levels/fatigue. Yes, no, how
Measure: Other		