

Design and evaluation of a digital wearable ring and a smartphone application to help monitor and manage the effects of Raynaud's phenomenon

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Abstract This paper presents the iterative research, design and evaluation phases of a digital wearable health system for monitoring, managing and possibly assisting in preventing the effects of a chronic disease called Raynaud's Phenomenon (RP). The wearable health system is composed of three main parts, a physical product of a smart ring, the digital infrastructure of the physical computing subsystem (hardware and software) and an accompanying smartphone application. A set of design requirements that best describe the functionality and the characteristics of wearable health systems have been selected to derive a thorough study and evaluate the design prototype. We present these along with a set of guidelines for designing wearable health systems (device products and software at the application level) with focus on usability and user experience. The purpose is to evaluate, the prototype which is based on multiple sensor inputs that acquire simultaneously several biomedical and environmental signals, the interaction techniques used and the feedback mechanisms of the smart ring and the accompanying smartphone application for logging and monitoring the progress of RP.

Keywords: Raynaud's phenomenon; wearable health systems; mhealth; smart ring; smartphone application; evaluation; design requirements

1 Introduction

Digital health is a well-established scientific and industrial domain while the introduction of wearable health technologies that monitor human activity in real-time and provide information for managing health related issues is a relatively new research area that receives serious attention from the industry, research institutions, political and economic unions and their initiatives [1]. It combines product and industrial design with computing, data analytics and healthcare [2, 3].

Following the concept of the "continuity of care" that has been adopted more than two decades from the health community, the broader scope of digital health and health wearables is to provide patients with technologies (hardware devices, software tools/systems and online services) to better monitor, track and potentially manage their health and wellness related activities. The traditional healthcare based on hospitalization is shifting towards an individual/patient centred health management while the practice of diagnosis-treatment is also changing to include technology driven prediction, prevention and early risk management [1, 4].

Today, the line between consumer wearable health systems and specialised medical instruments begins to blur, primarily because of the continuous improvement of the former in terms of accuracy, efficiency, aesthetics and form factor. Their use is changing the way people think about their health, but also provide the means to understand and anticipate health progress by a) providing innovative ways to monitor health and well-being, b) give greater access to information and c) support communication and collaboration over prognosis, diagnosis and treatment. According to Lupton [5], digital health

1 technologies and in particular wearable health systems are described as “products that encourage lay people to engage in
2 preventive health activities and improve patient adherence to treatment protocols and their self-management of chronic
3 diseases”. Moreover, such technologies afford human interaction and communication at various levels, including those
4 between healthcare providers and patients but lately, also, among patients and other stakeholders over social network
5 platforms [6].
6 In this project attention is given to a specific group of people who suffer from Raynaud’s Phenomenon (RP). In the
7 following sections, we analyse RP and its major characteristics that can be monitored and managed or possibly prevented
8 through the use of wearable health technologies. We provide an overview of related projects and present our research,
9 preliminary design stages and evaluation of a wearable health system prototype, as presented in Figure 1, for monitoring and
10 managing the effects of the chronic disease. We also provide a set of design requirements for wearable health systems and
11 finally, we also outline some insights for future work.
12



13
14 **Fig. 1** Prototype of wearable health system for monitoring and managing the effects of RP

15 **2 Raynaud’s Phenomenon**

16 People who suffer from RP very often experience cold fingers, toes and other extremities when they are exposed to
17 environmental temperature changes (e.g sudden temperature drop), come in contact with low temperature objects or liquids,
18 exposed to vibration, or engage in stressful situations [7–9]. It is due to a narrowing (constriction) of the small blood vessels
19 which in turn blocks the normal blood flow causing discoloration, numbness, prickly feeling or stinging pain. Figure 2 shows
20 the typical presentation of a RP event which involves the fingers turning white (ischaemia), then blue (cyanosis), and finally
21 red (reperfusion). Those events are described as cold ‘attacks’. RP appears in 5 to 10% of the world’s population with women
22 representing 90% of them. The phenomenon is either described as *Primary* or *Secondary*. *Primary RP* is idiopathic and is
23 described as a disease (Raynaud’s Disease). It occurs by unidentifiable reasons in the absence of an underlying disease and
24 can’t be cured. *Secondary RP* is considered an expression of another underlying disease - such as systemic lupus

erythematosus, scleroderma, or peripheral vascular disease - which, if identified and managed, it consequently cures RP as well [10].

Both types have common symptoms, but the attacks can differ on symmetry, severity, frequency and duration and can be distinguished with clinical criteria. Cold fingers and toes with skin discoloration in response to cold or stress may prevail RP [11]. The affected extremities turn white, then blue/purple and finally red upon rewarming. The “cold” attack starts by losing the sense of touch with a tingling feeling and pain. Upon rewarming or relieving from stress, the extremities sting like pins-and-needles. In severe cases, digital ulceration, tissue damage or even gangrene may happen [12].

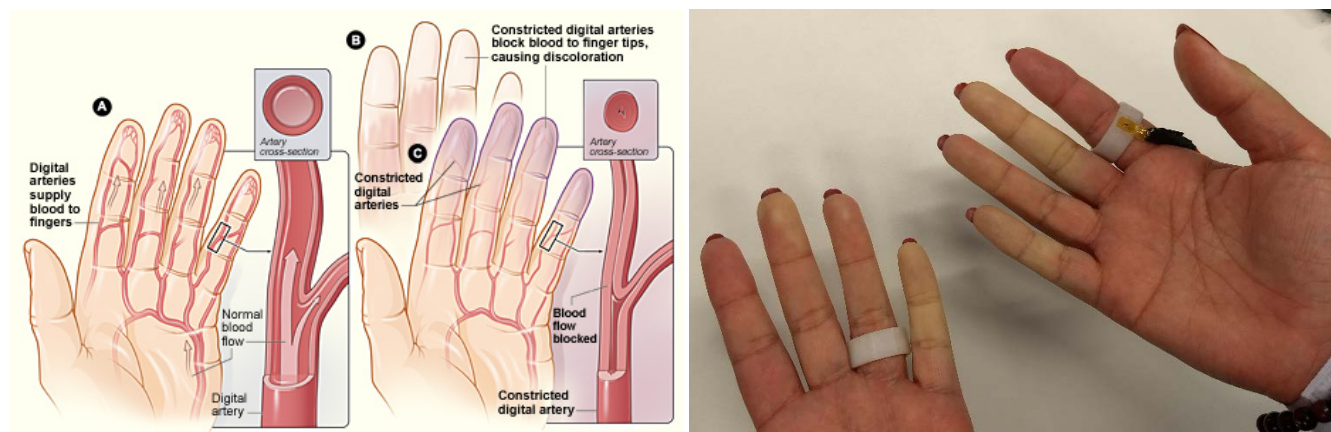


Fig. 2 Raynaud's phenomenon. On the left, symbol A shows the normal digital arteries with normal blood flow to the fingers. The inset images show cross-sections of a normal artery. Symbol B shows white discoloration of the fingertips caused by blocked blood flow. Symbol C shows narrowed digital arteries, causing blocked blood flow and purple discoloration of the fingertips. The inset images show cross-sections of a narrowed artery blocking the flow of blood [13]. On the right, a photo from one of our RP participants experiencing an attack during tests

Medications diminish the effects of the phenomenon without, yet, curing it. They usually cause side-effects for example fatigue, tachycardia (palpitations), orthostatic hypotension, headache and dizziness thus making everyday activities much more intolerable [11, 14, 15]. As of today, there's no known cure for RP while most treatment approaches focus in identifying ways to control or prevent the condition. Patient education for *prevention* is inseparable part for managing RP successfully. It is considered that patients should take proper precautions for avoiding direct interactions with cold objects and environments. Multi-layered clothing, glove liners, electric gloves, pocket heaters are essential for keeping the core body and extremities warm during the cold months [8]. A healthy eating, non-smoking lifestyle with daily exercising or meditation can help improve circulation and relieve stress in the long-term.

Typical clinical diagnostic investigations include blood count, ESR and ANA analyses, and nailfold capillaroscopy among others. These methods are expensive, available only in specialist centres [16] and require dedicated medical equipment: thermography, arterial Dopplers, large vessel imaging with X-ray, CT or MR angiography. The use of the “cold-challenge test” is often considered the standard measuring/testing mechanism for diagnosing RP while other testing techniques such as the ‘distal–dorsal difference’ (DDD) in temperature (hypothesis that the tip of a finger is $>1^{\circ}\text{C}$ colder compared to the dorsum of the hand at room temperature of 30°C), also help to identify and differentiate RP from other conditions [17].

Alternative treatment methods include Thermal Biofeedback Training (TBF) and Low-level Light Therapy (LLLT). Both have been identified as alternative to medication, efficacious non-invasive treatment methods. TBF refers to the skill of self-regulating skin temperature. It involves relaxation and meditation techniques supported by technological means (e.g. temperature sensors attached to the user's finger). The method involves the use of audio-visual feedback which allows users to understand how their thoughts and actions can help control their body temperature. The therapy is rated as ‘efficacious’ as

there is a moderate drop in frequency and severity of RP attacks [18]. An important finding in this research is that users who operated at domestic environments instead of clinical presented better results in handling RP. A mobile wearable device for thermal biofeedback can help integrate this non-invasive therapy into a patient's everyday life.

Low-Level Light Therapy (LLLT) can improve blood microcirculation to the extremities and make the attacks up to 82% less intense [19]. It requires laser or LED that emit photons of red or infrared wavelengths (600 to 1000 nm). LLLT requires regular applications to the palms and fingers of both hands to give patients long lasting relief [19–23]. No side-effects have ever been reported [24].

2.1 Benefits of Monitoring Raynaud's Phenomenon

Monitoring RP as a process has a great potential in managing the disease at various stages in its progress. The benefits can be summarised in: *Identifying the progress of the disease*, *Tracking and monitoring treatment*, *Improving self-management*, *Building a community* and *Developing useful knowledge from raw/collected data*.

Identify the progress of the disease: Sensors can alert on abnormal body temperature or blood pressure drops that could indicate a RP attack. Continuous monitoring of severity, duration and frequency of attacks can help in keeping a detailed record of past events automatically. By analysing the stored patterns of occurrence, it is possible to provide insights for the characteristics of future events. Monitoring can also assist in detecting a transition to *secondary* RP as it happens to 2% of patients every year [25]. Monitoring can also help in identifying specific conditions (e.g digital ulcerations) that occur during the course of RP and thus provide the grounds for educating users to reduce risks (e.g. scarring or gangrene).

Track and monitor treatment: Before engaging a patient to a specific treatment plan, the relative risks and benefits must be considered [9]. Thus, monitoring how patients' organisms react to a certain therapy can help identify early benefits or unforeseen risks. Digital health technologies have the potential to monitor the recovery processes that occur with a specific treatment phase and to detect improvements or complications as they arise. Captured data can be analysed and potentially utilised in measuring the effectiveness of a treatment.

Improve self-management: Adjust behaviour or get motivated for better health e.g. insight to stop smoking. Develop proactive mechanisms to identify and anticipate a 'cold' attack. Engage in a more proactive/prevention lifestyle. Train on thermal biofeedback. Organise post-attack actions. Understand the effects and severity of an attack.

Build a community: Benefits include the sharing of experiences, confessions, ideas and the way patients follow the course of their treatment either according to their prescribed by their doctors approach to therapy, or in terms of clinically suggested non-pharmacological lifestyle modifications for treating RP (discontinuation of smoking, avoidance of unnecessary cold exposure, protection of exposed skin during cool weather, avoidance of tools that cause vibrations etc.) [26]. Users can ask questions and exchange information related to their condition (forum). Come in direct contact with doctors and caregivers. Read news on research, medications, treatments etc.

Develop useful knowledge from raw data: The psychological nature of RP makes patients evaluate their health status by means of subjective empirical judgments. On the other hand, it is important to gather objectively measured data that can help in assessing the effectiveness of treatment plans. Data acquisition and analysis can provide both users and health professionals with new knowledge on how everyday habits, treatments and behaviours affect RP.

3 Related Work

Today's wearable devices enable real-time monitoring with the aim of self-care and prevention [3, 27]. Heart rate, blood pressure, oxygen saturation and other vital signs measurements are usually measured within the context of a physician's office, but health wearables are bound to change that [6, 28]. The same measurements can easily and accurately be acquired from today's state-of-the art sensors and portable or wearable devices. Tracking physiological parameters in real-time and continuously during the day helps provide instant feedback to users, doctors and caregivers while logging and alerting them

when measurements are beyond the limits becomes a necessity. Moreover, algorithms that can correlate findings and identify patterns that may reveal interesting physiological responses of the body during different activities and environments are needed [6, 29]. Wearable devices can potentially help understand users' routines and their baseline norms so as to inform on abnormal changes [29, 30] (e.g. changes in baseline heart rate or skin temperature when waking up). Data analysis should reveal differences among individuals with different health statuses (e.g. those with *Primary* Raynaud's versus those with *Secondary*). They should identify and inform people on habits that have positive or negative impact to their health [30]. Nowadays, wearable technologies are taking over the healthcare industry by providing new ways to assist users on early medical diagnosis, inform on disease development, track multiple parameters, keep doctors and caregivers updated in real-time. At the same time wearables are at the centre of just about every scientific discussion related to health informatics, the internet of things, human computer interaction and product design.

3.1 Related Projects

As of today, there are no low budget, consumer targeted wearable devices (non-medical instruments) or smartphone applications dedicated in real-time tracking of RP outside a clinical environment. In total, we identified only two experimental projects that are related to RP and aim at providing such a service to end-users/patients. In 2002, researchers from John Hopkins University developed a portable device that would wrap around a fingertip to measure RP symptoms at a domestic environment. It featured two temperature sensors for measuring skin and ambient temperatures while the use of a button recorded these values that could later be exported to a computer for further analysis. The device was re-patented in 2005, but no updates on design or user trials are reported ever since [31]. Another monitoring prototype for RP was developed in 2016 as a proof-of-concept for a hackathon event [32]. It featured two temperature sensors; one attached at the wrist and one at the finger in the form of a ring. The project's evaluation mechanism is similar to the 'distal-dorsal difference' hypothesis. The developer's ambition was to create a platform to collect and process everyday data, but the project was stalled, and no publications were reported. Other related experimental or commercial products and services with various functionalities (mentioned online or patented) and appear to be potential wearables for RP sufferers include: Embr Wave (Wristify) thermostat and temperature regulation device [33–35], Digitsole a smart feet heating device with sensors and a mobile application for tracking human activity and monitoring temperature [36], Soletics Raynaud's heating gloves based on temperature sensors and auto temperature regulation mechanisms to maintain human temperature [37].

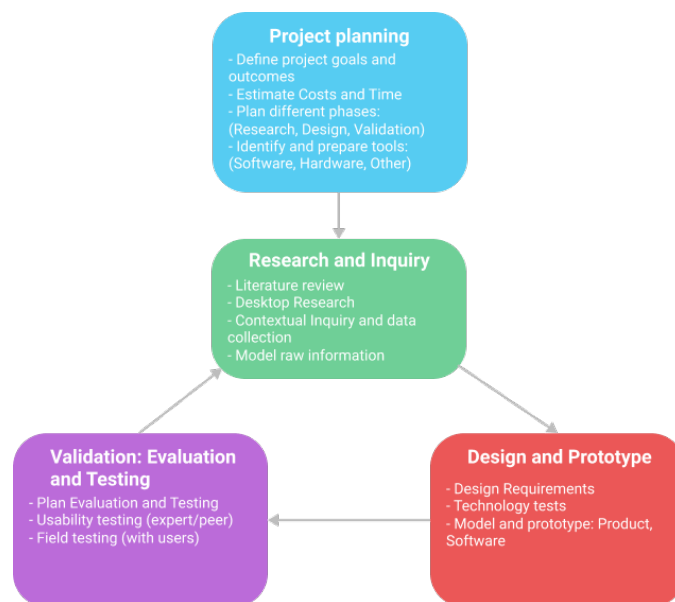
4 Methodology

This project is mainly influenced by a user-centred design paradigm, a common framework of design processes in the design industry that aims to increased product usefulness and usability [38, 39]. During the different stages of the design processes, involved in designing the physical product the electronics and the software, extensive attention is given to the user characteristics and goals, the context of use, the environment, the tasks and workflows and the usability goals.

The methodology used in the project is based on a mix and match of techniques [40], methods and methodologies used in designing interactive systems and services [41]. It is mainly a multi-methodological approach used in interaction design teams and is influenced by interaction design and user experience and extends to software, systems, industrial and service design [42]. It encompasses design goals focusing in dealing with product's behaviour (physical product, computational, data analytics), visual and physical form, interactivity, user experience and usability. The major methodological tools used for these means include Contextual Design, Goal Directed Design and Benyon's scoping technique which involves understanding of People, Activities, Context and technologies (PACT). Contextual Design is a structured, "user-centred design process that provides methods to collect data about users in the field, interpret and consolidate that data in a structured way, use the data to create and prototype product and service concepts, and iteratively test and refine those concepts with users" [44]. Goal Directed Design (GDD) is also a user-centred design methodology that helps designers and design

1 researchers to identify the goals and behaviours of users and represent them in the design process as design requirements.
2 According to Alan Cooper, goals are motivations for the user and describe what they are trying to achieve, whereas tasks are
3 the steps involved to help them achieve the goal. The research and design process proposed from GDD include a number of
4 steps for communicating with users, analysing their activities, and most importantly comparing their needs and goals by the
5 use of personas. It is a six step process: *Research* to collect qualitative data about the users, *Modelling* for creating user
6 archetypes and workflows that represent their activities and correlate their profiles, *Requirements definition* for each persona
7 (as opposed to detailed requirements for developers), *Framework Definition* for the concept development, *Refinement* which
8 places focus on detail and refinement of the concept and *Development support* for assisting in the developers [45]. Finally,
9 the scoping technique PACT is a tool for thinking holistically about a design situation in relation to the interactive system
10 [46]. Is a generic tool for research and inquiry as well as for supporting design activities and assist in identifying
11 improvements or envisioning future design possibilities.

12 This project included an initialisation phase mainly focused on *Project Planning*, followed by an iterative design approach
13 that included three main phases: *Research and Inquiry*, *Design and Prototyping* and *Validation: Evaluation and Testing*.
14 In Figure 3 we depict these major phases and in the sections below we analyse in more detail the methodological steps and
15 how we followed them for this project.
16



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18
19 **Fig. 3 Methodology of the project**

20 **5 Planning, Research and Inquiry**

21 **5.1 Project planning**

22 Project planning included the definition of project goals and outcomes, an estimation of necessary resources and their costs,
23 identification of possible technologies and tools to be used and a classification of the tasks to be performed into the different
24 phases of the iterative design process, identification of individual stakeholders and their interactions with the design team.
25 We also planned collaboration with RP patients, organised interviews and communicated project's goals with online

communities. Often in the course of the iterative design process we re-planned, in an Agile/Lean UX fashion, project tasks that were not well defined during this initial phase [43].

5.2 Research and Inquiry

During this phase we incorporated research methods and activities [45, 47, 48] with most important those of *desktop research and literature reviews*, *contextual inquiry* and *online surveying*. Desktop research and literature reviews initiated the research activities and introduced the research team to the concepts related to RP, wearable health technologies and mobile health (mhealth). It also iteratively complemented contextual inquiry with information and knowledge about trends and developments in related contexts at a worldwide scale.

Contextual inquiry was the most important research activity because it helped the design team to gain a deeper understanding about the particular situation, become aware of the context, identify the characteristics and behaviours of people and finally perceive and define their activities that influenced the anticipated design decisions. We conducted a mix of traditional interviews and observation of daily activity with two RP patients. We closely worked with them to identify their everyday needs, activities and practices in dealing with RP. We collected rich information about the social, technical and physical environments that the patients encounter as well as tools, methods and practices that they use or follow in their everyday life. We also collected data about their psychological and physiological status, details about the progress of the disease and its influence in their behaviour, attitudes and emotions. Based on these findings we collected a list of questions that later have been used for evaluation purposes on a larger scale questionnaire/survey.

Based on the aforementioned findings, during the second iteration of the design/evaluation process, we conducted a dedicated online survey, based on questionnaires, to collect data from a greater group of people who suffer from RP. We identified several online communities, societies and associations related to RP and we prepared a set of questions (demographic and rating scales) that were distributed to them through online social media.

We received responses from (n=379) RP sufferers from which 95.5% were female, 4% male and 0.5% other. Significant ages were: 39.3% between 45-64 years old, 27.4% between 34-44 years old, 17.7% 25-34 years old and 9.8% 19-24 years old. From them, 61.7% were diagnosed with Primary RP, 31.9% with Secondary RP and 6.3% have symptoms but are not officially diagnosed. On a scale from cold=1 (−15° C) to warm=10 (45° C) reflecting weather climate region, 33.5% lived on region 5, 19% on region 4, 14% on region 3, 11.6% on region 6 9.2% on region 7, 4.5% on regions 2 and 8, 2.1% on region 1, 0.5% on region 10 and 0.3% on region 9. Most of them (86.3%) use mobile phones (43.8% Android, 42.5% iPhone), 58% rings, 20.6% bracelets, 29.3% clock-watches while only 8.12% have a wearable smart tracker or smart watch.

Rate how much each part of your hand is affected by Raynaud's

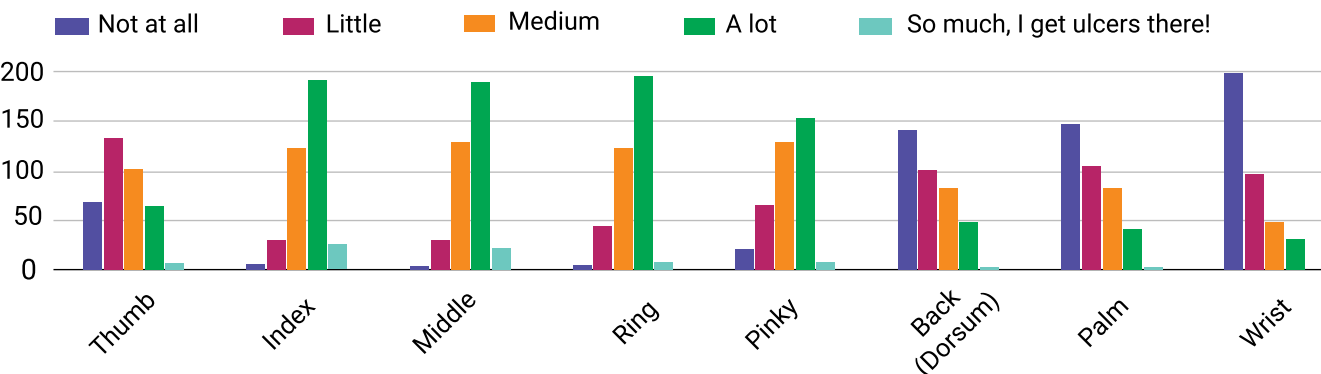


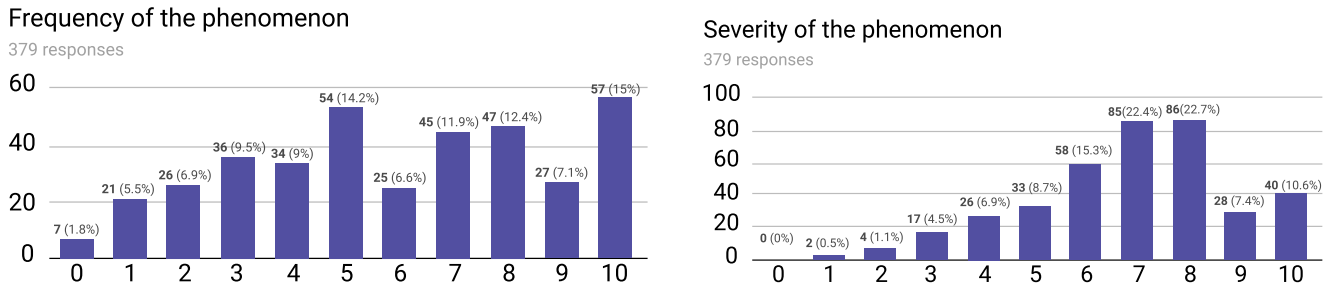
Fig. 4 Participant ratings related about RP affected areas of the hand

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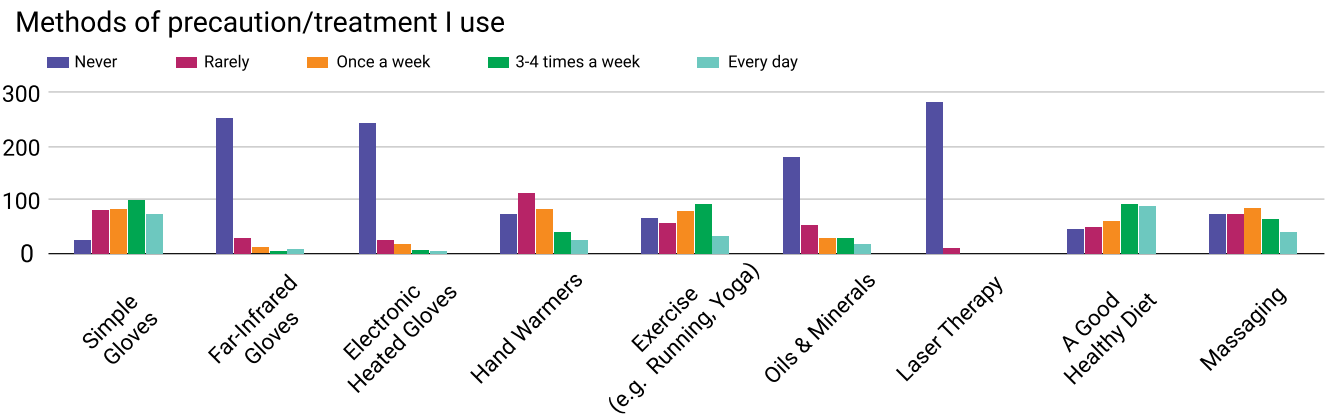
We also collected, as depicted in Figure 4, subjective data about the affected parts of the hands (thumb, index, middle, ring, pinky, dorsum, palm, wrist) the frequency, severity and duration of the phenomenon and methods of precaution or treatment. Most of the participants experienced serious attacks with the ring (51.71%), index (50.39%) and middle (50.13%) fingers, followed by pinky (40.1%) while thumb (17.41%), dorsum (12.9%) palm and wrist (8.7%) were less affected.

The frequency and severity of attacks cannot be easily and directly measured as they are influenced by a number of factors, including, weather, severity of underlying condition, subjective understanding of the patient, medication or treatment and psychological state among others. Based on evidence from desktop research on measuring RP activity [49, 50] we concluded that to identify the frequency of attacks the following categories could be used in our questionnaires: “one or more times a day” and “less than daily”, since, according to the aforementioned studies, there are relatively few patients (5.9%) who experience attacks less than once a week, with an average of M=3.89 RP attacks per day on an observable range of 0.8 minimum to 14.6 maximum attacks. Therefore, on a scale from 0 (low – less than daily) to 10 (high – one or more times a day), 67.2% of the participants answered that they have a frequency of attacks above the average (mapped as more than 3.89 attacks a day) while 15% were having many attacks (close to 14.6 attacks a day) and only 1.8% was close to less than an attack per day.

To identify current painful stimulus intensity and severity of RP in our group of participants we used Visual Analogue Scale (VAS) a unidimensional measure of pain intensity, which has been widely used in diverse adult populations that experience RP and other conditions that produce pain. On a scale of 0 (no issues or pain) to 10 (severe issues and pain), 87.1% answered that have a severity of attacks above the average, with 60.4% on scales 6 to 8 (moderate to severe) while none of them had no issues or pain. We present our findings on Figure 5.



21
22 **Fig. 5** Participant ratings about frequency and severity of the phenomenon



23
24 **Fig. 6** Participant answers related to methods of precaution and treatment used

1 Using a dichotomous type questionnaire (yes/no), we identified participant habits that mostly cause an attack. These
2 included: 75.2% touching a cold object, 72% air conditioning, 53.3% contact with water, 44.9% psychological stressors,
3 36.1% sitting still for long time, 31.9% working environment, 30.3% car steering wheel, 11.3% vibrating tools, 8.2%
4 smoking. The majority of participants use simple gloves or hand warmers and try to follow a healthy diet, to exercise and
5 massage. As presented in Figure 6, significant were the numbers for those that never used laser therapy 74.9%, far-infrared
6 66.49% or electronic heated gloves 64.64%.

7 In terms of socialising behaviour (we also used dichotomous type questionnaire: yes/no) 73.6% had no problem explaining
8 their condition to others, 38.8% ask others to help them (e.g. warm their hands), 38.3% mentioned that other people
9 occasionally feel uncomfortable with their condition (e.g. looking at their hands and express emotional empathy), 29.6%
10 found difficult to have skin contact with others (e.g. shake hands) while 19.8% have stigma related emotions and try quite
11 often to hide their hands from others (especially during an attack). Participants thought that it is important to keep track of
12 their attacks (72.8%) and identified a number of important metrics. The majority of the participants (90.6%) mentioned
13 environment temperature while 85.3% identified fingertip temperature as crucial for keeping track of the course of their
14 condition. A large number of participants 88.6% identified frequency of attacks as an important factor to be measured, 88.5%
15 mentioned duration of an attack, 88.3% added that the severity of an attack must also be considered, 88% thought that oxygen
16 saturation can be a useful metric, blood pressure and skin temperature was mentioned by 84.2% while 81.3% stated that heart
17 rate is important, sleep patterns (77.8%), steps (73.3%) and sweat (71.9%).

18 In summary, on Table 1 we present the need for better self-management for patients with RP based on data from empirical
19 studies with RP patients. According to literature review and findings from the survey, more than 60% of patients are on
20 medications that reduce the intensity and frequency of attacks, but at the same time they experience many and serious, in
21 some cases, side-effects while no cure is achieved or expected.

22 **Table 1** Pros, cons and percentage of acceptance regarding methods for managing and treating Raynaud's Phenomenon
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	MANAGEMENT			TREATMENT	
	PREVENT	EXERCISE	MONITOR	MEDICATION	ALTERNATIVE
PROS	- Easy to carry extra clothing to avoid cold. - Adopting healthier behaviours diminish RP's effects in the short and long-term.	- Increase blood circulation. - Diminish RP's effects in the long-term.	- Keep track of past RP attacks. - Identify abnormal 'cold' attacks. - Keep doctor fully updated.	- Successfully reduce intensity and frequency of attacks. - Easy task to take a pill every day.	- Thermal Biofeedback(TBF), Low-level Light Therapy (LLLT) reduce intensity of attacks ~82%. - No side-effects. - Immediate improvement, Long-term, systemic effects.
CONS	- Requires dedication, education, time & effort. - Stress can be difficult to manage. - Social and practical barriers in wearing gloves even in warm days.	- Requires dedication, education, time and effort.	- No digital tools for self-monitoring RP. - Takes time. - Increased Subjectivity/lack of objective data.	- Does not cure RP. - Many side-effects (fatigue, tachycardia, headache, dizziness etc.)	- Requires the help of professionals. - Sessions with physicians are costly. - No special devices are available for alternative treatment at home.
Acceptance¹	66%	28%	21%	60%	3.5%

¹ The percentage of acceptance are results of the project's survey (n=379 respondents)

1 Methods of alternative treatments (TBF, LLLT) are used by less than 3.5%. These two methods are scientifically proven
2 to reduce RP effects and by improving blood microcirculation to the extremities make the attacks up to 82% less intense [19].
3 On the other hand, they are costly, require application from professionals in clinical environments and involve the use of
4 special devices and medical equipment.
5 Everyday empowerment and self-management in handling RP are priorities that in turn require strategies for patient
6 education, engagement and motivation. These must be strongly related in task dedication for taking precautions from
7 environmental conditions and stressful situations, tolerating cold better in the long-term requires regular exercise, a good diet
8 and healthy lifestyle in general. Monitoring is the progress and everyday activity of RP is an important strategy. From our
9 survey we identify that few patients keep track of their RP symptoms e.g last attack, severity, time and date, ulcerations,
10 unusual discoloration on specific areas etc. Finally, evaluation and reinforcement based on monitoring findings are to be
11 considered important steps towards prevention.

12 6 Design and Prototyping

13 6.1 Design Requirements

14 During this phase, in which we came back a number of times because of the iterative nature of the design process, a set of
15 design requirements has evolved as inputs into the design stages of prototype development for wearable health systems. We
16 outline requirements based on factors of the [46]:

- 17 • **user:** demographics, physical and cognitive characteristics, behaviour, needs, abilities, mood, special needs and
18 accessibility, cultural factors etc,
- 19 • **activities:** goals, tasks, actions, frequency of use, well-defined or vague, continuous or interrupted, current task
20 practices, individual vs co-operative work, multi-tasking vs serial tasks, passive vs active, quality vs quantity trade-
21 off, data input requirements, length of time on tasks, need for fast response, coping with errors
- 22 • **context:** physical environment, social environment, organisational context, contextual characteristics (time, place,
23 pressure of work or time), service, support,
- 24 • **system/technologies:** functionality, design constraints, input & sensors, output (actuators and feedback
25 mechanisms), communication, collaboration, networking, multimodal interfaces (sound, GUI, gestures, tangible,
26 haptic, tactile, etc), safety & security, real-time.

27
28 Our initial inquiry showed that designing health wearable systems is a complex task involving various factors (user
29 activities, contexts, technologies involved) and stakeholders with different views, needs and preferences. Thus, we concluded
30 that it is important to better understand the perspectives of the different stakeholders involved in the design and use of the
31 system including patients, designers/manufacturers and caregivers.

32 During the design and development processes, we identified that an important aspect for clarifying the importance of the
33 features and functionalities that are set as design requirements and evaluation factors is to weight them for each stakeholder
34 and thus provide the researcher/designer/evaluator with a better toolkit for balancing their importance when used in the
35 product development lifecycle. Therefore, in Table 2 we provide a complete list of the factors and features under
36 consideration when gathering and developing requirements and later on when evaluating (evaluation features and factors)
37 health wearable systems. We also provide a way to identify the levels of their significance for the different stakeholders (user,
38 designer/developer/manufacture and caregiver) in a similar fashion to [2] and from the data collected from preliminary
39 questionnaires and interviews with colleagues, designer students, patients and caregivers. We merged them onto one list on
40 Table 2 and balanced their influence on the design process by weighting them depending on the stakeholder's view [1, 51,
41 52]. We used a weighting scale of '1=less important' to '5=very important' and calculated an average weight for every factor
42 and feature depicting its influence in the evaluation process.

1 **Table 2** Design Requirements and Evaluation Features and Factors for Wearable Health Systems: Human Factors, Context
2 Factors & System Features weighted in terms of importance for every stakeholder: User, Designer/Manufacturer, Caregiver
3

Factor Feature	Requirements	User	Designer Man/rer	Caregiver	Average	Description
FF1	Wearability	5	1	3	3	Is lightweight and small [53].
FF2	Appropriate Body Placement	5	1	3	3	Unobstructive and comfortable in order not to interfere with users' movement and activity daily.
FF3	Comfort (wear)	5	1	3	3	Concerns the freedom from discomfort and pain [54]. Users feeling enough comfort, no longer sense the device after some time wearing it [55, 56].
FF4	Anthropometry / Physiology	5	2	3	3.3	Take into consideration general physical ergonomics guidelines.
FF5	Hygienic Aspects	5	1	3	3	Take into consideration hygiene aspects.
FF6	Patient/User Safety	5	2	4	3.7	Patient safety: Avoid skin reactions, radiation.
FF7	Product Aesthetics	5	2	3	3.3	Consider user acceptance in terms of product aesthetics [57].
FF8	Emotional Acceptance (Stigmatization)	5	1	3	3	Consider user acceptance in terms of emotional barriers i.e. combat stigma of assistive products [58–60].
FF9	Social Comfort	5	1	3	3	Identify the social aspects (social comfort) of wearability [55, 61]
FF10	Physical Activity Interference	5	1	2	2.7	Interfere to other user's physical activities [56].
FF11	Quality of Life	5	1	4	3.3	Improve the users' quality of life [57].
FF12	Interaction and Ease of use	5	2	4	3.7	Incorporates friendly, easy-to-use, intuitive interactions [52, 62].
FF13	Learnability	5	2	3	3.3	Incorporates an easy-to-learn interface [63].
FF14	Real Application	5	1	5	3.7	Is applicable and useful to real-life scenarios conditions.
FF15	Real-time Application	5	4	2	3.7	Responds in near-real-time (alerts, displays measurements, other diagnostic feedback, read/write data).
FF16	Customisation	5	2	3	3.3	Supports customisation.
FF17	Personalisation	5	2	3	3.3	Incorporates personalisation techniques.
FF18	Persuasive Techniques (User Motivation)	4	1	1	2	Incorporate persuasive techniques to better engage users in a healthy lifestyle.
FF19	Security and Privacy	5	5	5	5	Encryption and security of transmitted data. Privacy of sensitive health data [64–67].

FF20	Performance and Test in Real Cases	5	5	5	5	Sufficient results and performance statistics are provided to verify the system's functionality in real cases.
FF21	Operational Lifetime	5	4	4	4.3	Maintenance free monitoring, energy autonomy (ultra-low power) [2].
FF22	Computational & Storage Requirements	2	5	2	3	The computational and storage requirements of the device and application to achieve desirable results.
FF23	Reliability	5	5	5	5	Produces reliable and accurate results.
FF24	Fault Tolerance	5	5	5	5	Produces reliable results under any circumstances of use (e.g. user movements, environmental conditions).
FF25	Cost	5	5	2	4	The amount of money required to produce and purchase the proposed wearable health system.
FF26	Maintenance Costs	5	5	2	4	The amount of money required to maintain the wearable health system and subscription fees.
FF27	Interference Robustness	2	5	2	3	Availability and reliability of wirelessly transmitted physiological measurements.
FF28	Scalability	3	3	3	3	Potentiality of upgrading, enhancing and easily incorporating additional components to the developed system.
FF29	Monitoring	4	5	4	4.3	Receives, analyses and logs data from its environment (user, physical environment).
FF30	Decision Support	5	2	5	4	Includes some type of diagnosis/decision mechanism or an algorithm/pattern recognition system for context aware sensing of parameters.
FF31	Data analytics	3	5	5	4.3	Analyse and correlate data.
FF32	Data Visualisation	4	5	4	4.3	Provide visualisations of data that are friendly to the user.
FF33	Clinical Validation of Data	3	1	5	3	Communicate and present data to clinical experts and request feedback.
FF34	Prognosis	5	1	5	3.7	Provide prognostic information and feedback.
FF35	Data sharing and Dissemination	5	1	5	3.3	The system provides the means to share data with other users or (health) stakeholders. Import and export EHR data in a more clinically meaningful way.
FF36	Interoperability with Other Services	3	5	3	3.7	The system provides the means to transfer data and use it on different services and applications. Integrate disparate data streams [1, 68].
FF37	Open mhealth	1	5	2	2.7	Supports Open standards and Open Source Data Integration Tools.
FF38	Data Take-out	3	5	3	3.7	Offer data take-out. Save data off-device, or export to human readable formats.

6.2 Design Decisions

According to a recent study, functionality and aesthetics gain surprisingly increased attention among a total of 22 user requirements when it comes to using wearable wellness devices [51]. People prefer lightweight, comfortable, durable and pleasing to use wearable devices that add value to their life. For these reasons, our design requirements for the physical product of the designed ring aim at unobtrusive design and interactions, elegant and minimal aesthetics, durable, waterproof and medical grade materials. Emphasis should be given to the physicality of the interaction where tangible and embodied interactions play a major role and coexist with graphical user interfaces (UIs) that are presented on the mobile application. The system should provide intuitive interaction and user experience and should adapt to the user's everyday activities in a continuous and non-intrusive way. The system must be context-aware and capable of alerting its users when the environment becomes risky, i.e. a 'cold' attack is imminent. Sensing interfaces should be designed to be minimally invasive based on technologies that are friendly and comfortable for the users' body and physiology.

Technical requirements include the use of tiny, fast-responding sensors for capturing data (temperature, humidity and skin conductance) and small output actuators for informing and providing feedback (tactile, visual). Data analysis should provide information about user's activity, the context of use, potential psychological distress and the overall RP status by comparing the different patterns of logged data. Other technical requirements include a long-lasting battery and a remote charging capability, as well as means for communicating with a mobile application (e.g Bluetooth, NFC). The accompanying smartphone application should work as an instant feedback medium to let users monitor and gain insight on their health status. It must keep track of the severity, duration and frequency of RP attacks. The minimum industrial requirements should be related to usability and ergonomics while tangible interactions should focus on delivering maximum integration of the program in everyday life and maximum user experience. At a social level, the final product (ring and mobile application) must support interactions among patients, doctors and caregivers and provide the means for sharing newly created information to online RP communities. Finally, the product must lead to behaviour change and promote individual's well-being by supporting users for a healthier lifestyle by promoting the values of disease prevention and active engagement.

6.3 Industrial design, electronic components and sensors

Industrial design is an important phase of this project as it focuses in fulfilling a number of design requirements related to the form of the physical product, its aesthetics, ergonomics, functional and technical specifications and constraints. It also prioritises technology acceptance and inclusive design by combining functionality and aesthetics as an attempt to avoid social stigma and misperceptions of assistive technologies [60, 69]. People who use medical devices in their everyday life are often stigmatised and socially discriminated and those who experience RP are not an exemption (cold, pale-coloured hands, recovery actions) [58, 59]. Therefore, the design of the physical artefact focusses in raising users' self-confidence while minimising the levels of psychological and emotional distress caused by social factors related to the use of wearable health systems.

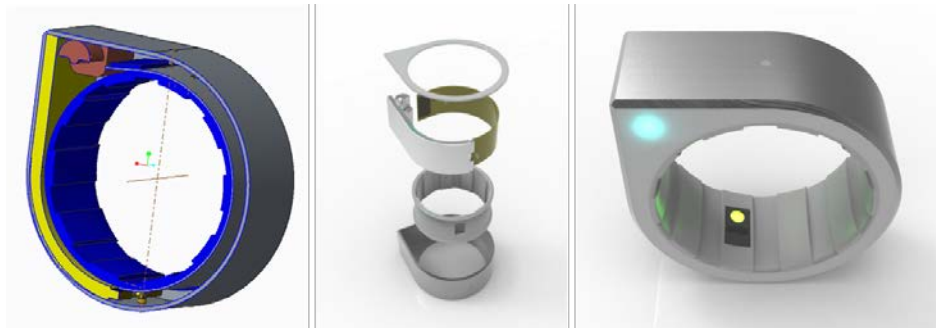
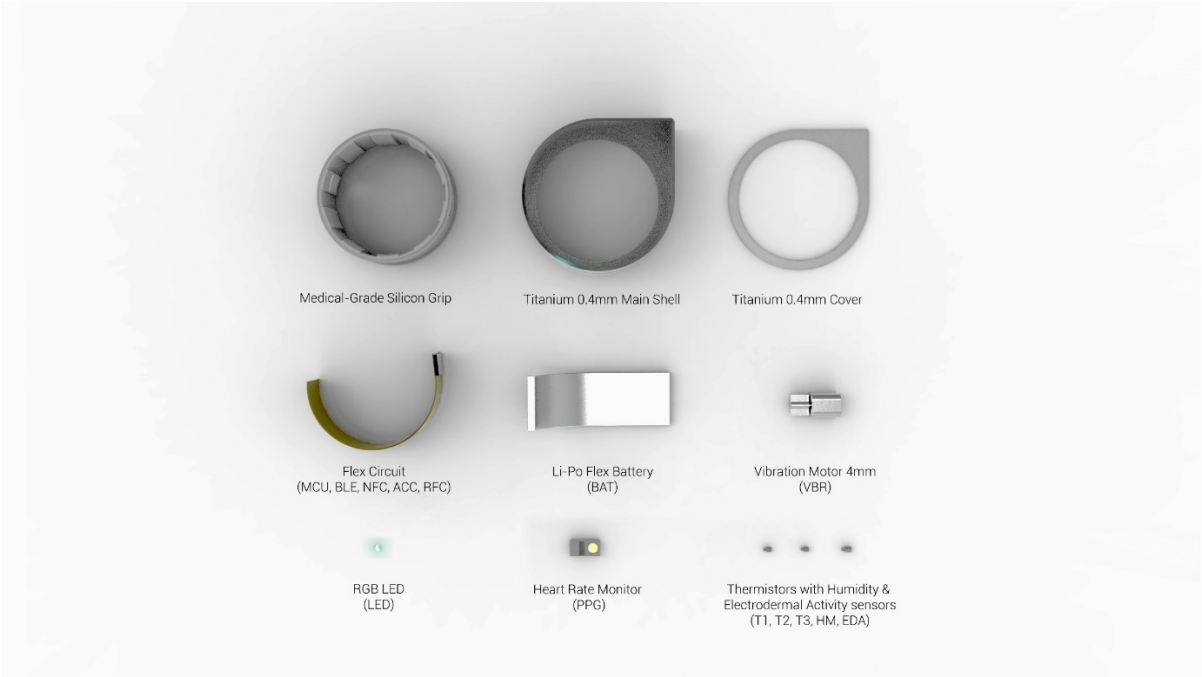


Fig. 7 Physical product of the smart ring and its components

1 The proposed design of the smart ring aims to be indistinguishable from other jewellery. Its form refers to state-of-the-art
2 smart devices with CNC-engineered 0.4mm titanium shell. The parts, depicted in Figure 8, are designed for a solid, sealed
3 assembly to allow high levels of water, scratch and drop resistance. The body of the ring is 10mm wide and 2.4mm thick,
4 like most metal rings while actual sizes (inside diameter and circumference) may vary. The inner cylindrical part is made of
5 tough, non-slippery medical grade silicon to ensure grasping and avoid skin irritation.



6

7 **Fig. 8** Physical product of the smart ring and its components

8 The internal electronic components Table 3 include three temperature sensors (environment temperature sensor T1, inner
9 ‘object-in-contact’ temperature sensor T2 and finger temperature sensor T3), a humidity sensor (HM) placed on top and an
10 electrodermal activity (EDA) sensor for monitoring changes in skin conductance. A flex circuit accommodates the
11 microcontroller unit (MCU), a 3-axis accelerometer (ACC), and a radiofrequency power receiver (RFC) for charging the ring
12 inductively. The curved Lithium-Polymer (Li-Po) battery is 1.3mm thick, 26mm long and 8mm wide (1.3x8x26 mm). Its
13 capacity is estimated to be enough for a two-day battery life (10-20mAh). The BLE protocol ensures tiny power consumptions
14 and deep sleep modes for when the device is not in use. In Table 3 we present how each component contributes to monitoring
15 user’s activity and RP symptoms.

16 **Table 3** Electronic Components and their role in the wearable smart ring device

I/O	ID	Component Type	Role
Sensor / Input	T1	Environment Thermistor	Monitor temperature - environment or object’s which covers the finger. (e.g. glove)
	T2	Object-in-contact- Thermistor	Monitor temperature of the things that the users hold or touch with their palm. If hand is on air, it also measures the environment’s temperature.

		T3	<i>Finger Thermistor</i>	Constantly monitors the temperature of the finger. A sudden temperature drop turns on the PPG sensor to verify the absence of pulse.
		EDA	<i>Electrodermal sensor</i>	Skin conductance, sweat rate, psychological distress, water presence.
		HM	<i>Humidity sensor</i>	Environmental sensing. Humidity sensor, water/moist presence or absence. Humid environments can trigger a RP attack even when temperature is high.
		PPG	<i>Photoplethysmography (PPG) sensor</i>	Measure blood volume changes, monitor heart rate (HR) and heart rate variability (HRV), detect the absence of pulse which indicates a RP attack.
		ACC	<i>3-axis Accelerometer</i>	Detect users' activity (e.g. walk, run) and input gestures (e.g. tap twice for checking RP status or tap three times for checking battery level)
	Output	VBR	<i>4mm Vibrator</i>	Receive alerts when environment becomes risky. Feedback to user inputs.
		LED	<i>RGB LED</i>	Feedback to users' interactions. RGB to represent RP status or battery level.
	Power	MCU	<i>System on Chip (SoC) Microcontroller Unit (MCU)</i>	Microprocessor with integrated Bluetooth Low Energy (BLE) chip and Near Field Communication (NFC) for very low energy consumption.
		BAT	<i>Flexible (Li-Po) Battery</i>	Flexible custom design to fit the product. Approximately two days of battery life.
		RFC	<i>Radio-frequency (RF) wireless charging chip + nest</i>	Wireless power receiver located in the ring. Requires a charging dock where a wireless power transmitter can be implemented to start charging the device when in close proximity.
		OTG	<i>On-the-go charger</i>	Accessory to charge ring from smartphone.

6.3.1 Mobile Application and User Experience

Presented in Figure 9, the smartphone application functions in relation to the ring device and supports automatic sensor data acquisition or manual handling of data and other customisations by the end user (personalisation, custom data entry, setting up goals etc).

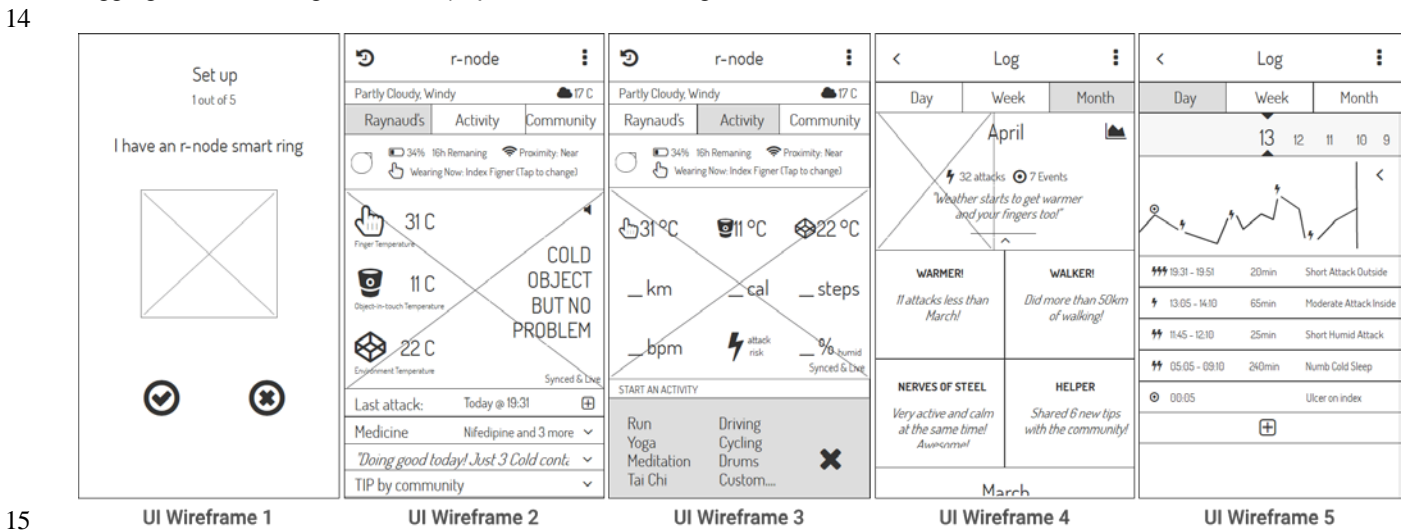


Fig. 9 Smartphone application interface and the ring

1 It aims in providing useful information for managing and monitoring the course of the disease (log of RP attacks, heartbeat
2 status, temperature, estimated stress levels, user's activity e.g. running, walking, sleeping etc.), it affords online
3 communication mechanisms and synchronisation with third party online applications and services.

4 The interface is intuitively designed to provide a reliable and pleasing user experience (gradient colours indicate the risk
5 factor; temperature changes can be announced by audible feedback). Device status can be monitored by the user at various
6 levels including proximity and ring's remaining battery life.

7 Other functionalities, presented in Figure 10, include: *Daily insight* for motivating users, *Track an Activity* for detailed
8 analysis of user's activity and goals and in relation to the potential risks for having a RP attack (UI Wireframe 3 depicted at
9 Figure 10), *Treatment Plan* for managing treatment or medication plans, *Achieve goals* for managing and setting goals related
10 to RP (e.g. proposed by therapist or online by a community, a challenge etc.), *History log* of RP attacks, medicine intakes,
11 tracked activities, achievements and notes are sorted out in a calendar which functions as a detailed history log (UI
12 Wireframes 4 & 5 depicted at Figure 10), *Share with Doctors* for sharing logged data with doctors, *Make notes* for custom
13 logging and notetaking, *Community of users* for connecting with other users, online communities and services.



15 UI Wireframe 1 UI Wireframe 2 UI Wireframe 3 UI Wireframe 4 UI Wireframe 5
16 **Fig. 10** Low fidelity prototypes (wireframes) of user interfaces of the smartphone application

17 The basic interactions and functionalities of the tangible product include gestures for, a) providing feedback in case of an RP
18 attack (upon detection and validation of an attack a system feedback is provided to the user by a specific vibration pattern),
19 b) a double-tap gesture at the top of the smart ring provides the current status (visual feedback through an RGB led turns a
20 specific colour for indicating the current status of the finger), c) a triple-tap gesture indicates battery level. To support
21 maximum portability and autonomy the device will also afford charging directly from the user's smartphone using *On-the-*
22 *go charging* while the *Drop-n-charge* functionality at the charger dock station will allow wireless charging.

23 7 Evaluation

24 When evaluating wearable health technologies the constructs measured are quite diverse and the results are often hardly
25 comparable [70, 71]. Different factors originating from the user (human factors), activity or task, context and system,
26 influence the evaluation process and its outcomes. Moreover, the different stages of development of the wearable health
27 system add another dimension to the complexity of the evaluation processes. For these reasons and as shown in Figure 11,

we performed a multistage evaluation process in parallel to the system's design lifecycle [72]. The goal of our research was to experimentally evaluate the comparative benefits of the wearable health system as a target platform for monitoring RP attacks. The goal of the evaluation was to inform the design process and evaluate the overall quality of the designed prototype (usability and user experience) during the different design phases and in terms of the research goal.



Fig. 11 Evaluation process with users experiencing Raynaud's Phenomenon

We conducted three evaluation sessions during the different phases of system & product development lifecycle in order to identify and fix usability problems while also benchmark the overall user experience for the high-fidelity prototypes. A number prototypes for both the wearable device and the smartphone application were designed and evaluated during the following iterative design/evaluation phases.

7.1 Phase One - Early prototyping (low-fidelity) and Formative Evaluation

This phase included the design of a *cardboard prototype*, shown in Figure 12, which was rapidly designed for supporting ideation and early ergonomics testing along with a basic *hardware/software prototype* for conducting technology tests. Hardware experiments involved physical computing, circuit design and sensor calibration. Software experiments involved user interface, data manipulation, logging and archiving. The purpose was to support ideation and provide an early evaluation of the physical prototype (wearable).

7.1.1 Phase One: Evaluation method (Formative/Exploratory)

During this phase we conducted formative tests using Expert Reviews with inspection methods, Cognitive walkthrough (CW) and Heuristic evaluation (HE) as well as Think-Aloud Protocol (TAP) for the cardboard prototype. CW evaluated whether the information architecture and navigation cues in the system reflect the way users cognitively processed tasks and anticipated future system responses. HE is based on a set of usability tests (heuristics) and used to evaluate early usability problems [63]. TAP is a method that required participants to verbalise what they were doing and thinking as they completed a task, and thus revealed aspects of the prototype that delight, confuse, and frustrate them. As there was no functional prototype of the hardware/software we did not evaluate the digital system with users or experts, but only did experiments with the technologies involved.

7.1.2 Phase One: Evaluation Process

A set of Expert Reviews for getting fast results was performed for evaluating the cardboard prototype based on specific scenarios. Two final year student product designers were involved one of them with RP. Based on a description of the system and the identified tasks to be designed, the experts were asked to carry out a list of actions to perform the tasks related to basic system/product functionality (identify and respond to a warning of an attack, wear/remove the wearable, turn on/off, charge the device, interact with the environment objects/conditions). The design team members performed several HE sets and TAP sessions to inspect the physical interfaces and detect baseline usability problems.

Evaluation findings: Evaluation findings assisted the iterative design process by providing valuable feedback to the design team related to the way people cognitively process tasks and anticipate future feedback from the system as well as characteristics and functionalities of the physical product. These include factors and features related to FF1-FF10.

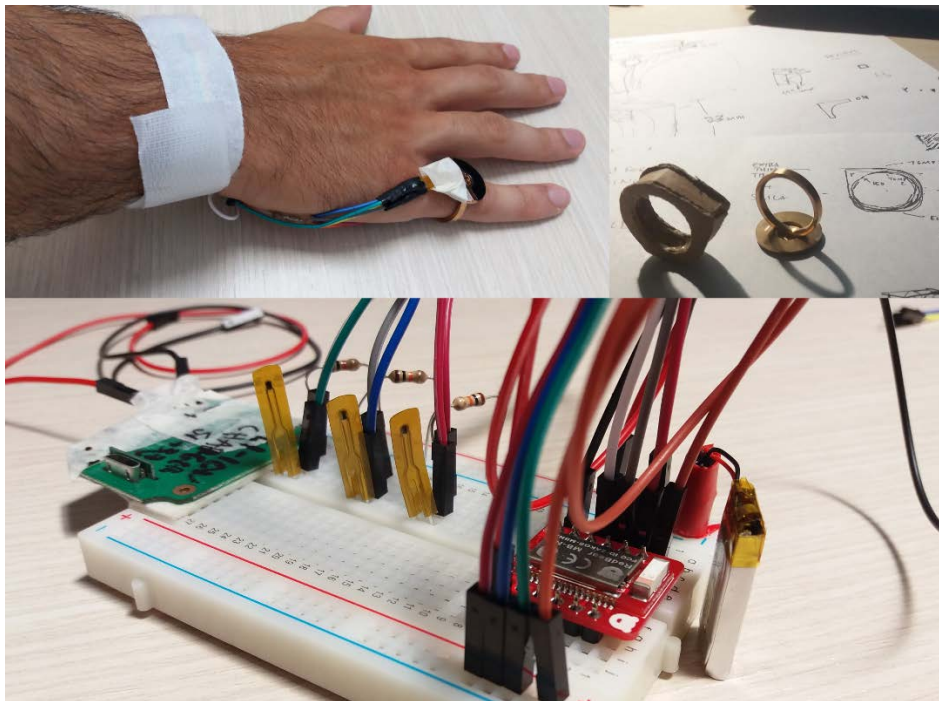


Fig. 12 Early technology tests and the initial Low Fidelity Cardboard Prototype

7.2 Phase Two - Prototyping of physical product (high-fidelity prototype) and application (low-fidelity prototype) and Formative Evaluation

This phase included the design of a *low fidelity prototype of the application* and its interface, a *Fabricated (3D printed) version* of the actual industrial product/ring and low fidelity prototype for the electronics/circuits were designed and developed as shown in Figure 13. The purpose was to explore the interaction techniques to be used and the equivalent user interfaces that need to be designed. Understand further the physical characteristics of the wearable - form factor (size, components fitment), ergonomics (sizing, comfort), manufacturing and embodiment - and identify the layout of the electronic circuits, and other internal components of the device.

7.2.1 Phase Two: Evaluation method (Formative/Exploratory)

Conducted formative tests for the low fidelity smartphone application prototype and for the hi-fidelity physical product prototype. Formative tests included Expert Reviews, UI Inspections (CW&HE), TAP testing. We also carried out the dedicated online survey which is analysed in section 4.3 Research and Inquiry.

7.2.2 Phase Two: Evaluation Process

Evaluation was performed in two stages. Initially we did a set of *expert reviews* with double experts for getting fast results, followed by a *user testing* on the low fidelity prototype of the application. For the later a total of four (n=4) subjects were recruited to evaluate the prototypes (one diagnosed with RP) under a mixed CW&HE evaluation. User subjects followed a specific scenario with a predefined number of tasks (t=27). Subsequently, a hybrid usability / aesthetics questionnaire was answered. As a research method we used Wizard of Oz for simulating system responses while the participants interacted with the system [73].

7.2.3 Phase Two: Evaluation findings

We collected a number of recommendations, both from experts and users, regarding the interfaces of the smartphone application and their related interactions. Through the evaluation of the fabricated version of the wearable device and in conjunction with the low-fidelity prototype of the application we collected a number of issues, new ideas and enhancements, related to: interaction techniques to support user experience between the device and the smartphone application, characteristics of the physical product (size, shape, materials of the device), ergonomics including wearability and comfort, aesthetics and emotional factors for product acceptance and social comfort, privacy, operational lifetime, monitoring, decision support, data analytics and data visualisation (FF1-FF10, FF12-21, FF29, FF31-32). The user with RP also provided feedback about clinical validation of data, prognosis and decision support (FF33-34, FF30).

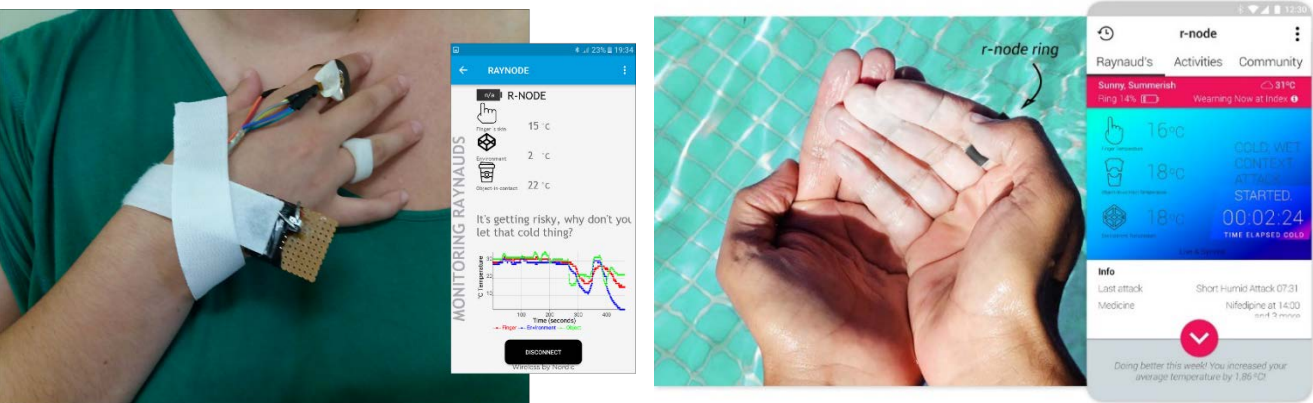


Fig. 13 On the left an early low-fidelity prototype and its application interface. On the right a working prototype and application interface

7.3 Phase Three - Prototyping of the system (physical product, electronics and application):

This phase included the design of a *working prototype* of the wearable ring with a low-fidelity electronics prototype and a hi-fidelity prototype of the smartphone application developed for Android OS, as shown on the right in Figure 13. The

1 purpose of the evaluation was to examine the interaction techniques according to user needs, assess effectiveness and
2 efficiency while measuring user satisfaction and acceptance of the system based on specific use scenarios.

3 7.3.1 Phase Three: Evaluation method (Exploratory & Assessment)

4 We conducted TAP based on scenarios with users for the exploratory session, Summative Tests by the use of Rating Scales
5 Questionnaires (RSQ) for evaluating the design requirements and evaluation factors and features that we proposed in section
6 6.1 and System Usability Scale (SUS) testing to assess effectiveness, efficiency and satisfaction of the final prototype.

7 7.3.2 Phase Three: Evaluation Process

8 In order to measure user's judgments about the system, we conducted TAP in relation to the set of use scenarios, followed
9 by RSQ (scale 1 to 5) based on the design requirements and evaluation factors and features we set during the design process
10 (FF1-FF38). Thirty-six ($n=36$) subjects were recruited to participate in the evaluation. The participant group had different
11 profiles and included, nineteen ($n_1=19$) user subjects with RP, twelve ($n_4=12$) RP caregivers/doctors and five ($n_3=5$)
12 designers. Depending on their profile, participants followed a specific scenario with a predefined number of tasks mainly
13 focused to address factors and features with higher correlation to their average profile score.

14 Patients followed an eight-task ($t_1=8$) scenario (s_1) which included interactions with their environment and the wearable
15 health system (put on/off the ring, interact with the physical product, interact with the application, touch two objects with
16 different temperatures, move/navigate while wearing the ring, change environment, experience a stressful situation, evaluate
17 system feedback).

18 Caregivers followed a scenario (s_2) of eight tasks ($t_2=8$) with more emphasis on clinical validation of data, data sharing
19 and dissemination, decision support, prognosis and monitoring (put on/off the ring, interact with the physical product, interact
20 with the application, touch two objects with different temperatures, evaluate system feedback, check accuracy of data, provide
21 feedback to the user, exchange and share data).

22 Designers followed a scenario (s_3) that included all the tasks ($t_3=11$) that were given to the other profiles with emphasis
23 on design intensive tasks and factors that influence the developers and manufacturers (FF15, FF19-FF27, FF29, FF31, FF32,
24 FF36-FF38).

25 Some participants from all groups were unable to answer all questions, without assistance from the interviewer, especially
26 those that involved empathic readings and technical skills. Subsequently, after each session, a SUS questionnaire was
27 answered by all participants.

28 7.3.3 Phase Three: Evaluation findings

29 TAP revealed a number of new issues that need to be improved related to the actual form of the physical product, the
30 interactions (input gestures/tangible, feedback) and the GUI of the smartphone application. During the RSQ we asked users
31 to evaluate the importance of each factor and feature and their overall satisfaction compared to their anticipation of the
32 system's functionality. Evaluation scale expands from '1=less important' to '5=very important'. In summary the RSQ and
33 the TAP provided the following results/feedback for each factor and feature for the different profiles of the users (see Table
34 2).

35 **User Subjects with RP** ($n=19$, female=14, male=5): The collected data from the subjects experiencing RP are shown in
36 Figure 14. For each factor and feature, the columns represent the mean values of the users' answers, the black dots show the
37 values repeated most often in the specific data set (mode values) and the white dots correspond to STD. The red stars indicate
38 the weighted values of the factors and features shown in user column on Table 2. The purpose of the chart is to compare the
39 values of the weighted factors and features created during the requirements acquisition phase with the collected data from
40 the present evaluation. The analysis of the data shows no significant statistical difference between the weighted and mode

values in most cases. This means that there is a strong correlation between the design requirements and the participants' expectations that followed the evaluation sessions.

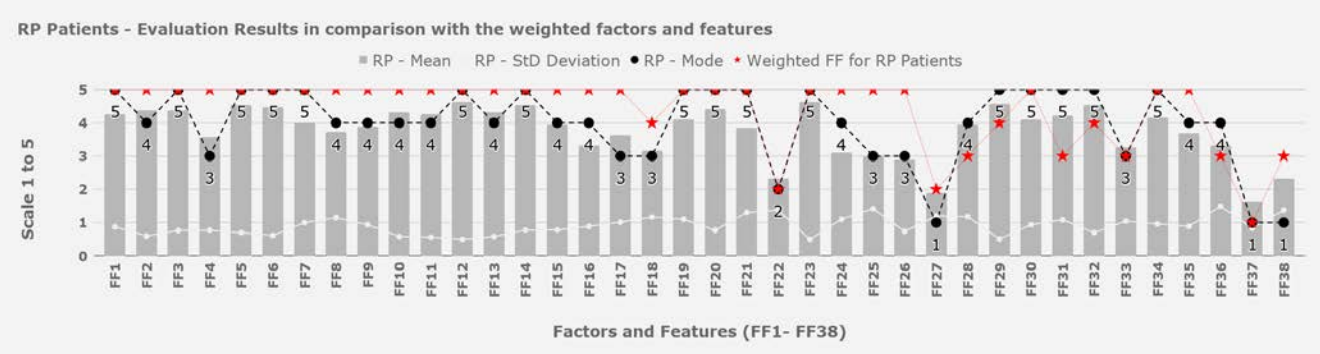


Fig. 14 Chart for participants with RP. Compares evaluation results with the weighted factors and features

Exceptions are the FF4 (Anthropometry / Physiology), FF17 (Personalisation), FF25 (Cost), FF26 (Maintenance costs) and FF38 (Data Take-out) where participants had significantly less expectations compared to the design prototype and considered the factors and features as less important. Opinions expressed during TAP with regards to the aforementioned differences, indicate that users did not fully understand the importance and role of anthropometric measurements and ergonomics guidelines when designing industrial products and especially wearables. Most participants thought that they will never come across such considerations when wearing and interacting with such a device. We discussed with them the difference in using wearables in comparison with other devices and presented the importance of the factor in cases where hands are affected (size of the fingers, age the influence of conditions related to RP like ulcerations, scarring etc). The role of personalisation in the use of a system/application (profiling, content delivery and functionality) also was not clear to users. Many considered it a special case of customisation and thought it as less important. They also could not recognise which functionalities of the UI support or present personalised data. Cost and maintenance costs were also less important for participants of this category as most of them expressed a willingness to spend a decent amount of money to obtain it. We also discovered that participants were unaware of the consequences of data silos, vendor lock-in and General Data Protection Regulation (GDPR) and the importance of the ability to have control over their data, especially in the case they want to migrate to a another service. The opposite appears in the case of FF31 (Data analytics) where participants expressed satisfaction and considered important this additional feature to the system. Opinions expressed during TAP about data analytics showed that, especially young, participants were more aware of the new technological advancements in computing and showed interest in techniques involving automations for examining health related data to draw conclusions about a patient's course.

RP caregivers/doctors (n=12, female=2, male=10): The collected data from the caregivers and doctor subjects are shown in Figure 15. For each factor and feature, the columns represent the mean values of the participants' answers, the black dots show the values repeated most often in the specific data set (mode values) and the white dots correspond to STD. The green boxes indicate the weighted values of the factors and features shown in user column on Table 2. The purpose of the chart is to compare the values of the weighted factors and features created during the requirements acquisition phase with the collected data from the present evaluation. The analysis of the data shows no significant statistical difference between the weighted and mode values in most cases. This means that there is a strong correlation between the design requirements and the participants' expectations that followed the evaluation sessions.

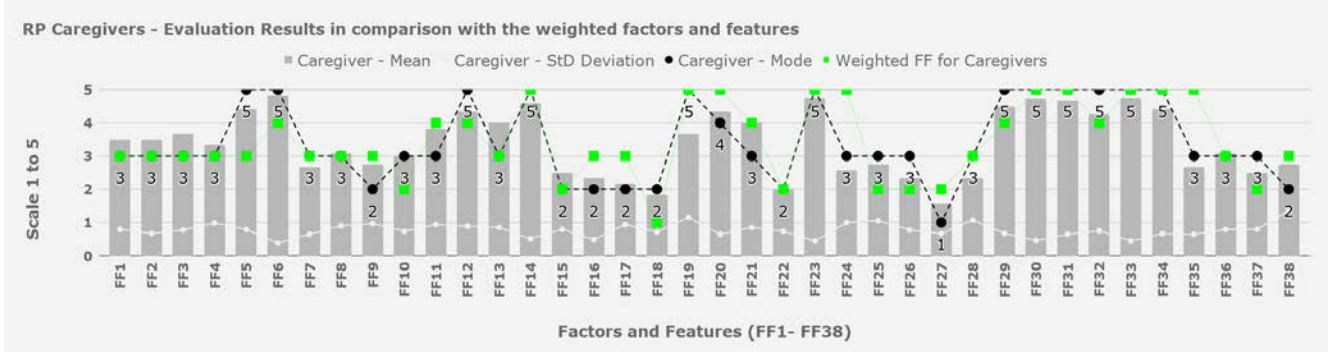


Fig. 15 Chart for participant caregivers and doctors. Compares evaluation results with the weighted factors and features

Exceptions are the FF5 (Hygienic Aspects), FF24 (Fault Tolerance), FF35 (Data sharing and dissemination). The participants expressed significantly more interest about the hygienic aspects of the design although this does not directly affect them. Opinions expressed during TAP indicate that participants consider this a very important design requirement primarily because of its connection to the patients' health. They mentioned that patient condition is heavily related to the fingers and many might experience serious complications (digital ulceration, tissue damage, gangrene) that can be worsen with bad hygiene. Participants had significantly less expectations compared to the design prototype and considered "Fault Tolerance" and "Data sharing and dissemination" as less important. Opinions expressed during TAP with regards to the aforementioned differences, indicate that participants did not comprehend the terminology used in the first case while thought that data sharing and dissemination can be done through other traditional paths of communication that they use in their every day professional activity (e.g email, e-health databases). In relation to this comment, it is indicative that they expressed concerns about security and data privacy (FF19), they stated that Interoperability with other services is preferable compared to data sharing and finally affirmed that data take-out is an important feature for both patients and themselves because of the short life span of current digital products and services.

Designers (n=5, female=2, male=3): To evaluate features and factors that affect manufacturers we set a small number of evaluation sessions with student product designers that acted on half of them. The collected data from the designer subjects are shown in Figure 16. For each factor and feature, the columns represent the mean values of the participants' answers, the black dots show the values repeated most often in the specific data set (mode values) and the white dots correspond to STD. The yellow triangles indicate the weighted values of the factors and features shown in designer column on Table 2. The purpose of the chart is to compare the values of the weighted factors and features created during the requirements acquisition phase with the collected data from the present evaluation. The analysis of the data shows significant statistical difference between the weighted and mode values for factors and features FF7 (Product Aesthetics), FF26 (Maintenance costs), and FF31 (Data analysis). The correlation between the design requirements and the participants' expectations that followed the evaluation sessions is strong, but we further investigated the differences with another set of in-depth interviews and focus groups for the benefit of the design. We realised that young designers considered themselves as in-between the manufacturers' and users' perspectives. Although we asked them to take into consideration that they act from the perspective of the manufacturer, they were engaged with the users' expectations and personal preference as designers themselves. From the focus groups we concluded that FF7 was valued as more important because designers considered this as a key factor for promoting the brand of the manufacturer as well as user acceptance in terms of aesthetics. FF26 was considered as less important because designers thought it only affects maintenance of the physical product from the user perspective. They did not take into consideration the additional supportive services that should be maintained for a longer period of time after the purchase. For a similar reason the factor FF31 was also considered as less important. Designers mentioned that data analytics

will have a medium to high importance for the manufacturer as it will be developed once. They did not take into consideration that data analysis is a resourceful process that needs maintenance and updating from the manufacturer.

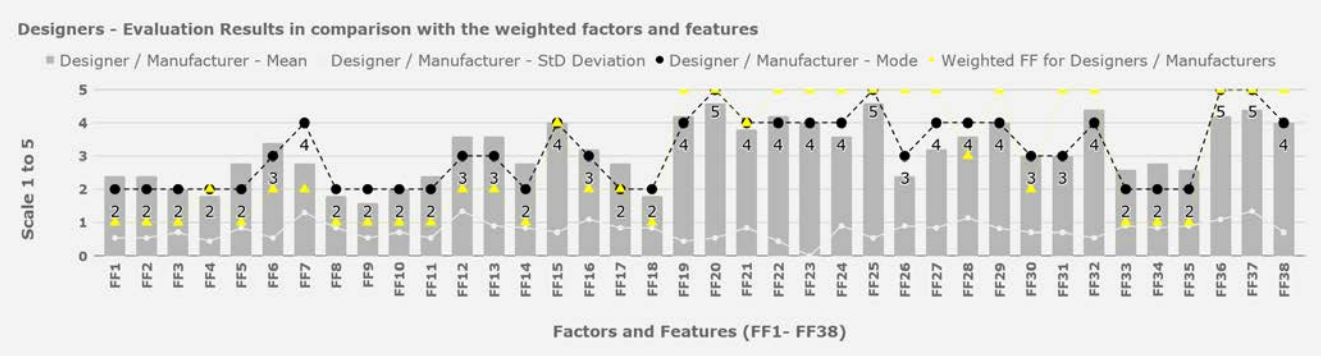


Fig. 16 Chart for designers & manufacturers. Compares evaluation results with the weighted factors and features

In a combined chart as shown in Figure 17, we present the evaluation findings for the three profiles regarding the most common preference in the data set (Mode).

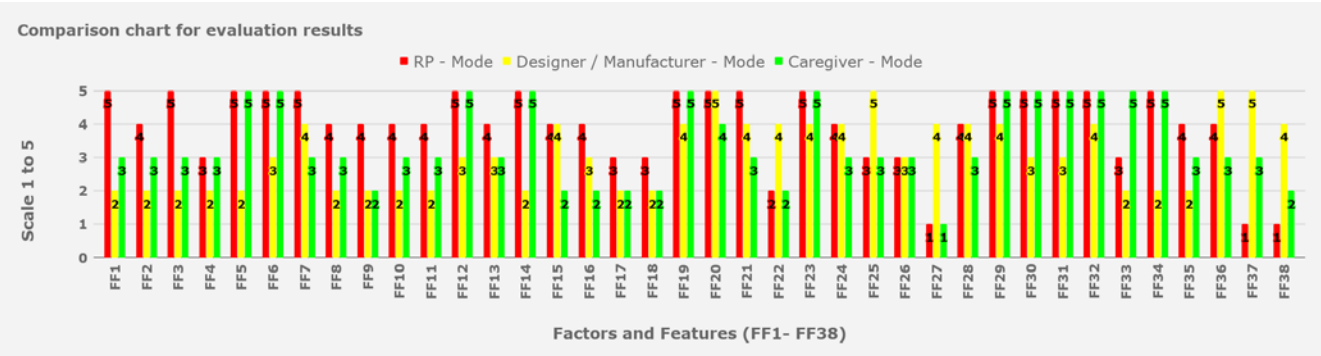


Fig. 17 Combined chart with all the Mode values for each profile

The SUS (modified version for ‘cumbersome’) score was 74.2 with a standard deviation 13.74. Accordingly, the average scores for each item of the questionnaire was 4.3 (1), 1.95 (2), 4.22 (3), 2.47 (4), 4.25 (5), 1.86 (6), 3.94 (7), 1.63 (8), 3.88 (9) and 3 (10). Independently for each group of participants the score was: 79.9 for the RP patients, 77 for the designers and 64.2 for the caregivers/doctors. From our observations, RP patients were enthusiastic about the project and its potentials, designers were satisfied with the overall quality of the designed system and assisted the design team with various ideas and recommendations for future work. Caregivers and doctors were positive about the overall usefulness of such a device for monitoring and collaborating with patients. They expressed concerns about its appropriateness in providing prognostic data, clinical validation through data analytics and decision support. Some caregivers heavily focused on the reliability of prototype and questioned its performance in real cases. Another significant finding from the SUS was the fact that most participants needed some support from a technical person to be able to use the system and thought that they needed to learn a lot of things before they could get going with the system. This is obviously a result that relates to the ambiguity of the prototype, as many of the functionalities proposed were not fully working (we had to incorporate Wizard of Oz in some cases), and the fact that the introduction to the evaluation sessions involved concepts from different scientific domains, jargon and special manipulations with the electronic components of the prototype.

SUS took place in Amsterdam (Netherlands), Athens and Syros (Greece) and we confirmed after each test that some of the participants answered incorrectly item 8 (average was 4.43 before modification, including those answered incorrectly), something that seems to be influenced by their native language [74]. Therefore, we modified values accordingly for the incorrect answers on specific participants.

8 Conclusion and Future Work

In this paper we identified the potential of a non-obstructive digital health wearable which can monitor and assist in managing the effects of RP at a cost-effective and aesthetically pleasing way for the user. We detailed our proposal for designing and evaluating the system and provided a set of design requirements for wearable health systems.

Our main aim is to promote behaviour change through minimal everyday interaction with a wearable product and provide accurate information to the end user through data analytics. User experience and interaction design for wearable health technologies, further exploration of the ‘distal–dorsal difference’ (DDD) hypothesis and cloud computing for scalable big data analytics are important domains that we intent to further explore in our future designs and research. Instead of designing a single product or application we aim at developing an ecosystem that is composed of several subsystems including a physical product, the online platform and its accompanying cloud and data analytics services [75] and a mobile application for the end users to interact with. Based on this design we plan to further conduct usability and performance tests with a larger number of RP sufferers.

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