# User-Driven Development of a Digital Behavioral Intervention for Chronic Pain: A Multi-Methods Study

Afra Taygar, Sara Laureen Bartels, Rocío de la Vega, Ida Flink, Linnéa Engman, Suzanne Petersson, Sophie I Johnsson, Katja Boersma, Lance M McCracken, Rikard K Wicksell

Submitted to: JMIR Formative Research
on: March 21, 2025

# Table of Contents

# User-Driven Development of a Digital Behavioral Intervention for Chronic Pain: A Multi-Methods Study

Afra Taygar[1]; Sara Laureen Bartels[1, 2] PhD; Rocío de la Vega[3, 4]; Ida Flink[5]; Linnéa Engman[1, 6, 7]; Suzanne Petersson[1, 8]; Sophie I Johnsson[9]; Katja Boersma[7]; Lance M McCracken[10]; Rikard K Wicksell[6, 1]

[1] Department of Clinical Neuroscience Karolinska Institutet Stockholm SE
[2] Department of Psychiatry and Neuropsychology Maastricht University Maastricht NL
[3] Department of Personality, Assessment and Psychological Treatment Universidad de Málaga Málaga ES
[4] Instituto de Investigación Biomédica de Málaga Málaga ES
[5] Department of Social and Psychological Studies Karlstad University Karlstad SE
[6] Pain clinic Saint Göran Hospital Stockholm SE
[7]School of Behavioural, Social and Legal Sciences Center for Health and Medical Psychology (CHAMP) Örebro University Örebro SE
[8]Department of Medicine and Optometry Linnaeus University Kalmar SE
[9]Department of Molecular Medicine and Surgery Karolinska Institutet Stockholm SE
[10]Department of Clinical Psychology Uppsala University Uppsala SE

**Corresponding Author:**
Afra Taygar

Department of Clinical Neuroscience
Karolinska Institutet
Nobels Väg 9
Stockholm
SE

## Abstract

**Background:** Recent research shows that chronic pain affects 27% of the adult population. For many, pain is significantly impairing quality of life and everyday functioning. Behavioral interventions have shown utility, but access remains limited. Digital health solutions can increase reach but there is a need for user-friendly, feasible, and evidence-based digital interventions.

**Objective:** This study aims to clarify how a digital behavioral intervention can be developed in a user-centered approach to address the needs and preferences of the target population.

**Methods:** This study used a multi-method approach to develop prototypes for a digital behavioral intervention across three phases: Preparation (Phase 0), Design (Phase 1), and Testing (Phase 2). End-user involvement was prioritized through fictional Patient Personas, focus groups with patients (n=5) and therapists (n=12), and pilot testing (n=11 patients, n=3 therapists) of the digital intervention.

**Results:** Based on end-user input, a 6-week digital behavioral intervention for chronic pain was created. Focus groups highlighted the importance of accessibility and adaptability of the digital intervention. Results from the pilot testing demonstrated the usability of the intervention.

**Conclusions:** Results illustrated the utility of Patient Personas when preparing, focus groups when designing, and end-user feedback when testing this new intervention. Findings indicated that the treatment is promising, while also providing relevant end-user suggestions to guide further improvements.

(JMIR Preprints 21/03/2025:74064)
DOI: https://doi.org/10.2196/preprints.74064

Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http
No. Please do not make my accepted manuscript PDF available to anyone.

# Original Manuscript

**Title:** User-driven development of a digital behavioral intervention for chronic pain: A multi-methods multi-phase study

**Abstract:**

**Background**: Recent research shows that chronic pain affects 27% of the adult population. For many, pain is significantly impairing quality of life and everyday functioning. Behavioral interventions have shown utility, but access remains limited. Digital health solutions can increase reach but there is a need for user-friendly, feasible, and evidence-based digital interventions.

**Objective:** This study aims to clarify how a digital behavioral intervention can be developed in a user-centered approach to address the needs and preferences of the target population.

**Methods**: This study used a multi-methods approach to develop prototypes for a digital behavioral intervention across three phases: Preparation (Phase 0), Design (Phase 1), and Testing (Phase 2). End-user involvement was prioritized through fictional Patient Personas, focus groups with patients (n=5) and therapists (n=12), and pilot testing (n=11 patients, n=3 therapists) of the digital intervention.

**Results**: Based on end-user input, a 6-week digital behavioral intervention for chronic pain was created. Focus groups highlighted the importance of accessibility and adaptability of the digital intervention. Results from the pilot testing demonstrated the usability of the intervention.

**Conclusion:** Results illustrated the utility of Patient Personas when preparing, focus groups when designing, and end-user feedback when testing this new intervention. Findings indicated that the treatment is promising, while also providing relevant end-user suggestions to guide further improvements.

**Keywords**: chronic pain; digital therapeutics; behavioral intervention; development; end-user involvement

## 1. Introduction

Chronic pain affects approximately 27% of adults (1), significantly impacting persons' daily life and general well-being (2). Behavioral interventions building on, for instance, the fear-avoidance (3) and psychological flexibility models (4, 5) aim at enhancing resilience to pain and distress. These interventions have robust empirical support and are increasingly used (6-8). However, access to evidence-based behavioral interventions remains low (9).

The evolution of digital solutions represents a paradigm shift, with the potential to maximize the accessibility of behavioral treatments, yet, there is a scarcity of evidence-based digital treatments in regular health care (10). To facilitate further development in the field, the innovation process should be concise and efficient (11). It should be executed within an established *framework* to facilitate standardization, *described* in detail for transparency and quality assurance, and *evaluated* scientifically for data-driven decisions on how to proceed for further testing and implementation (12).

Existing research suggests that user involvement is essential to match digital health interventions to preferences and needs (13-16). Additionally, stakeholders should be consulted early on to facilitate successful and sustainable implementation (17). Stakeholders include, for instance, *innovation facilitators* such as healthcare managers and IT developers, and *end-users* like patients and healthcare professionals. Especially end-user involvement provides insight into relevant needs and priorities (18, 19). Collaboration with end-users to tailor the treatment is critical in the development phase, to emphasize person-centeredness (20, 21). Further, end-user engagement throughout the development process is essential for creating effective digital health interventions (22) and increasing ease of use (23).

Recently, the UK Medical Council recommended that the development of novel interventions involves individuals with lived experiences in each phase (i.e., development, feasibility, evaluation, and implementation) to assure inclusivity, accessibility, and efficacy (24). While an increasing number of studies have identified preferences and needs in digital interventions for chronic pain (25-27), end-user involvement is usually limited to a certain phase of the innovation process. How end-users can be involved in the implementation and evaluation of digital behavioral interventions has been described (28, 29) but clear descriptions of end-user engagement during the development phase remain limited. There is, thus, a need for studies clarifying how the development of novel digital interventions for chronic pain can apply a user-centered approach, to facilitate replicability and establish standards for digital health innovation.

The ‘DAHLIA’ (Digital behaviourAl HeaLth for chronIc pAin) is a user-centered multiphase project with two distinct yet related purposes: 1) to generate an evidence-based digital health intervention for people with chronic pain, and 2) to provide a robust and replicable process for user-centered development, evaluation, and implementation process (30). The overarching aim of the present study is to clarify how a digital behavioral intervention can be developed in a user-centered approach to address the needs and preferences of the target population. The development includes three phases: preparation (phase 0), designing (phase 1), and testing (phase 2).

More specifically, the research questions were:

Phase 0 – Preparation: (i) How can Patient Personas be used to define the relevant patient characteristics, needs, and treatment targets of people living with chronic pain?, (ii) How can a better understanding of Patient Personas guide the prototype development?

Phase 1 – Designing: What are the preferences of end-users for the design (i.e., content, structure, format) of this digital intervention, as reported in end-user focus groups (patients and therapists)?

Phase 2 – Testing: How do end-users (patients and therapists) perceive engaging with the first treatment prototype (version 1.0), and how can the digital intervention be further improved to meet needs and preferences?

## 2. Methods

### 2.1. Study design

The present study utilizes a multi-methods approach in the development of the DAHLIA prototypes 1.0 and 2.0, and includes three phases (0: Preparation, 1: Designing, 2: Testing). The study is part of a larger project also containing evaluation and implementation phases (30), which will be presented elsewhere.

The development was centered around end-users (patients and therapists) and utilized complementary user engagement approaches, namely Patient Personas (phase 0, see section 2.3), qualitative focus groups (phase 1, see section 2.4), and multi-methods pilot testing based on perceived end-user experience (phase 2, see section 2.5). These development phases are presented in Figure 1 and further described below. The study was approved by the Swedish Ethical Review Authority (approval number: Dnr 2021-02437).

--- FIGURE 1 NEAR HERE---

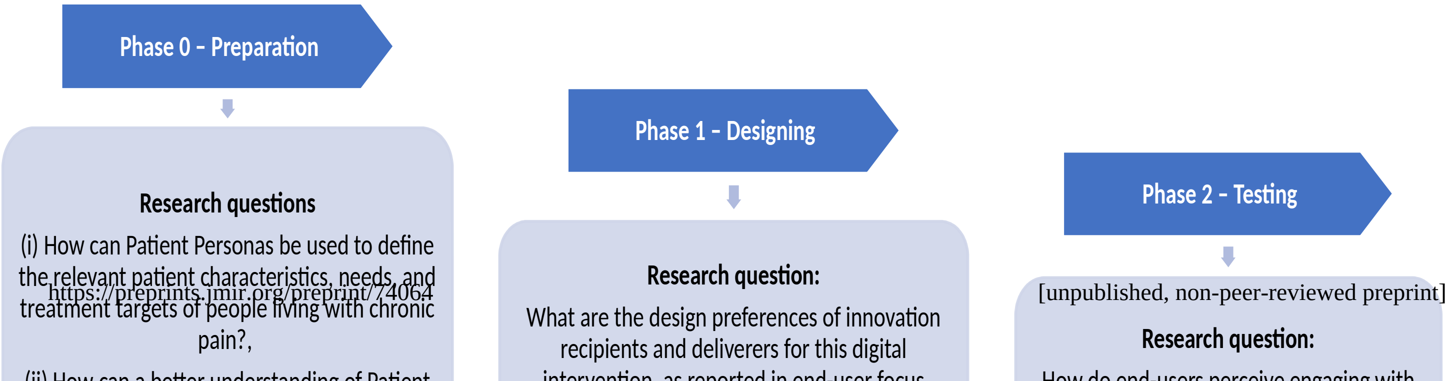
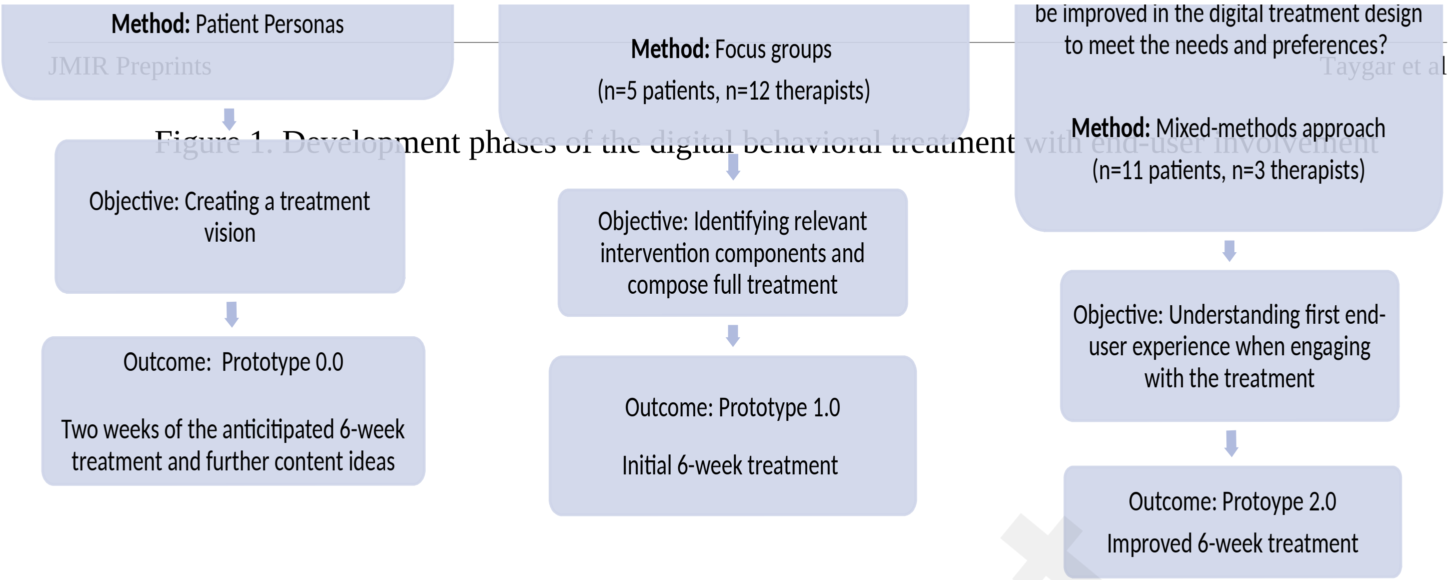


Figure 1. Development phases of the digital behavioral treatment with end-user involvement



## 2.2. Phase 0 – Preparation: Preliminary patient characteristics, needs and treatment targets

To address the first research question, the initial designing of the prototype was based on a theoretical framework and conceptual model, as well as a preliminary definition of the patient characteristics, needs and relevant treatment targets based on Patient Personas.

### *2.2.1 Theoretical frameworks and conceptual model*

The DAHLIA treatment program is based on learning theory (31), with the fear-avoidance model (3) and the psychological flexibility model (4, 5) integrated into a comprehensive conceptual model. The primary treatment objective is to increase resilience (i.e., being able to sustain living a fulfilling life in the presence of distress) (32) to chronic pain and distress by improving behavioral self-management skills relevant to well-being and functioning (33).

### *2.2.2 Patient Personas*

Personas, or fictional user profiles, aim to depict the target group of a treatment or product (34). Since the involvement of people with chronic pain may be challenging in the early stages of the development due to ethical or practical reasons, Personas can be utilized as representations of the target group (35). Personas is a design methodology, and their utility depends on the project aim.

In the DAHLIA project, three Patient Personas (PPs) were used during the initial conceptualization and preparation of the treatment. PPs were used to discuss whether the treatment vision (e.g., content, set-up, design) aligned with the needs and characteristics of PPs. These PPs were developed by clinical researchers (RW, IF, KB, LMcC, SP) building on PPs used in a previous study (36), discussed in three online workshops, adjusted based on the factors on existing chronic pain research (30) and clinical researcher input, and edited over several months (SB, SJ) until the project partners reached consensus. One of three PPs is presented in the appendix (Multimedia Appendix 1), and the other two are presented elsewhere (30, 37). Through narrative synthesis, a summary of PP's characteristics, key challenges in the development of the intervention, and potential ways to approach these challenges were identified, guiding discussions and decisions to refine the treatment content.

### 2.2.3 Intervention structure for prototype version 0.0

The treatment prototype version 0.0 was prepared based on theoretical considerations and implications of the PPs following consensus discussions in the project group (see results section 3.1). Moreover, a micro-learning approach (38, 39) was applied to organize treatment content into brief and frequent sessions, which was considered useful to prospective users experiencing challenges due to, for instance, dyslexia, fatigue, attention deficits, or reduced cognitive functioning. It was anticipated that the final treatment would include six modules, with four sessions per module, in total 24 treatment modalities. Overall, a six-week treatment duration was anticipated, with one module per week. The outcome of Phase 0 was treatment prototype version 0.0 including two modules of the treatment, building the foundation for end-user input in Phase 1.

## 2.3. Phase 1 - Designing: User-centered design of the digital intervention

Designing the digital health intervention (treatment protocol 1.0) was based on a preliminary understanding of patient needs and relevant treatment targets and guided by end-user input from focus groups.

### 2.3.1. End-user focus groups

To develop the full 6-week treatment, both prospective patients and therapists were involved to provide user input on the needs and preferences of the digital intervention. A qualitative study with two patient focus groups (n=5 in total) and three therapist focus groups (n=12 in total) was conducted. Notably, the initial research plan (30) was to involve six to eight participants per focus group and conduct the discussions face-to-face. However, due to the COVID-19 pandemic, focus groups were conducted digitally, and the target size of each group was reduced to three to five participants per group, based on previous research (40), especially for digital settings (41).

### 2.3.2. Participants and recruitment

Inclusion criteria to participate in a *patient focus group* were: (i) age 18 to 65 years (working ages), (ii) pain duration of three months or longer, (iii) ability to communicate in Swedish, and (iv) access to a computer, smartphone, and internet in a home environment. Individuals were excluded if they had serious psychiatric comorbidities (e.g., risk of suicide).

Inclusion criteria for the *therapist focus group* were: (i) Licensed psychologist/ psychotherapist with training in cognitive behavioral therapy, (ii) fluent in Swedish, and (iii) having access to a computer/ laptop with an internet connection. Experience in treating patients with chronic pain was recommended but not required. No exclusion criteria were specified, in order to increase external validity.

Eligible therapists received an email with a link to provide informed consent. End-users (patients and therapists) were recruited from two healthcare centers in two different regions of Sweden (Stockholm, Kalmar). For patient recruitment, flyers were distributed at clinics, and interested individuals scanned a QR code and were directed to a digital system (REDCap, Research Electronic Data Capture (42, 43)) to register. Registered individuals were contacted by a research assistant (SJ) to receive detailed information about the study. A clinical coordinator (SP, licensed psychologist) screened potential participants to check eligibility.

### 2.3.2. Materials and procedures

Eligible participants were contacted by email with a link to provide informed consent and sociodemographic information (e.g., age, sex, and occupation) in REDCap prior to the focus group. Therapists also reported their level of experience delivering psychological treatment (years) including for people with chronic pain (years). Patients were asked to complete questions specific to their pain condition.

The focus groups were conducted as two-hour-long recorded video meetings (MS Teams) held in the first half of 2022 and transcribed verbatim. The meetings were moderated by a research assistant (SJ) with support from two psychology students (HAS, OKJ), and were recorded and transcribed verbatim. Focus groups followed a semi-structured format (Multimedia Appendix 2), with two distinct objectives: to identify *general health needs* and to generate user input on *the digital treatment content and design*. The present study is focused on the user-centered input into the digital treatment, and user input into general health needs will be presented in another publication. To facilitate concrete feedback, participants were given access to the treatment prior to the focus groups and asked to focus on the first two modules of the treatment and the general treatment vision.

### 2.3.3. Data analysis: focus groups

Sample characteristics were analyzed using descriptive statistics. A qualitative framework analysis (44) was used to analyze the (qualitative) focus group data with the following steps:: 1) *familiarizing* with the data by listening to recordings and reading transcripts, 2) *identifying* the thematic framework by deciding whether to conduct an inductive or a deductive approach, 3) *indexing* by creating a coding frame of the highlights from the data, 4) *charting* by placing themes into rows and columns in summary, and 5) *mapping and interpretation* by looking into similarities and dissimilarities between participants' responses.

The Consolidated Framework for Implementation Research (CFIR) (45) was used to guide the coding of the focus group data. The CFIR consists of five main domains (i.e., intervention characteristics, outer setting, inner setting, individual characteristics, and implementation process) (45, 46). Phase 1 focused on the CFIR domain “intervention characteristics”, specifically the design and content of the digital behavioral intervention, including the sub-domains: evidence-base, relative advantage, adaptability, complexity, and design of the innovation (refers to the ‘digital intervention’) (see Table 1). Two independent researchers (AT and SB) performed the qualitative analysis, with a third reviewer (RV) validating the outcome of the analysis by reviewing the final framework.

--- TABLE 1 NEAR HERE---

Table 1. CFIR construct names from the 'Innovation' (refers to the ‘digital intervention’) domain that were applicable to the present phase and their definitions

| **CFIR Domain** | **Construct name** | **Construct definition** |
|---|---|---|
| | | |
| Innovation:<br>*The DAHLIA treatment prototype* | Evidence-Base | The effectiveness of the intervention is supported by robust evidence |
| | Relative Advantage | The intervention is better than other available innovations or current practice |
| | Adaptability | The intervention can be modified, tailored, or refined to fit local context or needs |
| | Complexity | The intervention is complicated, which may be reflected by its scope and/or the nature and number of connections and steps |
| | Design | The intervention is well designed and packaged, including how it is assembled, bundled, and presented |

## 2.4. Phase 2 - Testing: Piloting the digital intervention

The full six-module treatment (prototype 1.0) was piloted in phase 2, with the objective to test and identify areas for improvement of the digital treatment design (i.e., content, structure, format).

### 2.4.1 Participants and recruitment

The inclusion and exclusion criteria for patients and therapists in phase 2 are consistent with the eligibility criteria of the focus group study (Phase 1, see section 2.3.1.). Additionally, patients were excluded if they i) had an injury or illness that required an immediate assessment or treatment, ii) had changes in prescribed medication for the last 3 months or changes were expected in the next three months, or iii) received a cognitive-behavioral therapy treatment during the past six months. Participants (n=11 patients and n=3 therapists) were recruited from the same two regions (Stockholm and Kalmar).

### 2.4.2 Materials and procedures

The DAHLIA treatment (prototype version 1.0) consisted of four self-guided micro-sessions per week, for a total of 24 sessions delivered over 6 weeks. Moreover, participants had weekly contact with a therapist through a 30-minute phone or video call. The digital intervention was offered through the healthcare system, implemented into a digital system called 1177, the national healthcare web platform in Sweden (www.1177.se), in collaboration with healthcare providers from Region Stockholm and Kalmar, and healthcare developers and digital designers in Region Kalmar, and supported by the industry partner Inera for the maintenance.

#### 2.4.2.1 Evaluation of engagement with treatment

Every week, at the end of the contact with their therapists, patients were asked to evaluate the module based on how helpful, enjoyable, and comprehensible they perceived the module by responding to a set of statements, '*I experienced this week's session as helpful/ enjoyable/ understandable*' rated on a 7-point scale, ranging from 0 (not at all) to 7 (very much). Furthermore, after completing the intervention, a semi-structured exit interview (Multimedia Appendix 3, Multimedia Appendix 4) was conducted with each participant (i.e., patients and therapists) by a researcher (LE, SP, SLB, AST) to assess user experiences of engaging with prototype version 1.0, focusing on: overall experience of the treatment (e.g., *Did the digital treatment interfere with your daily routines?, Would you recommend this treatment to a friend with a similar condition?*), and more specific questions on micro-sessions and weekly contact with their therapist.

In addition, therapists were interviewed about their experience of providing the intervention (e.g., *Was it easy to navigate the digital treatment?, Was the frequency of communication with the* *patient adequate?)*. These evaluations and reflections from end-users, including treatment patients and therapists, were intended to guide the researchers in revising the treatment's design (structure, content, format). Overall, these evaluations were chosen to explore intervention and implementation success (see section 2.4.3).

### *2.4.3 Data analysis: pilot testing*

All quantitative data were analyzed using descriptive statistics (mean, standard deviation, range). The same stepwise approach as in Phase 1 (section 2.3.3) was used to analyze the qualitative data (44, 45). Specifically, the "Implementation Process" domain of the CFIR (45), was used as codes to analyze the qualitative data from patients' and therapists' weekly evaluations and exit interviews. For this analysis, the CFIR 'reflecting & evaluating' construct within the "Implementation Process" domain was utilized to explore the end-users' perceived intervention and initial implementation success (see Table 2).

--- TABLE 2 NEAR HERE---

Table 2. CFIR construct names from the 'Implementation Process' domain that were applicable to the present phase and their definitions.

| CFIR Domain | Construct name | Construct definition |
|---|---|---|
| Implementation Process<br>*The activities and strategies used to implement the intervention.* | Reflecting & Evaluating: Intervention | 1. Intervention: Qualitative and quantitative information that is collected to assess the **success of the intervention** |
| | Reflecting & Evaluating: Implementation | 2. Implementation: Qualitative and quantitative information that is collected to assess the **success of the implementation** |

## 3. Results

Results from each phase follow (0: Preparation, 1: Designing, 2: Testing).

### 3.1. Phase 0 - Preparation: Relevant patient characteristics, needs and treatment targets for the digital intervention to guide the preparation of the prototype (version 0.0)

Considering the literature and clinical experiences, the group of researchers and clinicians found it helpful and sufficient to use three PPs to describe patient characteristics, needs, and treatment targets.

Across all PPs, the four domains included: (i) Sociodemographics, such as education, work, family, background, social environment, and living location, (ii) pain profile, including pain problems, impact of pain, pain behavior, and attitude towards the treatment, (iii) health care, such as contact with healthcare, comorbid conditions, and medications, and (iv) personal needs and goals, particularly those related to treatment. The synthesis of characteristics, needs, and treatment targets across all three PPs resulted in a visual summary (Figure 2). Moreover, based on the PPs, the group identified a number of key challenges and ways to approach these challenges in the Design and Testing Phases, which are summarized in Table 3.

--- FIGURE 2 NEAR HERE---

**Patient Persona Summary**

**Domain: SOCIODEMOGRAPHICS**

**Age:** Various ages, all 18 or older

**Employment:** Diverse professions including sick leave, retirement, and students.

**Education:** At least middle school graduates, need to be able to read and write in Swedish

**Family:** Various marital statuses (e.g., divorced, married, single)

**Background and social context:** Various cultural backgrounds and social contexts, though needs to be able to communicate in Swedish and able to use digital devices

**Social support (related to pain)**: Different types and levels of social support

**City/ countryside:** Diverse locations (e.g., city, countryside, etc.)

**Domain: PAIN PROFILE**

**Pain problems:** Primary and secondary pain, pain as a primary interfering symptom/condition. Not specific pain diagnosis/mechanisms/localization, examples need to be appliable for various pain profiles

**Consequences:** Diverse consequences on patients' well-being and functioning

**Pain behavior:** Dysfunctional behavior patterns, including withdrawal from activity as well as excessively engaging. Range of activity levels, both avoidants and over-compensators.

**Attitude to treatment:** Various perceptions of and openness to psychological treatment. Psychoeducation on pain and different options for the mode of communication with the therapist should be provided

**Domain: HEALTH CARE**

**Contact with health care:** Previous and ongoing assessments/treatment. Different levels of health literacy and insight, and self-referral to the clinic should be allowed

**Comorbidities:** Range of psychological comorbidities, except suicidality. Possibility of using add-ons in treatment (e.g., alcoholism, sleep problems, etc.)

**Medication:** Use of painkillers varies in dose, type, and frequency

**Domain: PERSONAL NEEDS & GOALS**

**Needs:** Various levels of confidence in healthcare. Various expectations from the design and content of the treatment in accordance with the needs.

**Goal:** Various life goals and values (e.g., to be more present, to be more active, to have a more balanced lifestyle)

Figure 2. Implications of Patient Personas on the treatment development

--- TABLE 3 NEAR HERE---

Table 3: Key challenges in the development of DAHLIA intervention and potential ways to approach these challenges.

| Key challenges | Approach |
|---|---|
| The chronic pain population is heterogeneous due to various characteristics, | The content needs to be written using inclusive language (e.g., easy reading level) and contain diverse examples; the treatment needs to be |

| | |
|---|---|
| including age, gender, pain history, needs, co-morbidities, abilities, ethnicity, etc. | tested in a heterogeneous sample; sub-group analysis might be necessary to explore which specific characteristics influence treatment outcomes. |
| Digital literacy will vary significantly, as some patients will be reluctant or not able to use technology. | A non-digital alternative and technology training in the onboarding phase (during enrollment) needs to be offered. |
| The varying needs and expectations in this heterogenous population may require flexibility regarding treatment content. | The theoretical foundation of the treatment (section 2.2.1) is transdiagnostic and a standardized prototype treatment can therefore be assumed to benefit the population but tailoring or add-on elements may be needed to provide support for patients with specific or more complex health challenges. |

## 3.2. Phase 1 – Designing: Preferences of end-users for the design (i.e., content, structure, format) of the digital intervention

### *3.2.1. Characteristics of participants*

#### 3.2.1.1. Patient focus groups

Seven patients signed informed consent, resulting in n=4 participants in the first focus group and n=3 participants in the second focus group. Despite rescheduling both groups once, one participant per group was unable to join (reasons for drop-out: n=1 sickness, n=1 doctor's appointment). Consequently, n=5 patients (retention: 71%) participated in the focus groups (n=3 in the first focus group, n=2 participants in the second). Participants were on average 43.6 years old (SD: 7.8, range: 37-53), and n=1 identified as men and n=4 as women. Educational levels of participants ranged from high school degree to college/university degree (n=3 high school degree, n=1 ongoing university studies, n=1 college/university degree). All participants reported having chronic pain, three were unsure of or did not receive a specific pain diagnosis, two reported being diagnosed with Ehlers-Danlos syndrome (EDS) (of which one reported a fibromyalgia diagnosis as well). Using a numerical rating scale (NRS) from 0-10 (2), participants reported a current pain level of 5.8 (SD: 1.5, range: 4-8), and an average pain level during the last week of 6.6. (SD: 1.14, range: 5-8). A summary of the characteristics of patients is provided in Table 4.

Table 4. Sociodemographic and pain characteristics of the patient focus group participants

| | Patient 1 | Patient 2 | Patient 3 | Patient 4 | Patient 5 | Patient 6 | Patient 7 |
|---|---|---|---|---|---|---|---|
| Participation | Yes | Yes | Yes | Yes | Yes | Drop-out | Drop-out |
| Age | 40 | 37 | 53 | 37 | 51 | | |
| Gender | Woman | Man | Woman | Woman | Woman | | |
| Educational level | High school degree | High school degree | Ongoing university studies | High school degree | College/ university degree | | |
| Pain diagnosis | Ehlers- | Unsure/ | Undiagnosed | Ehlers-Danlos | Undiagnosed | | |

| | Danlos syndrome | do not know | pain | syndrome, fibromyalgia | | | |
|---|---|---|---|---|---|---|---|
| Current pain level (from 0 to 10) | 6 | 4 | 5 | 6 | 8 | | |
| Pain level during last week (from 0 to 10) | 7 | 6 | 5 | 7 | 8 | | |

### 3.2.1.2. Therapist focus groups

Three focus groups with n=4 therapists each were conducted. Twelve therapists (n=8 from Region Kalmar, n=4 from Region Stockholm) provided informed consent and joined the focus groups (100% retention rate). Participants were on average 42.8 years old (SD: 12.0, range 29-64), n=3 identified as men and n=9 as women. All participants were licensed psychologists with on average 12.3 years of clinical experience (SD: 9.4, range: 2-31), and 9.5 years of experience working with chronic pain patients (SD: 9.8, range 0-28).

## *3.2.2. Outcomes from the patient and therapist focus groups*

The focus groups provided input on the treatment relevant to the CFIR's 'Intervention' domain and its related constructs (evidence-base, relative advantage, adaptability, complexity, and the design, see Table 1), which is presented in brief below.

### 3.2.2.1 Evidence-base of the treatment

Therapists expressed that they perceived the content as relevant, valid, and evidence-based. Participants did not mention any outcome regarding the evidence-based content.

### 3.2.2.2. Relative advantage of the treatment

Patients and therapists reported different advantages and disadvantages, in relation to other types or formats of treatment, which are presented in Table 5 in detail and summarized below. Some patients reported that group-based treatment has an advantage over individual treatment as it facilitates the exchange of experiences with others, while others endorsed individual treatment as the pace could be adjusted to the participants' needs. Also, it was mentioned that digital delivery may be challenging for older adults who struggle with technological devices. Furthermore, therapists reported that the digital self-help format with pre-existing content and structure enables the delivery to be more concise than standard treatment, that the micro-session format is preferable over longer modules, and that the digital format treatment could be introduced to the patients earlier and cover a broader geographical area (i.e., rural areas) than traditional approaches.

Table 5. Relative advantages of the digital behavioral treatment as reported by the focus group participants.

| **Participant group** | **Sub-categories: Relative advantage** | **Exemplary quote** |
|---|---|---|
| | | |
| Patient | Pro/ cons of individual vs group-based treatment | Patient 2: *"I think that's a good thing: if someone has difficulties with something that might not be so easy to deal with in a group, then there might be an opportunity for private, individual sessions that."*<br>Patient 5: *"It's always good to exchange experiences with others I think"* |
| | Potential disadvantage: digital delivery (e.g., older age, low economic status) | Patient 4: *"[Father of participant] was born in 50s', hates technology and everything surrounding it, doesn't even have a computer and refuses to get one. Is there any kind of technology help? What is required to do these programmes? Do you need a computer or is it enough to have a phone? How do you deal with those on welfare, if they can't afford a smartphone and computer?"* |
| | ACT preferred over traditional CBT | Patient 5: *"I've tried CBT. I'm not a big fan of CBT, to be honest. I put more stock in ACT. Acceptance, which is something I've worked really hard on because I've been a bit black or white."* |
| Therapist | Online treatment enables therapists to provide knowledge to the patient in a more structured way than face-to-face or telephone-based treatment | Therapist 1: *"I personally would have had a more difficult time if [I] met the patients face-to-face in this type of treatment without any support [...] Having a treatment program that you follow, I feel that the knowledge I have [then] about chronic pain is good enough."*<br>Therapist 4: "*This kind of program [is not so bad], because there is built-in structure and the knowledge that the patient is getting, is what the patient needs so that it doesn't depend as much on my structure."* |
| | Online treatment offers more training options to therapists (than currently available) | Therapist 4: *"It is difficult to become good at something that requires a lot from the practitioner [...]. I think that a program like this can fulfil such a [training] function."* |
| | iCBT for chronic pain currently not available | Therapist 2: *"It's worth developing this because it's needed."* |
| | Micro-session format potentially advantageous over longer iCBT sessions | Therapist 7: "*It's very different from the regular internet-based CBT we [therapists] work with but [when] you get the patient to understand to go in ten minutes every day, then it becomes more of a habit."* |
| | Online treatment could be offered earlier to patients than traditional therapy | Therapist 7: *"Internet-based [treatment] is one of the first steps [...]. [If the system would] be able to [refer patients at] an earlier stage and in that case, we would be able to be helpful with patients that we don't see today."* |
| | Online treatment could cover a wider area than traditional therapy | Therapist 5: *"The possibility of practicing because I have the whole region as a 'catchment area'. It's really good to be able to reach out in this way [digitally]."* |

### 3.2.4 Adaptability of the treatment

In both patient and therapist focus groups, participants discussed the mode of communication for the weekly therapist-patient contact. While therapists emphasized the benefits of an asynchronous messaging function over a live chat function and expressed potential preference for phone calls over video calls, patients expressed a general preference towards video calls over phone calls or messages. The varying views and preferences imply a need for flexibility in the mode of communication.

Furthermore, therapists suggested that the online treatment should be adaptable according to patients' level of knowledge and interest as some patients might have sufficient pain education, while others would benefit from additional information. The therapists argued that the treatment length might also need to be adapted to symptom complexity, for instance, patients with longer and more complex pain and health issues might benefit from longer treatment periods, and the frequency of contact should be flexible, as highlighted by therapists. Finally, both patients and therapists proposed a text-to-speech function and subtitles in videos to better accommodate people with disabilities such as hearing, visual, and/or cognitive limitations. Details and supporting quotations can be found in Table 6.

Table 6. Adaptability aspects of the digital behavioral treatment as reported by the focus group participants.

| **Participant group** | **Sub-categories: Adaptability** | **Exemplary quote** |
|---|---|---|
| | | |
| Patient | Flexibility in mode of communication; preference towards video calls | Patient 3 *"There's someone who sees me. Once a week, I know I'll be seen"*<br>Patient 4 *"I think you should be able to choose. [...] You might feel that's enough writing for today. I don't have anything to say but today I want to talk on the phone because I don't feel I can sit at the computer [and type a message]. So I can make the call while sitting in the car, taking the bus. But then I might feel like, now I want to see another human being [and I chose a video call]."* |
| | Flexibility in engagement with treatment (i.e., choosing certain exercises) | Patient 2 "*That maybe there's the possibility to adapt, if there's somebody who's having a very hard time, [then] you don't have to do all of this, but we can just do a specific part. To be able to adapt it to the individual a little bit because in my experience [of those who] have chronic pain, we are all different with different functions, different personalities, basic stages, other difficulties. I think it would do some good to be a bit flexible from person to person"* |
| | Text-to-speech function and subtitles in videos | Patient 4 *"Is it possible to have the text read aloud, or will this be made possible? [...] text-to-speech and audio description or subtitling are a must I think."* |
| | Inclusivity towards people with disabilities | Patient 4 *"Because if you do as much preparatory work as possible, e.g., you put in a glossary, you prepare for audio description and subtitling and text-to-speech and everything, because if you have a good foundation, the target group doesn't really matter because then you can just update."* |
| | Mobile and computer versions | Patient 4 "*You can make one [version of the program] that's a mobile version but with even less text and even more in summary form, but still the same content"* |
| | Provide technical support if needed | Patient 4 *"But will they be any kind of technical help then [for those who need it]?"* |
| | Paper-based version (if technology is not usable and) as long-term resource | Patient 4 *"You [could] have some kind of physical book available with information and everything that you can go back to and read parts of. [...] You've undergone the treatment, you received the information, but five-ten years later the time may be ripe to put it to use and then you still have the book"* |

| | | |
|---|---|---|
| Therapist | Online treatment needs to be adaptable to patients' (dis)abilities (e.g., linguistic/ cognitive) and preferences | Therapist 10 "*Pain patients often have difficulty with concentration and with reading a text. If an audio file could be added for each text, so that [the patient] can press [play] on it [and] there is a voice that says exactly the same things as in the text so [the patient] can both listen and somehow follow the text."* |
| | Online treatment should be adaptable according to patients' level of knowledge/ interest | Therapist 3 *"If you [patient] want to delve deeper, then, maybe have something that you can activate and read on if you want more information about it [...] Maybe some patients already know what pain is and want to go directly do the exercises [...] make it more efficient."* |
| | Treatment length might need to be adapted to symptom complexity | Therapist 5 *"I think that pain is very complex, and it can take time to implement behavioral changes [...] if you want to implement a proper behavioral change to something that has been going on for thirty years, six weeks may be a very short time. [...] It depends on which patient group you think should be included in this [treatment]. Is it really severe pain patients or is it primary care patients with a little milder pain who haven't had pain for so long? Then I think that then it [the six-week duration] is quite reasonable."* |
| | No space limitations on patients' response to exercises (i.e., word limit) | Therapist 10 *"[The patient could] have the possibility of filling in more."* |
| | Flexibility in frequency of contact | Therapist 7 *"With some patients, you maybe have many phone calls while with others you may have nothing in the meantime but a follow-up at the end or something in the middle and then at the end. It can be varied and timewise it is also a bit different."* |
| | Flexibility in mode of communication (i.e., telephone, video, messaging) | Therapist 2 *"Let them choose when we book an appointment: should I call you up or do you want to write in the chat function if you want some feedback on any particular part of it [the exercise]."* |
| | Reason to provide flexibility in mode of communication (1): Scheduling (P/T) | Therapist 4 *"It's better [for one's own structure] to have a clear that this is the feedback day. This is when you can expect to get a response from me. [...] They know that there is a specific day and that we have a contract at the beginning that this is what the agreement looks like."* |
| | Reason to provide flexibility in mode of communication (2): Time for Preparation (T) | Therapist 8 *"You have to be very aware of what [the patients] have worked on because it is difficult to go [into the treatment] and have video [the camera on] at the same [while talking online face-to-face with the patient]."* |
| | Reason to provide flexibility in mode of communication (3): Therapist encourage use of messaging function (T) | Therapist 7 *"We always encourage people doing internet-based CBT to write to us in this messaging function. [...] There are quite a few who never write in that box no matter how much you encourage them. [Therapists could have personal contact regularly]."* |
| | Reason to provide flexibility in mode of communication (4): Preference for phone call (P) and video not superior to phone call (T) | Therapist 3 *"If you choose only chat function then it is very difficult [...] Video is also an option, if it works. You often waste a lot of time if it's not working, and then phone always works."* |
| | Asynchronous messaging (not live chat-) function | Therapist 8 *"I write answers and feedback based on what they [patients] wrote previously, not that it is a live chat."* |

### 3.2.5 Complexity of the treatment

Concerning the complexity of the treatment, patient focus groups suggested that the amount of text in the digital treatment could be challenging for some individuals and should be reduced to improve feasibility and user-friendliness. Additionally, bullet points and summaries could enhance clarity, and exercise instructions preferably clear.

Therapists further reported that the treatment could be considered demanding for both patients and therapists.

### 3.2.6. Design of the treatment

Within the CFIR construct 'design' two subthemes were identified: ‘design elements’ which refers to technology, branding, media, text, and aesthetics, and ‘content elements’ refers to reflections from participants on how the content, or treatment elements delivered, should be improved or what should be added or removed.

Design elements of the treatment: Figure 3 summarizes preferences and suggestions on the design of the digital intervention suggested by patients and therapists.

--- FIGURE 3 NEAR HERE---

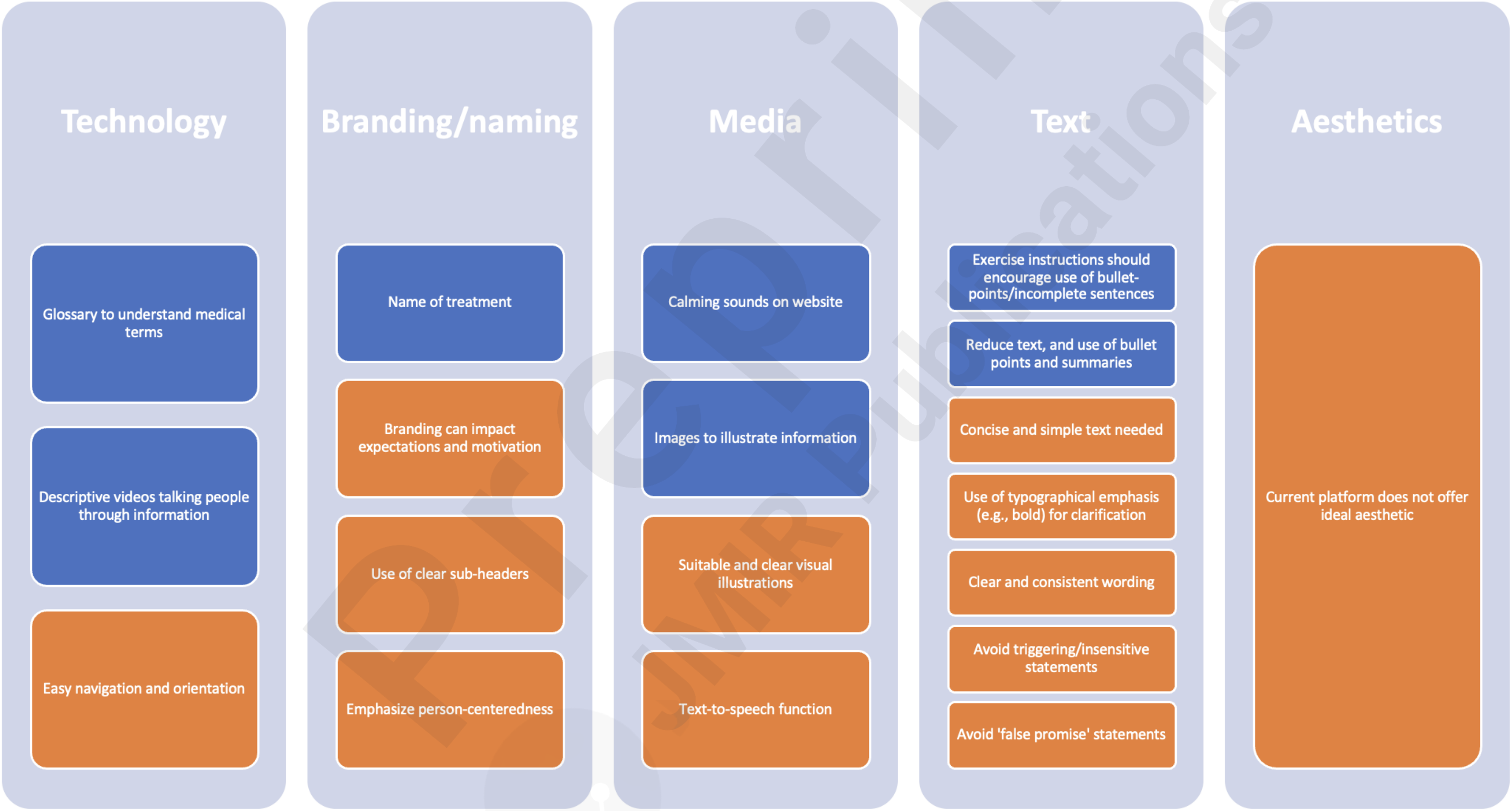


Figure 3. Preferences and suggestions for the design elements for the digital intervention provided by the focus group participants. (blue boxes: patients, orange boxes: therapists)

Content elements of the treatment*:* Table 7 presents preferences and suggestions from participants regarding the content of the digital intervention, which is also summarized below. The treatment program (prototype 0.0, with suggestions for full version) was evaluated as well-structured by therapists. Therapists suggested having a table of contents and summaries at the beginning of the treatment, including psychoeducation on pain, and inclusive and diverse examples. Moreover, therapists highlighted the importance that the content must fit diverse patient groups, potentially targeting behaviors such as pacing or overcompensating.

Patients suggested that the content, including exercises, should ideally be tailored to individuals' needs such as involving sleep-related content for participants who struggle with insomnia and by assessing treatment expectations. Extra material to the treatment content could potentially be offered through external links and further readings. Patients suggested one or two sessions as a 'booster' after the completion of the intervention period as a reminder and relapse prevention. Patients also mentioned the importance of content that focuses on enabling a meaningful life, for instance focused on how to find things that bring feelings of happiness and contentment in life, by identifying things that are important for participants, and targeting (mourning of) the loss of function and realizing current capacity. Further details and exemplary quotes are presented in Table 7.

Table 7. Preferences and suggestions on the structure and content elements for the digital intervention of focus group participants.

| **Focus group** | **Sub-categories: Design (specifically on the content)** | **Exemplary quote** |
|---|---|---|
| | | |
| Patients | Sleep-related content | Participant 3: "I'm thinking more about how to sleep, what you can do in bed, how to relieve things in the best way to get a better sleep." |
| | Several booster sessions | Participant 3: *"I would recommend two (booster sessions)"* |
| | Ask patients about treatment expectations | Participant 1: *"[Talking about expectations] makes it easier to move on to the next step, because I'm open with what I expect and where I come from, what I've chosen not to do and how it's affected me. [...] And if you are honest and say that this is what I expect, then the person who meets me can be honest and say this is what we can provide you with."* |
| | Focus on enabling a meaningful life | Participant 2: "*That's what I've been missing. Getting back a little more, meaning to live life instead of surviving it. To be able to find fun things to feel content, happy and satisfied."* |
| | Focus on life values | Participant 5: *"I think it's important to reflect and look at what works for me in everyday life, and what it is that drives me in life. You may sometimes think it's really hard to have a family when dealing with pain, but at the same time, they have been a driving force. They are my motor. I also have my work, which I really enjoy, and I have an understanding employer and all my co-workers know that I am sometimes in pain. And I think it's important to take the time to stop and reflect [though these exercises] and realize, today is a bad day, but I can still make things work."* |
| | Focus on (mourning) loss of function and realizing current capacity | Participant 1: *"You mourn yourself; you've passed away in some way [...]. You had a hard time finding your purpose again"* |
| | Micro sessions likely to be suitable | Participant 1: *"[Micro-sessions are] just enough. More than that would be too much. It then becomes like homework. [...] you can squeeze it in here and* |

| | | |
|---|---|---|
| | | *there [...] 10 minutes is easier to fit into life."* |
| | Optional extra material | Participant 4: *"[The program is] good as it is but you might want the opportunity to be able to understand a bit more. You [could] link to a page where you can read more about [a certain topic]. There should be some opportunity to delve deeper."* |
| | Body scans/ meditative exercises | Participant 4: *"For each day, you might have the option of doing one of those body scans.[...] For those panic attacks where my body stops working. I couldn't walk for six months and [doing a body scan] was the only thing that got me to learn to walk again. I became aware of my body"* |
| | Reusing existing content sources | Participant 4: *"I've learned when doing these projects that it's unnecessary to make material that already exists."* |
| | | |
| Therapists | Structured program | Therapist 1: *"It feels really good to finally have a structural treatment program."* |
| | Emphasize on exercise and skill training | Therapist 10: *"[Therapists] train the [patients] to observe, and that is a skill to learn, [to] observe nuances as well. Not everything is [about] pain, it might also be other things, [e.g., tiredness]."* |
| | Mandatory reflections on exercises | Therapist 1: *[Currently,] you can write to your practitioner how you perceived [the exercise] and I think that is valuable information [...] maybe not leave it optional."* |
| | Pros/cons of stating duration and word count per exercise | Therapist 1: *"A detail that bothered me a lot, is that it says how long the exercises take, it takes 2 minutes to complete this one [exercise]. I don't understand the purpose of that. I think that each patient will be very individual. […] It can still be good to have a short [text] here do a short reflection' [...] should write two sentences or two hundred."*<br>Therapist 10: *"Super great thing that it says four minutes [to do this session] and [the patient might think] yes I have that [time right now], so I think that is good."* |
| | Micro-sessions | Therapist 5: *"It's good that [the treatment] seems to be very brief [...]. This whole idea of taking small sections every day instead of longer pieces [like in other iCBT programs] might be a good adaptation for these patients who usually have much lower energy."* |
| | Importance of first exercise | Therapist 5: *"It's good that [the treatment] takes values and goals into account early."* |
| | Table of content and summaries | Therapist 5: *"It would have been nice to have a bit more of a summary that sums up all these sections. [...] For the patient to keep track of all these things"* |
| | Fits diverse patient group (i.e., pacing vs. overcompensating) | Therapist 6: *"The material seems to be about a patient [with more] fear of movement, but many of these patients are over compensators who are angry and struggling with their pain thinking 'I won't let the pain win' and they do too much."* |
| | Inclusive and diverse examples as part of exercise | Therapist 10: *"[The patient] can press on [a symbol] and then [they] get more information about an exercise [and] what [they] can answer in this exercise. I think it would be possible to have a few more examples and maybe a few more pain-related examples. [...] Pain patients can sometimes have difficulty with generalizing. If I [as the therapist give an example about] pain in my knee, then a patient who has back pain will say 'but then this doesn't apply to me'. You often need to have a lot of variations of examples so that the [patients] will be able to recognize themselves."* |
| | Psychoeducation on pain | Therapist 9: *"[The program should] have an explanation [on the] physiology of chronic pain to understand why [is the patient] doing this [program]. Many [patients] can be quite preoccupied with [the idea of] what is wrong with [their] body and finding [a] cause behind it. [the program needs to] explain that there is a very big difference between acute and chronic pain, they are driven by completely different mechanisms."* |
| | Ask patients to report limitations at start of treatment | Therapist 6: *"At the beginning of the treatment, the patient had to report 'Do I have any limitations, or have I been told that there is something I shouldn't or can't do?' [It is difficult as a therapist] having to play detective and find out and the patient can also have more concerns, but then you can discuss things."* |
| | Include more complex ACT processes (e.g., self as context) | Therapist 6: *"Internet-based treatment is now mature enough to take a step further and include more [ACT] processes [..] maybe self as a context. It [this process] is really hard to grasp even as a therapist."* |

## 3.3. Phase 2 - Testing: End-users perceptions of engaging with the treatment prototype and areas for improvement

Based on the focus group findings, the intervention prototype (version 1.0) was created by three researchers with clinical expertise (RW, LE, IF). The treatment consisted of six modules, including weekly contact with a therapist where patients and therapists together chose the mode of communication (phone or video call) as well as two booster sessions (after 2- and 4-months). Each module included four micro-sessions, resulting in a total of 24 micro-sessions. An overview of the content and a picture of the design are provided in the appendix (Multimedia Appendix 5).

Each new module was enabled by the therapist after the previous module was completed; while it was suggested that patients should complete one module per week, flexibility was allowed. Suggestions from the focus groups that were not implemented in the treatment prototype version 1.0 are presented in section 3.3.4.

### *3.3.1. Participant flow and characteristic*

For Phase 2 (testing), n=15 patients expressed interest of which n= 4 were not eligible, due to ongoing pain treatment or rehabilitation (n=3) or brain damage (n=1). Thus, n=11 patients (n=8 from Region Stockholm, n=3 from Region Kalmar) signed informed consent and started the treatment. Two participants dropped out and n=9 participants completed all modules (see Figure 4 for details).

--- FIGURE 4 NEAR HERE---

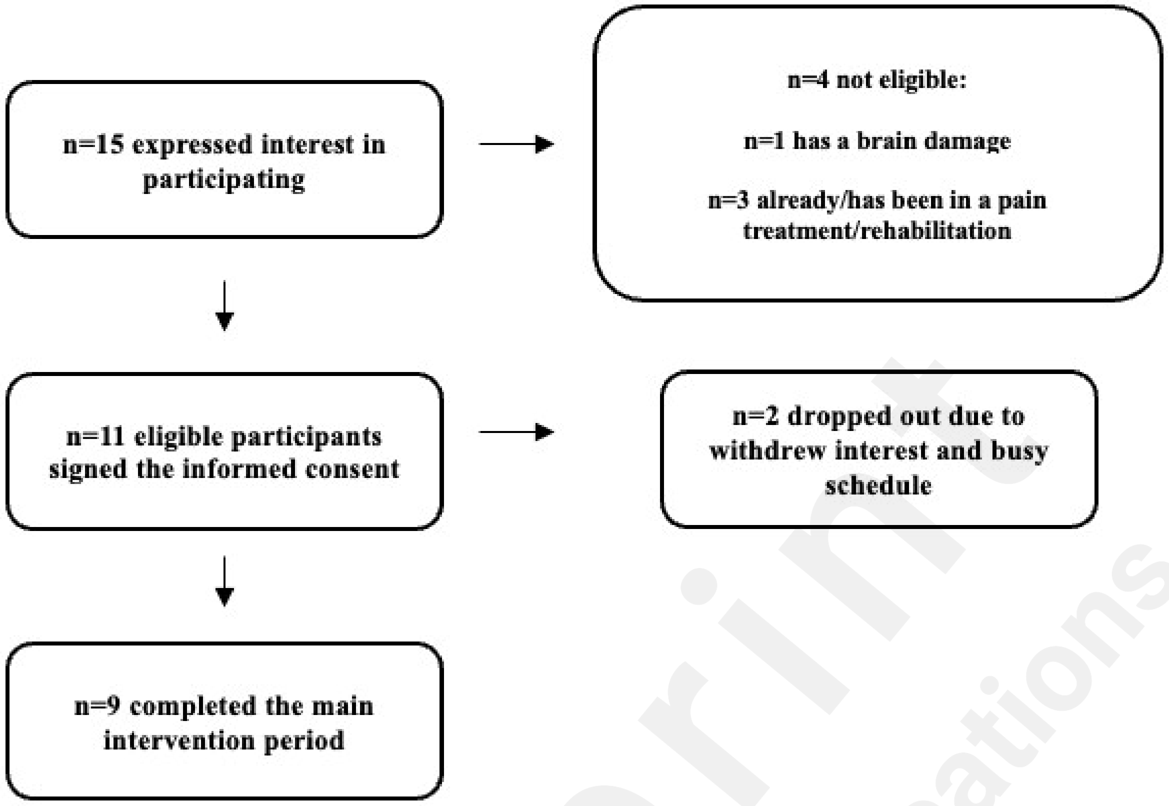


Figure 4. Patient flow in the piloting of the treatment (phase 2).

Patients were on average 46.6 years (SD: 7.28, range: 36-58), and n=1 identified as man and n=8 identified as women. Educational levels ranged from high school degree (n=2) to college/university degree (n=2 ongoing university studies, n=5 college/university degree). At baseline, NRS scores (0-10) showed that the current pain level was on average 5.1 (SD: 2.3, range: 3-10), and mean pain level in the last week was 5.6 (SD: 2, range: 3-10). Participants had various diagnoses: migraine, chronic fatigue syndrome, herniated disc, arthritis, fibromyalgia, complex regional pain syndrome, and hypermobile Ehlers-Danlos syndrome, and one participant did not know their pain diagnosis.

Three licensed psychologists delivered the treatment (n=2 from Region Stockholm, n=1 from Region Kalmar). Therapists were women, 47.6 years old (SD: 11.06, range: 36-58) with 21.7 years of experience with providing psychological therapy (SD: 13.31, range: 7-33), 18.3 years of experience working specifically with people with chronic pain (SD: 14.6, range 2-30), and 12 years of experience of using ACT (SD: 9.84, range 1-20).

### 3.3.2. End-user perceived success of the intervention

The success of the intervention refers to the direct reflection and evaluation of engaging with the intervention. As such, patients rated the modules as very helpful (mean=5.1, range 1-7), moderately enjoyable (mean=4.3, range 1-7), and very understandable (m=5.4, range 1-7). In addition, qualitative feedback was provided. Input varied, resulting in different suggestions for improvement (See Table 8).

---TABLE 8 NEAR HERE---

Table 8. Weekly ratings of helpfulness, enjoyability, and understandability (scores: 1-7) and exemplary elaborations of patients reflecting on micro-sessions

| | **Helpful**<br>mean (SD), range | **Enjoyable**<br>mean (SD), range | **Understandable**<br>mean (SD), range |
|---|---|---|---|
| | | | |
| **Module 1 (n=11)** | 4.27 (2.05), 1-7<br>*'a good start to understand pain, however, a bit more theoretical'* | 4.81 (2.08), 1-7<br>*‘fun and motivating to continue’* | 5.45 (1.80), 2-7<br>*'easy to understand'* |
| **Module 2 (n=9)** | 4.89 (2.20), 1-7<br>*'already thought about the things'* | 4.56 (1.94), 1-7<br>*'it is good that the module is difficult'* | 6 (1.30), 3-7<br>*'instructions for the exercises were difficult to understand'* |
| **Module 3 (n=9)** | 5.27 (1.19), 3-7<br>*'exercises led to a conversation with the therapist which in turn led to insights’* | 3.81 (1.53), 1-5<br>*'the navigation in between exercises messy'* | 4.45 (1.86), 1-7<br>*'highlights should be used for different exercises to make them more distinct'* |
| **Module 4 (n=9)** | 5.45 (2.01), 1-7<br>*'difficulty with changing things in combination with the high load in life'.* | 4.09 (1.75), 1-7<br>*'satisfying to get new insights'* | 5.63 (1.36), 3-7<br>*'more theoretical rather than practical'* |
| **Module 5 (n=8)** | 5.36 (1.20), 4-7<br>*'a bit less concrete than earlier chapters'* | 4.63 (1.12), 3-7<br>N/A | 5.45 (1.50), 2-7<br>*'more difficult than the previous modules'* |
| **Module 6 (n=7)** | 5.36 (1.50), 2-7<br>*'difficult and overwhelming due to the number of boxes that needed to be filled in each exercise'.* | 3.90 (1.57), 2-6<br>*'very difficult to navigate in between exercises'* | 5.54 (1.43), 2-7<br>*'the exercises were massive'* |
| **Total** | 5.1 (1.69), 1-7 | 4.3 (1.66), 1-7 | 5.4 (1.54), 1-7 |

Note: Perceived helpfulness, enjoyability, and usability were scored on a scale from 1: not at all, to 7: very much

Reflecting on the treatment as a whole during the exit interviews, patients considered the written material understandable and the text easily readable in terms of font size and formatting. Four sessions per week over six weeks were considered adequate, and the time needed to complete the sessions was acceptable.

Therapists evaluated the intervention as very beneficial for patients, they were overall satisfied, and self-reported that the intervention was delivered as intended. All therapists expressed interest in delivering the intervention again in the future. The overall time investment to deliver the intervention was considered acceptable, while the time saved to deliver this treatment online was perceived as moderate. Details of patients' and therapists' perceived intervention success are provided in Table 9.

---TABLE 9 NEAR HERE---

Table 9. Exit interview questions for participants on 'reflecting and evaluating' the intervention.

| Questions | Mean (SD), range | Exemplary quotes |
|---|---|---|
| | | |
| **Patients feedback** | | |
| Did you experience the online treatment as helpful overall? | 5.75 (2.05), 1-7 | *"I really think so. Mainly thanks to the sessions with my therapist. They were invaluable. Without them I am unsure of the value of the program." (Participant D)* |
| Did you experience the online treatment as meaningful overall? | 5.88 (1.72), 2-7 | N/A |
| Was the written material understandable? | 5.50 (1.30), 3-7 | *"First chapters were a bit tricky to understand, talked to my therapist and it got better." (Participant F)* |
| Could you easily read the text in the treatment (i.e., in terms of font size and formatting)? | 5.88 (1.80), 3-7 | *"Font size and formatting were OK, but there could be bold and italic text formatting or different colors can be used to link parts together better. And [there should be] clickable links instead of having to go back and forth, that was messy! Extra difficult to do in the phone. Text-to-speech function would be an improvement." (Participant A)* |
| Was the number of sessions per week (4 sessions) adequate? | 5.50 (1.41), 4-7 | *"A good number of sessions per week, and you could do them more or less thoroughly, you could adjust to what is needed for you, personally." (Participant B)* |
| Was the total number of sessions adequate? | 6.38 (0.91), 5-7 | *"In general, six weeks felt adequate. During this specific period, it was a bit stressful. Don't think that it is possible to do it in a shorter amount of time. But think that 6-8 weeks is optimal." (Participant D)* |
| Was the time needed to complete the sessions acceptable? | 5.83 (1.16), 4-7 | *"Sometimes it took a very long time, depending on how much writing I have done, or how much pain I have" (Participant C)* |
| Did micro-sessions influence your behavior in everyday life? | 4.88 (2.58), 1-7 | *"[The treatment] made me think about how I do things and how I can improve" (Participant F)* |
| Did micro-sessions influence your emotions? | 4.75 (1.90), 2-7 | *"[The treatment] made me think about things, in the back of my head." (Participant D)* |
| Did micro-sessions influence your thoughts? | 5.38 (1.30), 3-7 | *"I become more aware, was able to see myself from a different perspective" (Participant C)* |
| **Therapist feedback** | | |
| Was the online treatment overall beneficial for your patients? | 6.33 (0.58), 6-7 | *"For the majority of them it was very beneficial in different ways"* |

| | | |
|---|---|---|
| How satisfied are you with the intervention overall? | 5.67 (0.58), 5-6 | *"I like that it is 6 weeks, quite easy to understand. Seems to be inspiring for the patient. The therapist has to talk to patient every week and has to be prepared for the questions."* |
| Was the overall time investment to deliver the online treatment acceptable? | 5.67 (1.15), 5-7 | *"It was well, and 6 weeks treatment is short, but also enough"* |
| Did delivering this treatment online save you time? | 3.67 (2.08), 2-6 | *"Documentation and contact with participants take time similar to that of which I had seen them in person. However, [there is] greater flexibility in the digital format."* |
| Was the online treatment delivered as intended? | 7 (0) | *"I was lucky with my participants, they did what they were expected. It may not always be the case, everyone got the treatment in the intended time"* |
| Would you deliver the intervention again in the future? | 7 (0) | N/A |
| What facilitated you to deliver the intervention? | n.a. | *"The protocol and the documentations helped a lot, contact with the supervisors helped a lot"* |
| What hindered you in delivering the intervention? | n.a. | *"Nothing that I can think of, but it can be messy to set up time with the patients."* |
| What aspects of the intervention need improvements? | n.a. | *"In this stage, module 3 should be clarified. All of my patients got stuck there, and did not understand. It seems like it is unclear that active pain patients have recommendations about being active, but they are already too active,"* |

### 3.3.3. End-user perceived implementation success

The success of the implementation refers to the engagement with the wider treatment process (beyond the direct engagement with the treatment). As such, patients found information regarding the use of the digital platform clear, experienced few technical problems, and considered the navigation of the digital platform as easy. The weekly communication with the therapist was evaluated as very helpful, and it was perceived as easy to schedule the weekly meeting with the therapist. Therapist contact was considered a very motivating experience, and participants mentioned that they felt supported by their therapist.

Similarly, therapists did not report any technical problems, found the platform very easy to navigate, and the support for delivering the intervention, namely training, technical guidance, and supervision, as sufficient. The frequency of communication with patients and the time per interaction were very acceptable. Details on the end-user perceived implementation success are provided in Table 10.

---TABLE 10 NEAR HERE---

Table 10. Exit interview questions for participants on reflecting and evaluating the implementation

| Questions | Mean (SD), range | Exemplary quotes |
|---|---|---|
| | | |
| **Patient feedback** | | |
| Did the online treatment interfere with your daily routines (work or other things)? | 3.88 (2.16), 1-7 | N/A |
| The treatment was delivered using a digital platform on 1177. Was the information about the digital 1177 platform clear? | 6.43 (0.53), 6-7 | *"I was clearly guided during the briefing call before the intervention"* |
| Was it easy to navigate the digital 1177 platform? | 5.38 (1.59), 3-7 | *"Yes, but a bit difficult to find your way back to earlier exercises."* |
| Did you experience any technical problems using 1177? | 0.88 (0.35), 0-1 | N/A |
| Did you experience communicating with your health care professional as helpful overall? | 6.50 (0.92), 5-7 | *"Absolutely, it was what I needed. Without it I do not know how much progress I would have made. Very meaningful!"* |
| Was it easy to schedule meetings with your health care professional? | 6.75 (0.70), 5-7 | *"Very easy, my therapist was very helpful and flexible"* |
| Did you experience communicating with your health care professional as motivating? | 6.50 (0.92), 5-7 | *"Yes, my therapist has really made me think about things and given me new ideas."* |
| Did you feel supported by your health care professional? | 6.50 (1.41), 3-7 | *"Yes, in a way that I didn't expect. I didn't think that it would give so much and much of it was my therapist's merit."* |
| Would you consider the past 6 weeks "ordinary"? | 4.50 (1.77), 1-6 | N/A |
| Did anything unusual occur during the treatment period? | 2.38 (2.26), 1-6 | N/A |
| Would you recommend this online treatment to a friend with a similar condition? | 6.38 (1.18), 4-7 | *"Already talked to a friend and recommended her."* |
| **Therapist feedback** | | |
| Did you experience any technical problems using 1177? | 1 (0) | N/A |
| Was it easy to navigate 1177? | 7 (0) | |
| Was the support for delivering the intervention (e.g., training, technical guidance when issues arose, supervision) sufficient? | 7 (0) | *"I did not have any problems, but I felt very secure, it was not hard for me to receive help"* |
| Was the frequency of communication with the patient acceptable? | 7 (0) | *"It would be very time-consuming with so many patients, e.g. in primary care. It is not very frequent for written feedback but when you speak with them it is a little intense"* |
| Was the time per interaction (e.g., phone call) acceptable? | 5.66 (1.15), 5-7 | *"I thought 30 minutes [per interaction] would be tight, but on the contrary 30 minutes was perfect. Of course, some of them [the patients] exceeded but in general it was within 30 minutes."* |
| Did you feel prepared to deliver this treatment? | 6.33 (1.15), 5-7 | *N/A* |
| Would you recommend the intervention to a colleague? | 5.67 (1.53), 4-6 | "*I think it is a bit too early to say, but I am also drafting a couple of colleagues so we can say that I am already recommending; the intervention needs further elaboration."* |

### 3.3.4. End-user suggestions for further treatment improvements

Taken all end-user input together, the following additional suggestions for improvements emerged in this study and require further refinement and testing to meet user needs: 1) create video content and add pictures or graphics to make the treatment more visually appealing; 2) integrate text-to-speech function; 3) create and integrate add-on materials, for instance, methods to improve sleep; 4) facilitate navigation in between exercises. Moreover, according to participants' views, it will be important to test if the communication mode, namely messaging only compared to phone or video calls, contributes to intervention and implementation success, as user preferences differed.

## 4. Discussion

## Principal findings

This study aims to clarify how a digital behavioral intervention can be developed in a user-centered approach to address the needs and preferences of the target population and the specific user input on the DAHLIA prototype 1.0, as part of the multiphase DAHLIA project. This study contains data from the first iteration, which is considered part of the development phase. The following iterations are included in the evaluation phase and used to assess the feasibility and preliminary efficacy of the treatment and will be presented elsewhere. The primary objective of this study was to develop a user-centered and evidence-based digital behavioral intervention for individuals with chronic pain by clarifying how the intervention should be designed in terms of structure, content, and format to address the needs and preferences of the target population.

The study contained three phases: preparation, designing, and testing. The user-centered approach during the preparation phase was built on fictional Patient Personas, resulting in a representation of heterogeneous patient characteristics, needs, and potential treatment targets that shaped the treatment vision. During the designing phase, input from end-users via focus groups, provided insight on the treatment content, design, and structure, with an emphasis on flexibility and person-centeredness. In the testing phase, 11 patients and three therapists participated, and findings confirmed that a behavioral approach was considered suitable for individuals with chronic pain. Also, digital delivery of the intervention, using a micro-session format combined with regular contact between therapists and patients, was seen as beneficial by end-users, as the modules were overall perceived as helpful, understandable, and enjoyable. End-users rated their experiences of using the intervention as good or excellent, indicating initial satisfaction with both the treatment and wider implementation procedure, such as the use of digital platforms for delivery, as well as research-related informed consent and data collection.

Finally, end-users provided suggestions for further improving the design and content, such as text-to-speech function, additional content for specific needs such as insomnia, and aesthetic adjustments through images and videos.

### *4.1 End-users involvement: Complementary and contradictory views*

Critically reflecting on the input provided by end-users regarding the utility of the development process, and the DAHLIA prototype 1.0, is important for outlining the next steps in the DAHLIA project, namely the further treatment improvements, testing, and implementation (30). While the existing literature does not provide specific information on the recommended level of involvement of end-users (47), user engagement is generally encouraged (20, 48) and is considered a cornerstone in healthcare innovation (49). Although many studies have focused on a single end-user group such as patients or healthcare professionals, Rosser and Eccleston (50) emphasizes the utility of including healthcare providers alongside patients during the development of a novel treatment (51). However, while combining views from different stakeholders may be beneficial, it can also result in challenges. In the present study, end-user input varied, with both consensus and discrepancies between individuals and end-user groups regarding preferences in treatment design. For instance, some patients preferred group-based treatment while others favored individual treatment as it provided opportunities to choose your own pace. Moreover, patients mentioned that digital delivery may be suitable for some but can be a barrier to engage for specific groups, such as older adults with chronic pain, which is in line with research highlighting that the digitalization of healthcare systems may result in the exclusion, especially of those who are older and have a lower socioeconomic status (52).

Importantly, patients' and therapists' preferences for the mode of communication differed. While patients generally expressed a preference for video calls over phone calls, therapists viewed phone calls as similarly useful as video calls and suggested that patients should be able to choose. This finding is in line with results from a systematic review aimed at examining the attitudes toward video- and phone-based telehealth (53). Even though some studies presented no significant differences between patients' and healthcare providers' attitudes toward mode of communication (54), others preferred video calls, and only a small number preferred phone calls (55). This lack of consensus in the field underlines the importance of flexibility and adapting the mode of communication to patients', and potentially also therapists', preferences and needs. In the testing phase, therapists and patients decided together how to communicate, and the number of phone calls and video meetings was nearly equal, with phone calls being slightly more preferred. Future studies can empirically compare modes of communication to explore for instance, if drop-out rates or user experiences vary based on this treatment feature.

Examining treatment content and design, both patients and therapists perceived a need to condense the text, to reduce the risk of the treatment being (too) challenging for some patients, and provided helpful suggestions, such as the use of bullet points, overviews, or summaries. Additionally, they highlighted the importance of incorporating images into the intervention to illustrate information and a text-to-speech function to enhance accessibility. In the testing phase, end-user experiences also varied between individuals. While therapists' ratings were rather similar, patients’ experiences showed larger differences. In the weekly evaluations where patients evaluated each module and in the exit interviews where they evaluated the intervention in general, they provided ratings that spanned almost the entire scale (from 1 to 7), indicating that individual differences may influence how the treatment is perceived. This finding points to a need to balance the end-user voices with practical requirements during the development process to optimize feasibility.

### 4.2 Heterogeneity of the target population: One size does not fit all

A key challenge in designing a digital intervention is to meet varying individual needs (56). Therefore, for the preparation phase of the development, Patient Personas with different age groups, co-morbidities, and pain experiences were created as potential representatives of the target population, aiming to amplify patient perspectives early on. Although seemingly useful, there is not a standardized way to apply Patient Personas are used in the design of novel pain treatments (35). Groos et al. (57) has suggested that different types of PPs can be insightful for researchers while deciding the next steps of the development process. In the DAHLIA project, experiences from the preparation phase suggest that Patient Personas can be helpful also in the continuous refinement of the treatment, or in tailoring the treatment to different patient groups, to initially consider important characteristics such as disabilities, socioeconomic status, language skills, or cultural background that may reflect varying needs.

The heterogeneity in the chronic pain population is well-known (1), and during the testing phase, patients with various pain profiles, such as migraine, chronic fatigue syndrome, herniated disc, arthritis, fibromyalgia, complex regional pain syndrome, and hypermobile Ehlers-Danlos syndrome, provided valuable input.

Therapists suggested that treatment should be tailored according to the patient's needs and highlighted the importance of providing inclusive and diverse examples as part of exercises within the treatment. In a consensus statement that aims to provide a practical guideline for researchers in the field of e-mental health, Seiferth et al. (23) emphasized the necessity of considering the target group when deciding the structure (e.g., exercises, division into modules) and the complexity of the content. Similarly, Evangelista et al. (58) highlighted the significance of participatory involvement of those who might be considered as minority groups during the design of an intervention to better determine and meet the needs.

## Strengths and limitations

By involving both patients and therapists in the development of the initial treatment version, this study adopts a user-centered approach that adapts the intervention to end-users' needs and preferences. Additionally, the study has a strong emphasis on empirical data and various methodologies, integrating qualitative feedback and quantitative ratings. Patient Personas were utilized to create awareness of potential target populations and their diverse needs. The treatment is tested in heterogeneous samples, providing insights into applicability across various demographics. In addition, the integration of established frameworks such as the CFIR strengthens the design.

Several limitations need to be considered when interpreting the results. First, a larger sample of end-users would have provided more information, and potentially a more diverse group. There was a discrepancy between the number of participants involved in patient (n=5) and therapist focus groups (n=12). The targeted sample size for patients could not be reached as interest was low, two patients dropped out, and the project period did not allow for further recruitment. While more therapists than anticipated participated, the limited number of patient participants raised a risk that data saturation was not achieved, particularly given the goal of capturing a heterogeneous population. This remains a limitation, though the enrollment of eleven patients in the pilot study may have strengthened patient voices. Secondly, more female than male end-users participated in the study. In the pilot phase, nine patients participated, mostly women (n=8), with an average age of 46.6 years, consistent with similar studies (26, 59). While this distribution should be considered when interpreting the findings, it aligns with the higher prevalence of chronic pain in women (60, 61) and the female dominance in psychology and psychotherapy professions (62). However, future studies should include more male end-users and explore potential gender differences in preferences and needs. Additionally, the narrow range of pain diagnoses may limit the generalizability of the results. While there was a diversity of pain diagnoses among patients in the pilot test, only two of the focus group participants had received a specific diagnosis (n=2 Ehlers-Danlos syndrome, n=3 undiagnosed/did not know the diagnosis). Although inclusion criteria aimed to increase heterogeneity, future iterations of the DAHLIA project should ensure the intervention aligns with the needs of the broader pain population.

This limited diversity suggests the findings may not fully represent a broader population, highlighting the need to examine inclusivity in future research. Incorporating diverse groups—considering gender identity, sexual orientation, age, race and ethnicity, diagnosis, and medical and psychiatric comorbidities—can provide broader end-user feedback.

## Conclusion

This study aimed at presenting the user-centered development of a digital behavioral intervention for chronic pain, the DAHLIA prototype 1.0. Results illustrate the utility of Patient Personas when preparing, focus groups when designing, as well as end-user feedback when testing this new intervention. Findings indicated that the treatment holds promise and provided relevant end-user suggestions to guide further improvements.

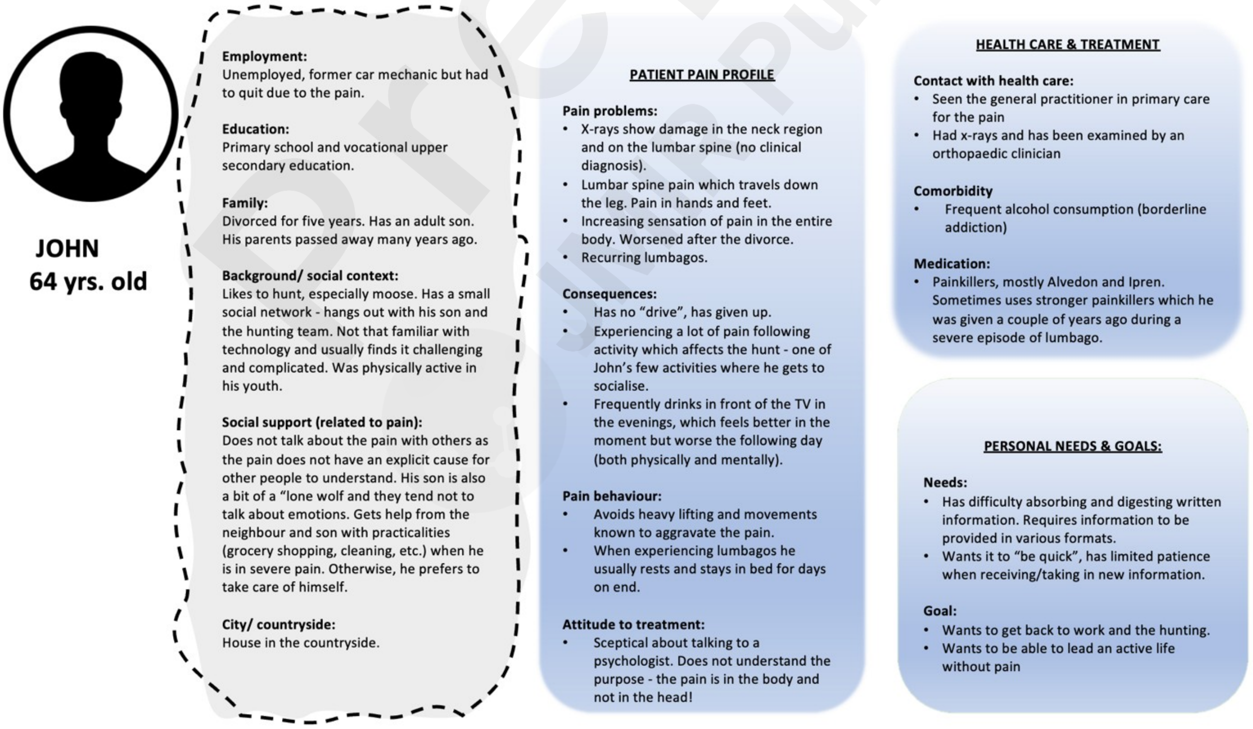
## Acknowledgement

The authors would like to thank Emelie Albertsson, Hanna Solstrand, Haya Al Sharaa, and Oriana Kolokotronis Johansson for their valuable contributions in transcribing focus groups. This work was funded by AFA insurance grant number (Dnr: 190 252).

## Conflicts of interest

None declared.

## Multimedia Appendix 1:



**JOHN**
**64 yrs. old**

**Employment:**
Unemployed, former car mechanic but had to quit due to the pain.

**Education:**
Primary school and vocational upper secondary education.

**Family:**
Divorced for five years. Has an adult son. His parents passed away many years ago.

**Background/ social context:**
Likes to hunt, especially moose. Has a small social network - hangs out with his son and the hunting team. Not that familiar with technology and usually finds it challenging and complicated. Was physically active in his youth.

**Social support (related to pain):**
Does not talk about the pain with others as the pain does not have an explicit cause for other people to understand. His son is also a bit of a “lone wolf and they tend not to talk about emotions. Gets help from the neighbour and son with practicalities (grocery shopping, cleaning, etc.) when he is in severe pain. Otherwise, he prefers to take care of himself.

**City/ countryside:**
House in the countryside.

**PATIENT PAIN PROFILE**

**Pain problems:**
- X-rays show damage in the neck region and on the lumbar spine (no clinical diagnosis).
- Lumbar spine pain which travels down the leg. Pain in hands and feet.
- Increasing sensation of pain in the entire body. Worsened after the divorce.
- Recurring lumbagos.

**Consequences:**
- Has no “drive”, has given up.
- Experiencing a lot of pain following activity which affects the hunt - one of John’s few activities where he gets to socialise.
- Frequently drinks in front of the TV in the evenings, which feels better in the moment but worse the following day (both physically and mentally).

**Pain behaviour:**
- Avoids heavy lifting and movements known to aggravate the pain.
- When experiencing lumbagos he usually rests and stays in bed for days on end.

**Attitude to treatment:**
- Sceptical about talking to a psychologist. Does not understand the purpose - the pain is in the body and not in the head!

**HEALTH CARE & TREATMENT**

**Contact with health care:**
- Seen the general practitioner in primary care for the pain
- Had x-rays and has been examined by an orthopaedic clinician

**Comorbidity**
- Frequent alcohol consumption (borderline addiction)

**Medication:**
- Painkillers, mostly Alvedon and Ipren. Sometimes uses stronger painkillers which he was given a couple of years ago during a severe episode of lumbago.

**PERSONAL NEEDS & GOALS:**

**Needs:**
- Has difficulty absorbing and digesting written information. Requires information to be provided in various formats.
- Wants it to “be quick”, has limited patience when receiving/taking in new information.

**Goal:**
- Wants to get back to work and the hunting.
- Wants to be able to lead an active life without pain

One of three Patient Personas used in the development phase of the DAHLIA project (Swedish name: Göran)

# Multimedia Appendix 2

**Semi-structured focus group guide**
6-8 participants per focus group

FOR PATIENTS (*2 focus groups; heterogenic in terms of age, gender, pain condition, pain history, etc.*):

1. General introduction, informed consent, collect sociodemographic details (10min.)
2. Short introduction round (10min.)

3. Core question 1: **Living with chronic pain** (30min.)
   It would be amazing to have a magic pill to just take all the pain away, so you could live without it. But unfortunately, we don't have that magic pill. Instead, we want to help you and other people with chronic pain to find a way to live well with the pain. (*Presentation on definition of health (Huber et al., 2011): ability to adapt and self-manage physical, mental and social aspects of health, and examples*).
   a. Based on this definition of health, can you describe your own health needs? Which (aspects of your) needs are currently unmet?
   b. In which moments of your life do you feel happiest/ most engaged/ most satisfied?
   c. What helps you to engage in these 'happy moments'?
   d. What are barriers to engage in these 'happy moments'?
   e. What would you need to engage in these moments more often?

BREAK 10 Min.

4. Core question 2: **The DAHLIA treatment**
   Presentation of the proposed treatment, aim, design, theoretical background, and examples of exercises (10min); following a discussion (30min)
   a. What do you think of this treatment? What do you like, what do you dislike? (Please reflect on (1) design, (2) set-up, (3) content, (4) other (e.g., terminology: treatment, intervention, program; patient vs. person))
   b. How feasible would it be to do this treatment?
   c. Do you think this treatment meets you needs?
   d. Is there anything else you would like to add?

---

FOR HEALTH CARE PROFESSIONALS (*1 focus group, psychologists/ psychotherapists trained in cognitive-behavioural therapy; heterogenic in terms of age, gender, cultural background)*:

1. General introduction, informed consent, collect sociodemographic details (10min.)
2. Short introduction round (10min.)

3. Core question 1: **Supporting people with chronic pain** (30min)
   People with chronic pain have complex needs and treatment has to meet these needs. We are interested in your experiences in what works well to improve the overall health and well-being of patients with chronic pain. (*Presentation on definition of health (Huber et al., 2011): ability to adapt and self-manage physical, mental and social aspects of health, and examples*).
    a. Which (aspects of) your patient's health needs are unmet? What is needed to support chronic pain patients in the best way?
    b. What barriers and facilitators to deliver support to chronic pain patients do you face? Please reflect on elements related to the patient, treatment options, and the health care in general.

BREAK 10 Min.

4. Core question 2: **The DAHLIA treatment**
   Presentation of the proposed treatment, aim, design, theoretical background, and examples of exercises (10min); following a discussion (30min)
    a. What do you think of this treatment? What do you like, what do you not like? (Please reflect on (1) design, (2) set-up, (3) content, (4) other (e.g., terminology: treatment, intervention, program; patient vs. person))
    b. How feasible would it be for you to deliver this treatment?
    c. Does the treatment meet the needs of the patients with chronic pain?
    d. Is there anything else you would like to add?

Multimedia Appendix 3

Semi-structured exit interview guide to evaluate the general feasibility and acceptability of the treatment for patients.

| **Topics** | **Questions** | **Answering scores** | **Open question** |
|---|---|---|---|
| You recently completed the 6-week treatment. Your experiences help us to improve the treatment. Thank you for taking the time to provide us with your input. First, we would like to ask you to reflect on and rate the **past weeks and treatment** in general. | | | |
| General | 1.Would you consider the past 6 weeks "ordinary"? | 7-points scale: from 1='not at all' to 7= 'very much' | Please elaborate if possible |
| | 2.Did anything unusual occur during the treatment period? | | |
| | 3.Did the online treatment interfere with your daily routines (work or other things)? | | |
| | 4.Would you recommend this online treatment to a friend with a similar condition? | | |
| | 5.Did you experience the online treatment as helpful overall? | | |
| | 6.Did you experience the online treatment as meaningful overall? | | |
| Secondly, we would like to ask you to reflect on and rate the **sessions, overall treatment, and 1177 online environment**. | | | |
| Micro-sessions/ online environment | 7.Was the written material understandable? | 7-points scale: from 1='not at all' to 7= 'very much' | Please elaborate if possible |
| | 8.The treatment was delivered using a digital platform on 1177. Was the information about the digital 1177 platform clear? | | |
| | 9.Was it easy to navigate the digital 1177 platform? | | |
| | 10.Could you easily read the text in the treatment (i.e., in terms of font size and formatting)? | | |
| | 11.Was the number of sessions per week (4 sessions) adequate? (Follow-up if needed: Would you prefer more/less (open question)? | | |
| | 12.Was the total number of sessions adequate? (Follow-up if needed: Would you prefer more/less (open question)? | | |
| | 13.Was the time needed to complete the sessions acceptable? | | |
| | 14.Did you experience any technical problems using 1177? | | |
| | 15.Did micro-sessions influence your behavior in everyday life? | | |
| | 16.Did micro-sessions influence your emotions? | | |
| | 17.Did micro-sessions influence your thoughts? | | |
| Third, we would like to ask you to reflect and rate the communication with your health care professional. | | | |
| Messenger function/ health care professional | 18.Which communication tool(s) (e.g., messenger function, phone call, video call) was used when communicating with the health care professional? (Multiple choice) | 7-points scale: from 1='not at all' to 7= 'very much' | Please elaborate if possible |
| | 19.Did you experience communicating with your health care professional as helpful overall? | | |
| | 20.Was it easy to schedule meetings with your health care professional? | | |
| | 21.Did you experience communicating with your health care professional as motivating? | | |
| | 22.Did you feel supported by your health care professional? | | |
| 33.In which way did the treatment improve your well-being? | | | Please elaborate |
| 34.Is there anything else you would like to add? | | | Free text |

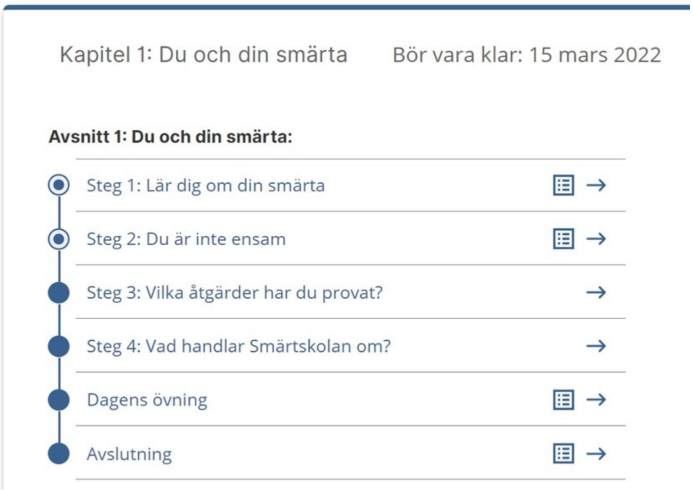
## Multimedia Appendix 4

Semi-structured exit interview guide to evaluate the general feasibility and acceptability of the treatment for healthcare professionals.

| Topics | Questions | Answering scores | Open question |
|---|---|---|---|
| You recently provided the 6-week treatment to patients with chronic pain. For us, it is very important to hear how you experienced it so that we can improve the content, design, and other aspects further. Thank you for taking the time to provide us with your input. | | | |
| General | 1.To how many patients did you deliver the digital intervention to? | (add number) | |
| | 2.Did you experience any technical problems using 1177/SOB? | 7-points scale: from 1='not at all' to 7= 'very much' | Please elaborate if possible |
| | 3.Was it easy to navigate 1177/SOB? | | |
| | 4.Was the online treatment overall beneficial for your patients? | | |
| | 5.Did you feel prepared to deliver this treatment? | | |
| | 6.Was the support for delivering the intervention (e.g., training, technical guidance when issues arose, supervision) sufficient? | | |
| | 7.How satisfied are you with the intervention overall? | | |
| | 8.Was the frequency of communication with the patient acceptable? | | |
| | 9.Was the time per interaction (e.g., phone call) acceptable? | | |
| | 10.Was the overall time investment to deliver the online treatment acceptable? | | |
| | 11.Did delivering this treatment online save you time? | | |
| | 12.Was the online treatment delivered as intended? | | |
| | 13.Would you deliver the intervention again in the future? | | |
| | 14.Would you recommend the intervention to a colleague? | | |
| | 15.What facilitated you to deliver the intervention? | Open question | |
| | 16.What hindered you in delivering the intervention? | Open question | |
| | 17.What aspects of the intervention need improvements? | Open question | |
| 18.Is there anything else you would like to add? | | | Free text |

## Multimedia Appendix 5

Examples (screenshots) of the treatment prototype



Kapitel 1: Du och din smärta Bör vara klar: 15 mars 2022

**Avsnitt 1: Du och din smärta:**

- Steg 1: Lär dig om din smärta
- Steg 2: Du är inte ensam
- Steg 3: Vilka åtgärder har du provat?
- Steg 4: Vad handlar Smärtskolan om?
- Dagens övning
- Avslutning

AVSNITT 1: DU OCH DIN SMÄRTA

Steg 2: Du är inte ensam

En av fem personer i Sverige lever med långvarig smärta. För många kvarstår problemen även efter att de fått hjälp av vården.

Att problemen kvarstår är inte konstigt, all smärta går inte att ta bort. Det betyder inte att smärtan i sig är farlig, eller att den orsakas av en skada eller sjukdom som är farlig. Tvärtom är detta vanligt. Många människor lider av bestående värk trots att ingen sjukdom eller skada finns att behandla. Även om smärtan inte är farlig kan den vara väldigt obehaglig och påfrestande.

**Smärtan kan förekomma på olika ställen i kroppen**

En del har smärta i ryggen, axlarna och nacken, andra i magen eller huvudet. Vissa upplever att det värker nästan överallt och andra att smärtan flyttar sig mellan olika kroppsdelar. Oavsett var det gör ont medför långvarig smärta så gott som alltid en påfrestning och kan bidra till andra svårigheter.

**Hur långvarig smärta påverkar livet och vardagen**

För den som lever med långvarig smärta påverkas vardagen på olika sätt. Sömnen kan försämras och det kan vara svårt att orka med barnen eller arbetet. Ibland har värken bidragit till att man slutat träffa sina vänner eller delta i andra aktiviteter som utan smärta hade varit självklara delar av vardagen.

Det kan även vara svårt att sätta upp mål eller göra planer. Det kan vara svårt att veta hur ont det kommer att göra och hur mycket man kommer att orka just den dagen. Att ta en dag i taget blir för många ett sätt att slippa ställa in planer.

**Kort övning: Vad väljer du bort?**

Övningen tar ungefär en minut att genomföra.

Med slutna eller öppna ögon, fundera kort över aktiviteter du väljer bort på grund av smärtan. Det kan vara sådant som du gjorde tidigare eller något du skulle vilja göra, men låter bli av rädsla för att det ska göra ont. Registrera tyst för dig själv.

Om du vill kan du skriva dina tankar och reflektioner i rutan nedan.

## References

1. Zimmer Z, Fraser K, Grol-Prokopczyk H, Zajacova A. A global study of pain prevalence across 52 countries: examining the role of country-level contextual factors. Pain. 2022;163(9):1740-50.

2. Breivik H, Borchgrevink P-C, Allen S-M, Rosseland L-A, Romundstad L, Breivik Hals E, et al. Assessment of pain. British journal of anaesthesia. 2008;101(1):17-24.

3. Vlaeyen JW, Crombez G, Linton SJ. The fear-avoidance model of pain. Pain. 2016;157(8):1588-9.

4. McCracken LM. Psychological flexibility, chronic pain, and health. Annual Review of Psychology. 2024;75(1):601-24.

5. Hayes SC, Villatte M, Levin M, Hildebrandt M. Open, aware, and active: Contextual approaches as an emerging trend in the behavioral and cognitive therapies. Annual review of clinical psychology. 2011;7(1):141-68.

6. Vowles KE, Witkiewitz K, Levell J, Sowden G, Ashworth J. Are reductions in pain intensity and pain-related distress necessary? An analysis of within-treatment change trajectories in relation to improved functioning following interdisciplinary acceptance and commitment therapy for adults with chronic pain. Journal of Consulting and Clinical Psychology. 2017;85(2):87.

7. Wicksell RK, Melin L, Lekander M, Olsson GL. Evaluating the effectiveness of exposure and acceptance strategies to improve functioning and quality of life in longstanding pediatric pain–a randomized controlled trial. PAIN® . 2009;141(3):248-57.

8. Lai L, Liu Y, McCracken LM, Li Y, Ren Z. The efficacy of acceptance and commitment therapy for chronic pain: A three-level meta-analysis and a trial sequential analysis of randomized controlled trials. Behaviour Research and Therapy. 2023;165:104308.

9. Darnall BD. Psychological treatment for chronic pain: improving access and integration. Psychological Science in the Public Interest. 2021;22(2):45-51.

10. Subbiah V. The next generation of evidence-based medicine. Nature medicine. 2023;29(1):49-58.

11. Michie S, Yardley L, West R, Patrick K, Greaves F. Developing and evaluating digital interventions to promote behavior change in health and health care: recommendations resulting from an international workshop. Journal of medical Internet research. 2017;19(6):e232.

12. Dziallas M, Blind K. Innovation indicators throughout the innovation process: An extensive literature analysis. Technovation. 2019;80:3-29.

13. Yardley L, Spring BJ, Riper H, Morrison LG, Crane DH, Curtis K, et al. Understanding and promoting effective engagement with digital behavior change interventions. American journal of preventive medicine. 2016;51(5):833-42.

14. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. Journal of medical Internet research. 2011;13(4):e1672.

15. Schouten MJ, Derksen ME, Dekker JJ, Goudriaan AE, Blankers M. Preferences of young adults on the development of a new digital add-on alcohol intervention for depression treatment: A qualitative study. Internet Interventions. 2023;33:100641.

16. de Beurs D, van Bruinessen I, Noordman J, Friele R, van Dulmen S. Active involvement of end users when developing web-based mental health interventions. Frontiers in psychiatry. 2017;8:72.

17. Baker TB, Gustafson DH, Shah D. How can research keep up with eHealth? Ten strategies for increasing the timeliness and usefulness of eHealth research. Journal of medical Internet research. 2014;16(2):e36.
18. Higgins KS, Tutelman PR, Chambers CT, Witteman HO, Barwick M, Corkum P, et al. Availability of researcher-led eHealth tools for pain assessment and management: barriers, facilitators, costs, and design. Pain Reports. 2018;3(7):e686.
19. Slater H, Campbell JM, Stinson JN, Burley MM, Briggs AM. End user and implementer experiences of mHealth technologies for noncommunicable chronic disease management in young adults: systematic review. Journal of medical Internet research. 2017;19(12):e406.
20. Keogh E, Rosser BA, Eccleston C. e-Health and chronic pain management: current status and developments. Pain. 2010;151(1):18-21.
21. Jessen S, Mirkovic J, Ruland CM. Creating gameful design in mHealth: a participatory co-design approach. JMIR mHealth and uHealth. 2018;6(12):e11579.
22. Ledel Solem IK, Varsi C, Eide H, Kristjansdottir OB, Mirkovic J, Børøsund E, et al. Patients' needs and requirements for eHealth pain management interventions: qualitative study. Journal of medical internet research. 2019;21(4):e13205.
23. Seiferth C, Vogel L, Aas B, Brandhorst I, Carlbring P, Conzelmann A, et al. How to e-mental health: a guideline for researchers and practitioners using digital technology in the context of mental health. Nature mental health. 2023;1(8):542-54.
24. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. bmj. 2021;374.
25. Stinson JN, Lalloo C, Harris L, Isaac L, Campbell F, Brown S, et al. iCanCope with Pain™: User-centred design of a web- and mobile-based self-management program for youth with chronic pain based on identified health care needs. Pain Research & Management. 2014;19(5):257-65.
26. Ledel Solem IK, Varsi C, Eide H, Kristjansdottir OB, Børøsund E, Schreurs KMG, et al. A User-Centered Approach to an Evidence-Based Electronic Health Pain Management Intervention for People With Chronic Pain: Design and Development of EPIO. J Med Internet Res. 2020;22(1):e15889.
27. Jibb LA, Cafazzo JA, Nathan PC, Seto E, Stevens BJ, Nguyen C, et al. Development of a mHealth real-time pain self-management app for adolescents with cancer: an iterative usability testing study. Journal of Pediatric Oncology Nursing. 2017;34(4):283-94.
28. Wilson K, Bell C, Wilson L, Witteman H. Agile research to complement agile development: a proposal for an mHealth research lifecycle. NPJ digital medicine. 2018;1(1):46.
29. De Korte EM, Wiezer N, Janssen JH, Vink P, Kraaij W. Evaluating an mHealth app for health and well-being at work: mixed-method qualitative study. JMIR mHealth and uHealth. 2018;6(3):e6335.
30. Bartels SL, Johnsson SI, Boersma K, Flink I, McCracken LM, Petersson S, et al. Development, evaluation and implementation of a digital behavioural health treatment for chronic pain: study protocol of the multiphase DAHLIA project. Bmj Open. 2022;12(4):e059152.
31. Cordier L, Diers M. Learning and unlearning of pain. Biomedicines. 2018;6(2):67.
32. Goubert L, Trompetter H. Towards a science and practice of resilience in the face of pain. European Journal of Pain. 2017;21(8):1301-15.
33. Gentili C, Rickardsson J, Zetterqvist V, Simons LE, Lekander M, Wicksell RK.

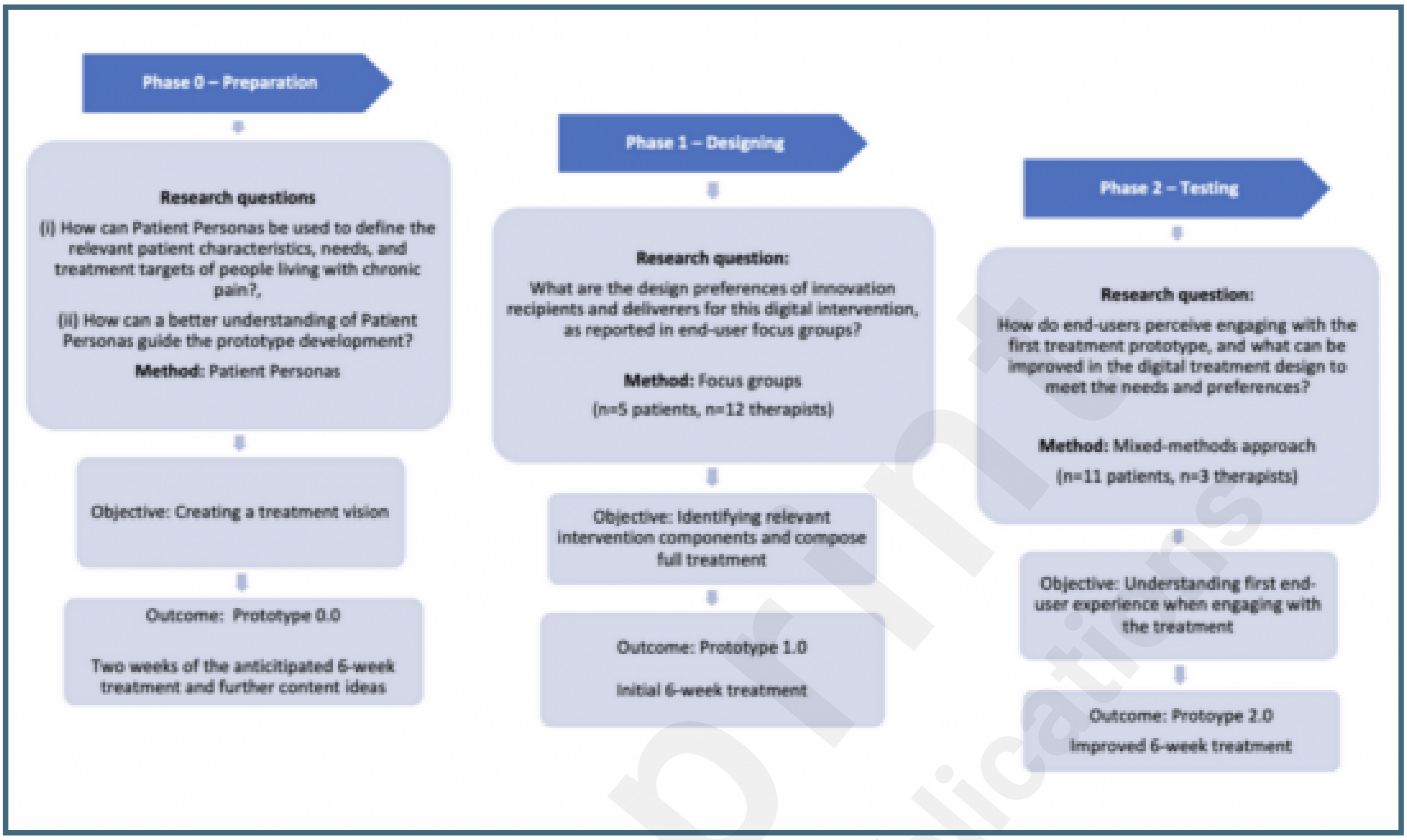
Psychological flexibility as a resilience factor in individuals with chronic pain. Frontiers in psychology. 2019;10:2016.
34. Pruitt J, Adlin T. The persona lifecycle: keeping people in mind throughout product design: Elsevier; 2010.
35. Bartels SL, Taygar AS, Johnsson SI, Petersson S, Flink I, Boersma K, et al. Using Personas in the development of eHealth interventions for chronic pain: A scoping review and narrative synthesis. Internet Interventions. 2023;32:100619.
36. Gentili C, Zetterqvist V, Rickardsson J, Holmström L, Simons LE, Wicksell RK. ACTsmart - development and feasibility of digital Acceptance and Commitment Therapy for adults with chronic pain. NPJ Digit Med. 2020;3:20.
37. Bartels SL, Taygar AS, Johnsson SI, Petersson S, Flink I, Boersma K, et al. Using Personas in the development of eHealth interventions for chronic pain: A scoping review and narrative synthesis. Internet Interv. 2023;32:100619.
38. Rickardsson J, Zetterqvist V, Gentili C, Andersson E, Holmström L, Lekander M, et al. Internet-delivered acceptance and commitment therapy (iACT) for chronic pain-feasibility and preliminary effects in clinical and self-referred patients. Mhealth. 2020;6:27.
39. Reyes AT. The process of learning mindfulness and acceptance through the use of a mobile app based on acceptance and commitment therapy: a grounded theory analysis. Issues in Mental Health Nursing. 2022;43(1):3-12.
40. Jayasekara RS. Focus groups in nursing research: methodological perspectives. Nursing outlook. 2012;60(6):411-6.
41. Haugland MJ, Rosenberg I, Aasekjær K. Collaborative learning in small groups in an online course–a case study. BMC Medical Education. 2022;22(1):165.
42. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. Journal of biomedical informatics. 2009;42(2):377-81.
43. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. Journal of biomedical informatics. 2019;95:103208.
44. Thompson D, Deatrick JA, Knafl KA, Swallow VM, Wu YP. A pragmatic guide to qualitative analysis for pediatric researchers. Journal of Pediatric Psychology. 2022;47(9):1019-30.
45. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. Implementation science. 2022;17(1):75.
46. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implementation science. 2009;4:1-15.
47. Elkes J, Cro S, Batchelor R, O'Connor S, Yu L-M, Bell L, et al. User engagement in clinical trials of digital mental health interventions: a systematic review. BMC medical research methodology. 2024;24(1):184.
48. Ludden GD, Van Rompay TJ, Kelders SM, van Gemert-Pijnen JE. How to increase reach and adherence of web-based interventions: a design research viewpoint. Journal of medical Internet research. 2015;17(7):e172.
49. Eysenbach G. Medicine 2.0: social networking, collaboration, participation, apomediation, and openness. Journal of medical Internet research. 2008;10(3):e1030.

50. Rosser BA, Eccleston C. Smartphone applications for pain management. Journal of telemedicine and telecare. 2011;17(6):308-12.
51. de la Vega R, Serrano-Ibáñez ER, Ruiz-Párraga GT, Palermo TM, Wicksell R, Fernández-Jiménez E, et al. Protocol for a multi-phase, multi-center, real-world, hybrid effectiveness-implementation study of a digital intervention for pediatric chronic pain co-designed with patients (Digital SPA). Digit Health. 2023;9:20552076231219490.
52. Tappen RM, Cooley ME, Luckmann R, Panday S. Digital health information disparities in older adults: a mixed methods study. Journal of racial and ethnic health disparities. 2022;9(1):82-92.
53. Connolly SL, Ferris SD, Azario RP, Miller CJ. Patient and provider attitudes toward video and phone telemental health care during the COVID-19 pandemic: A systematic review. Clinical Psychology: Science and Practice. 2024.
54. Békés V, Ménard CG, Schmitz N, Aafjes-van Doorn K. Therapist-reported differences between teletherapy via phone and via videoconferencing. Brain Sciences. 2023;13(12):1714.
55. Mirbaha S, Morgan A, Tang A, Smith-Turchyn J, Richardson J. Models of telehealth service delivery in adults with spinal cord injuries: Scoping review. JMIR Rehabilitation and Assistive Technologies. 2023;10:e41186.
56. Graham AK, Lattie EG, Powell BJ, Lyon AR, Smith JD, Schueller SM, et al. Implementation strategies for digital mental health interventions in health care settings. American Psychologist. 2020;75(8):1080.
57. Groos SS, Linn AJ, Kuiper JI, van Schoor NM, van der Velde N, van Weert JC. Combining user-centered design and behavioral theory to enhance health technologies: A personas-based approach for a primary-care based multifactorial falls risk assessment tool. International journal of medical informatics. 2024;186:105420.
58. Evangelista L, Steinhubl SR, Topol EJ. Digital health care for older adults. The Lancet. 2019;393(10180):1493.
59. Bostrøm K, Børøsund E, Varsi C, Eide H, Flakk Nordang E, Schreurs KM, et al. Digital Self-Management in Support of Patients Living With Chronic Pain: Feasibility Pilot Study. JMIR Form Res. 2020;4(10):e23893.
60. Sá KN, Moreira L, Baptista AF, Yeng LT, Teixeira MJ, Galhardoni R, et al. Prevalence of chronic pain in developing countries: systematic review and meta-analysis. Pain reports. 2019;4(6):e779.
61. Tsang A, Von Korff M, Lee S, Alonso J, Karam E, Angermeyer MC, et al. Common chronic pain conditions in developed and developing countries: gender and age differences and comorbidity with depression-anxiety disorders. The journal of pain. 2008;9(10):883-91.
62. Gruber J, Mendle J, Lindquist KA, Schmader T, Clark LA, Bliss-Moreau E, et al. The future of women in psychological science. Perspectives on Psychological Science. 2021;16(3):483-516 %@ 1745-6916.

# Supplementary Files

# Figures

Development phases of the digital behavioral treatment with end-user involvement.



**Research questions**

(i) How can Patient Personas be used to define the relevant patient characteristics, needs, and treatment targets of people living with chronic pain?,

(ii) How can a better understanding of Patient Personas guide the prototype development?

**Method:** Patient Personas

Objective: Creating a treatment vision

Outcome: Prototype 0.0

Two weeks of the anticitipated 6-week treatment and further content ideas

**Research question:**

What are the design preferences of innovation recipients and deliverers for this digital intervention, as reported in end-user focus groups?

**Method:** Focus groups

(n=5 patients, n=12 therapists)

Objective: Identifying relevant intervention components and compose full treatment

Outcome: Prototype 1.0

Initial 6-week treatment

**Research question:**

How do end-users perceive engaging with the first treatment prototype, and what can be improved in the digital treatment design to meet the needs and preferences?

**Method:** Mixed-methods approach

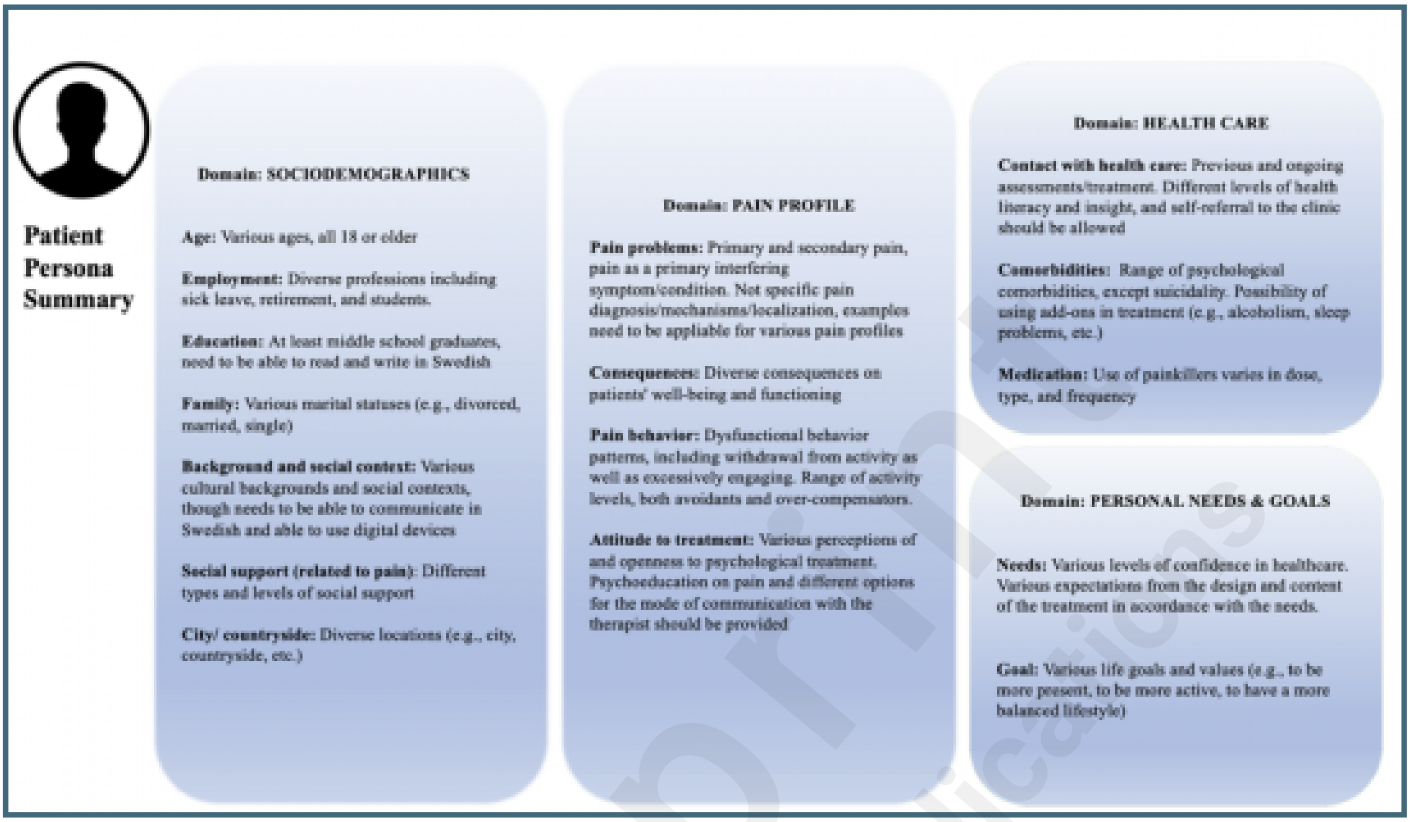
(n=11 patients, n=3 therapists)

Objective: Understanding first end-user experience when engaging with the treatment

Outcome: Protoype 2.0

Improved 6-week treatment

Implications of Patient Personas on the treatment development.



**Patient Persona Summary**

**Domain: SOCIODEMOGRAPHICS**

**Age:** Various ages, all 18 or older

**Employment:** Diverse professions including sick leave, retirement, and students.

**Education:** At least middle school graduates, need to be able to read and write in Swedish

**Family:** Various marital statuses (e.g., divorced, married, single)

**Background and social context:** Various cultural backgrounds and social contexts, though needs to be able to communicate in Swedish and able to use digital devices

**Social support (related to pain)**: Different types and levels of social support

**City/ countryside:** Diverse locations (e.g., city, countryside, etc.)

**Domain: PAIN PROFILE**

**Pain problems:** Primary and secondary pain, pain as a primary interfering symptom/condition. Not specific pain diagnosis/mechanisms/localization, examples need to be appliable for various pain profiles

**Consequences:** Diverse consequences on patients' well-being and functioning

**Pain behavior:** Dysfunctional behavior patterns, including withdrawal from activity as well as excessively engaging. Range of activity levels, both avoidants and over-compensators.

**Attitude to treatment:** Various perceptions of and openness to psychological treatment. Psychoeducation on pain and different options for the mode of communication with the therapist should be provided

**Domain: HEALTH CARE**

**Contact with health care:** Previous and ongoing assessments/treatment. Different levels of health literacy and insight, and self-referral to the clinic should be allowed

**Comorbidities:** Range of psychological comorbidities, except suicidality. Possibility of using add-ons in treatment (e.g., alcoholism, sleep problems, etc.)

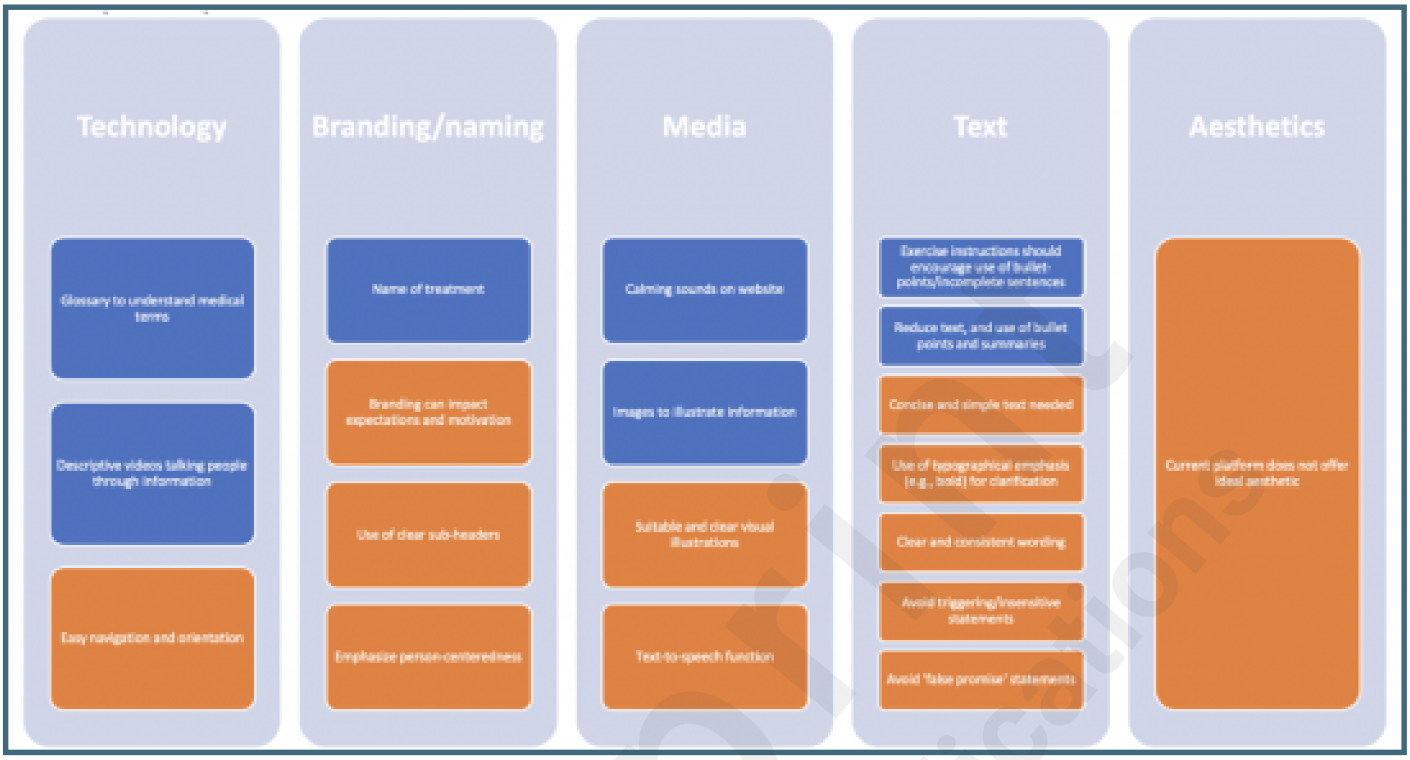
**Medication:** Use of painkillers varies in dose, type, and frequency

**Domain: PERSONAL NEEDS & GOALS**

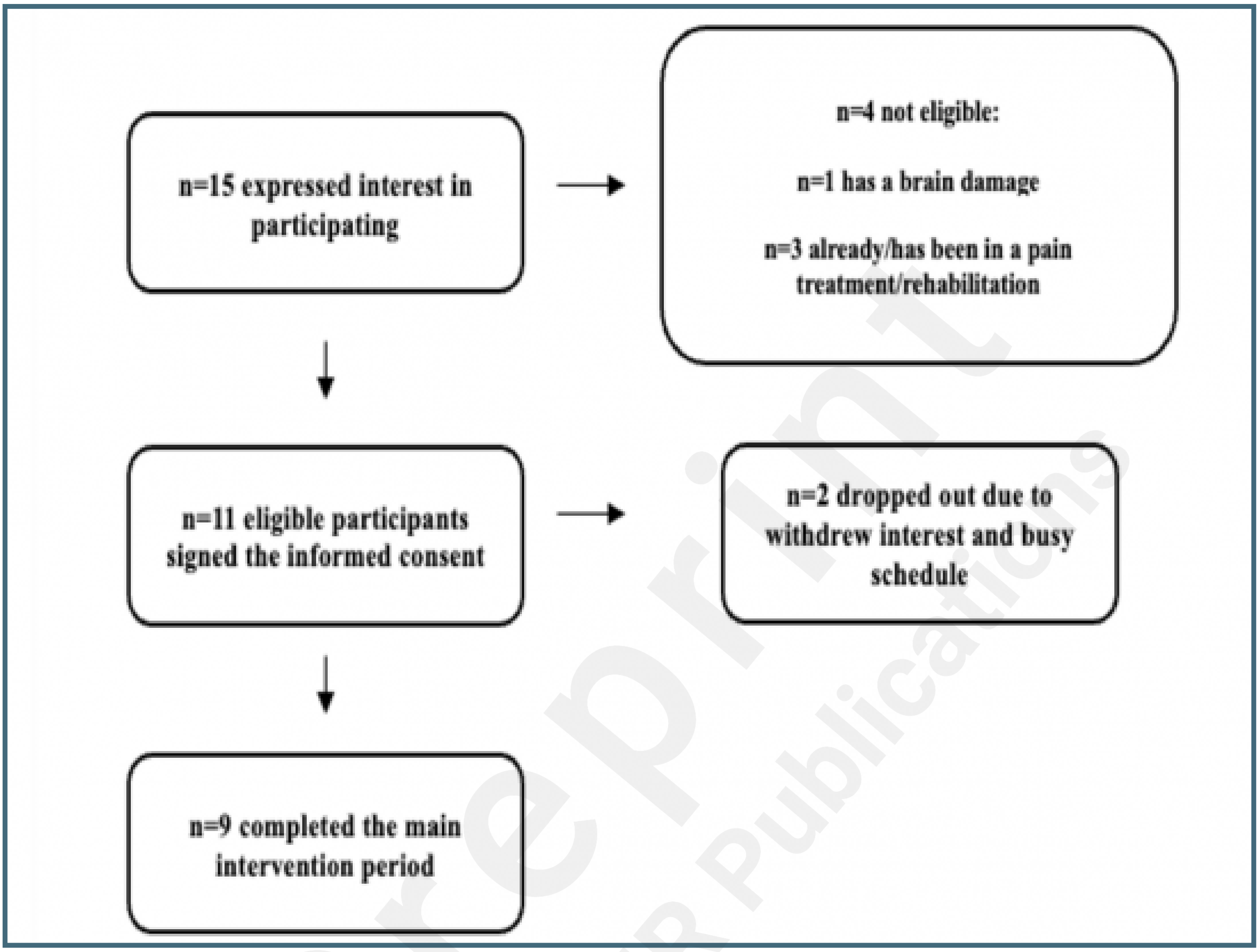
**Needs:** Various levels of confidence in healthcare. Various expectations from the design and content of the treatment in accordance with the needs.

**Goal:** Various life goals and values (e.g., to be more present, to be more active, to have a more balanced lifestyle)

Preferences and suggestions for the design elements for the digital intervention provided by the focus group participants (blue boxes: patients, orange boxes: therapists).



Patient flow in the piloting of the treatment (phase 2).



# Multimedia Appendixes

One of three Patient Personas used in the development phase of the DAHLIA project (Swedish name: Göran).
URL: http://asset.jmir.pub/assets/0a759a1f776481a3043af848e47dd467.docx

Semi-structured focus group guide.
URL: http://asset.jmir.pub/assets/c7998d12513381be94244e3c06e91017.docx

Semi-structured exit interview guide to evaluate the general feasibility and acceptability of the treatment for patients.
URL: http://asset.jmir.pub/assets/fc81d5d2b44cea6e94a051f0f4bcfbef.docx

Semi-structured exit interview guide to evaluate the general feasibility and acceptability of the treatment for healthcare professionals.
URL: http://asset.jmir.pub/assets/7b0c1c9c0cbb973cc0aebec7b067152b.docx

Examples (screenshots) of the treatment prototype.
URL: http://asset.jmir.pub/assets/be709f1a76afb25f303ddcddd595468b.docx