A digital platform to enhance participant recruitment in clinical trials

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Abstract:

Introduction: Recruitment of participants for clinical trials is insufficient, with up to 80% of trials failing to meet their recruitment targets. Participants request digital information about clinical trials, but existing solutions do not address key participant barriers. This Master's thesis aims to develop and evaluate a recruitment platform.
Method: A digital recruitment platform was developed through an agile software process. A trial presentation for a clinical trial was designed and evaluated through a heuristic evaluation, an A/B test, and a usability test. Participants were recruited via social media advertisements and randomly allocated to version A or version B of the trial presentation.
Results: Over 26 days, the advertisements generated 12,845 unique views, resulting in 272 website views and 16 recruited participants. This corresponds to a conversion rate of 0.12%, 0.61 participants per day, and a cost of 105 DKK per participant. The A/B test showed a conversion rate of 5.9% for version A and 5.8% for version B ($p = 0.976$). The mean System Usability Scale score for the usability test was 81 and 76.5, respectively ($p = 0.446$).
Conclusion: The platform successfully recruited participants for the trial, however, no significant improvements in recruitment efficiency or usability were observed. Future research should explore personalized content and involve a diverse user population.

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Abstract:

Introduktion: Rekruttering af deltagere til kliniske forsøg er utilstrækkeligt hvor op mod 80% af kliniske forsøg ikke når deres rekrutteringsmål. Deltagere efterspørger digital information om kliniske forsøg, men eksisterende løsninger adresserer ikke centrale deltagerbarrierer. Formålet med dette kandidatspeciale er at udvilke samt evaluere en rekrutteringsplatform.
Metode: En digitalt rekrutteringsplatform, blev udviklet gennem en agil software proces. En forsøgspræsentation for et smerteforsøg blev designet og evalueret gennem en heuristisk evaluering, A/B test og brugervenlighedstest. Forsøgsdeltagerne blev rekrutteret via annoncer på sociale medier og tilfældigt fordelt til version A eller version B af forsøgspræsentation.
Resultat: Over 26 dage skabte annoncerne 12.845 eksponeringer, hvilket gav 272 besøg på hjemmesiden og 16 rekrutterede deltagere. Dette svarer til en konverteringsrate på 0,12%, 0,61 deltagere per dag og en pris på 105kr per deltager. A/B testen viste en konverteringsrate på 5.9% for version A og 5.8% for version B ($p = 0{,}976$). System Usability Scale scoren for brugervenlighedstesten var henholdsvis på 81 og 76,5 ($p = 0{,}446$).
Konklusion: Platformen rekrutterede successfuldt deltagere til forsøget, men forbedret effektivitet og brugervenlighed kunne ikke påvises. Fremtidig forskning bør undersøge individualiseret indhold og indrage en varieret brugergruppe.

Preface

This master's thesis was written by university students from the 10th semester of Biomedical Engineering and Informatics at Aalborg University. The thesis was written from the 3rd of February to the 2nd of June, 2025. We want to express our gratitude to our supervisors, Pernille Heyckendorff Secher and Samuel Emil Schmidt, for the guidance and support throughout the project. A special thank you to our collaboration partners, Daniel Ciampi de Andrade and his research team, for an inspiring and constructive partnership. Additionally, we are grateful to *Foreningen af Kroniske Smerteramte og Pårørende* for the opportunity to interview members and gain insight into their experiences.

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Reading instructions

To ensure clarity and consistency throughout the project, text in *italics* will be used to highlight names or specific information for readability. Specific terms will be written in full upon their first mention, followed by associated abbreviations in parentheses. Appendices are supplementary material, providing additional knowledge and information relevant to different parts of the project. References to specific appendices are made throughout the project as "Appendix X", where X corresponds to the appendix letter. To represent decisions made by the project group, the group will be referred to as "the team." This terminology will be used consistently in the project and the associated collaboration portfolio.

Reference method

The project utilizes the Vancouver referencing style, which assigns consecutive numbers to citations. The first citation is labeled [1], followed by [2], and so on. A sequentially numbered reference list at the end of the project provides complete details of the corresponding citations. If a citation appears before a full stop, it refers to a specific sentence. If a citation appears after the full stop at the end of a section, it applies to the entire section.

Use of Generativ AI

Generative AI has been used as an assistive tool, with ChatGPT-4o by OpenAI serving as the primary model. The model guided the analysis of new domains, system architecture, code implementation, and assisted with grammar and language refinement.

Contents

1 Introduction

Clinical trials play a pivotal role in the development and validation of new medical treatments and technologies. To ensure safety and efficacy, clinical trials are systematically conducted to evaluate the effects of interventions on human participants [1]. Each year, thousands of clinical trials are conducted worldwide to collect data that supports clinical research, involving millions of participants. In 2024, approximately 28,500 clinical trials involving around 21,800,000 participants were registered in the ClinicalTrials.gov database [2]. However, the successful execution of clinical trials depends on the ability to recruit participants, which is a major challenge [3].

Nearly 80% of clinical trials fail to meet their initial enrollment targets, resulting in financial losses up to $500,000 per day for medical companies, while also delaying access to potentially life-changing treatments for patients [4, 5]. In addition, approximately 12% of clinical trials are early terminated, primarily due to recruitment challenges [6]. Trial delays and early termination of clinical trials result in wasted research resources and raise ethical concerns for the enrolled participants. These challenges have led to the following initiating problem.

1.1 Initiating problem

Why is the recruitment of participants in clinical trials a challenge?

2 Problem analysis

Clinical trials are experimental studies designed to evaluate the effects of specific interventions on human participants. These interventions can include pharmacological treatments, medical devices, surgical procedures, physical or psychotherapeutic approaches, and rehabilitation strategies.[1] Participants in clinical trials are typically categorized as either healthy volunteers or patients. Healthy volunteers are individuals without the condition under investigation, while patients are those affected by the specific disease or condition being studied [7].

The World Health Organization has defined 14 principles of Good Clinical Practice to guide the conduct of clinical trials [8]. These principles can be broadly categorized into four phases: Planning, Recruitment, Intervention, and Analysis & Reporting, as illustrated in Figure 1.

Figure 1: Overview of the clinical trial process divided into planning, recruitment, intervention, and analysis & reporting. These phases are structured based on the 14 principles of Good Clinical Practice by the World Health Organization [8], with each phase encompassing steps to ensure ethical and scientific conduct of clinical trials.

In the planning phase, the researcher develops the trial protocol and related documentation, all of which must be ethically reviewed and approved by regulatory authorities. This phase also includes the selection of qualified trial locations and investigators. During the recruitment phase, eligible participants are identified, informed about the trial, and asked to provide informed consent. In the intervention phase, participants receive either the investigational treatment or control, while data are collected and safety and protocol compliance are monitored. Finally, the analysis & reporting phase involves managing and validating trial data, ensuring quality assurance, and preparing a comprehensive trial report that presents the results and conclusions of the trial.

2.1 Challenges with clinical trials

Clinical trials encounter several challenges, including recruiting a sufficient number of participants, ensuring diversity within the participant population, and retaining participants throughout the trial [3, 9]. As illustrated in Figure 2, these challenges are interconnected, as difficulties in one area often affect the others.

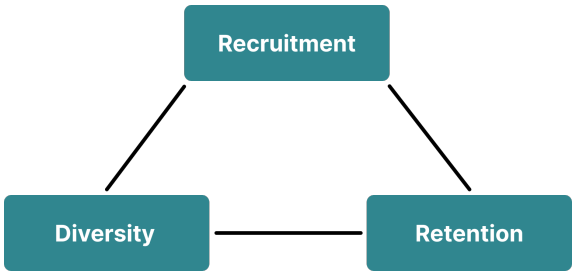


Figure 2: Overview of the interrelated challenges commonly faced in clinical trials.

Achieving diversity is particularly critical to enhance the generalizability of clinical trial results across broader populations. However, 76% of participants identify as white, resulting in the underrepresentation of other ethnic populations [10]. This imbalance of participant population may compromise the external validity of findings and obscure potential variations in treatment response across demographic populations. This issue is often linked to recruitment and retention challenges, as these underrepresented populations may face barriers to enrollment. Addressing this issue requires targeted outreach efforts, culturally sensitive trial designs, and fewer barriers to participation for these underrepresented populations.[4, 11]

Another challenge is participant retention. Maintaining participants engaged throughout a clinical trial is essential to preserve data integrity and ensure a sufficient sample size for reliable results. High dropout rates can lead to incomplete data and introduce bias, potentially compromising the reliability of the findings. To enhance retention, strategies such as regular follow-ups, flexible scheduling, and personalized communication are necessary to maintain participant commitment and minimize dropout.[12]

A key contributor to these challenges is participant recruitment. The difficulties in enrolling participants extend beyond simply reaching enrollment targets. Difficulties often arise from stringent eligibility criteria and limited access to research centers, which hinder the ability to assemble a diverse and representative study population.[9] An estimated 80% of clinical trials fail to meet their planned recruitment goals within the expected timeline, resulting in delays [4, 13]. In trials involving pharmacological treatments, delays typically range from 21 to 27 months [14]. Surgical trials experience average delays of around 12.2 months, while pediatric studies have reported delays up to 2.2 years [5, 15]. These delays not only escalate costs but can also threaten the feasibility of the trial, increasing the risk of early termination.

Approximately 12% of clinical trials are terminated prematurely, leading to incomplete studies, wasted financial and human resources, and ethical concerns for participants whose contributions may not produce meaningful scientific outcomes [6]. The primary reason for early termination is poor participant recruitment, which accounts for approximately 43% to 57% of discontinued trials [6, 16]. Multiple studies [3, 17, 18] acknowledge that a critical factor contributing to these recruitment challenges is the lack of awareness about clinical trials. Low awareness reduces the potential number of eligible participants, hindering the achievement of enrollment targets and slowing the progress of clinical research. To improve recruitment, enhancing the dissemination of trial information is essential for potential participants to be informed about clinical trial opportunities, but also to receive guidance from healthcare professionals about participation. However, when information is accessible, participants often remain hesitant to participate due to concerns about potential risks and uncertain benefits.[19] Several studies have shown that participants encounter barriers and motivations when considering participation in a clinical trial [20, 21]. In these studies, common factors affecting participation include the logistics of attending the trial, the clarity and accessibility of trial information, perceived risks and benefits, and the level of trust and connection with researchers. This highlights the need for recruitment processes that are better aligned with participants' motivations and barriers.

2.2 Recruitment process: Identifying participants

The recruitment process for clinical trials typically involves four sequential phases: identifying participants, obtaining informed consent, screening for eligibility, and enrolling participants into the trial, as illustrated in Figure 3. This structured approach ensures that individuals are appropriately selected, fully informed, and meet the required inclusion and exclusion criteria before enrollment [22].

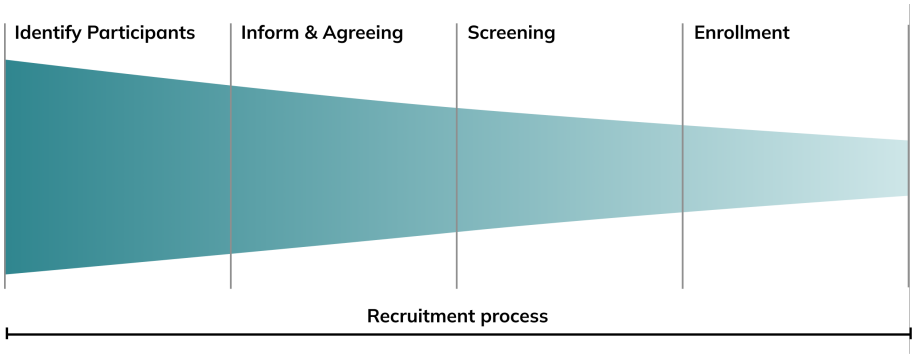


Figure 3: The four phases of the recruitment process in clinical trials: identifying participants, inform and agreeing, screening, and enrolling. Each phase of the recruitment process progressively narrows down participant eligibility, ensuring suitable candidates advance to enrollment.

Identifying participants involves a range of recruitment strategies that can generally be categorized into non-digital and digital approaches. Non-digital approaches include distributing flyers, newsletters, and posters, relying on word-of-mouth or community networks, and involving healthcare professionals to inform patients directly within clinical settings [18, 23]. In contrast, digital approaches leverage tools such as clinical trial registries, emails, websites, online advertisements (e.g., social media), phone outreach, and mass media channels such as television or radio. Some digital approaches also incorporate automated identification of eligible participants using electronic health records [17, 18]. Furthermore, emerging technologies, such as artificial intelligence, are being explored to automate chart reviews within electronic health records to identify potential participants more efficiently, although these technologies are still under development [24]. Participant preferences for these approaches can vary by demographic factors such as age. For instance, adults over the age of 65 tend to favor less digitalized methods, such as receiving information

via telephone [25], whereas younger individuals are more inclined to engage with apps, websites, and other digital platforms [26].

A study by Zahren et al. (2021) [18] investigated how participants prefer to receive information about clinical trials and identified a gap between preferred and actual information sources. While most participants prefer to receive information from healthcare professionals and social media, only 11% reported receiving information through social media. Similarly, although 47% of respondents preferred to receive information through websites and clinical trial registries, only 19% of participants were informed through websites and 23% through registries. This discrepancy highlights the need for digital recruitment strategies that are better aligned with participant preferences to improve awareness and engagement.

2.3 Digital recruitment platforms

Digital recruitment has gained increasing popularity due to the ability to efficiently reach broad and diverse populations. In particular, social media has demonstrated great potential for expanding outreach while offering substantial time and cost savings compared to non-digital recruitment methods [4, 19]. Online platforms allow targeted outreach to a specific population, thereby increasing the effectiveness of recruitment efforts. Using platforms, such as clinical trial registers and online advertisements, enables tailored messaging to individuals who are more likely to meet eligibility criteria. However, despite these advantages, participants have reported challenges related to the usability of current digital recruitment platforms [5].

Current digital recruitment platforms provide web-based solutions where potential participants can browse and sign-up for clinical trials. Examples of such platforms include Antidote.me, MatchMiner.org, and Trialfacts.com. These platforms focus on streamlining the recruitment process through features such as electronic consent, algorithm-based trial matching, and various e-recruitment tools aimed at improving efficiency and participant engagement. Although many of these platforms are designed with user-friendly interfaces, some individuals with limited computer or internet access may find these platforms hard to navigate or confusing to use. Ad-

ditionally, not all clinical trials are listed or accessible through these platforms, which can result in missed opportunities for participation. Geographical restrictions further limit access, making it challenging for individuals in certain locations to participate in available trials.[13]

Another digital recruitment platform is clinical trial registries, such as ClinicalTrials.gov, which are pivotal in connecting potential participants with ongoing trials [3]. However, despite the importance of clinical trial registers, participants frequently encounter difficulties navigating these registries. Challenges include understanding complex technical language, interpreting inconsistently presented data, and assessing eligibility for the trials. Furthermore, limited search functionality and the absence of personalized content make it difficult for participants to identify trials that align with their specific health condition.[27]
To create effective digital platforms, it is essential to understand and incorporate insights from the participants. These insights form the foundation for designing user experiences that meet users' needs, preferences, and expectations. User experience encompasses the entire interaction a user has with a digital platform, from initial discovery to ongoing use and support. A well-designed user experience can increase user engagement, satisfaction, and trust, all of which are critical for the success of digital recruitment platforms.[28]

A systematic literature search presented in Appendix A identified a study by Miller et al. (2021) [12] which evaluates an aspect of user experience on a digital recruitment platform. The study employed A/B testing to compare versions of a recruitment website featuring different media formats, such as images and videos. The results showed no significant improvement in engagement based solely on the type of media used. It is important to note that the intervention in the study was limited to changing a single media element on the page shown to participants. More meaningful improvements may be achieved by incorporating participant feedback and addressing common barriers to participation. Improving clinical trial recruitment may be achieved by leveraging targeted social media outreach in combination with a digital recruitment platform designed to meet participant needs.

3 Problem definition

Clinical trials have insufficient participant recruitment, often resulting in delays or early termination of trials. The current barriers that hinder recruitment are the logistical difficulties in attending trial visits, unclear trial information, uncertainty about potential risks and benefits, and limited trust in the research process. Enhancing the user experience of digital recruitment platforms may help overcome these barriers by strengthening participant confidence in the enrollment process. Moreover, targeted outreach strategies, such as social media, have shown potential in increasing the visibility and reach of clinical trials by engaging a broader population of participants. While social media can effectively generate interest, current digital recruitment platforms rarely consider the user's experience and how participants interact with these platforms. As a result, the ability to convert initial interest into active participation remains limited. This highlights the need for an integrated approach that combines improved user experience design with targeted outreach. By focusing on usability, transparency, and communication tailored to the needs of participants, a digital recruitment platform has the potential to increase participant enrollment and contribute to successful and efficient clinical trials.

3.1 Problem statement

How can a digital recruitment platform be developed to enhance participant enrollment in clinical trials by improving user experience and utilizing social media for targeted outreach, while addressing common recruitment barriers?

4 Solution strategy

To address the problem statement, the recruitment platform called ReLinkee will be developed to reduce the barriers that often prevent potential participants from enrolling in clinical trials, making the process simpler, accessible, and user-friendly. The team represents the company behind ReLinkee, which will be developed as a complete website, including a *homepage*, *trial page*, *sign-up form*, *confirmation pop-up window*, *privacy policy*, and an *about page*. The official website can be accessed at: www.relinkee.dk.

The intention with ReLinkee is to create an inclusive and user-friendly platform that is accessible to all individuals, including healthy individuals and individuals with health conditions, who may be interested in participating in clinical trials. However, for this project, ReLinkee will be evaluated exclusively in the context of individuals living with chronic pain. The evaluation is based on an ongoing clinical trial titled *Forsøg med personlig smertebehandling til patienter med kroniske smerter*, which investigates the use of transcranial magnetic stimulation, serving as the use case for this project. The trial is led by researcher Daniel Ciampi de Andrade and his team at Aalborg. Throughout the project, two versions of the *trial page* were created: version A, created by the research team responsible for the trial, and version B, designed by the team behind ReLinkee. Both versions have received approval from the Scientific Ethics Committee for the North Jutland Region. The designs of each version are provided in Appendix B.

To guide the development of ReLinkee, a set of internationally recognized ISO standards will be used to guide the development of a secure and privacy compliant solution using software standards. The ISO standards that will be applied are listed in Table 1.

Table 1: ISO standards guiding the development of ReLinkee.

ISO standard	Title	Summary
ISO 12207:2017 [29]	Systems and software engineering — Software life cycle processes	Defines a comprehensive framework of processes, activities, and tasks for managing the software life cycle to ensure quality, consistency, and standardization in software engineering.
ISO 29100:2024 [30]	Information technology – Security techniques – Privacy framework	Defines a privacy framework outlining principles, actors, and safeguarding requirements for protecting personal data in digital environments.
ISO 29101:2021 [31]	Information technology – Security techniques – Privacy architecture framework	Provides a framework for designing and implementing IT architectures that support privacy protection based on defined services, capabilities, and interfaces.
ISO 27560:2023 [32]	Privacy technologies – Consent record information structure	Specifies a standardized structure for capturing, managing, and storing user consent to ensure accountability and compliance in digital systems.

The ISO 12207:2017 [29] serves as a framework for the software life cycle with recommendations on developing, maintaining, and retiring software solutions. The software life cycle consists of four processes: *Agreement process*, *Organizational Project-Enabling process*, *Technical Management process*, and *Technical process*.

4.1 Agreement process

The agreement process ensures that involved organizations define and agree on their roles, responsibilities, and obligations, establishing a mutual understanding before commencing collaboration [29]. In this project, an agreement was established between the company and the researcher to explore whether ReLinkee could enhance

participant recruitment for the clinical trial. This agreement specifies the responsibilities and expectations for the collaboration, ensuring adherence to ethical guidelines, including obtaining informed consent from participants and compliance with data protection regulations.

4.2 Organizational Project-Enabling process

The Organizational Project-Enabling process ensures that an organization has the resources, structures, and support needed for successful project execution, including planning, resource allocation, and quality control.[29] In this project, structured processes were established early to coordinate planning, define team roles, and assign tasks based on individual expertise. Resource allocation was managed continuously, allowing the team to adapt to changing project tasks while maintaining alignment with the requirements from the researcher and participants. Although not all elements of the Organizational Project-Enabling process were fully implemented, foundational aspects such as life cycle management and structured coordination played an important role in the project.

4.3 Technical Management process

The Technical Management process focuses on structured planning, progress tracking, and oversight of technical activities such as the development, operation, and maintenance of software and systems, ensuring alignment with the project's intended goals [29]. In this project, a Gantt chart was used to plan and structure tasks, define milestones, and track progress. This tool enabled a flexible approach, allowing the team to review progress regularly and adjust workflows to meet deadlines. The chart is illustrated in Section 10 in Figure 31. Additionally, the Technical Management process emphasizes verification and validation to ensure the system is developed correctly and meets user requirements [29]. To validate ReLinkee, the team conducted a heuristic evaluation, A/B testing, and usability testing.

4.4 Technical process

The Technical process ensures a software system is properly planned, developed, verified, validated, and maintained throughout the life cycle, covering requirements definition, design, implementation, and ongoing support for stability, compliance, and usability [29, 33]. In this project, the team adopted an agile development approach consisting of two iterations, each including the phases of analysis, design, implementation, and evaluation. Each evaluation was structured using elements from the usability testing process outlined by Salvendy and Karwowski [34, p.980-900].

The first iteration was based on version B of the *trail page*. The findings of the first iteration were used to refine and improve ReLinkee for the second iteration, with the improvements compared to version A of the *trial page*. The comparison between the two versions corresponds to the final results. These iterations are illustrated in Figure 4, which visualizes the progression from initial analysis to final results.

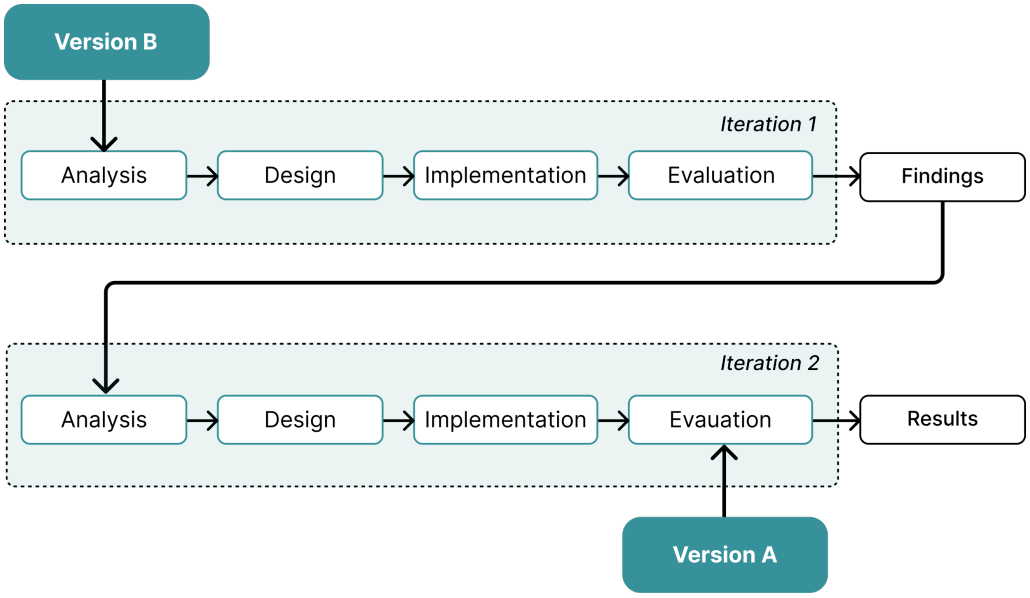


Figure 4: The agile software development process, including two iterations, each comprising four phases: analysis, design, implementation, and evaluation. The two versions of the trial page are incorporated at different stages across the iterations.

5 Iteration 1

The first iteration centers on defining requirements derived from the needs of stakeholders, serving as a guideline for the development of ReLinkee across the analysis, design, implementation, and evaluation phases as illustrated in Figure 5. The focus during iteration 1 will be on the *trial page*, *sign-up form*, and *privacy policy*.

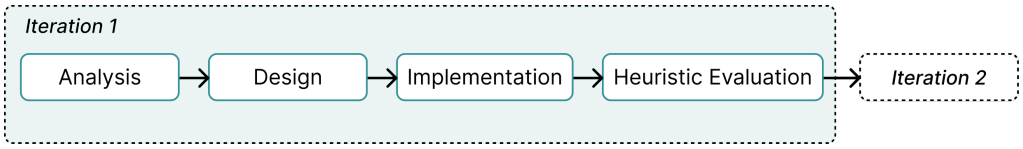


Figure 5: Iteration 1 illustrating the process of analysis, design, implementation, and evaluation through a heuristic evaluation. The findings from iteration 1 feed into the next iteration.

5.1 Analysis

The analysis commenced by identifying the three stakeholders involved in developing ReLinkee: the company, the researcher, and the participants. The company was responsible for building and maintaining the system, as well as recruiting participants. The researcher provided the clinical trial description and conducted the trial while adhering to ethical and legal data management practices. The participants influenced the design choices and usability of ReLinkee through their personal needs and experiences. Their feedback ensured that ReLinkee was intuitive, accessible, and aligned with the user expectations for clinical trial recruitment. Each stakeholder had specific needs crucial to ensuring ReLinkee functioned as intended.

Following ISO 12207:2017 [29], which emphasized the importance of managing stakeholder requirements throughout the software development life cycle, these needs were identified. To structure these needs, user stories were employed, following the format outlined by Kannan et al. (2019) [33], which had previously been successfully applied in medical application development. This user story format enabled clear, consistent articulation of the needs of the company, researcher, and participants, guiding the further development of ReLinkee.

5.1.1 Company and researcher needs

The company needs focused on system development and data management, with attention to compliance with the General Data Protection Regulation (GDPR), integration with social media platforms, and the use of a secure, cloud-based solution. The user stories for the company are listed in Table 2.

Table 2: A list of company needs derived from business requirements, each assigned a unique ID (CN-X) for traceability.

ID	Company needs
CN-1	As a company, we want to comply with GDPR so that we can handle personal data legally and transparently.
CN-2	As a company, we want to use a cloud solution for our platform so that the cost can be kept as low as possible, and it will be possible to scale the company.
CN-3	As a company, we want to use social media for recruiting participants, as this has shown to perform better than conventional strategies.

The researcher's needs were derived from input provided by the collaborating researcher, Daniel Ciampi de Andrade. These needs centered on GDPR compliance, the secure collection and transfer of personal data, and strict adherence to ethics committee approvals during recruitment. To support these requirements, the researcher emphasized the use of Research Electronic Data Capture (REDCap), a secure, web-based platform widely used in academic research for managing surveys and storing clinical data. The user stories for the researcher are listed in Table 3.

Table 3: A list of researcher needs derived from an interview with the researcher, each assigned a unique ID (RN-X) for traceability.

ID	Researcher needs
RN-1	As a researcher, I want to ensure that all personal data is handled in compliance with GDPR so that privacy, security, and data protection regulations are met.
RN-2	As a researcher, I need to collect and store participant contact data (name, phone number, email) so that participants can be contacted for trial-related communication while ensuring compliance with data protection regulations.
RN-3	As a researcher, I want to securely transfer collected trial data, including participant contact data, to REDCap so that all data is stored in a structured, compliant, and accessible system for analysis and follow-up.
RN-4	As a researcher, I want to ensure that my trial complies with ethics committee approvals and that the trial follows ethical guidelines and regulatory requirements.

The needs of the company and the researcher, presented in Table 2 and Table 3, focused on the collection, processing, and transfer of personal data, including name, email, and phone number. As this data was covered by GDPR, the company and the researcher were required to implement compliant practices. To ensure GDPR compliance, ISO 29100:2024 [30] was used as a framework to define privacy principles and identify roles and responsibilities in data processing. The transfer of personal data from the participant (the principal) to the company (the controller), the company became accountable for ensuring that the data was processed under the lawful data processing. Following ISO 29100:2024 [30], this required the collection of valid consent to the privacy policy. Based on this consent, the company subsequently transferred personal data to the researcher (the third-party controller). To manage consent properly and enforce appropriate security measures, privacy controls defined in ISO 29101:2021 [31] were applied. These controls were implemented across three layers: the Privacy Settings Layer, the Identity and Access Management Layer, and the Personal Data Management Layer, each targeting specific aspects of privacy protection.

The Privacy Settings Layer presented a privacy policy aligned with the GDPR and the 10 privacy principles provided by the Danish Data Protection Agency [35]. This ensured that the processing of personal data complies with national and international standards. Additionally, data processing was based on obtaining valid consent to fulfill the criteria of voluntary, unambiguous, specific, and informed consent as defined by the Danish Data Protection Agency [36]. Participant consent was considered voluntary and unambiguous only when given freely and through active agreement. To be specific and informed, the consent process requires clearly defining the purpose of data collection, identifying the data controller, and explaining the nature of personal data processing. To document the participant consent, ISO 27560:2023 [32] defined 13 mandatory attributes when storing consent. The attributes ensured traceability, accountability, and transparency in the collection and management of consent.

The Identity and Access Management Layer required strict access control to ensure only authorized users could access personal data. Access control was aligned with the privacy policy, restricting access to personal data and ensuring the data was contained within a cloud solution. The system used integrated secure authentication methods, such as multi-factor authentication, to verify the identity of users requesting access to personal data. Access control should be granted based on the principle of least privilege, ensuring that individuals only have access to the personal data necessary for their tasks.

The Personal Data Management Layer required secure handling, storage, and transmission of personal data. The personal data has to be validated before data was securely stored within the cloud. To ensure data accuracy and security, personal data was validated before transfer, and transfers to the cloud were authenticated and encrypted [37]. Finally, all data was stored encrypted within the cloud infrastructure to ensure secure storage following ISO 29101:2021 [31]. By following these layers and ensuring that privacy controls were consistently applied, the system met the regulatory compliance obligations, ensuring that personal data was handled securely and in accordance with GDPR.

5.1.2 Participants needs

The participants needs were based on statements from 23 individuals (6 males, 17 females, mean age 53 years) from Denmark, all of whom experienced chronic pain. The general educational level was 3-4 years of higher education, with a positive attitude towards new digital platforms and a positive perception of other people's intentions. Their digital skill and domain knowledge of clinical trials were generally high. The user stories for the participants are listed in Table 4.

Table 4: A list of participants needs derived from interviews participants, each assigned a unique ID (PN-X) for traceability.

ID	Participant needs
PN-1	As a participant, I want the trial page to feature a visually appealing design with clear, intuitive navigation and well-organized sections so that I can quickly locate and understand the information without feeling overwhelmed by excessive text or confusing elements.
PN-2	As a participant, I want a detailed and easy-to-read schedule that outlines the total duration of the trial, specific time slots, and milestones so that I can effectively plan my involvement and ensure the trial aligns with my daily life.
PN-3	As a participant, I want the trial location to be communicated, including the exact address, city, and distance details, so that I can determine if the location is conveniently accessible and aligns with my geographical constraints.
PN-4	As a participant, I want a clear, transparent overview of potential risks, side effects, and any specific health-related requirements so that I can make an informed decision regarding my participation based on a thorough understanding of what I am agreeing to.
PN-5	As a participant, I want a clear description of the procedure, including what the trial involves, without being overwhelmed with too much detail, so that I easily understand what I am agreeing to and what is expected of me.

The participants needs presented in Table 4 were translated into specific requirements, using principles identified from Garett et al. (2016) [38] and Brehmer et al. (2016) [39]. Garett et al. emphasize strategies for creating engaging and visually appealing interfaces, including the use of pictures, icons, and navigation bars, while Brehmer et al. highlight the use of timelines for enhancing engagement. In addition, the clinical trial should be presented following the recommended structure from the Danish National Center for Ethics, with careful attention to headings

and essential content [40]. This included the presentation of potential benefits and risks associated with participation. To enhance participant understanding, the risks were categorized as "Frequent/Non-serious" and "Rare/Serious," helping to easily distinguish between different levels of trial-related risk.

5.1.3 System requirements specification

Translating the stakeholders needs presented in Table 2, Table 3, and Table 4 into a clear and actionable System Requirements Specification (SRS) enabled the development of a well-integrated and efficient system that addressed the stakeholders priorities. These were structured according to the principles of requirement abstraction, clarity, traceability, and validation, as outlined in the IEEE Guide for Developing System Requirements Specifications [41]. These SRS are presented in Table 5 and form the foundation for the subsequent design, implementation, and evaluation phases.

Table 5: System requirements, each labeled with a unique ID (SRS-X) and accompanied by a detailed description. Each requirement is linked to one or more specific stakeholder needs to ensure traceability. An exception is CN-3, which involves an external solution integrated into ReLinkee and thus requires no system implementation.

ID	System requirements	Stakeholder Needs
SRS-1	The system must comply with the section structure outlined in the guidelines provided by the Danish National Center for Ethics.	**PN-1**
SRS-2	The system must use pictures to enhance the visual presentation of the trial.	**PN-1, PN-5**
SRS-3	The system must use icons to enhance the visual presentation of the trial.	**PN-1**
SRS-4	The system must display a navigation bar on all pages.	**PN-1**
SRS-5	The system must display the location of the trial, including street address and city.	**PN-3**

ID	System requirements	Stakeholder Needs
SRS-6	The system must display a timeline of the trial, marking the most important events.	**PN-2**
SRS-7	The system must display the benefits and risks (categorized as "Frequent/Non-serious" and "Rare/Serious") of the trial on the *trial page*.	**PN-4**
SRS-8	The system must only present ethics-approved recruitment material.	**RN-4**
SRS-9	The system must collect participant name, phone number, email, and the version of the *trial page* used.	**CN-1, RN-1, RN-2**
SRS-10	The system must transfer participant name, phone number, email, and *trial page* version to the researcher's REDCap.	**CN-1, RN-1, RN-3**
SRS-11	The system must present a privacy policy that complies with the 10 principles from the Danish Data Protection Agency	**CN-1, RN-1**
SRS-12	The system must collect consent to the privacy policy.	**CN-1, RN-1**
SRS-13	The system must verify that valid consent from the participant exists before processing personal data.	**CN-1, RN-1**
SRS-14	The system must store the consent record using the 13 attributes defined in ISO 27560:2023.	**CN-1, RN-1**
SRS-15	The system must enforce access control to restrict access to personal data stored in the cloud.	**CN-1, CN-2, RN-1**
SRS-16	The system must require multi-factor authentication for access to cloud-based resources.	**CN-1, CN-2, RN-1**
SRS-17	The system must validate personal data before the data is transferred to cloud storage.	**CN-1, CN-2, RN-1**
SRS-18	The system must encrypt all personal data stored in the cloud.	**CN-1, CN-2, RN-1**
SRS-19	The system must use encrypted connections when transferring personal data between the cloud and REDCap.	**CN-1, CN-2, RN-1**
SRS-20	The system must authenticate REDCap as an external recipient before transferring personal data from the cloud.	**CN-1, CN-2, RN-1**

5.2 Design

To provide a structured overview of ReLinkee, Figure 6 illustrates a use case diagram presenting the interactions between actors and components. The diagram includes five actors: Researcher, REDCap, Social Media, Participant, and the Company employee, each representing different roles or systems that interact with ReLinkee and the associated Website.

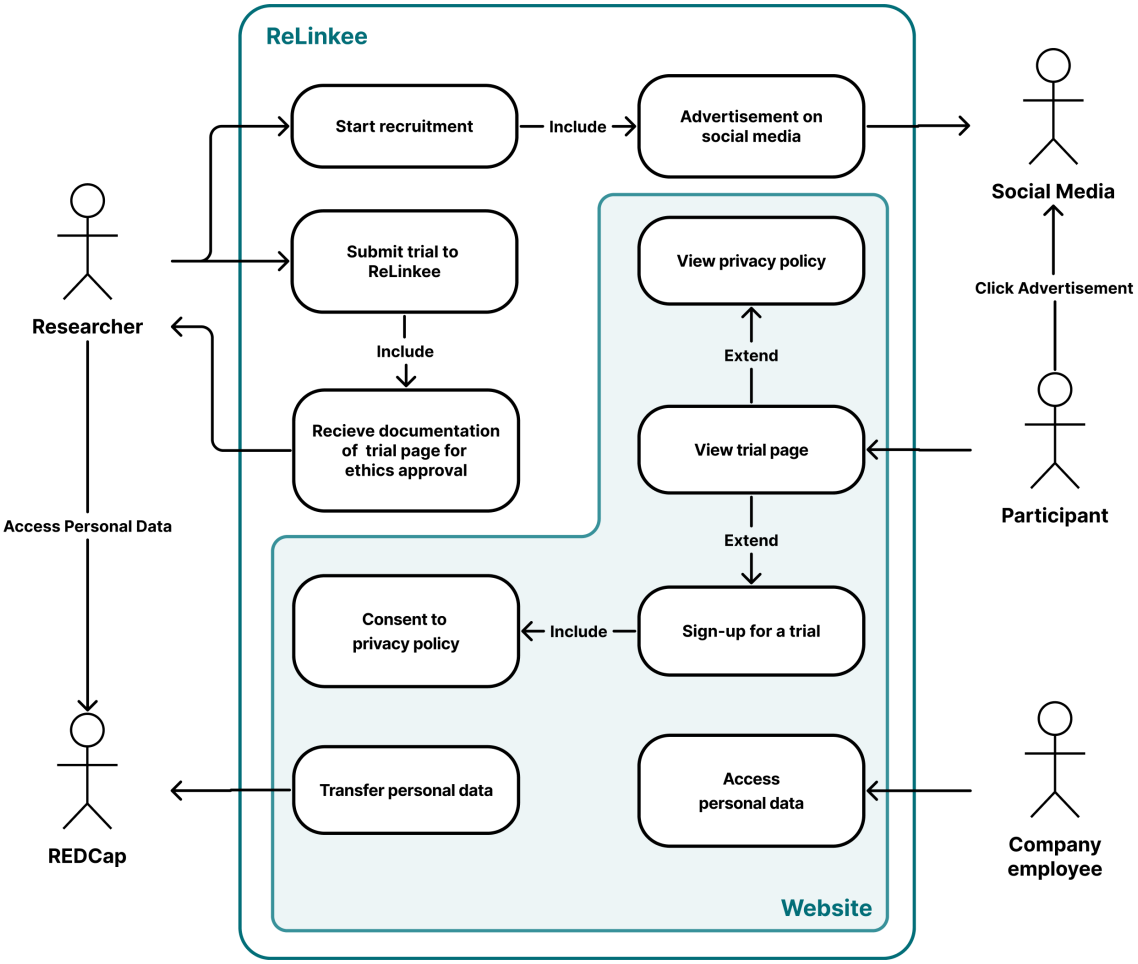


Figure 6: The use case diagram providing an overview of the interactions of five actors with ReLinkee and the associated Website.

The use case diagram illustrates the process by which the researcher submitted a trial to ReLinkee. Following submission, the researcher received documentation of the *trial page*, which required approval from the ethics committee before recruitment could begin. Once approved, recruitment was initiated through trial advertisements displayed on social media to attract potential participants. When a participant

clicked on the advertisement, they were redirected to the Website, where the participant could view the *trial page* and the *privacy policy page*. To sign-up, the participant was required to actively provide consent to the privacy policy. A company employee accessed the personal data as needed to maintain and operate the Website. Once the participant completed the sign-up process, their personal data was transferred to REDCap, where the researcher could access the data. The Website illustrated in Figure 6 was further divided into four modules: front-end, storage, back-end, and Application Programming Interface (API), to build the architecture as illustrated in Figure 7.

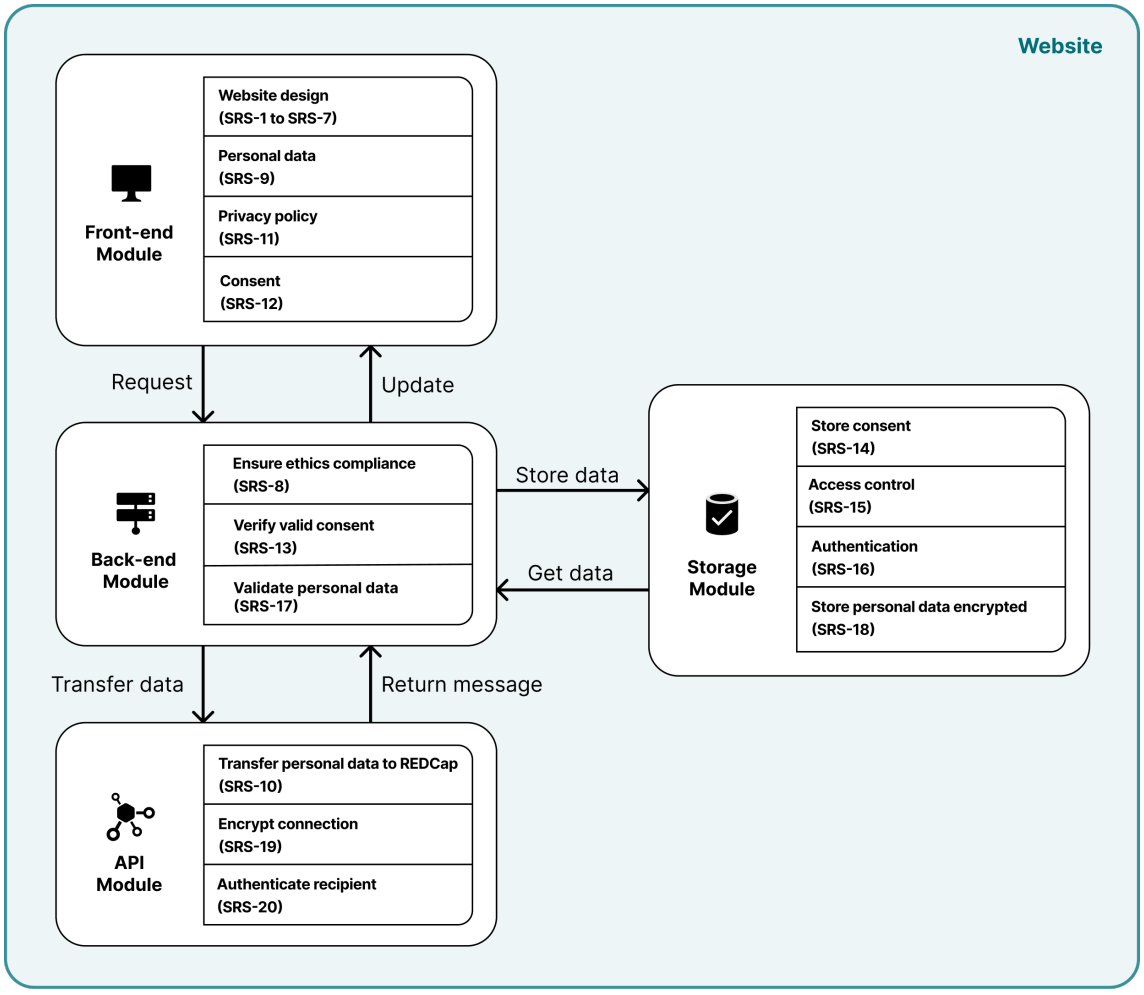


Figure 7: The architectural diagram of the data flow within the Website. The front-end module requests data from the back-end module, which updates the front-end. The back-end module exchanges data with the storage module and receives a return message from the API module. Each module refers to a specific SRS.

5.2.1 Front-end module

The design of ReLinkee's front-end focused on three main pages: the *trial page*, the *sign-up form*, and the *privacy policy page*. The design of the *trial page* followed the format outlined by the Danish National Center for Ethics [40] and fulfilled requirement SRS-1, by organizing the content into six sections: purpose of the trial, biological material, plan for the trial, benefits, risks, and side effects.

To meet requirements SRS-2, SRS-3, SRS-4, and SRS-6, visual elements, such as images, icons, navigation bar, and timeline, were incorporated to enhance the representation of the trial. The Risks and Side Effects section was further divided into two categories: "Frequent/Non-serious" and "Rare/Serious" in accordance with SRS-7. Finally, the trial location was placed at the top and bottom of the page with an accompanying image fulfilling SRS-5. A low-fidelity design of the *trial page* was created, as illustrated in Figure 8.

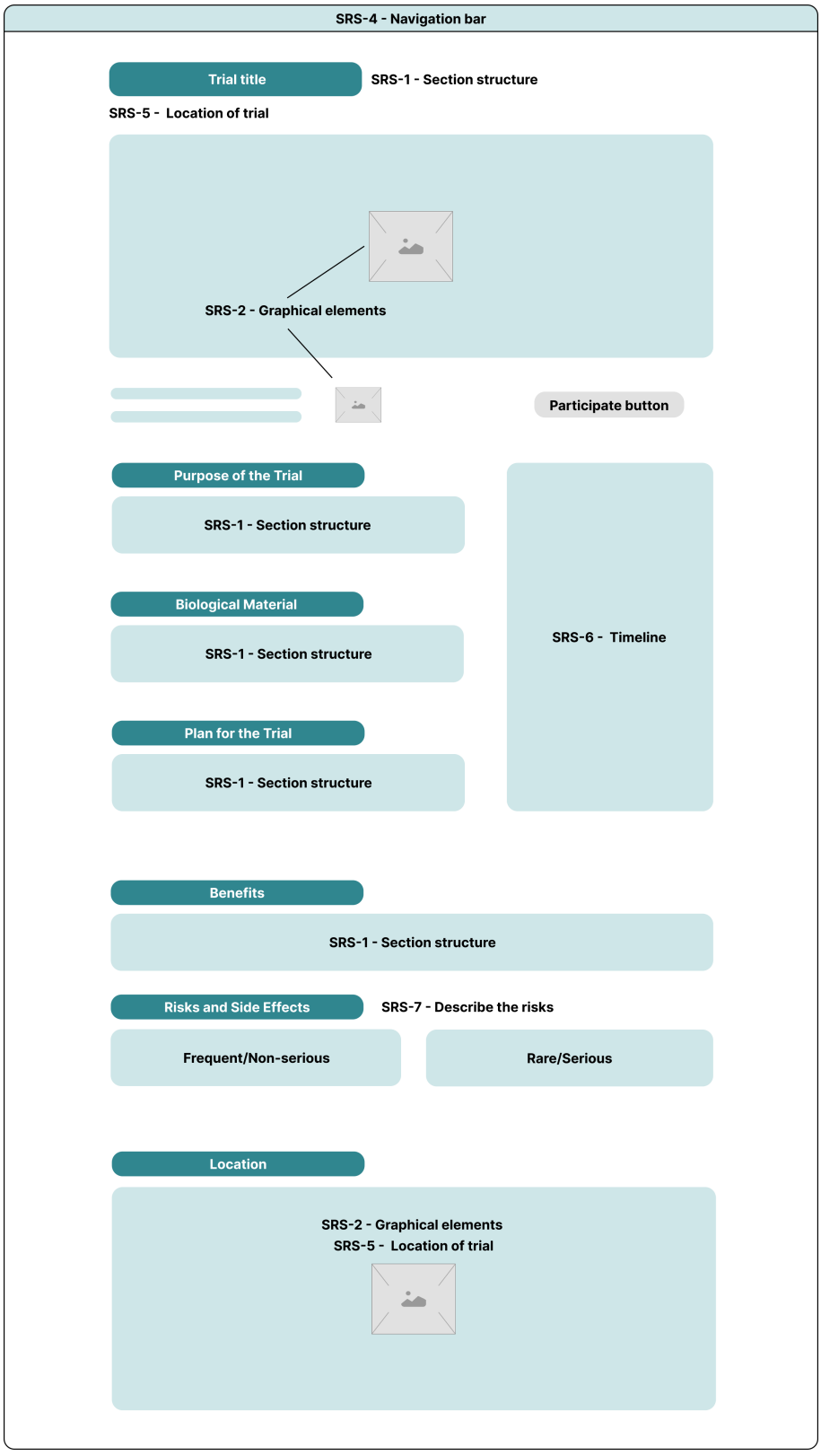


Figure 8: A low-fidelity design of the *trial page* designed with the sections and elements to address specific requirements from SRS-1 to SRS-7, with indications of where and how each requirement is fulfilled.

The design of the *sign-up form* aligned with requirements SRS-9 and SRS-12, incorporating fields for the participant's name, phone number, and email address. Additionally, a checkbox was included to ensure that consent was obtained in a manner that was unambiguous, voluntary, and expressed through an active choice. The low-fidelity design of the *sign-up form* is illustrated in Figure 9.

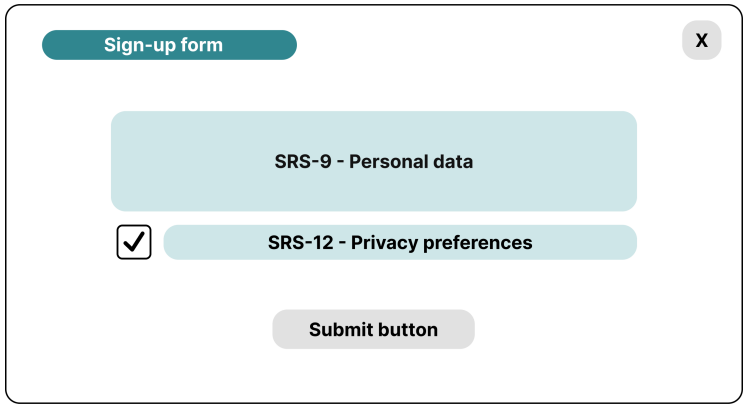


Figure 9: A low-fidelity design of the *sign-up form* containing input fields for name, phone number, and email address. Below the input fields is a checkbox and a consent section, followed by a submit button. Each design element is linked to the corresponding SRS.

To comply with SRS-11, a *privacy policy page* aligned with the 10 principles established by the Danish Data Protection Agency [35] was incorporated on the Website. This page was designed to clearly communicate the purpose of collecting and storing personal data. The *privacy policy page* also detailed how data usage could be limited, outlined the defined retention period for data storage, and explained the measures in place to restrict access to and disclosure of the data.

5.2.2 Storage module

To fulfill SRS-14, SRS-15, SRS-16, and SRS-18, the storage structure was designed using an Entity-Relationship (ER) diagram, a widely used method in software engineering for visualizing database structures [42]. Figure 10 illustrates the relationships within the database through the ER diagram that outlines seven entities, along with their attributes, interrelationships, and cardinality constraints.

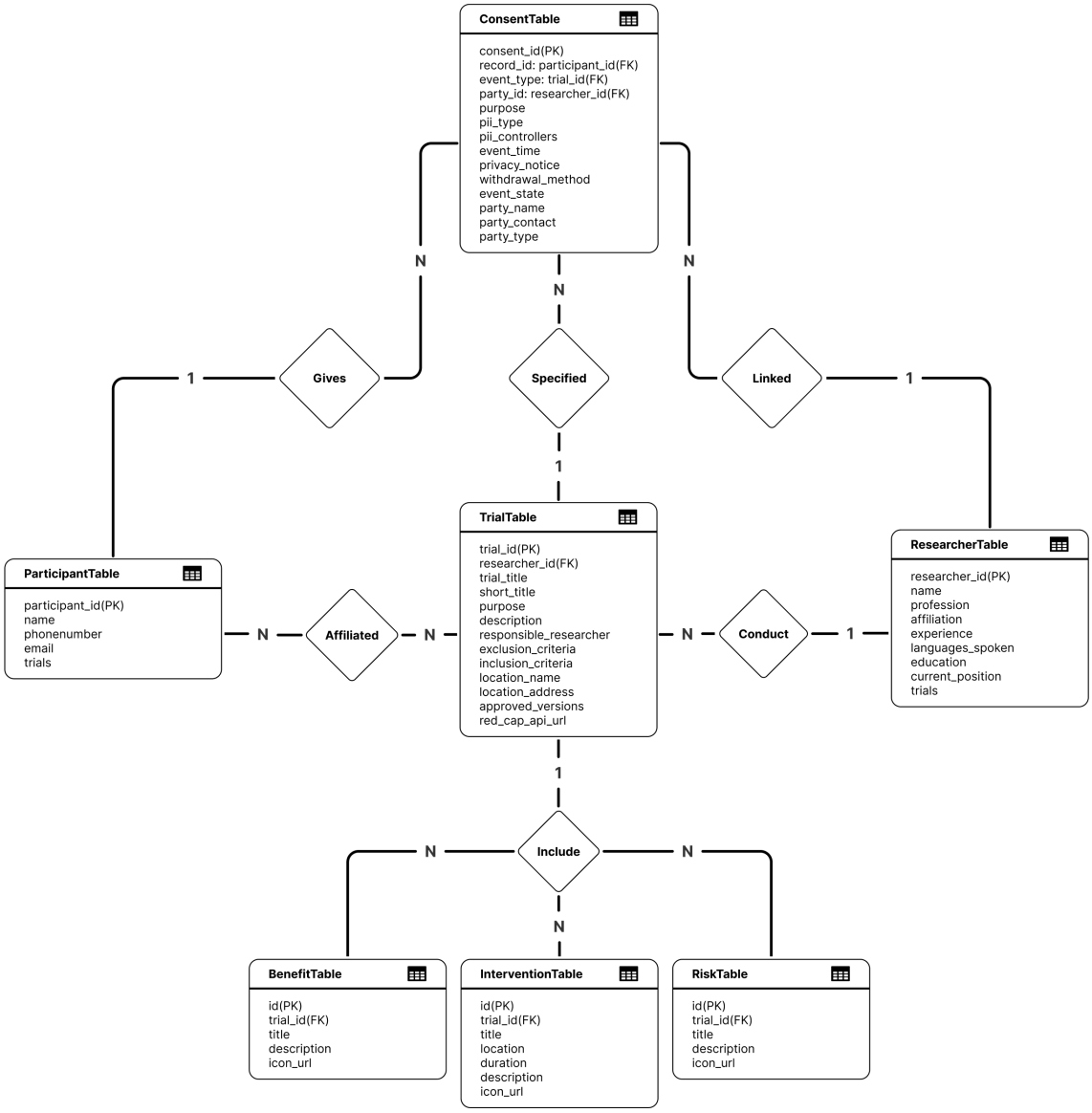


Figure 10: Entity-Relationship diagram illustrating the seven entities: *ConsentTable*, *ParticipantTable*, *TrialTable*, *ResearcherTable*, *BenefitTable*, *InterventionTable*, and *RiskTable*. Relationships are depicted using diamond-shaped symbols, with cardinalities indicated by numbers. "1" denotes a one-to-one or one-to-many relationship from one entity, while "N" (many) indicates that multiple instances from one table can be associated with a single instance of the related entity. Primary keys (PK) uniquely identify records, while foreign keys (FK) create links between tables and represent dependency relationships. Each table includes the associated attributes.

The *ParticipantTable* and *TrialTable* had a many-to-many relationship, meaning a participant could be affiliated with multiple trials, and each trial could include multiple participants. Similarly, the *TrialTable* and *ResearcherTable* shared a many-to-many relationship, where a single trial may involve several researchers, and each researcher could conduct several trials. The *ParticipantTable*, *TrialTable*, and *ResearcherTable* were linked with the *ConsentTable* through many-to-one relationships. This relation meant each consent entry was uniquely associated with one participant, one trial, and one researcher. However, a participant may give multiple consents, a trial may have multiple consent entries, and a researcher could be linked to several consents. Additionally, the *TrialTable* is connected to the *BenefitTable*, *InterventionTable*, and *RiskTable* through one-to-many relationships. This indicated that each trial could include multiple benefits, interventions, and risks, however, each benefit, intervention, and risk was associated with one trial.

The 14 attributes of the *ConsentTable* were implemented to fulfill SRS-14 and to ensure compliance with ISO 27560:2023 by capturing key consent data such as scope, purpose, timestamp, and version [32]. To fulfill SRS-15 and SRS-16, the storage module incorporated role-based access control and multi-factor authentication. Additionally, all personal data was stored in encrypted form, as required by SRS-18.

5.2.3 Back-end module

To fulfill SRS-8, SRS-13, and SRS-17, the back-end was designed using Object-Oriented Programming, which was considered the preferred method for designing complex solutions [43]. In Object-Oriented Programming, each element is represented as an object, which encapsulates attributes describing the characteristics and methods defining the behavior. To illustrate the structure and relationships between these objects, a class diagram is used. Figure 11 illustrates the class diagram for the back-end, containing four distinct classes.

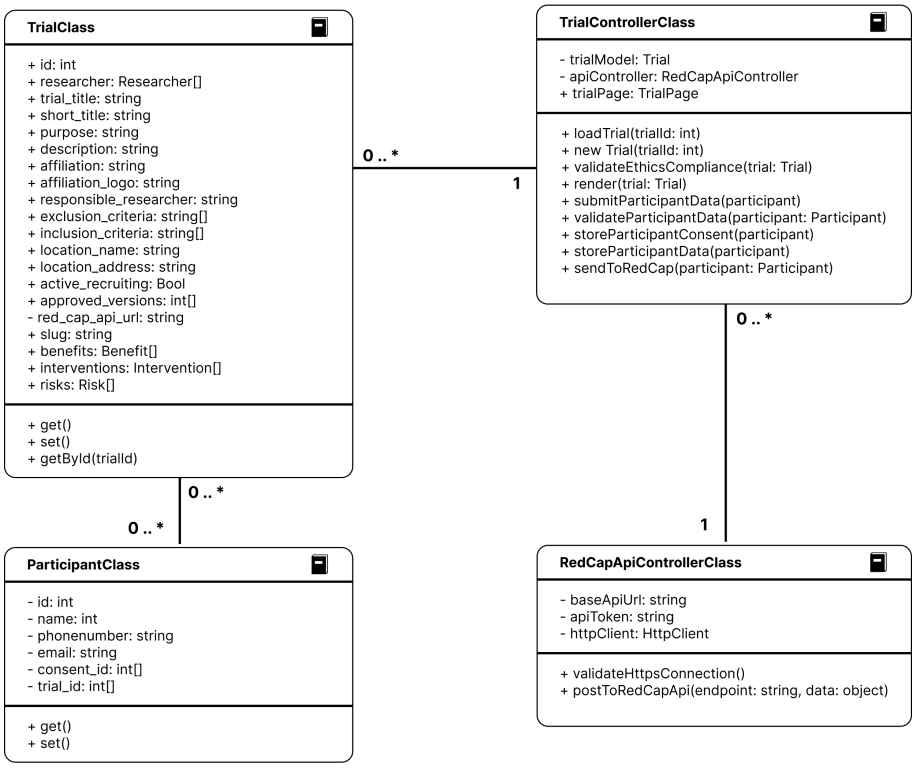


Figure 11: Class diagram illustrating the back-end model containing the four classes: *TrialClass*, *ParticipantClass*, *TrialControllerClass*, and *RedCapApiControllerClass*. Each class includes attributes and methods, with public access modifiers (+) and private modifiers (-). Relationships between classes are depicted using multiplicities, where numbers and asterisks (*) denote the possible number of associated instances.

The *TrialClass* was connected to the *ParticipantClass* with multiplicities indicating a many-to-many relationship, meaning a trial could have zero or multiple participants, and participants could be part of zero or multiple trials. The *TrialControllerClass* was also linked to the *TrialClass* in a one-to-many relationship, where each trial was managed by one controller, but a controller could manage several trials. Additionally, the *TrialControllerClass* was associated with zero or multiple *RedCapApiControllerClass*, while each *RedCapApiControllerClass* was linked to one *TrialControllerClass*.

To illustrate how the classes in Figure 11 and the tables presented in Figure 10 interact with the *trial page* and the database, a sequence diagram was created, as illustrated in Figure 12.

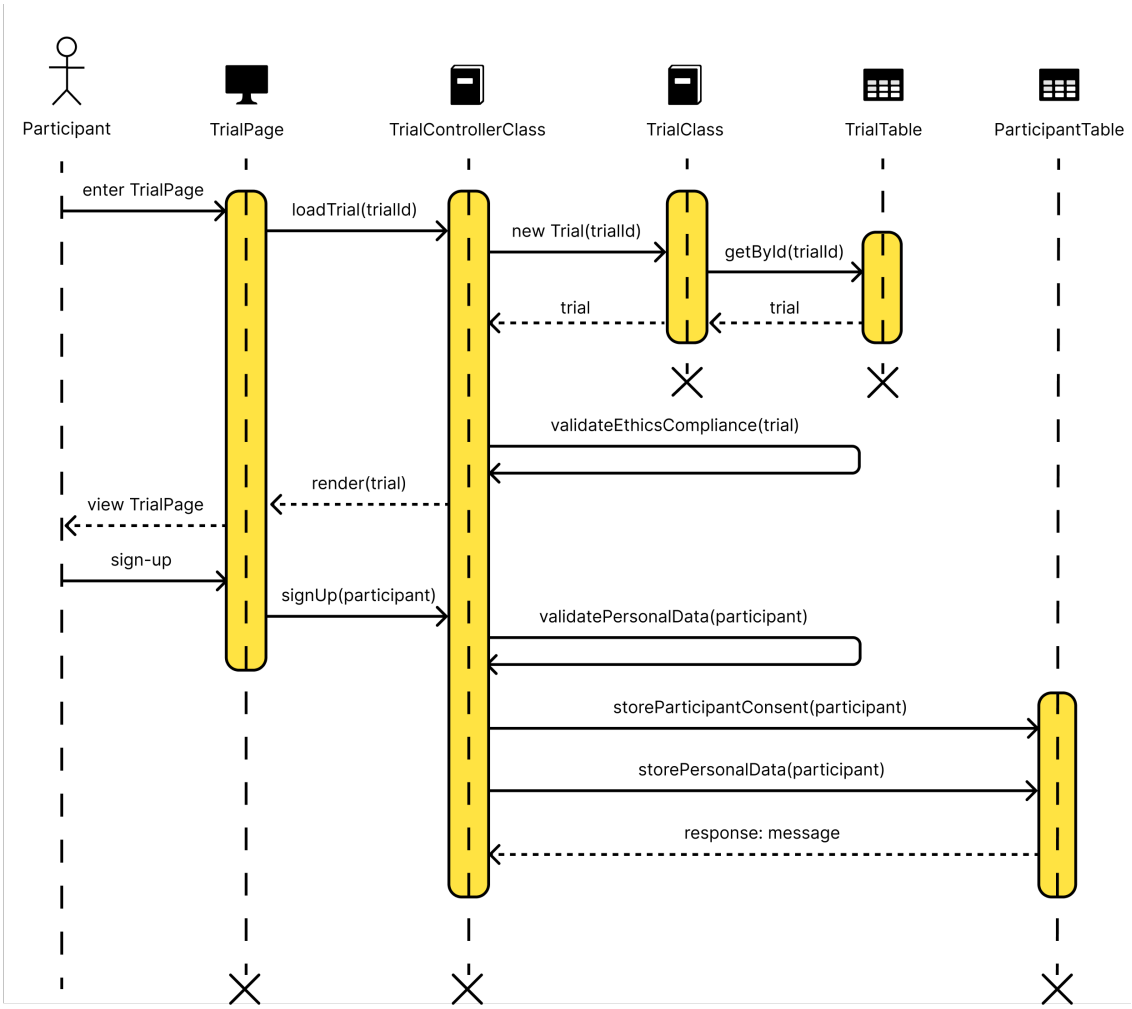


Figure 12: Sequence diagram illustrating the interactions between participant, *trial page*, classes, and databases. Participant interaction with the *trial page* triggers a sequence of method calls handled by *TrialControllerClass* and *TrialClass*, which retrieve trial data from *TrialTable* and store personal data in *ParticipantTable*.

When a participant entered the *trial page*, the Website initiated the loading process of the trial using the method *loadTrial* with the requested *trialId*. This triggered the *TrialControllerClass* to create an empty trial object from the *TrialClass*, calling the *getById* method to fetch the trial ID from the *TrialTable*. Once retrieved, the populated instance was returned to the *TrialControllerClass*, which verified whether the trial had sufficient approval. If approved, the trial data was rendered and displayed to the participant. If the participant signed up for the trial, the Website triggered the *signUp* method. The *TrialControllerClass* validated the personal data and stored consent and personal data in the *ParticipantTable*. This process returned with either a success message or an error message, depending on the outcome.

5.2.4 API module

The Website was designed to securely transfer personal data to REDCap in alignment with requirements SRS-10, SRS-19, and SRS-20. The API was designed to enable safe and efficient data transmission. The API process began with the *TrialControllerClass* collecting the required personal data, and the version of the *trial page* used. This data was transmitted to the *REDCapAPIControllerClass*, which validated the connection to REDCap and ensured that a valid response was received. If validation failed, an error message was returned to the *TrialControllerClass*, otherwise, the personal data was forwarded to REDCap. Upon receiving a response, the API Controller checked for errors and returned a corresponding message to the *TrialControllerClass*, ensuring that personal data was correctly transferred to the researcher's REDCap system. The detailed interaction is illustrated in Figure 13, presenting the data flow between system components during the data exchange process.

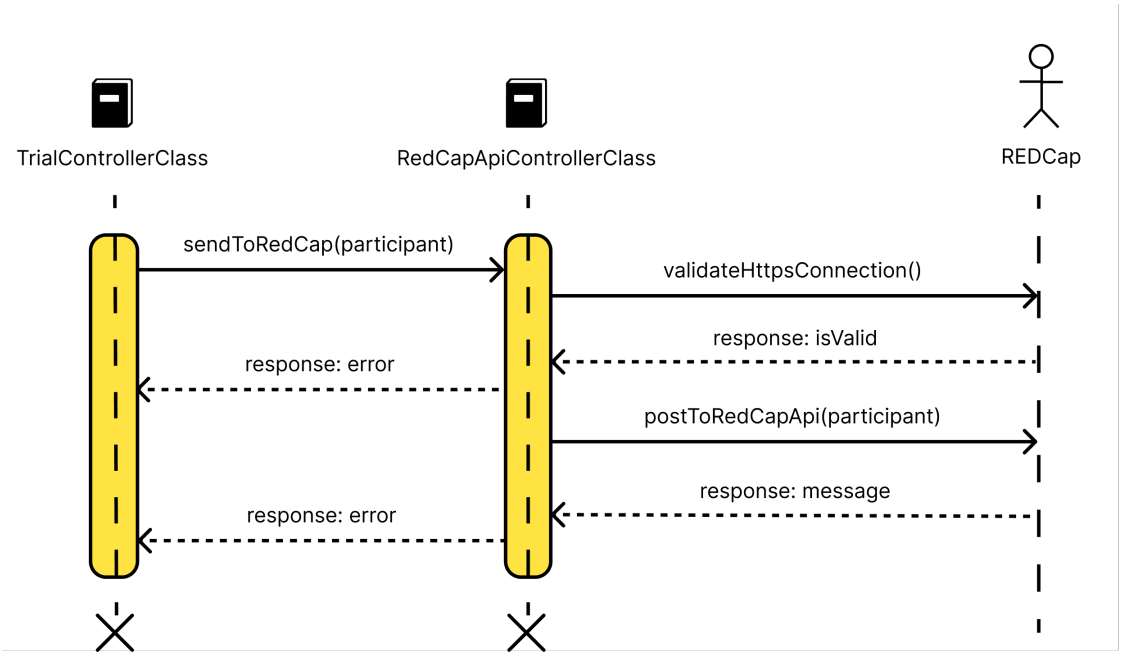


Figure 13: Sequence diagram illustrating the interactions between the *TrialControllerClass*, *RedCapApiControllerClass*, and REDCap. The *TrialControllerClass* transmits personal data to the *RedCapApiControllerClass*, which validates the data and forwards it to REDCap. If any errors occur, a response is returned to the *TrialControllerClass*.

To protect personal data during transmission, the design required all transfers between the cloud and REDCap to be encrypted, thereby fulfilling SRS-19. Encryption was designed to ensure personal data remained confidential and protected against unauthorized interception during transmission. Furthermore, before any personal data was sent, the Website was designed to authenticate REDCap to verify that the external recipient was trusted and authorized to receive the information. This authentication step was designed to fulfill SRS-20 and safeguard against accidental or malicious data disclosure to unverified parties.

5.3 Implementation

The Website was implemented according to the design of the four modules: front-end, storage, back-end, and API as outlined in Figure 7. The modules were implemented in the cloud platform Microsoft Azure, utilizing six integrated services: *Web App*, *Storage Queue*, *SQL Database*, *Key Vault*, *Application Insights*, and *Azure Functions*, with an underlying *Privacy Control* layer, as illustrated in Figure 14.

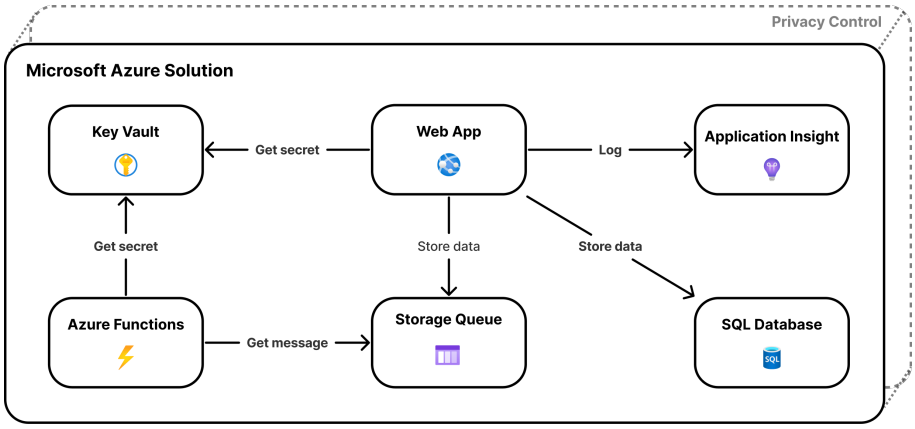


Figure 14: An architectural diagram illustrating the implementation of the recruitment solution in Microsoft Azure. The architecture comprises six services supported by an underlying privacy control layer.

In the implemented *Microsoft Azure Solution*, the participant interacted with the *Web App*, which was connected to the *Key Vault* to securely store sensitive information, such as the database connection string. Additionally, the *Web App* also connected to *Application Insights*, which logged the number of randomizations and button clicks on the *sign-up form*. The *Web App* also interfaced with two storage

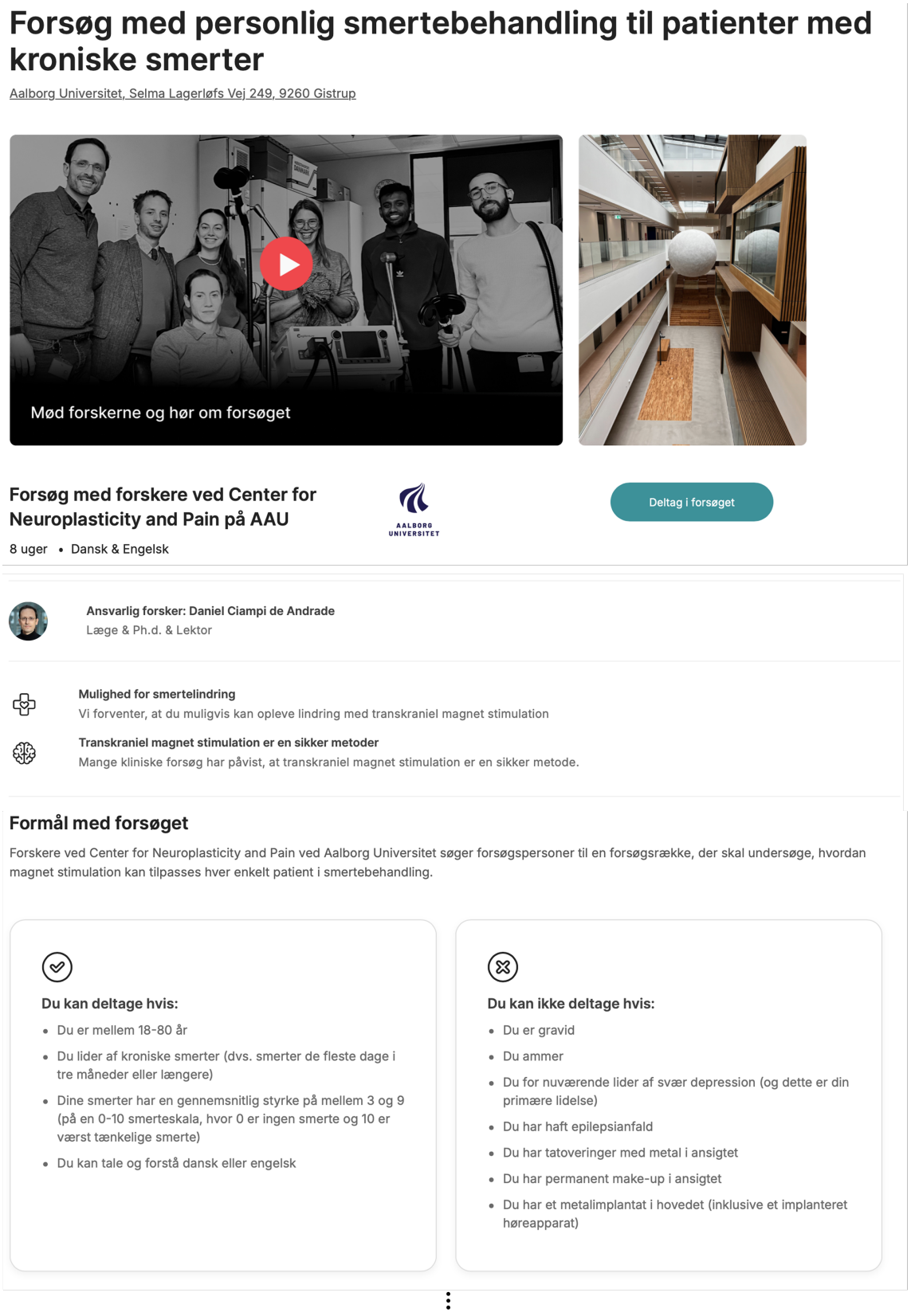
services: *Storage Queue*, which temporarily stored sign-up data for later transfer to REDCap, and *SQL Database*, which held participant and consent information in compliance with GDPR. For back-end processing, *Azure Functions* handled API communication, retrieving personal data from the *Storage Queue*, and forwarding the data to REDCap, where the researcher could access the data.

To ensure the secure storage of personal data, a *Privacy Control* layer was implemented. This layer included authentication and access control, managed through Microsoft Entra ID and Azure Role-Based Access Control. Microsoft Entra ID enforced multi-factor authentication and verified the identity of company employees before granting them access to the Azure environment. Role-Based Access Control ensured that each user was granted only the minimum permissions necessary to develop and maintain the system. This approach increased transparency and control over which employees had access to sensitive participant and researcher data. The six services used in the *Microsoft Azure Solution* are described below.

5.3.1 Web App

The *Web App* allowed participants to view the *trial page* and sign-up for the trial, requiring front-end and back-end components in the implementation. The front-end was implemented with HTML 5, providing the structure, CSS used for styling, and JavaScript to add interactive features and functionality. The front-end implementation of the *trial page* is illustrated in Figure 15.

Figure 15: A screenshot of the implemented *trial page* available at: https://relinkee.dk/TrialsPage



Plan for forsøget

- **Indledende telefonsamtale(10 min.)**

I løbet af telefonsamtalen har du helt uforpligtende mulighed for at stille spørgsmål og finde ud af, om forsøget passer til dig. Herefter inviterer vi dig til et fysisk møde, hvor vi gennemgår forsøget i detaljer og giver dig endnu en mulighed for at få svar på dine spørgsmål.

- **Individuel måling af hjerneaktivitet(3-4 timer)**

Her vil du blive bedt om at udfylde spørgeskemaer, der omhandler din smerteoplevelse, søvnkvalitet, mobilitet og dit humør. Efter disse spørgeskemaer skal du gennemgå en undersøgelse i form af målinger af signaler fra din hjerne. Målingerne foregår ved hjælp af hætte fyldt med elektroder, som du skal bære under forsøget. Disse målinger vil gøre det muligt for os at forstå, hvordan din hjerne reagerer på de kroniske smerter, og dermed gøre os i stand til at bestemme den bedste måde, hvorpå vi kan påføre magnet stimulationerne.

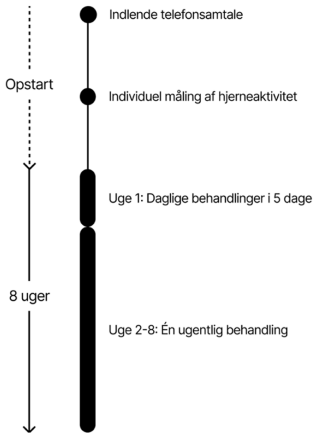
- **Uge 1: Daglige behandlinger i 5 dage(25. min per session)**

Du skal deltage i fem forsøgssessioner med magnet stimulation fordelt over en uge. Hver session varer 25 minutter og indeholder 15 minutters påføring af magnet stimulationer.

- **Uge 2-8: Én ugentlig behandling(25 min. per session)**

Du skal deltage i én ugentlig forsøgssession over en periode på syv uger. Disse forsøgssessioner varer ligeledes 25 minutter. Også her består sessionerne af påføring af magnet stimulationer i 15 minutter.

Forsøgsoverblik



Nytte ved forsøget

Du vil kunne opleve en vis lindring af dine smerter i forbindelse med forsøget. Dog kan vi ikke garantere, at du vil opleve dette samt hvilket omfang lindringen vil have. Endvidere kan vi ikke forudse varigheden af en eventuel lindring af dine smerter, ligesom det ikke vil være muligt at fortsætte med forsøgsprocedurerne efter afslutning af forsøget. Vi forventer endvidere, at den viden, der genereres i forsøget, vil hjælpe læger og forskere til en bedre forståelse af sammenhængen mellem magnet stimulationer og oplevelsen/følelsen af smerter. Dette kan give en bedre forståelse af, hvordan kroniske smerter påvirker vores hjerner og give mulighed for at udvikle mere målrettede og personlige ikke-medicinske behandlingsmuligheder.

Ny viden om smertebehandling

Projektet vil bidrage med ny viden om, hvordan magnet stimulation kan anvendes til effektiv behandling af kroniske smerter.

Potentiel smertelindring for deltagerne

Som deltager i projektet vil du kunne opleve en vis lindring af dine kroniske smerter.

Bidrag til videnskabelig udvikling

Din deltagelse hjælper med at udvikle bedre behandlingsmuligheder for fremtidige patienter, der lider af kroniske smerter.

Potentielle ulemper og risici ved deltagelse

De metoder, som vi anvender i forsøgene, er alle velafprøvede og har været anvendt i adskillige lignende forsøg både hos CNAP og hos andre forskningslaboratorier. Der foreligger ikke meldinger om langvarige bivirkninger ved metoderne.

Hyppige/ikke alvorlige

En mulig bivirkning af magnet stimulationerne kan være forøgelse af støjfølsomheden. Endelig kan du udvikle en let smerte i nakken eller hovedpine efter de første stimulationer. Dette vil normalt forsvinde af sig selv efter kort tid og kræver sjældent behandling.

Sjældne/alvorlige

Der en lille risiko for et epileptisk anfald (1/10.000), hvis du er disponeret herfor. Derfor vil vi bede dig udfylde et spørgeskema, som har til formål at undersøge, om du er disponeret for epileptiske anfald.

Udelukkelse fra og afbrydelse af forsøg

Den forsøgsansvarlige kan til enhver tid vælge at afslutte din deltagelse i forsøget, hvis du reagerer uventet på forsøgets procedurer eller hvis det i øvrigt viser sig, at du ikke kan gennemføre forsøget. Forsøget som helhed vil blive stoppet, hvis det skulle vise sig, at forsøgspersonerne generelt ikke tolererer procedurerne i forsøget eller finder forsøget for udmattende.

Oplysninger om økonomiske forhold

Forsøget er igangsat af lektor Daniel Ciampi de Andrade, Aalborg Universitet. Forsøget er finansieret af Det Europæiske Forskningsråd (Consolidator Grants 2022, modtaget af Daniel Ciampi de Andrade - EUR 120.000). Beløbet administreres af Institut for Medicin og Sundhedsteknologi, Aalborg Universitet. Ingen af forskerne bag forsøget har økonomiske interesser heri.

Adgang til forsøgsresultater

Forsøgets resultater offentliggøres uanset udfaldet.

Mød den ansvarlig forsker

Daniel Andrade

Forsker på ReLinkee siden 2024

Uddannelse: Læge med specialisering i neurologi

Nuværende stilling: Lektor på Aalborg Universitet ved Center for Neuroplasticity and Pain (CNAP)

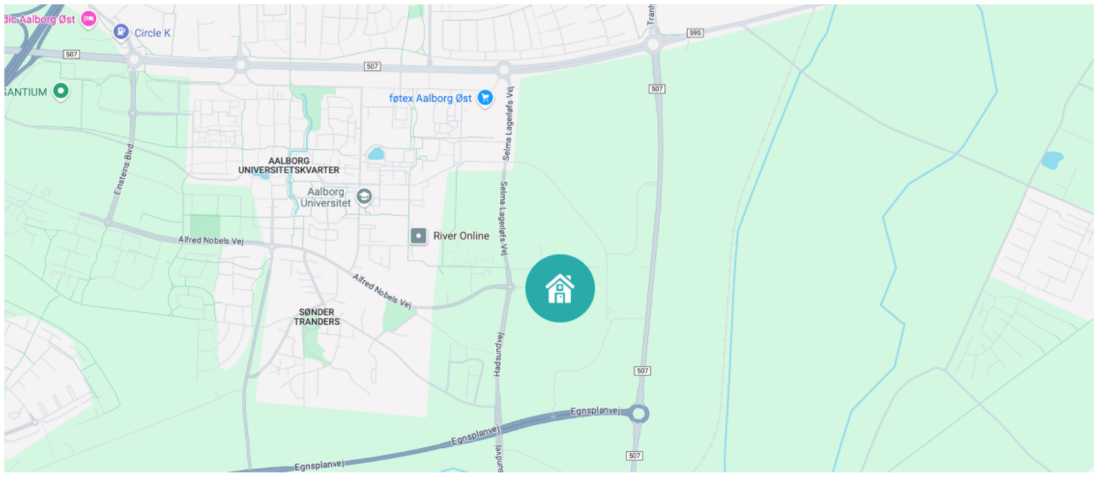
Erfaring: Over 11 års klinisk erfaring og 177 videnskabelige publikationer

Sprog: Dansk & Engelsk

Passion: Jeg interesserer mig for vurdering, diagnosticering og behandling af personer med kroniske smerter.

Tag kontakt til forskeren her

Her skal det være



Institut for Medicin og Sundhedsteknologi, Aalborg Universitet, Selma Lagerløfs Vej 249, 9260 Gistrup, Selma Lagerløfs Vej 249, 9260 Gistrup

Godkendt hos Videnskabsetisk Komité

Forsøget er godkendt af Den Videnskabsetiske Komité for Region Nordjylland, sagsnummer N- 20230076.

Dine rettigheder som forsøgsperson

Som forsøgsperson har du ret til at trække dig fra forsøget til enhver tid uden konsekvenser for din fremtidige behandling. Du vil blive informeret om alle risici og bivirkninger, og dine personlige oplysninger behandles fortroligt i overensstemmelse med databeskyttelsesreglerne.

Læs om dine rettigheder her

Participants who decided to sign-up for the trial could click the "Deltag i forsøget" button shown in Figure 15, which directed the participant to the *sign-up form* illustrated in Figure 16. On the *sign-up form*, the participant was required to complete the form and actively consent to the privacy policy by checking a box. The implemented *privacy policy page* of ReLinkee can be found in Appendix C.

Figure 16: The implemented design of ReLinkee's *sign-up form*, showcasing the layout and required input fields for trial sign-up and consent.

The back-end was implemented using ASP.NET, a framework for building web applications using Microsoft Azure. The back-end implementation of the sign-up process is illustrated through a sequence diagram in Figure 17. When a participant initiated sign-up through the *trial page*, the *submitParticipant* method with *inputData* in the *ParticipantControllerClass* was triggered. The input fields were validated, and trial details were retrieved using the *getTrial(id)* function in the *TrialServiceClass*, which returned the relevant trial object. This object was combined with the *requestData* to construct the personal data, which was passed to the *DbControllerClass* and stored in the *ParticipantTable* of the database. Additionally, personal data intended for REDCap was added to the *QueueTable*, returning a success or failure message to the participant.

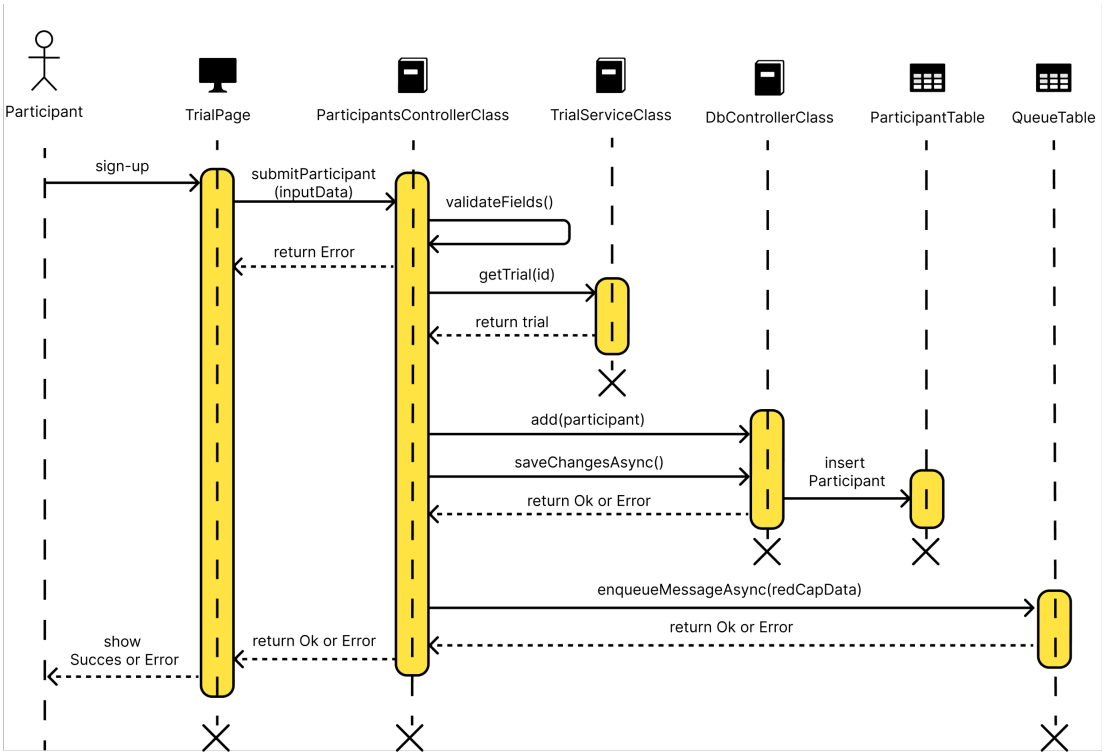


Figure 17: The back-end implementation of the sign-up process for the participant involved the trial view, three classes—ParticipantControllerClass, TrialServiceClass, and DbControllerClass—and two tables: ParticipantTable and QueueTable.

5.3.2 Storage Queue and SQL Database

The implementation of storage was based on two services: *Storage Queue* and *SQL Database*. The *QueueTable* was used by the *Storage Queue* to support the transfer of personal data to REDCap, while the *ParticipantTable* was used in the *SQL Database* to store participant records. These tables are presented in Figure 18. In the *QueueTable*, the fields trial_id, name, phone, and email were used to identify and contact participants. The api_url field facilitated data transfer to REDCap, while design_version indicated which version of the *trial page* the participant was presented with. In the *ParticipantTable*, the fields participant_id, name, and email were used to identify participants, and consent_date recorded when consent was given. The tables followed the principle of data minimization, storing only essential personal information to ensure compliance with GDPR requirements [44].

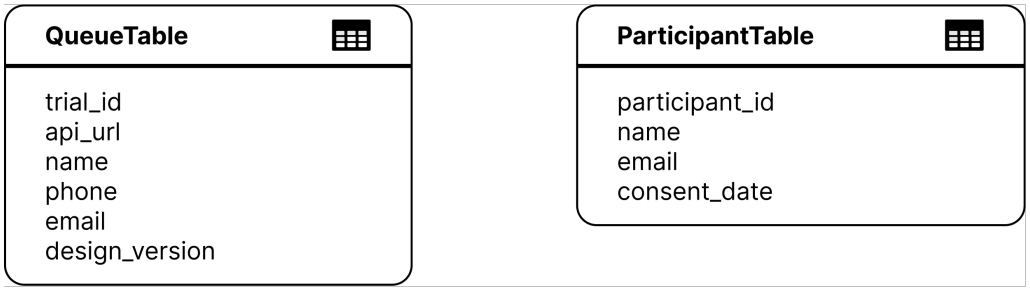


Figure 18: The tables for storage was defined for the *Storage Queue* and the *SQL Database*. The *Storage Queue* used a table called *QueueTable* with corresponding attributes, while the *SQL Database* used a table called *ParticipantTable*, which also contained corresponding attributes.

5.3.3 Key Vault and Application Insights

The two services, *Key Vault* and *Application Insights*, were incorporated to ensure secure handling of sensitive credentials and to monitor system behavior for performance and stability. *Key Vault* was implemented to securely store sensitive information such as REDCap API keys and database connection strings. Rather than embedding this information directly in the source code, the back-end retrieved the sensitive information from the *Key Vault*. This approach minimized the risk of credential exposure, supported maintainability, and helped prevent unauthorized access. *Application Insights* was implemented to monitor how users interacted with the Website, including the number of randomizations and button clicks. This behavioral data helped analyze usage patterns and improve the system's design. In addition, *Application Insights* logged successful operations and system errors, providing visibility into performance metrics and supporting debugging, maintenance, and optimization.

5.3.4 Azure Functions

To enable the transfer of personal data to REDCap through API, *Azure Functions* were implemented to asynchronously transfer data from the *Storage Queue* to REDCap. This process is illustrated in Figure 19.

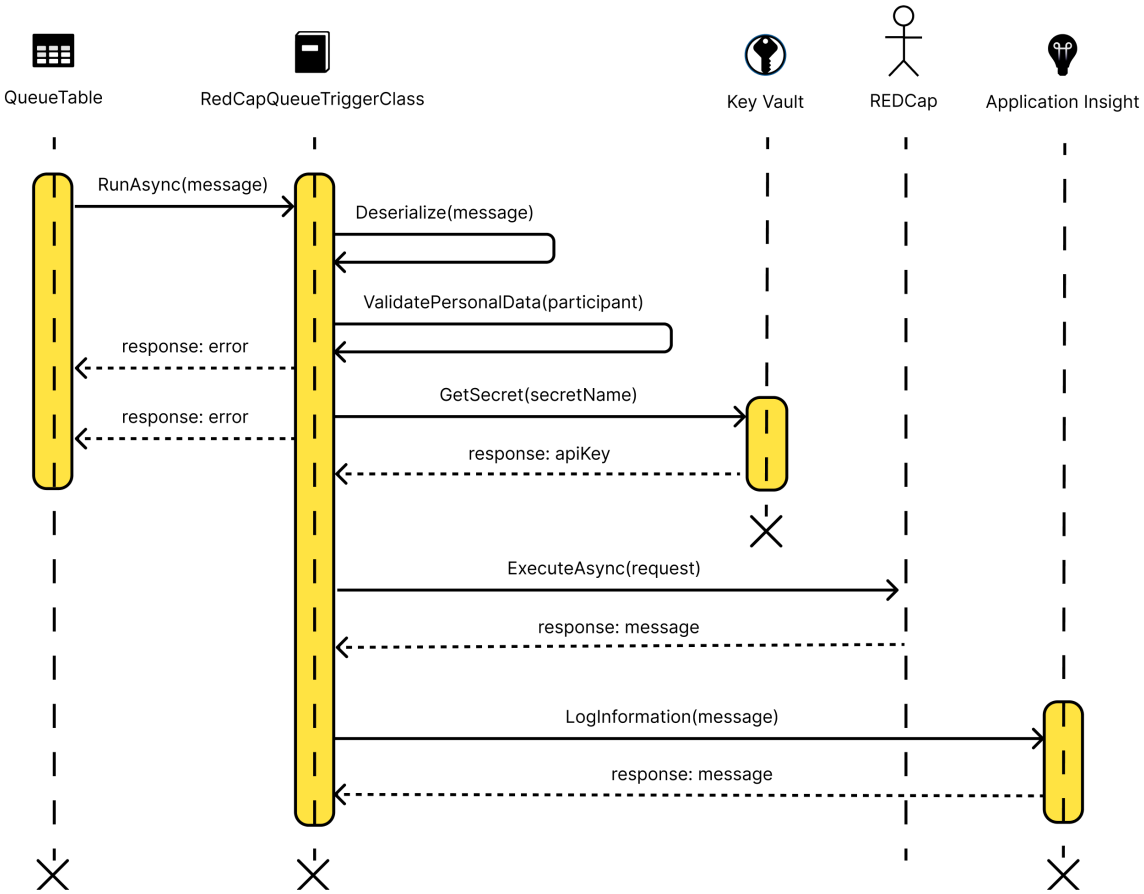


Figure 19: The API implementation handled the process of transferring data from the QueueTable in the *Storage Queue* to REDCap. The class RedCapQueueTriggerClass managed this process by retrieving secrets from *Key Vault*, transferring the data to REDCap, and logging the events in *Application Insights*.

The API flow began with personal data and consent being stored in the *QueueTable* in the *Storage Queue*. The *RedCapQueueTriggerClass* fetched the message by calling *RunAsync*. The message was deserialized and validated, after which the API key was retrieved from *Key Vault* to communicate with REDCap. The data was transferred to REDCap, and a success or error message was returned and logged in *Application Insights*.

5.4 Evaluation: Heuristic evaluation

A heuristic evaluation was used as the assessment method to determine the effectiveness of the decisions made in the analysis, design, and implementation phases.

Purpose

The heuristic evaluation aimed to identify potential usability problems by evaluating the design of ReLinkee against selected usability heuristics. Jakob Nielsen's 10 usability heuristics [45, 46] were chosen as the framework for the evaluation, as it is a well-used framework in the medical domain [47]. These heuristics served as guidelines for assessing the functionality of ReLinkee based on human behavior and information processing [45]. The 10 usability heuristics are listed below:

1. Visibility of System Status
2. Match Between the System and the Real World
3. User Control and Freedom
4. Consistency and Standards
5. Error Prevention
6. Recognition Rather than Recall
7. Flexibility and Efficiency of Use
8. Aesthetic and Minimalist Design
9. Help Users Recognize, Diagnose, and Recover from Errors
10. Help and Documentation

Participants

Participants for the heuristic evaluation were recruited through Aalborg University. The characteristics of each participant, including gender, age, and education, were recorded [47]. In addition, each evaluator's experience with heuristic evaluation was captured, as this was considered to influence the outcome. A sample size of five evaluators was chosen, as this has shown to be sufficient to identify 80 % of usability problems [47].

Procedure

Before the heuristic evaluation began, each evaluator received an introduction including an overview of the evaluation process, the purpose of the assessment, and an explanation of the usability heuristics to ensure a clear understanding of the methodology. During the evaluation, each evaluator independently assessed ReLinkee by completing eight tasks on their laptop. The eight tasks were presented one at a time and are presented below:

- Task 1: Can you find and access an ongoing trial?
- Task 2: Can you find the address where the trial will take place?
- Task 3: Can you find out how much time you need to allocate to participate in the trial?
- Task 4: Can you play the video presentation of the trial?
- Task 5: Can you determine whether you meet the eligibility criteria for the trial?
- Task 6: How is the balance between graphics and the amount of text?
- Task 7: Try to sign-up for the trial.
- Task 8: Can you find information about the team behind ReLinkee?

A facilitator from the team documented the problems identified during each task, noting the related heuristics, recommendations, and severity level. This approach aimed to ensure consistency among evaluators by systematically documenting issues based on Jakob Nielsen's 10 usability heuristics. Each problem's severity was assessed using Jakob Nielsen's severity ratings, a scale used for assessing a digital solution in the healthcare domain [48]. The severity rating scale for usability problems is listed below:

0. No problem: This is not a usability problem at all
1. Cosmetic problem: No need to be fixed unless extra time is available
2. Minor problem: Fixing this should be given low priority
3. Major problem: Important to fix, and should be given high priority
4. Usability catastrophe: Imperative to fix this before the product can be released

To ensure that the heuristic evaluation was appropriately designed, a pilot test consisting of a single session was conducted before the five evaluators carried out the heuristic evaluation. Once all evaluators had completed their assessments, a debriefing session was performed where evaluators collectively reviewed all problems identified in the individual assessments. The problems were grouped into categories, limited to those with a severity level between 2 and 4. Together, the evaluators prioritized the three most positive and the three most critical aspects of the system to guide future development [47].

5.4.1 Findings from the heuristic evaluation

Five evaluators (2 males, 3 females, mean age 30 years) from Aalborg University conducted the heuristic evaluation. The characteristics of the evaluators are detailed in Table 6.

Table 6: Characteristics of evaluators conducting the heuristic evaluation.

	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5
Gender	Female	Male	Female	Female	Male
Age [year]	28	26	30	32	37
Education	Ph.d. (Cand.Scient)	Research Assistant (Cand.Scient)	Research Assistant (Cand.Scient)	Ph.d. (Cand.Scient)	Associate Professor (Cand.Scient)
Heuristic evaluations performed [number]	5+	0-5	5+	5+	0-5

The evaluators identified a total of 52 problems, identifying between 8 and 16 problems during their assessment. A comprehensive list of all 52 problems is provided in Appendix D. Figure 20 provides an overview of the identified problems, categorized by severity according to Jakob Nielsen's 10 usability heuristics as assessed by the evaluators.

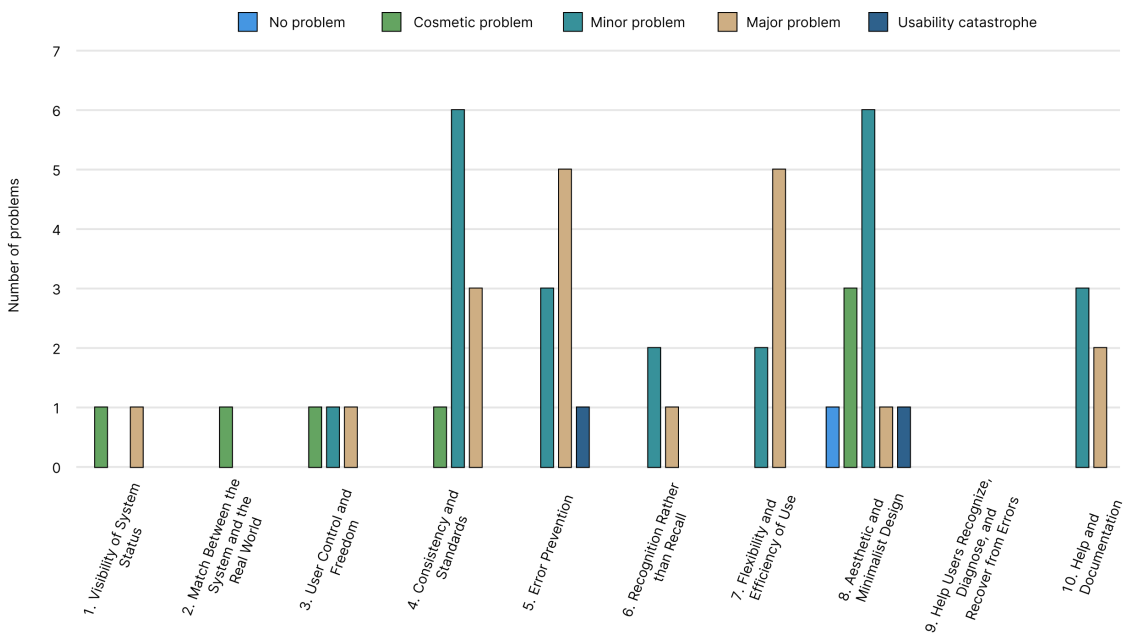


Figure 20: Distribution of the 52 identified usability problems across Jakob Nielsen's 10 heuristics (x-axes), along with their corresponding severity levels as assessed by the evaluators. The most frequently cited heuristics were *4. Consistency and Standards* with a total of 10 problems (19.2%), *5. Error Prevention* with 9 problems (17.3%), and *8. Aesthetic and Minimalist Design* with 12 problems (23.1%).

From the performed debriefing session, three positive and three critical problems were identified. The three positive aspects were all related to the design of ReLinkee. First, the minimalist design helped users to focus on the content. Second, the aesthetics made ReLinkee feel credible. Third, the consistent use of icons and uniform presentation of text made ReLinkee easier to navigate and improved the discoverability of information.

The first critical problem was that the presented trial timeline was not intuitive. The evaluators found the timeline difficult to estimate how much time that needed to set aside for the trial and how frequently participation was needed. Second, during the registration process, the information about which trial the user was signing up for disappeared. Furthermore, there was no option to cancel the registration, and a lack of clarity about what would happen after registration. Lastly, the video content did not meet the expectations of the evaluators. The video failed to clearly explain the purpose, execution, and expected outcome of the trial. The insights from the debriefing will be used to improve ReLinkee in the next iteration.

6 Iteration 2

The identified problems during the heuristics evaluation in iteration 1 will guide improvements to ReLinkee. These improvements will be refined through analysis, design, and implementation, followed by evaluation using an A/B test and a usability test, as illustrated in Figure 21. The focus during iteration 2 will be the *homepage*, *about page*, and *confirmation pop-up window*.

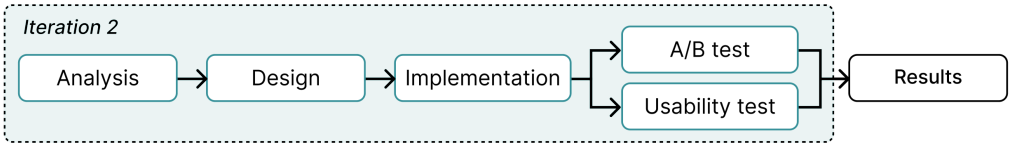


Figure 21: Iteration 2 illustrating the process of analysis, design, and implementation, followed by parallel evaluation through A/B and usability testing. The outcomes of these tests were incorporated into the results.

6.1 Analysis

As outlined in Section 5.4, 52 problems were identified during the heuristic evaluation, including the three most critical problems highlighted by the evaluators. These identified problems were intended to inform the improvements to ReLinkee. However, due to the ethical approval granted by the Scientific Ethics Committee for the North Jutland Region, it was not possible to directly address 38 of the 52 problems, as doing so would have violated the ethical approval of the *trial page*. As a result, this analysis focused on the problems related to aspects other than the *trial page*. Consequently, of the 52 problems identified, 14 were eligible for further analysis and were categorized into eight system requirements presented in Table 7.

Table 7: Unique ID (SRS-2.X) for each requirement with a description in the detailed requirement.

ID	Detailed requirement
SRS-2.1	The system must indicate currently ongoing trials on the *homepage*.
SRS-2.2	The system must use consistent terms for clarity.
SRS-2.3	The system must use consistent buttons for clarity.
SRS-2.4	The system must present illustrations useful for the trial purpose and provide additional information.
SRS-2.5	The system must provide a clear, visible address.
SRS-2.6	The system must inform the participant which trial they are signing up for upon completing the registration.
SRS-2.7	The system must have a withdrawal option.
SRS-2.8	The system must provide clear and comprehensive information on the *about page*.

6.2 Design

The design was based on the eight system requirements outlined in Table 7. These requirements were related to the *homepage*, *about page*, and *confirmation pop-up window*, which will be elaborated below.

6.2.1 Homepage

The *homepage* was designed to indicate whether a trial was actively recruiting participants. To fulfill SRS-2.1, an icon was placed on the clinical trial illustration to indicate that the trial was ongoing. Additionally, the design of the *homepage* revolved around using consistent terms, buttons, useful illustrations, and a visible address to fulfill SRS-2.2, SRS-2.3, SRS-2.4, and SRS-2.5. A low-fidelity design of the *homepage* is presented in the Figure 22.

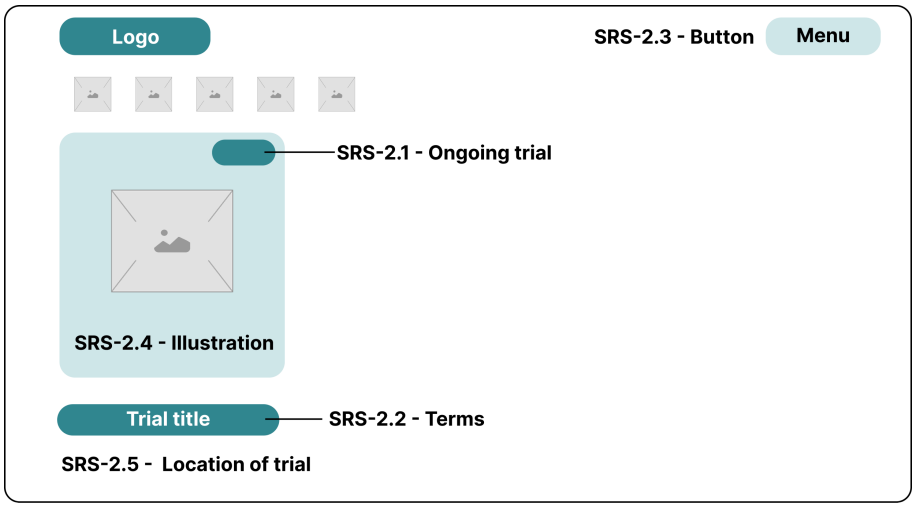


Figure 22: A low-fidelity design of the *homepage*, where icons and boxes serve as placeholders for content. Each design element is linked to the corresponding SRS.

6.2.2 About page

The *about page* was designed to fulfill SRS-2.8, to establish credibility by ensuring participants could identify and trust ReLinkee. Furthermore, the *about page* was designed with an emphasis on the consistent use of terminology to enhance clarity and the inclusion of meaningful illustrations, in alignment with requirements SRS-2.2 and SRS-2.4. A low-fidelity design of the *about page* is presented in the Figure 23.

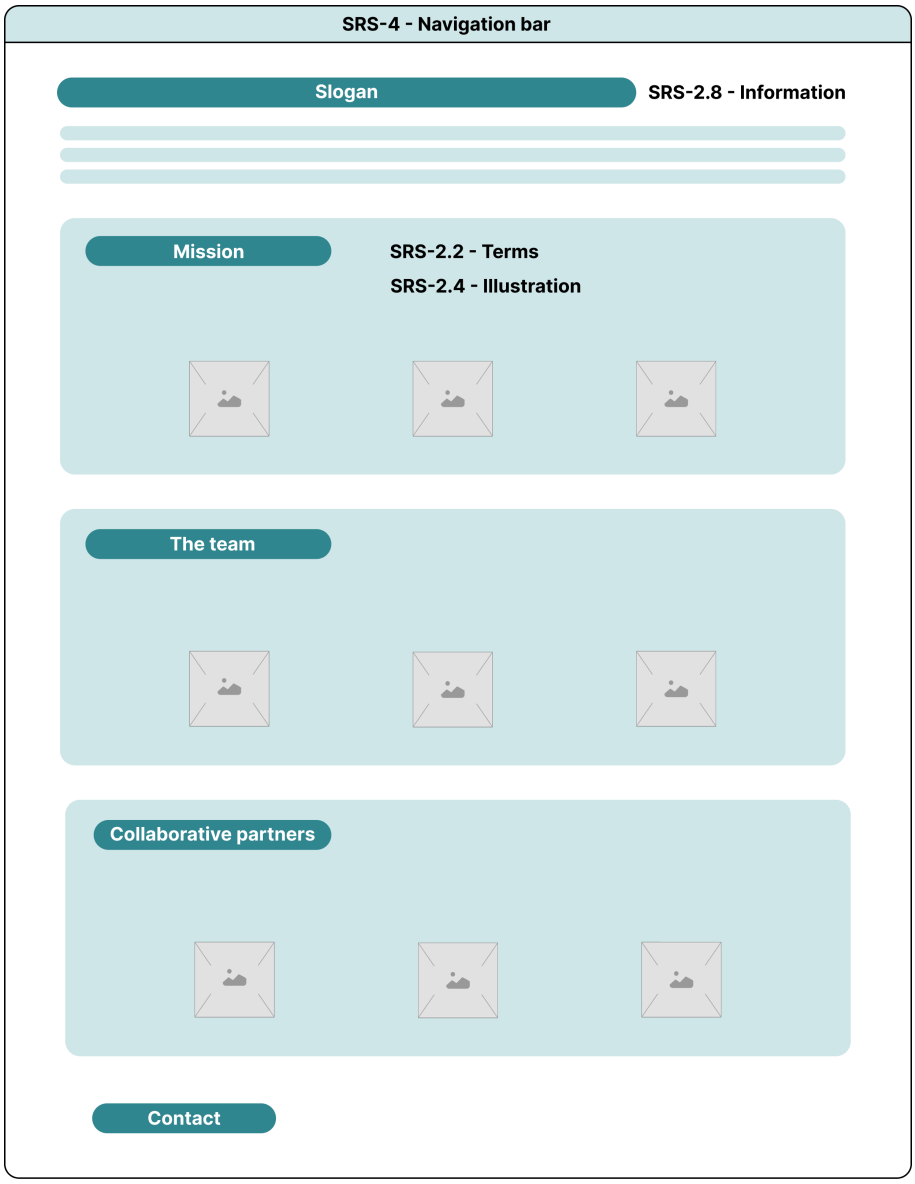


Figure 23: A low-fidelity design of the *about page*, where icons and boxes serve as placeholders for content. Each design element is linked to the corresponding SRS.

6.2.3 Confirmation pop-up window

The design of the *confirmation pop-up window* was aligned with requirement SRS-2.7 by incorporating a withdrawal option. Additionally, requirement SRS-2.6 was considered, ensuring that the Website informed the participants about the specific trial upon completion of the registration process. A low-fidelity design of the *confirmation pop-up window* is illustrated in Figure 24.

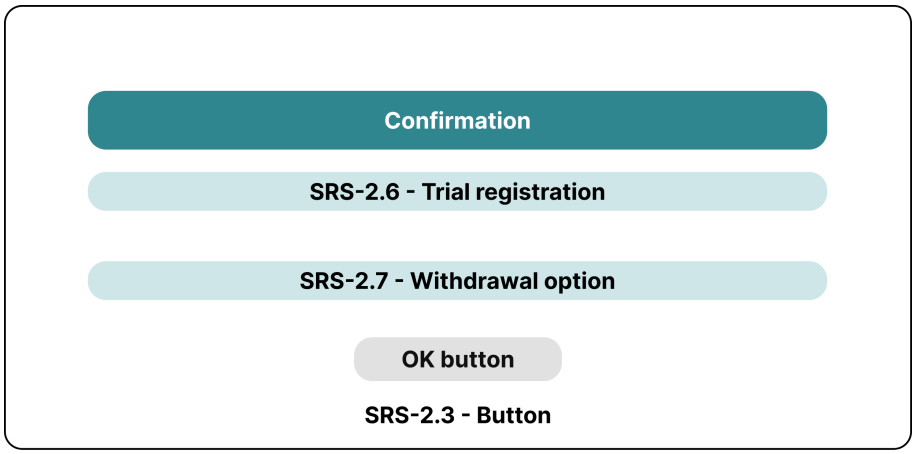


Figure 24: A low-fidelity design of the *confirmation pop-up window*, where icons and boxes serve as placeholders for content. Each design element is linked to the corresponding SRS.

6.3 Implementation

The Website was implemented according to the design of the *homepage*, *about page*, and *confirmation pop-up window*. The design was implemented in the Microsoft Azure Solution, utilizing two integrated services: *Web App* and *Application Insights*, with an underlying *Privacy Control* layer, as illustrated in Figure 25.

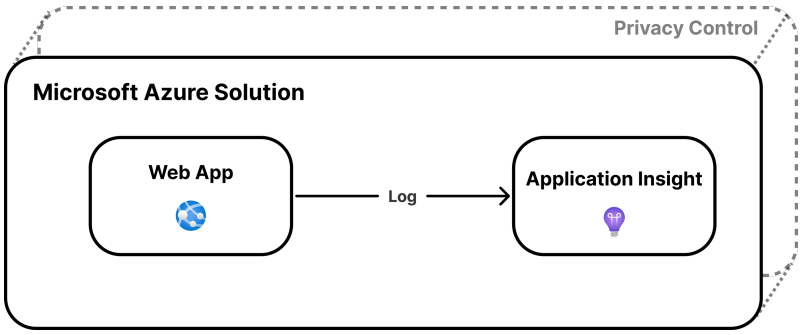


Figure 25: An architectural diagram illustrating the implementation of the recruitment solution in Microsoft Azure. The architecture comprises two services supported by an underlying privacy control layer.

6.3.1 Homepage

The implementation of the *homepage* was based on the presented design, with particular emphasis on the "Tilmelding åben" icon to indicate that the trial was actively recruiting participants, as illustrated in Figure 26. A filtering functionality was implemented, allowing participants to filter trials based on location. This aimed to make the identification of relevant trials easier for potential participants.

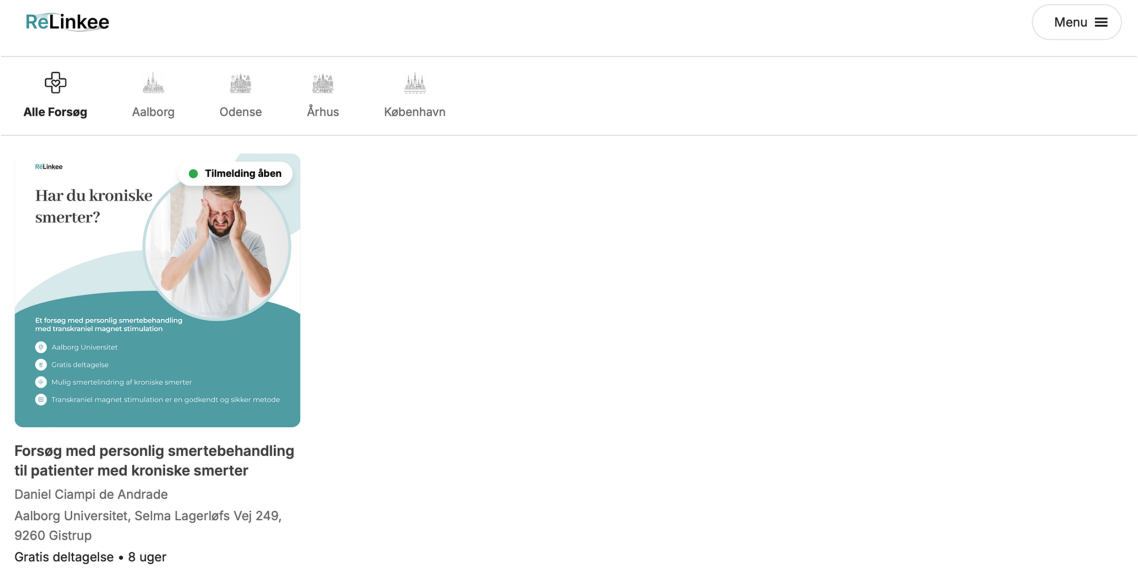


Figure 26: A screenshot of the implemented *homepage* available at: `https://relinkee.dk/HomePage`.

6.3.2 About page

The implementation of the *about page* was carried out according to the proposed design, which emphasized the importance of clearly communicating the mission of ReLinkee, identifying the founders of the company, and highlighting key collaborators. Additionally, the *about page* was implemented with a focus on consistent use of terminology to enhance clarity, as well as the inclusion of meaningful illustrations to support user understanding. An illustration of the implemented *about page* is presented in Figure 27.

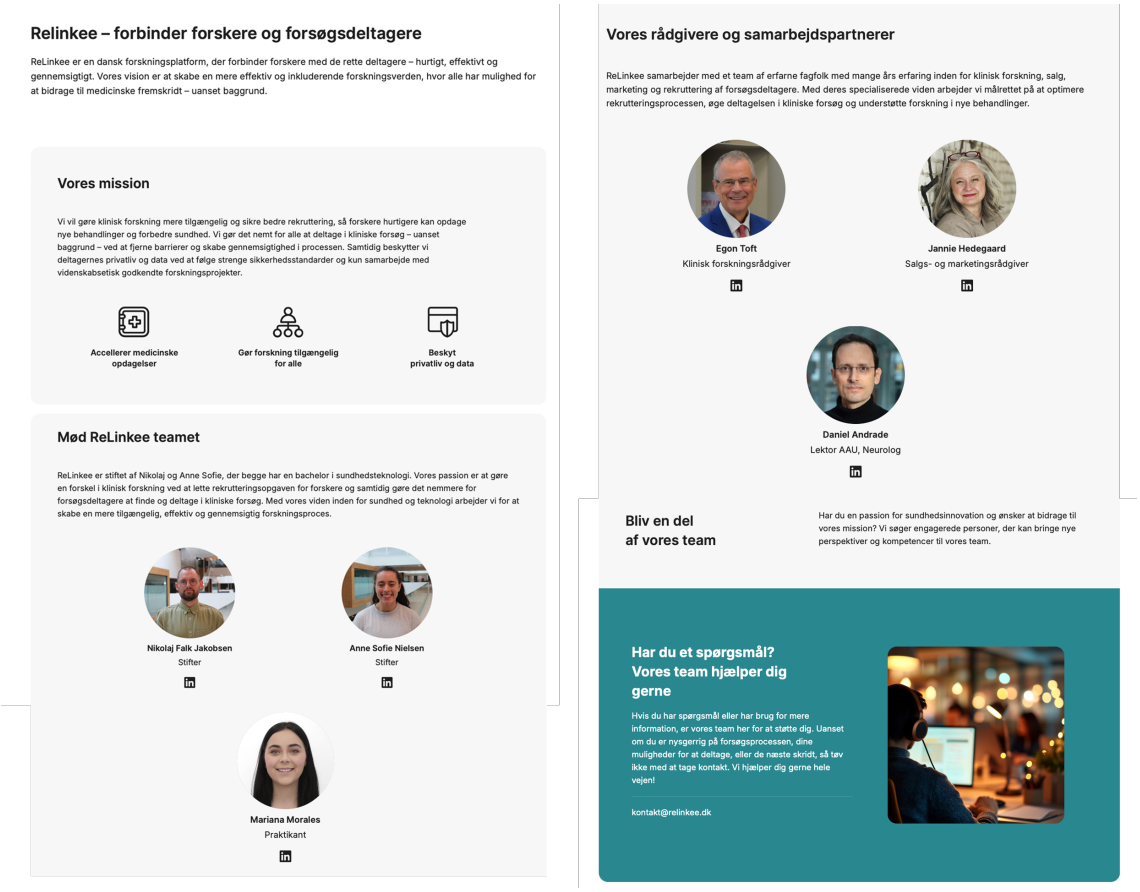


Figure 27: A screenshot of the implemented *about page* available at: `https://relinkee.dk/AboutPage`.

6.3.3 Confirmation pop-up window

The design of the *sign-up form* in iteration 1 and the *confirmation pop-up window* in iteration 2 were presented to the collaborating researcher. In response, the researcher requested that personal data be submitted directly to their REDCap database through the researcher's existing *sign-up form*. This introduced a constraint on the implementation of the designed *sign-up form* and *confirmation pop-up window*. As a result, the designed *confirmation pop-up window* was not implemented. Instead, participants were redirected to the researchers' *sign-up form* on REDCap, which is presented in Figure 28.

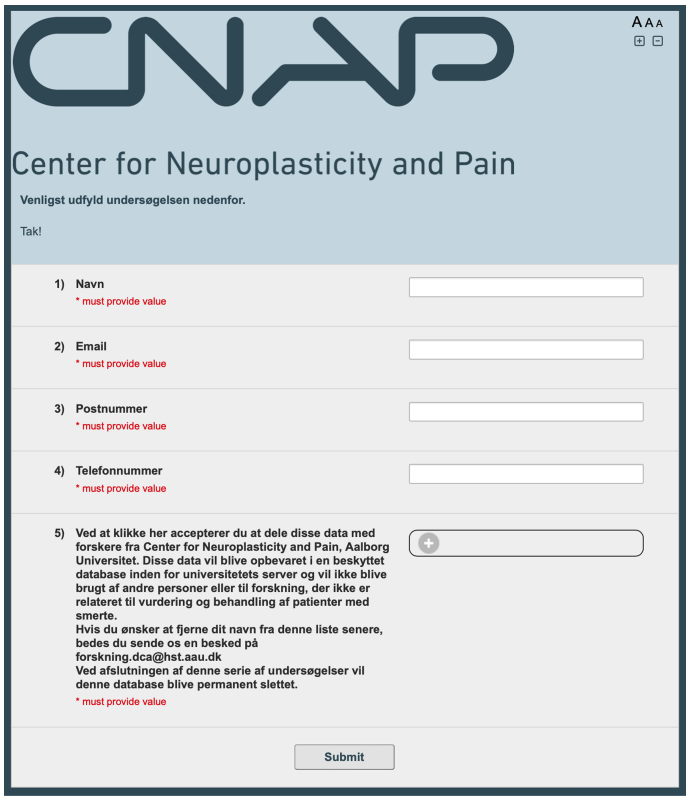


Figure 28: The *sign-up form* on REDCap provided by the collaborating researcher.

6.4 Evaluation: A/B test

An A/B test was used to determine the performance of the two *trial pages*, version A created by the research team behind the trial and version B designed by the team behind ReLinkee. The two *trial pages* can be found in Appendix B.

Purpose

The purpose of the A/B test was to evaluate whether version B led to more eligible participants being recruited compared to version A by investigating participant enrollment. To evaluate this, the following null and alternative hypotheses were formulated:

- Null hypothesis: There is no difference in participant enrollment between version A and version B.
- Alternative hypothesis: There is a difference in participant enrollment between version A and version B.

To interpret participant enrollment, the metric conversion rate was employed. The conversion rate was described as the proportion of participants who were successfully recruited out of the total number of unique users on the Website. This metric served as an indicator of the effectiveness of each version in encouraging user engagement. The calculation for the conversion rate was:

$$ConversionRate_{Version} = \frac{\text{Number of participants enrolled}}{\text{Number of unique users on the Website}} \times 100$$

In addition to the conversion rate, three other metrics were used to evaluate specific aspects of the A/B test: recruitment rate, social media conversion rate, and cost per participant. The calculation for these metrics was:

$$RecruitmentRate_{Participant} = \frac{\text{Number of participants enrolled}}{\text{Days of active recruitment}}$$

$$ConversionRate_{SocialMedia} = \frac{\text{Number of participants enrolled}}{\text{Number of unique views on social media}} \times 100$$

$$Cost_{Participant} = \frac{\text{Cost of social media campaign}}{\text{Number of participants enrolled}}$$

Participants

Participants for the A/B test were recruited through four paid advertisements on Facebook and Instagram, targeting users based on gender (male/female), age (18-45/46+), and location (Aalborg). The four advertisements can be found in Appendix E. Upon interacting with the advertisement, users were assigned to either version A or version B of ReLinkee using a block randomization algorithm. To ensure a balanced allocation between the two versions in case of a low number of users, block sizes of 2, 4, and 6 were used, as these have been recommended by Kim et al. (2014) [49]. The sample size for the A/B test was determined through a power analysis using G*Power [50]. A two-tailed Z-test was performed with a significance level of

0.05, a power of 0.8, and a Cohen's effect size of 0.8 [51, 52]. This resulted in a total sample size of 56 participants, with 28 participants allocated to each of the two groups, one for each version.

Procedure

The A/B test began by launching the advertisements on social media. If a participant received the advertisement on Facebook or Instagram and engaged with the advertisement, the participant was directed to the *trial page* of either version A or version B. On the *trial page*, the participant could sign-up for the clinical trial through the *sign-up form*. Participants who signed up were screened by the team through a telephone conversation. The team was blinded to which version the participant had signed up for. Participants who met the trial criteria were invited to participate in the trial. To ensure the A/B test was properly designed, a pilot test with a duration of one week from March 12th to March 16th was conducted to ensure that the randomization algorithm worked as intended.

Data analysis

Statistical analyses were conducted to determine whether there was a statistically significant difference between the conversion rates. The analyses were performed using IBM SPSS Statistics. A Z-test was conducted to examine whether the difference in conversion rates was statistically significant.

6.5 Evaluation: Usability test

A usability test was used to understand participant behavior and preferences, as well as uncover opportunities for improvement when using ReLinkee.

Purpose

The purpose of the usability test was to assess how users interacted with and navigated ReLinkee to determine whether there was a difference in usability between version A and version B. To evaluate the results of the usability test, the following null hypothesis and alternative hypothesis were defined:

- Null hypothesis: There is no difference in usability between version A and version B.
- Alternative hypothesis: There is a difference in usability between version A and version B.

To evaluate these hypotheses, the System Usability Scale (SUS) was used, as this scale is a widely adopted tool for quantifying usability in software products [53]. The SUS consists of 10 questions, covering various aspects of usability, including the need for support, training, and system complexity [54]. Each question was rated on a five-point likert scale, ranging from one (strongly disagree) to five (strongly agree), allowing the participant to express their level of agreement with each statement. The 10 SUS questions applied can be found in Appendix F.

Participants

Participants for the usability test were selected based on the following criteria: age between 18 to 80 years, suffering from chronic pain (pain most days for 3 months or longer), and speaking Danish or English, as these represent the criteria for the trial presented on ReLinkee [55]. To promote balanced group distribution, participants were stratified by gender to encourage equal gender representation in each group. Within each group, participants were randomly assigned to either version A or version B. The characteristics of each group were assessed using a nine-question survey based on Salvendy and Karwowski [34, p.986-988]. These questions were used to evaluate group similarity and describe the sample's representativeness of the broader population. The measured characteristics encompassed gender, age, culture, educational level, digital skills, previous experience with clinical trials, and the personality characteristics: confidence in using new digital platforms and perception of other people's intentions. The nine questions can be found in Appendix G.

The sample size for the usability test was determined through a power analysis using G*Power [50]. Based on the assumption by Suria et al. (2024) [56] that SUS scores are not normally distributed, a non-parametric two-tailed Wilcoxon-Mann-Whitney test was conducted. The test was performed with a significance level of 0.05, a power

of 0.8, and a Cohen's effect size of 0.8 [51, 52]. This resulted in a total sample size of 60 participants, with 30 per group.

Procedure

The usability test was conducted in a neutral setting with a facilitator from the team instructing the participant. The test began by informing the participant about the procedure and signing informed consent. This was followed by capturing the nine questions about participant characteristics. Afterward, the participant was guided through three task scenarios, which were designed to simulate real user interactions on ReLinkee and conducted on the participant's mobile phone. The first task was to find a clinical trial on ReLinkee. The second task was to sign-up for the trial, and the third task was to find information about the company's mission. After completing the tasks, the participants were asked to answer a SUS questionnaire at the end of the test. A pilot test of the procedure was conducted with a total of 3 participants (1 male, 2 females, mean age 27 years) from Aalborg University. One participant tested version A, while two participants tested version B.

Data analysis

Statistical analyses were conducted on participant characteristics and SUS scores for the two versions. To perform the statistical analyses, the tool IBM SPSS Statistics was used. A Shapiro-Wilk test was performed to assess whether the characteristics were normally distributed. The test indicated that the variable of age was normally distributed, whereas the remaining characteristics were not. Hereby, an Independent-Samples T-test was performed for the variable of age, while Chi-squared tests were conducted for the remaining characteristics to examine whether there was a statistically significant difference between the groups.

A mean SUS score was calculated based on each participant's ratings on the individual questions. The ratings on the five-point scale were converted to a score ranging from zero to four. For odd-numbered questions (1, 3, 5, 7, and 9), the contribution was calculated by subtracting one from the selected scale position. For even-numbered questions (2, 4, 6, 8, and 10), the contribution was found by sub-

tracting the rating from five. The sum of these contributions was multiplied by 2.5 to produce the SUS score, which ranges from 0 to 100, representing the overall usability of ReLinkee. A Shapiro-Wilk test was performed to assess whether the SUS scores were normally distributed. The test indicated that SUS scores were not normally distributed, therefore, a Mann-Whitney U-test was performed to examine whether there was a statistically significant difference between the groups of version A and version B.

7 Results

This section presents the results of iteration 2 based on the A/B test and the usability test described in Section 6.4 and 6.5.

7.1 A/B test

The A/B test was conducted from March 17 to April 11, allowing 26 days of advertisement exposure on social media. Version A was created by the research team behind the clinical trial, while version B was designed by the team behind ReLinkee. During this period, a total of 272 unique users visited ReLinkee, with the randomization algorithm assigning 49.6% of users to version A and 50.4% of users to version B. An overview of the user distribution between the two versions of ReLinkee is presented in Figure 29. In total, 135 users visited version A, while 137 users visited version B. For both versions, 9 users were screened, and 8 were enrolled.

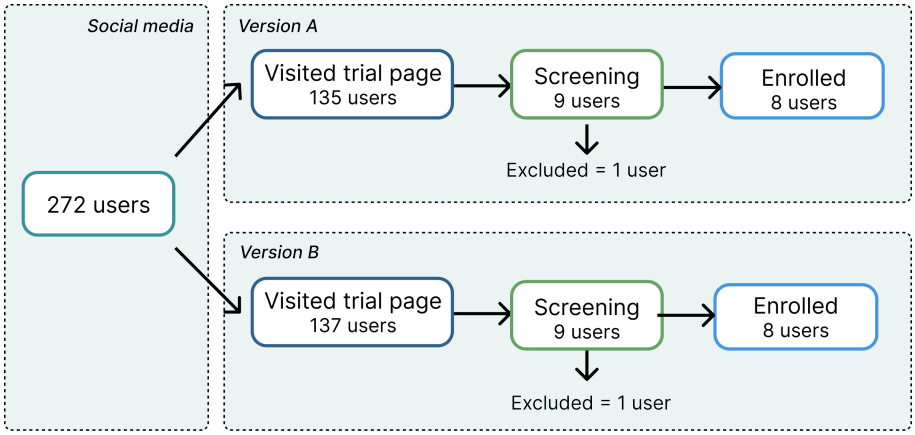


Figure 29: Users flow from initial contact through social media ads to final enrollment in the trial, including the number of users retained at each stage.

For the versions, the conversion rate was measured separately to evaluate the effectiveness of each version's ability to achieve sign-ups. The conversion rate for users who viewed version A was 5.9%, while the conversion rate for those who viewed version B was 5.8%. The calculations are presented below:

$$ConversionRate_A = \frac{8}{135} \times 100 = 5.9\%$$

$$ConversionRate_B = \frac{8}{137} \times 100 = 5.8\%$$

The performed Z-test showed a p = 0.976, which was greater than the significance level of 0.05. This implied that the null hypothesis could not be rejected, which indicated no statistically significant difference in the participant enrollment between version A and version B. An overview of these findings is presented in Table 8.

Table 8: Overview of the A/B test results, presenting the conversion rates for version A and version B and the corresponding p-value.

Metric	Version A	Version B	p-value
Conversion rate	5.9%	5.8%	0.976

7.1.1 Secondary recruitment metrics

Over the 26-day recruitment period, the advertisements on social media reached a total of 12,845 unique views. This resulted in the enrollment of 16 participants at a total cost of 1,693 kr, with 8 users from version A and version B. An overview of the recruitment process is illustrated in Figure 30

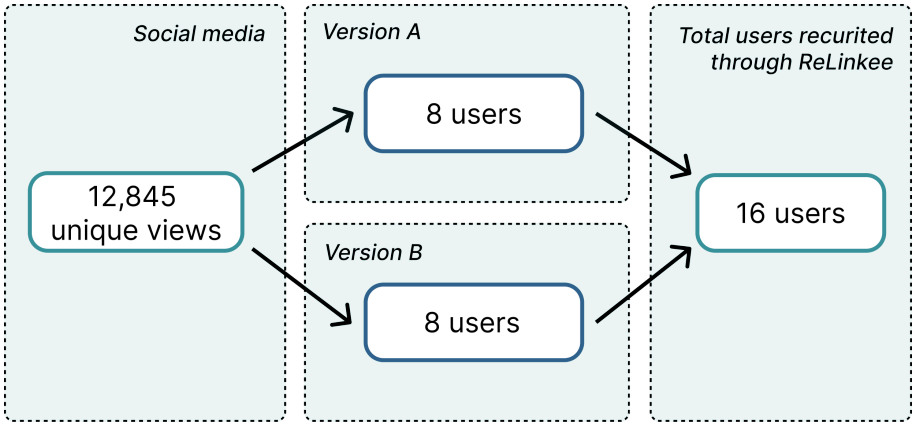


Figure 30: User flow from initial contact through social media ads to final enrollment in the trial, including the number of users retained at each stage.

The conversion rate for social media was measured to assess the effectiveness of the advertisements and the Website was found to be 0.12%. The calculation is presented below:

$$ConversionRate_{SocialMedia} = \frac{16 \text{ participants}}{12{,}845 \text{ unique views}} \times 100 = 0.12\%$$

Additionally, the recruitment rate was calculated to be 0.61 participants per day, and the cost per participant was 105 DKK. The calculations for the metrics are presented below, and an overview of these findings can be found in Table 9:

$$RecruitmentRate_{participant} = \frac{16 \text{ participants}}{26 \text{ days users}} = 0.61 \text{ participants per day}$$

$$Cost_{Participant} = \frac{1,693 \text{ kr}}{16 \text{ participants}} = 105 \text{ kr per participant}$$

Table 9: An overview of recruitment metrics: recruitment rate, social media conversion rate, and cost per participant.

Metric	Result
$RecruitmentRate_{Participant}$	0.61
$ConversionRate_{SocialMedia}$	0.12%
$Cost_{Participant}$	105 DKK

7.2 Usability test

A total of 23 participants (6 men, 17 female, mean age 53.1 years) were recruited for the usability test. All participants were Danish and reported living with chronic pain. The majority of the participants had completed an education lasting between 3-4 years. Overall, participants demonstrated strong digital skills, a positive perception of other people's intentions, and expressed confidence in using new digital platforms. Additionally, most participants reported prior experience with clinical trials. Through stratification, the six male participants were randomly allocated such that four were assigned version A and two version B. Furthermore, random allocation of the 17 female participants resulted in nine being assigned to version A and eight to version B.

Overall, the Independent-Samples T-test and the Chi-squared test showed p-values above 0.05, indicating no statistically significant differences between version A and version B across all participants' characteristics. The characteristics of the participants for each version are summarized in Table 10.

Table 10: Characteristics of version A and version B, including corresponding p-values. The statistical significance level is at $p < 0.05$.

Category	Version A	Version B	p-value
Gender	Male: 4	Male: 2	0.660
	Female: 9	Female: 8	
Mean age	52 years	54 years	0.694
Nationality	Danish: All	Danish: All	-
Chronic pain	Yes: All	Yes: All	-
Education	Folkeskole: 2		0.372
	Gymnasium: 1	Gymnasium: 2	
	Erhversudannelse: 2	Erhversudannelse: 1	
		Kort (1-2 år): 1	
	Mellem (3-4 år): 5	Mellem (3-4 år): 6	
	Lang (5-6 år): 2		
	Andet: 1		
Good intentions		Disagree: 1	0.411
		Neutral: 1	
	Agree: 6	Agree: 4	
	Strongly agree: 7	Strongly agree: 4	
Digital skills		Strongly disagree: 1	0.114
	Neutral: 2	Neutral: 1	
	Agree: 1	Agree: 4	
	Strongly agree: 10	Strongly agree: 4	
New digital platform		Strongly disagree: 1	0.755
	Disagree: 1	Disagree: 1	
	Neutral: 3	Neutral: 1	
	Agree: 5	Agree: 4	
	Strongly agree: 4	Strongly agree: 3	
Clinical trials	Strongly disagree: 3	Strongly disagree: 4	0.431
		Disagree: 1	
	Neutral: 2		
	Agree: 2	Agree: 2	
	Strongly agree: 6	Strongly agree: 3	

7.2.1 System usability scale scores

The data collected through the SUS questionnaire, as described in Section 6.5, showed a mean SUS score of 81 for version A (±19.7) and 76.5 for version B (±18.8). The performed Mann-Whitney U-test yielded a p-value of 0.446, which exceeds the significance level of $p < 0.05$. This implied that the null hypothesis could not be rejected, which indicated no statistically significant difference in the usability between version A and version B. The SUS scores for each participant in the usability test are presented in Table 11.

Table 11: The SUS scores for each user for version A and version B, including corresponding user demographics.

User	Gender	Age	Version	SUS score
1	Male	25	A	85
2	Male	45	A	95
3	Male	64	A	85
4	Male	50	A	50
5	Female	66	A	30
6	Female	63	A	95
7	Female	47	A	95.5
8	Female	44	A	95.5
9	Female	49	A	90
10	Female	69	A	90
11	Female	71	A	87.5
12	Female	39	A	75
13	Female	49	A	80
			Mean (SD)	81 (±19.7)
14	Male	38	B	85
15	Male	36	B	90
16	Female	47	B	90
17	Female	52	B	80
18	Female	56	B	82.5
19	Female	71	B	87.5
20	Female	77	B	42.5
21	Female	64	B	60
22	Female	32	B	97.5
23	Female	67	B	50
			Mean (SD)	76.5 (±18.8)

8 Discussion

This project aimed to explore how a digital recruitment system could be developed to enhance participant enrollment in clinical trials by improving user experience and leveraging social media for targeted outreach. Following the two iterations, ReLinkee was developed and evaluated through an A/B test and a usability test. The A/B test compared version A, created by the research team behind the trial, and version B, designed by the team behind ReLinkee. The evaluation engaged 272 unique users and successfully recruited 16 participants for the clinical trial presented on ReLinkee. A systematic literature search was conducted, which can be found in Appendix A, to identify relevant studies, which serve as a reference point for comparing and reflecting on the outcomes of ReLinkee.

8.1 Results: A/B test

The results from the A/B test indicated no statistically significant difference between $ConversionRate_A$ of 5.9% for version A and $ConversionRate_B$ of 5.8% for version B. A systematic review by Whitaker et al. (2017) [57] reported a median conversion rate of 4% (range 0.06%-29.50%) across 35 studies evaluating digital recruitment systems utilizing social media. The review spanned multiple countries and involved participants aged 13 and older. The study design was interventional (n=10) and observational (n=25), targeting healthy individuals and individuals with various health conditions. When comparing the $ConversionRate_A$ and $ConversionRate_B$ from ReLinkee to the conversion rate reported by Whitaker et al., version A and version B showed higher conversion rates, which suggests potentially effective recruitment. However, the wide range of conversion rates presented by Whitaker et al. indicates substantial variability, potentially influenced by the diverse trial characteristics included in the systematic review. Given this difference, it remains uncertain whether ReLinkee's observed conversion rates definitively represent recruitment performance.

A study by Miller et al. (2021) [12] explored the use of A/B testing on a recruitment website targeting adults aged 70 and above at high risk of falling, offering a vitamin D intervention. The study investigated two website versions and found conversion rates of 7.2% (original version) and 5.7% (new version), and both conversion rates were higher than those observed for ReLinkee. Several factors may explain Miller et al.'s stronger performance. Firstly, the study utilized a multimodal recruitment strategy that combined the digital platform with a non-digital approach tailored to target the older population. This approach was different from ReLinkees, which relies solely on social media as a recruitment strategy, which may not resonate as effectively with certain demographics.

Moreover, trial characteristics, such as the type of intervention and participant incentives, could also have interfered with the conversion rate. The vitamin D supplementation offered in Miller et al. is perceived as a safe and familiar intervention. In contrast, the trial presented on ReLinkee involved on-site transcranial magnetic stimulation, a procedure that may be perceived as invasive or unfamiliar. This type of intervention not only introduces logistical barriers such as transportation to the trial site but also raises potential concerns about side effects or discomfort, which may deter participation. Lastly, Miller et al. offered financial incentives of $40 for each of the three follow-up visits, which could have served as an additional motivator, enhancing the conversion rate. These differences underscore how the perceived burden and benefits of participation, as well as the framing of the intervention, can significantly influence conversion rates across studies.

8.1.1 ReLinkee recruitment efficiency

ReLinkee achieved a $RecruitmentRate_{Participant}$ of 0.61 participants per day, a $ConversionRate_{SocialMedia}$ of 0.12%, and a $Cost_{Participant}$ of 105 DKK. By comparison, a study by Aily et al. (2023) [58] recruited participants with knee osteoarthritis for a 12-week online training intervention using a Facebook-based strategy. The study achieved a $RecruitmentRate_{Participant}$ of 0.21 participants per day over 151 days, a $ConversionRate_{SocialMedia}$ of 0.09% (32 participants from 33,319 unique users), and a $Cost_{Participant}$ of approximately 340 DKK (USD 51.94) per partici-

pant. Although Aily et al. and the trial presented on ReLinkee targeted similar participant populations and used social media recruitment, ReLinkee outperformed Aily et al. across all three metrics. ReLinkee recruited participants nearly three times faster and at roughly one-third of the cost per participant. The improved performance metrics may be attributed to ReLinkee, however, trial-specific characteristics could also be influential. Aily et al. targeted participants with knee osteoarthritis, a condition with a global prevalence of 16% [59]. This prevalence is lower than the global prevalence of chronic pain (30%) [60], which is the target population for the trial presented on ReLinkee. This broader target population for ReLinkee likely provided a larger participant pool, potentially contributing to the enhanced performance metrics for ReLinkee.

Another trial-related characteristic that may have influenced the results could be the distinction between online and in-person interactions. Aily et al. conducted a 12-week online intervention, recruiting participants across the United States. This format allowed for broader reach and potentially greater accessibility. In contrast, the trial presented on ReLinkee was conducted in person over eight weeks in Aalborg, relied on a geographically limited area. Despite the broader reach with the online recruitment strategy used by Aily et al., ReLinkee yielded better results. While the broader reach in Aily et al. likely gave access to a larger participant pool, this did not translate into better recruitment performance. Additionally, a study by Cowie et al. (2018) [61] targeted healthy adults (aged 60 years and older) for a Phase 1 pharmaceutical trial, recruiting 45 participants over 56 days. The study reported a $RecruitmentRate_{Participant}$ of 0.80, a $ConversionRate_{SocialMedia}$ of 0.03% (142,228 unique users reached), and a $Cost_{Participant}$ of 988 DKK (total recruitment cost of USD 6,770). While Cowie et al. achieved a higher participant recruitment rate than ReLinkee, the study's approach was less effective at converting social media reach into enrolled participants, and the cost per participant was nine times more expensive than ReLinkee. The trial-related characteristics described in Cowie et al. may have influenced the recruitment performance, with factors such as restrictive eligibility criteria and the intensity of the intervention potentially playing a role. The study employed stringent inclusion and exclusion criteria, targeting healthy in-

dividuals aged 21 to 45 within specific BMI parameters and excluding participants with various medical conditions. The intervention also involved an intensive ten-day in-clinic stay with daily assessments, testing, and medication administration. Contrary, the trial presented on ReLinkee had broader eligibility criteria, recruiting individuals aged 18 to 80 with chronic pain, with a less extensive list of exclusions. The clinical trial, presented on ReLinkee, was conducted over eight weeks, generally involved shorter contact times. The highly selective eligibility criteria and the demanding ten-day in-clinic intervention in Cowie et al. likely account for their lower social media conversion rate and higher cost per participant.

Collectively, these findings emphasize that, while ReLinkee seems to demonstrate greater recruitment efficiency, direct comparisons with other trials should be made with caution. The efficacy of recruitment is determined not only by the system design but also by trial characteristics such as the target population, inclusiveness of eligibility criteria, and intervention burden. These factors can vary between trials and influence the recruitment efficiency metrics.

8.2 Results: Usability test

The usability test involved 23 participants, aged 25 to 77 years, with 60% having completed a higher education. The usability test resulted in mean SUS scores of 80.5 for version A and a mean SUS score of 76.5 for version B, with no statistically significant difference between the two versions. To further interpret these results, the SUS scores were compared against the commonly accepted benchmark of 68 and the usability acceptability ranges proposed by Bangor et al. (2008) [62]. The versions exceeded the numerical benchmark, placing version A and version B within the acceptable range (mean SUS score > 70) of Bangor et al. scale, indicating an acceptable level of usability [63, 64].

In comparison, a study by Valerian et al. (2018) [63] evaluated the usability of an old and new version of a university website with 30 participants aged 15-60 years, reporting SUS scores of 54 (old) and 70 (new). While the study showed improved usability with the new design exceeding the benchmark, neither version reached

the acceptable range according to Bangor et al. [62], as the SUS scores are within the marginal range (between 50 and 70). A further comparison can be made with the study by Hopstock et al. (2022) [64], which evaluated a web-based dietary assessment tool involving 60 participants aged 60–74, the majority of whom had higher education (73.3%). The study reported a mean SUS score of 55.5, falling below the accepted benchmark of 68 and remaining within the marginal usability range. Although Valerian et al. and Hopstock et al. reported lower mean SUS scores than those obtained for versions A and B of ReLinkee, this does not necessarily imply that ReLinkee offers a better user experience. The reliability of SUS scores is known to be influenced by various participant characteristics, such as prior experience with similar systems, trust in other people, and openness to new experiences have all been shown to significantly affect usability ratings [65, 66]. These characteristics were not reported in either Valerian et al. or Hopstock et al., making it unclear whether the characteristics influenced users' perceptions and interactions with digital systems. However, the usability test of ReLinkee included these characteristics, as outlined in Section 7.2 in Table 10, with participants reporting higher levels of prior experience with clinical trials, a strong willingness to try new experiences, and a general belief in the good intentions of others. These characteristics may have contributed to the higher SUS scores observed for ReLinkee.

8.3 Limitation of ReLinkee

ReLinkee engaged 272 unique users, indicating promising visibility and initial interest. However, this did not result in a proportional number of sign-ups, raising questions about the effectiveness of the two design versions.

The A/B test resulted in nearly identical conversion rates, which is difficult to interpret due to the lack of detailed user information for each version. One limitation was the lack of demographic or behavioral data on users exposed to each version. Given the equal conversion rates, it would have been valuable to analyze whether the users differed in meaningful ways, such as gender, age, personal characteristics, and experience with the product. Without insights into these characteristics, it is unclear whether the A/B test reached homogeneous or heterogeneous groups. This absence

of user insight reduces the interpretability of the A/B test results and underscores the need for detailed user profiling in future studies to support reliable conclusions. However, one characteristic shared by all participants is their active presence on social media, indicating a high level of comfort with digital platforms. This may have contributed to the nearly identical conversion rates observed between version A and version B, as the participants' comfort with technology likely minimized the impact of design changes on their attitudes toward using ReLinkee. Another limitation of conducting the A/B test was the inability to identify which individual design changes influenced user responses, as multiple elements were modified simultaneously, and no element was tested in isolation. This design complexity made it difficult to identify what worked and what did not. Even if one version had outperformed the other, the absence of variable control made it challenging to attribute that difference to a particular design element.

The usability test provided valuable insights into how users navigated and experienced ReLinkee. However, several factors may have influenced the results and should be considered when interpreting the findings. As highlighted in a study by Aiyegbusi et al. (2020) [67], the level of facilitator involvement is an important methodological consideration during the usability test. In cases where participants were guided through specific tasks or received verbal information, there is a risk that their natural interaction with the interface was altered, particularly when users encountered difficulties or were unable to complete tasks independently. Aiyegbusi et al. suggest several strategies to account for such influences. One approach that could have been applied during the usability test is the collection of data on task failures and completion rates. This would have provided quantitative metrics to identify specific interactions or tasks that posed usability challenges for participants. Furthermore, the presence of an observer during testing introduces a potential source of bias. Being watched can affect how participants behave, particularly in situations where they may feel judged or evaluated. Ideally, usability testing would occur under conditions that minimize external influence, allowing participants to engage with the interface as naturally as possible. This external influence may have contributed to positive user experiences and, consequently, to higher SUS scores.

Another limitation relates to the composition of the sample group. As presented in Section 7.2 in Table 6, participants in the usability test reported high technical proficiency, a positive perception of other people's intentions, and a positive attitude toward new technologies. These factors likely contributed to an elevated mean SUS score, whereas a different sample group with lower technical proficiency may not have achieved a similarly high mean SUS score. It remains uncertain whether the group is representative of the broader population of individuals with chronic pain.

9 Conclusion

A digital recruitment system was developed using an agile software development process and based on requirements gathered from participants, the researcher, and the company behind ReLinkee. Through targeted outreach on social media, ReLinkee engaged 272 users and successfully recruited 16 participants for the clinical trial presented on ReLinkee. Additionally, ReLinkee received usability ratings, with mean SUS scores of 81 (version A) and 76.5 (version B), indicating an acceptable level of user satisfaction.

Neither the A/B test nor the usability test revealed statistically significant differences between the two versions, indicating no enhancement in participant enrollment and no improvement in user experience. Although ReLinkee did not significantly improve participant enrollment, the findings indicate a promising potential in leveraging social media to reach and engage participants. However, the acceptable mean SUS scores may be influenced by participant characteristics, which could limit the generalizability of the results. The characteristics include positive perception of other people's intentions and positive attitudes towards new technologies, and strong digital competencies.

Future research should be focused on refined targeting strategies to optimize performance outcomes by aligning recruitment efforts with user preferences and behaviors. Additionally, evaluations should be conducted in more representative populations, including individuals with a more neutral attitude towards new technologies.

10 Collaboration portfolio

This master's thesis integrated the team's accumulated experiences from prior semesters and project work. The collaboration portfolio places particular emphasis on articulating the competence-based learning objectives.

Project management and planning

This project was structured using a Gantt chart, providing a visual representation of the project timeline, including tasks, durations, and deadlines. At the beginning of the project, the team used backcasting to define the goals and traced the necessary steps in reverse, which encouraged a thoughtful approach to organizing milestones in a logical order and distributing responsibilities. This approach helped to set realistic deadlines and allocate resources effectively. As the project progressed, the Gantt chart proved to be more than just a chart. The chart became a way to continually assess the direction of the project, identify when adjustments were needed to avoid bottlenecks, and ensure that tasks remained aligned with the goals, thereby the team maintained progress and stayed on track throughout the project.

Throughout the project, there were a few times the team had to adjust the time allocated to certain tasks. This was due to either underestimating the scope of the tasks or misjudging the time to tackle the tasks. The team used different colors in the Gantt chart to track these adjustments and mark whether the adjustment was a delayed start or an extension. These added colors helped the team visualize how the adjustments impacted the current workload and upcoming tasks. Furthermore, it allowed the team to reflect on the planning process and improve the ability to prioritize and allocate time more effectively moving forward. The Gantt chart is illustrated in Figure 31.

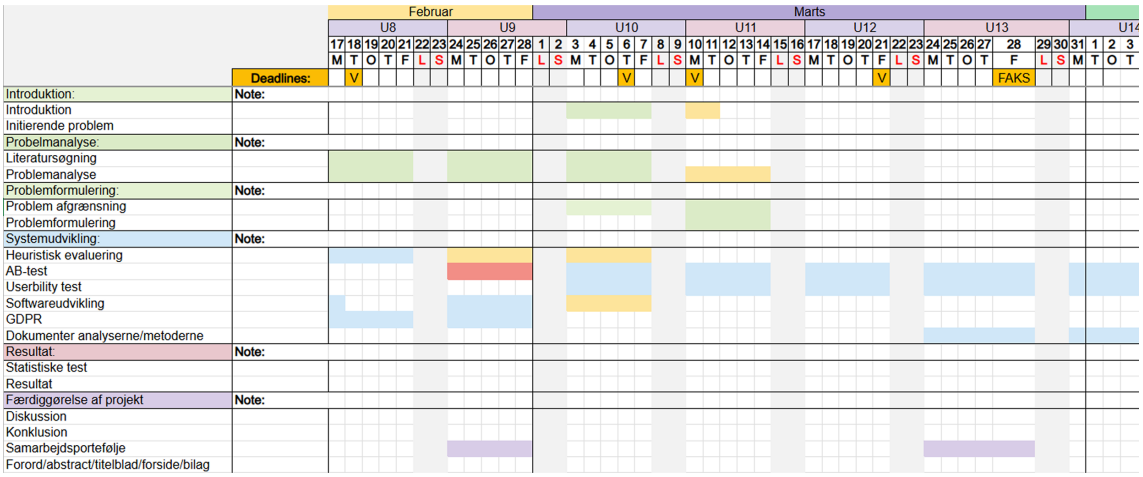


Figure 31: Gantt chart illustrating project tasks and their scheduled timeframes. Each task is color-coded for clarity, with bar lengths representing task duration. Red bars indicate tasks with delayed starts, while yellow bars denote tasks that were extended. Abbreviations: V = vejledermøde, SS = statusseminar.

In addition to the Gantt chart, the team also used a shared calendar as a practical tool for coordinating group and individual activities. This allowed the team to align the efforts while remaining mindful of personal responsibilities, which proved essential in managing the complexity of the project. Having a transparent overview of everyone's availability not only reduced the risk of scheduling conflicts but also encouraged a more considerate and accountable team dynamic. The ability to update and adapt the calendar gave the team the flexibility to plan around unforeseen changes without losing progress throughout the project.

Supervisors and external involvement

The team collaborated with a primary and a secondary supervisor, as well as a researcher whose ongoing trial was crucial in shaping the platform. Each supervisor provided guidance in their respective area. The primary supervisor provided expertise in usability and methodological approaches, while the secondary supervisor offered expertise within technical development and legal compliance. While this multi-perspective support enriched the project, it also resulted in numerous meetings and a broad range of inputs that occasionally made it challenging to navigate priorities and maintain a clear direction. To manage this complexity, the team prioritized internal alignment by regularly debriefing after meetings to discuss the

feedback received, assess the relevance to the project's goals, and decide collectively which suggestions to implement. This helped ensure that input was integrated thoughtfully, allowing the team to stay focused while still benefiting from diverse perspectives.

In addition to the feedback from supervisors and the researcher, the team also received input from external participants through the heuristic evaluations, A/B testing, and usability tests conducted by the team. These activities generated valuable user-centered insights that prompted the team to critically reassess design choices, refine key functionalities, and ensure the platform aligned more closely with the needs of the intended users. This iterative process not only improved the quality of the recruitment system but also deepened the team's understanding of how to integrate user feedback meaningfully into system development.

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12 Appendix

A Systematic literature search

A systematic literature search was conducted following the methodology outlined by Bartels et al. (2013) [68], which provides a framework for performing systematic and organized literature searches. The first step involved defining the research question, which is presented below:

What is known about the efficiency and user experience of digital platforms used for the recruitment of participants in clinical trials?

Based on the research question, five concept areas were identified to guide and structure the literature search: *Efficiency*, *User experience*, *Digital platforms*, *Recruitment*, and *Clinical trial*. Through an unstructured search, relevant synonyms and related terms for each concept were identified. The systematic literature search was performed across different search engines and biomedical databases, including PubMed and Embase. Together, these databases cover approximately 90% of medicine and health-related topics, ensuring the identification of relevant articles on participant recruitment for clinical trials [69]. In addition, the IEEE database was employed to identify high-quality technical and engineering publications [70]. For each database, a search strategy was developed by structuring the identified synonyms and related terms using the boolean operator 'OR' and grouping elements using parentheses, and combining the concept areas using the boolean operator 'AND'. This structured approach allowed for the systematic retrieval of approximately 200 articles, which is considered a reasonable number to review by looking at titles and abstracts [68].

The literature search was conducted on May 1, 2025, and is documented in the five search tables presented below. The search was divided into two main parts: the first focusing on *Efficiency*, and the second on *User Experience*. To ensure the relevance of the records, all searches were filtered to include only articles written in English and published within the last 10 years (2015–2025). After each table, the specific search string used is provided, along with the total number of records retrieved.

PubMed:

PubMed			
Efficiency	Digital platforms	Recruitment	Clinical trials
"conversion rate" [tiab] OR "engagement rate" [tiab] OR "cost-effective" [tiab]	"Internet-Based Intervention"[MeSH] OR website[tiab] OR web-based[tiab] OR "social media"[tiab]	"Patient Selection"[MeSH] OR "recruit*"[ti] OR enrollment[ti] OR accrual[ti]	"Biomedical Research"[MeSH] OR "clinical trial*" [tiab] OR "health research"[tiab]
95,431 results	**88,256 results**	**32,403 results**	**425,988 results**

The applied search string was:

("conversion rate" [tiab] OR "engagement rate" [tiab] OR "cost-effective" [tiab]) AND ("Internet-Based Intervention"[MeSH] OR website[tiab] OR web-based[tiab] OR "social media"[tiab]) AND ("Patient Selection"[MeSH] OR "recruit*"[ti] OR enrollment [ti] OR accrual[ti]) AND ("Biomedical Research"[MeSH] OR "clinical trial*" [tiab] OR "health research"[tiab])

Results: 38 records

PubMed			
User experience	Digital platforms	Recruitment	Clinical trials
"User-Centered Design"[MeSH] OR "usability"[tiab] OR "user experience"[tiab] OR "a/b test*"[tiab]"	"Internet-Based Intervention"[MeSH] OR website[tiab] OR web-based[tiab] OR "social media"[tiab])	"Patient Selection"[MeSH] OR "recruit*"[tiab] OR enrollment[tiab] OR accrual[tiab]	"Biomedical Research"[MeSH] OR "clinical trial*" [tiab] OR "health research"[tiab]
25,107 results	**88,256 results**	**32,403 results**	**425,988 results**

The applied search string was:

("User-Centered Design"[MeSH] OR usability[tiab] OR "user experience"[tiab] OR "a/b test*"[tiab]) AND ("Internet-Based Intervention"[MeSH] OR website[tiab] OR web-based[tiab] OR "social media"[tiab]) AND ("Patient Selection"[MeSH] OR "recruit*"[ti] OR enrollment [ti] OR accrual[ti]) AND ("Biomedical Research"[MeSH] OR "clinical trial*" [tiab] OR "health research"[tiab])

Results: 10 records

Embase:

Embase			
Efficiency	Digital platforms	Recruitment	Clinical trials
'conversion rate':ti,ab OR 'engagement rate':ti,ab OR 'cost effective':ti,ab	website:ti,ab OR 'web based':ti,ab OR 'social media':ti,ab	recruit*:ti OR enrollment:ti OR accrual:ti	'clinical trial*':ti,ab OR 'health research':ti,ab
127,644 results	**114,551 results**	**22,195 results**	**517,320 results**

The applied search string was:

('conversion rate':ti,ab OR 'engagement rate':ti,ab OR 'cost effective':ti,ab) AND (website:ti,ab OR 'web based':ti,ab OR 'social media':ti,ab) AND (recruit*:ti OR enrollment:ti OR accrual:ti) AND ('clinical trial*':ti,ab OR 'health research':ti,ab) AND [english]/lim AND [2015-2025]/py

Results: 31 records

Embase			
User experience	Digital platforms	Recruitment	Clinical trials
usability:ti,ab OR 'user experience':ti,ab OR 'a/b test*':ti,ab	website:ti,ab OR 'web based':ti,ab OR 'social media':ti,ab	recruit*:ti,ab OR enrollment:ti,ab OR accrual:ti,ab	'clinical trial*':ti,ab OR 'health research':ti,ab
29,516 results	**114,551 results**	**22,195 results**	**517,320 results**

The applied search string was:

(usability:ti,ab OR 'user experience':ti,ab OR 'a/b test*':ti,ab) AND (website:ti,ab OR 'web based':ti,ab OR 'social media':ti,ab) AND (recruit*:ti OR enrollment:ti OR accrual:ti) AND ('clinical trial*':ti,ab OR 'health research':ti,ab) AND [english]/lim AND [2015-2025]/py

Results: 10 records

IEEE:

IEEE		
Digital platforms	Recruitment	Clinical trials
"digital platform" OR website OR "web-based" OR "web platform" OR "social media"	"recruit*" OR "enrollment" OR "accrual"	"clinical trial*" OR "clinical research" OR "medical studies" OR "healthcare trials" OR "health research"
81,324 results	**11,918 results**	**6,014 results**

The applied search string was:

("digital platform" OR "website" OR "web-based" OR "web platform" OR "social media") AND ("recruit*" OR "enrollment" OR "accrual") AND ("clinical trial*" OR "clinical research" OR "medical studies" OR "healthcare trials" OR "health research")

Results: 8 records

While these three databases provided access to relevant literature, the selection of articles was further refined using inclusion and exclusion criteria to ensure alignment with this project. Exclusion criteria were applied to eliminate literature not relevant to the research question. The criteria are presented in Table 12.

Inclusion	Exclusion
Articles which are written in English	Articles where full text is not accessible
Articles published within the last 10 years	Articles which include participants under 18 years of age
	Articles not reporting usability, engagement, or recruitment outcomes
	Articles not evaluating a digital platform
	Articles which are conference papers

Table 12: Inclusion and exclusion criteria for the structured literature search.

To visually represent the structured literature search process, a flowchart was developed inspired by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework. Figure 32 illustrates the flowcharts corresponding to the applied search strategies, aiming to identify studies on the *efficiency* and the *user experience* of digital platforms that recruit participants for clinical trials. A total of 97 records were identified across the three databases. After applying the inclusion and exclusion criteria, 93 records were excluded, resulting in four records included in the project. These four records identified through the systematic literature search are presented in Table 13.

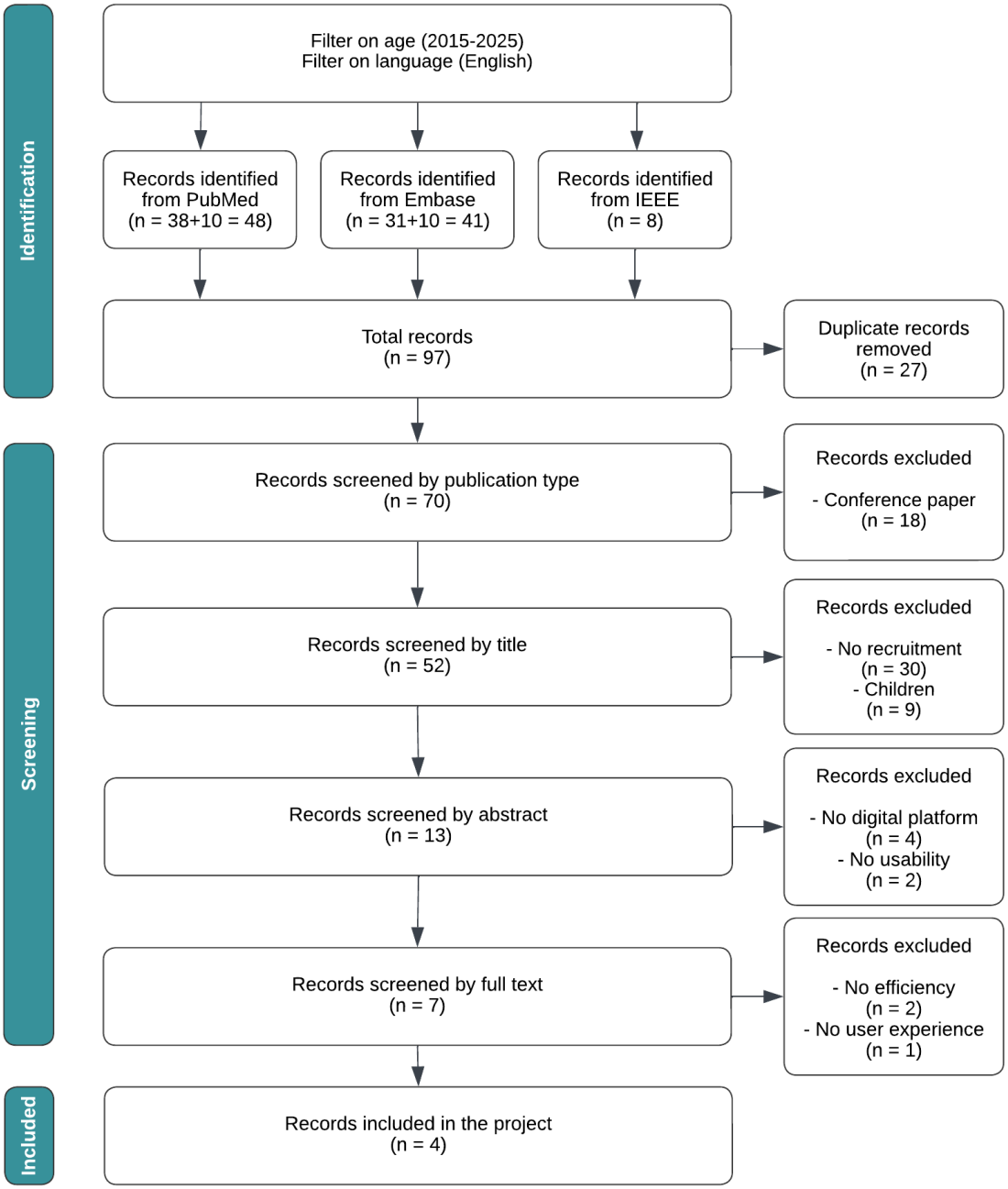

Figure 32: A PRISMA diagram of the identification, screening, and inclusion process resulting in four records being included in the project. For each step, the number of excluded records is listed to the right. For each database, the total number of found records is illustrated.

Table 13: Overview of the included literature based on the structured literature search. For each study, the aim, utilized method, and conclusion are listed.

Citation	Aim	Method	Conclusion
Miller et al. (2021) [12]	To understand if A/B testing could be used to improve the effectiveness of a recruitment website.	An A/B test on a recruitment website assigned older adults (65+) to standard (A) or enhanced (B) versions. Engagement and enrollment metrics compared design effectiveness.	Using A/B testing platforms in a clinical trial recruitment website provides a foundational understanding of the role of this approach for optimizing content and enhancing recruitment.
Whitaker et al. (2017) [57]	To systematically review the literature on Facebook's effectiveness as a recruitment tool for health research, focusing on cost, speed, and demographic reach.	A March 2017 systematic review analyzed 35 English-language papers (12 years, multiple databases) on Facebook recruitment metrics, cost, and demographics.	Facebook is a cost-effective, faster recruitment tool with improved reach for young and hard-to-reach demographics. Limitations include internet access dependency and overrepresentation of young, white women.
Aily et al. (2023) [58]	To report Facebook ad click-to-consent conversion rates and recruitment costs for a telehealth OA study.	A 5-month secondary analysis of a US-based telehealth OA study (age 45+) tracked Facebook ad recruitment through measuring conversion metrics.	Despite low click-to-consent, Facebook recruitment efficiently enrolled 32 participants in 5 months at low cost (USD 51.94/participant), proving feasible for older adults with OA across the US.
Cowie et al. (2018) [61]	To demonstrate targeted Facebook advertising's effectiveness in recruiting healthy individuals (60+) for a Phase 1 clinical trial.	An 8-week Facebook ad campaign supplemented traditional recruitment for a Michigan-based residential Phase 1 trial, directing potential participants to a landing page for screening.	The Facebook campaign effectively recruited a full cohort of 45 healthy elderly subjects within eight weeks, proving to be a fast and cost-effective recruitment solution.

B Version A and version B of trial page

Figure 33 and Figure 34 illustrate the two design versions of the clinical *trial page*. Version A was developed by the research team responsible for the trial and can be accessed via the following link: https://relinkee.dk/TrialsPageA. In contrast, version B was designed by the team behind ReLinkee, incorporating user-centered design principles aimed at improving usability and engagement. The *trial page* (version B) can be accessed via the following link: https://relinkee.dk/TrialsPageB

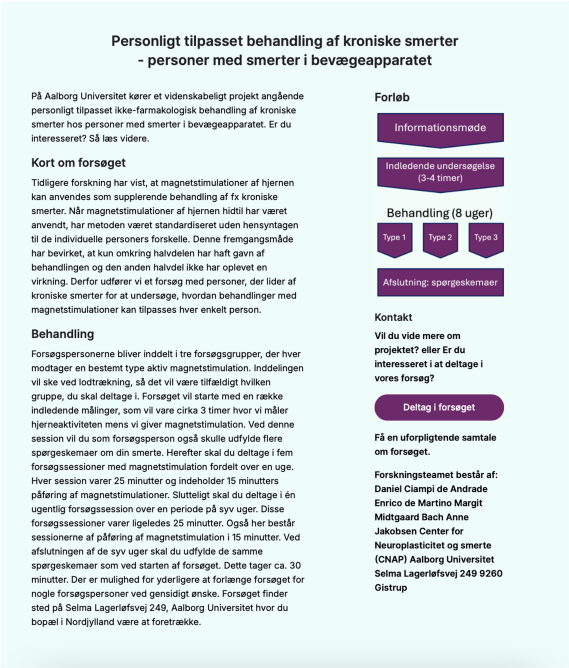

Figure 33: Version A.

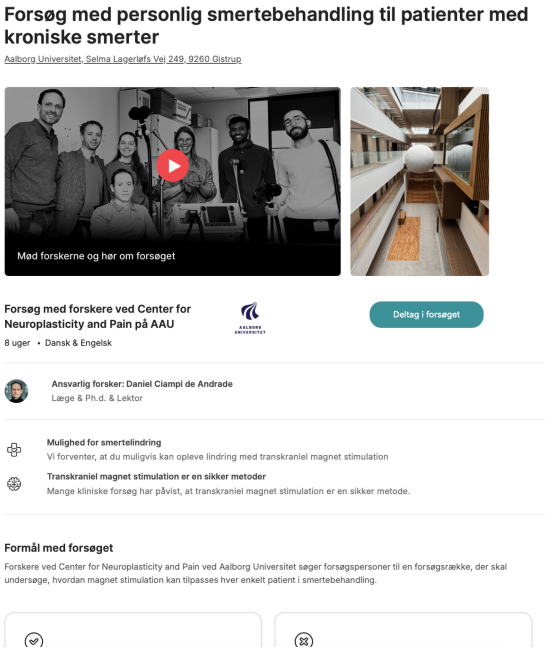

Figure 34: Version B.

C Privacy policy page

The implemented *privacy policy page* is illustrated in Figure 35. The figure shows that the privacy policy covers the following areas: an introduction to the handling of personal information, contact details, the privacy policies themselves, cookies, data storage, participant rights, contact information for the supervisory authority, and finally, changes and updates. The full version of the ReLinkee *privacy policy page* can be accessed via the following link: https://relinkee.dk/PrivacyPolicy

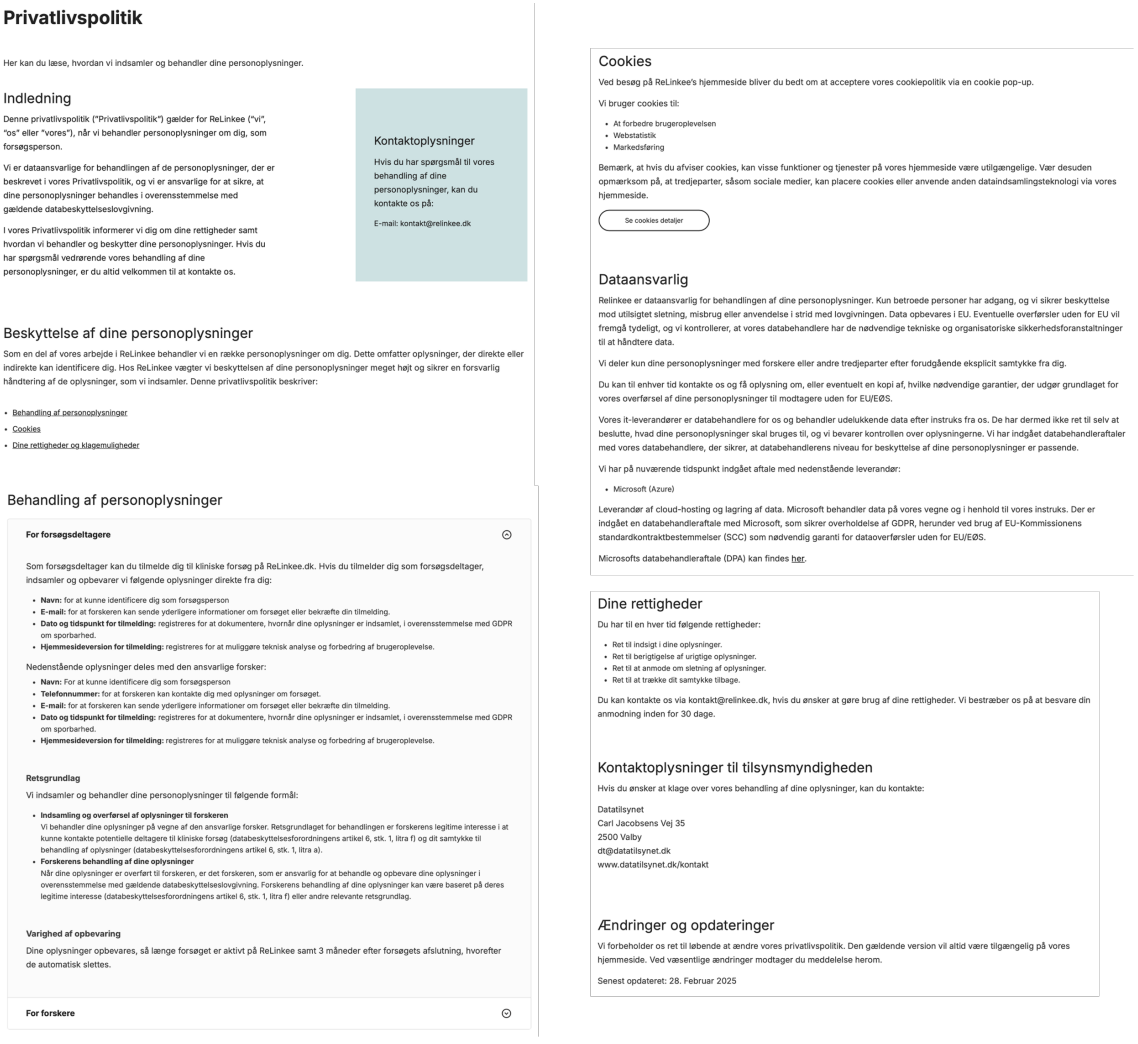

Figure 35: The implemented design of ReLinkee's privacy policy page, showcasing the layout and content structure

D Heuristic evaluation outcomes

The evaluators identified 52 problems during the heuristic evaluation. Table 14 is a comprehensive list of these problems, including the task number, the associated heuristic, the severity level, and a description of each issue.

Table 14: 52 problems found by the evaluators through the heuristic evaluation.

Opgave	Heuristisk retningslinje	Sværheds-grad	Problem
1	6	3	Svært at se, om forsøget er i gang. Der mangler information på "forsiden".
3	3	2	Hvad indebærer opstart? Hvor ofte modtager deltageren behandling?
3	10	2	Der er ingen information om, hvad de 8 uger i toppen af siden refererer til.
3	10	2	Der er ingen information om betydningen af dansk/engelsk i toppen af siden.
4	4	3	Talte og skrevne formål stemmer ikke overens.
4	10	2	Ingen forklaring på "banebrydende metoder" og andre specifikke begreber.
5	8	1	"×" og "✓" overses let, hvis de ikke har farve.
6	8	2	Brødteksten er for lille, især da siden ikke udnytter hele bredden.
7	3	3	Ingen mulighed for at fortryde tilmelding.
7	3	2	Der er ingen information om, hvad der sker efter tilmelding.
7	4	2	Formularen er et nyt og udefineret begreb.
7	5	2	Der mangler information om, hvilket forsøg man har tilmeldt sig.
7	8	1	To knapper med forskelligt design, men samme funktion. Forvirrende.
7	10	3	Ingen pre-screening; alle kan tilmelde sig uden at opfylde kriterierne.

Opgave	Heuristisk retningslinje	Sværheds-grad	Problem
8	4	2	Sparsom information under "Om" – mangler mission, forskere og samarbejdspartnere.
8	8	2	DNA-billedet er irrelevant.
2	8	0	Det er ikke intuitivt, hvad adressen er.
4	2	1	Afspilningsknappen er muligvis ikke genkendelig for alle aldre.
4	8	1	"×"-knappen er svær at se
7	5	2	Systemet informerer ikke om, hvilket forsøg man har tilmeldt sig.
8	4	2	Atypiske placering af drop-down-menuen.
8	8	2	Siden "Om" virker tom – der forventes mere beskrivende tekst.
1	6	2	Er jeg på den rigtige hjemmeside?
1	7	3	Ingen form for sundhedsfiltrering af forsøg.
2	7	3	Adressen fremstår utydelig, når hele linjen er understreget.
3	1	3	Det er svært at danne et overblik over forsøgsdesign og elementer.
3	5	3	Flere tidsperioder nævnes, men der gives ingen samlet forklaring.
4	3	1	"×"-knappen på videoen er svær at se.
4	4	2	Man forventer, at musen ændrer form over interaktive elementer (video).
4	8	4	Manglende informationer om forsøgets udførelse, formål og forventede resultater.
5	8	3	Brugere forstår ikke smerteskalaen. Tvetydig tekst i kriterierne.
5	10	3	Det er ikke muligt at oversætte siden.
7	7	2	Ikke tydlig placering af tilmelding

Opgave	Heuristisk retningslinje	Sværheds-grad	Problem
8	8	2	Mangelfuld information om mission, ReLinkee's formål og rollefordeling.
2	7	2	Der er usikkerhed om adressen er forsøgets lokation eller noget andet.
3	5	3	Uklart, hvor meget tid forsøget kræver.
4	8	2	"×"-knappen mangler på videoen.
4	4	3	Der mangler information om i videoen.
4	4	3	Videoen introducerer ikke forsøget ordentligt.
6	6	2	Formål er måske ikke passende til inklusions-/eksklusionskriterierne.
6	7	3	Der mangler overblik over basisinformation.
7	5	4	Det er ikke klart, om man tilmelder sig et forsøg eller en telefonsamtale.
8	8	2	DNA-billedet skaber forvirring og fylder.
8	4	2	Mangelfuld information og uhensigtsmæssigt design på "Om"-siden.
2	5	3	Der er behov for mere uddybende information om forsøgets lokation.
3	5	3	Forsøgsplanen er uoverskuelig.
4	7	3	Der mangler information i videoen om formål, metode og fremgangsmåde.
5	5	2	Uklar instruktion – sidder man i stol, eller skal man cykle i en time?
6	5	3	Det er uklart, om forsøget er for kroniske smerter eller raske personer.
6	7	3	Forsøgsplanen og interventionen bør beskrives.
7	1	1	Hvad sker der efter tilmelding? Skriv, at der sendes en mail.
8	4	1	Roller i teamet og teknisk support bør beskrives mere detaljeret.

E Advertisements for clinical trial

Figure 36: The four advertisements displayed on Facebook and Instagram. The top-left ad targeted males aged 18–45, the top-right targeted males aged 46+, the bottom-left targeted females aged 18–45, and the bottom-right targeted females aged 46+.

F System usability scale questions

The SUS questionnaire was used in the usability test to assess the usability of ReLinkee. Originally developed in English by Brooke et al. (1996) [54], however, the questions were translated into Danish for this project and are listed below:

- Jeg tror, at jeg ville bruge dette system ofte.
- Jeg synes, systemet er unødvendigt kompleks.
- Jeg synes, at systemet var let at bruge.
- Jeg tror, at jeg vil have brug for hjælp fra en teknisk person for at kunne benytte systemet.
- Jeg synes, at de forskellige funktioner i systemet var godt integreret.
- Jeg synes, at der var for mange uoverensstemmelser i dette system.
- Jeg forestiller mig, at de fleste mennesker hurtigt vil lære at bruge systemet.
- Jeg synes, at systemet var meget besværligt at bruge.
- Jeg følte mig meget sikker i brugen af systemet.
- Jeg havde brug for at lære en masse nyt, før jeg kunne bruge dette system.

G Usability survey

The nine questions were used to investigate the characteristics of the participants. The questions used in the usability test are used to capture age, gender, culture, educational level, agreeableness, digital proficiency, openness to experience and domain experience as recommended in Salvendy and Karwowski [34, p.985]. The questions are listed below:

- Hvad er dit køn?
- Hvad er din alder?
- Hvad er din nationalitet?
- Hvad er din sidst afsluttede uddannelse?
- Lider du af kroniske smerter?
- Jeg stoler generelt på, at andre mennesker har gode intentioner.
- Jeg er komfortable med at bruge min telefon til at navigere på hjemmesider.
- Jeg føler mig tryg ved at bruge nye digitale platforme.
- Jeg har erfaring med kliniske forsøg.