# Digital vs. Traditional

Development and evaluation of an FHIR conformant computed tomography explanation application in comparison to traditional paper-based information sheets

Master Thesis

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by
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I hereby declare that,

- I have written the work at hand on my own without help from others and I have used no other resources and tools than the ones acknowledged.
- I have complied with the Standards of Good Scientific Practice in accordance with the St. Pölten UAS' Guidelines for Scientific Work when writing this work.
- I have neither published nor submitted the work at hand to another higher education institution for assessment or in any other form as examination work.

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Having read and understood the St. Pölten UAS' Guidelines for Scientific Work, I am aware of the consequences of a dishonest declaration.

# Preface

I would like to thank my friends and family for their support over the past two years. Thank you for understanding that I often had less time for you during this period. Your encouragement and patience meant so much to me.

A big thank you also goes to my fellow students, who made my time at university so enjoyable. You made this experience so much better, and I'm grateful for all the moments we shared.

Finally, I want to thank my supervisors Mario Heller and Oliver Krauss for their guidance and support. Your advice was invaluable and helped me greatly along the way.

# Abstract

This thesis investigates the development and evaluation of a digital application aimed at enhancing patient understanding of computed tomography (CT) procedures. Language barriers in healthcare, particularly in multilingual settings, often hinder effective communication and informed consent processes. To address this challenge, a mobile application prototype was developed as part of the MedBuddy project, incorporating multilingual capabilities and structured in compliance with international healthcare data standards.

The methodology was divided into two phases. First, the prototype was developed with key functionalities, including a user-friendly interface and a standardized data structure for interoperability. Second, the prototype was evaluated in a randomized controlled pilot trial, comparing its effectiveness in improving patient knowledge against traditional paper-based information sheets. Eighteen participants were recruited and divided into Intervention and Control groups. Knowledge acquisition was measured using Pre- and Post-Test tests, while participants' emotional responses and satisfaction levels were also assessed.

The results showed significant knowledge gains in the Control group, with a large effect size, while the Intervention group demonstrated only modest improvements. Factors such as higher baseline knowledge in the Intervention group and the deactivation of multimedia features in the prototype likely limited its impact. Despite these limitations, the findings highlight the potential of digital tools to modernize patient education and bridge language barriers. Future iterations of the prototype should incorporate interactive features and be tested with larger and more diverse populations to fully realize the benefits of digital healthcare solutions.

# Kurzfassung

Diese Masterarbeit untersucht die Entwicklung und Evaluierung einer digitalen Anwendung zur Verbesserung des Patientenverständnisses von Computertomographie-Verfahren. Sprachbarrieren im Gesundheitswesen, insbesondere in multikulturellen Kontexten, erschweren häufig die effektive Kommunikation und den Prozess der informierten Zustimmung. Um dieses Problem zu adressieren, wurde ein Prototyp einer mobilen Anwendung im Rahmen des MedBuddy-Projekts entwickelt, der mehrsprachige Funktionen integriert und nach internationalen Standards für den Austausch von Gesundheitsdaten strukturiert ist.

Die Methodik dieser Arbeit gliedert sich in zwei Phasen. Zunächst wurde der Prototyp entwickelt, der eine benutzerfreundliche Oberfläche und eine standardisierte Datenstruktur zur Interoperabilität umfasst. Anschließend wurde der Prototyp in einer randomisierten kontrollierten Pilotstudie evaluiert, bei der seine Effektivität hinsichtlich der Wissensvermittlung mit traditionellen papierbasierten Informationsblättern verglichen wurde. Insgesamt nahmen 18 Personen teil, die in Interventions- und Kontrollgruppen aufgeteilt wurden. Die Wissensvermittlung wurde anhand von Vorher-Nachher-Tests gemessen, während auch die emotionalen Reaktionen und Zufriedenheitsniveaus der Teilnehmenden untersucht wurden.

Die Ergebnisse zeigten signifikante Wissenszuwächse in der Kontrollgruppe mit einer großen Effektstärke, während die Interventionsgruppe nur moderate Verbesserungen verzeichnete. Faktoren wie ein höheres Ausgangswissen in der Interventionsgruppe sowie die Deaktivierung von Multimedia-Funktionen im Prototyp könnten dessen Wirksamkeit eingeschränkt haben. Trotz dieser Einschränkungen unterstreichen die Ergebnisse das Potenzial digitaler Tools, die Patientenaufklärung zu modernisieren und Sprachbarrieren zu überwinden. Zukünftige Iterationen des Prototyps sollten interaktive Funktionen integrieren und in größeren, diverseren Populationen getestet werden, um die Vorteile digitaler Gesundheitslösungen vollständig auszuschöpfen.

# Table of Content

# 1 Introduction

As of the end of 2023, over 117.3 million people worldwide were forcibly displaced due to factors such as persecution, conflict, violence, human rights violations and climate change. This number has been steadily increasing over the past decade, while millions of people seek refuge in foreign nations. [1]

This large-scale displacement contributes to significant linguistic diversity in host countries, particularly in healthcare settings. Language barriers between displaced individuals and healthcare providers pose challenges in accessing healthcare services, impacting patient satisfaction, safety, and overall healthcare outcomes. The lack of a shared first language complicates communication, making it difficult for healthcare providers to deliver effective care. [2]

Language barriers have as well become a significant issue in Austria. In 2021, approximately 81% of migrants in Austria spoke a first language other than German. Within this group, 15.7% reported having only a basic knowledge of German, while an additional 5.5% indicated they had little to no knowledge of the language. This translates to at least 300,000 people in Austria who either had only basic German proficiency or none at all. [3]

As previously stated, language barriers can significantly impact patient outcomes, including the effectiveness of treatment, the level of trust between patients and healthcare providers, and the timeliness of receiving necessary medical interventions. These barriers may lead to miscommunication, which can compromise the accuracy of diagnoses, adherence to treatment plans, and overall patient satisfaction. [4]

Studies have shown the use of digital technologies providing patients with digital information about their medical condition and procedures leads to better understanding, increased motivation for self-care, improved confidence in interacting with healthcare providers, and a greater willingness to follow medical advice. [5]

## 1.1 Problem

In Austria, about 1,468 X-ray tests, were done per 1,000 people in 2015. Even though computed tomography (CT) scans make up only 11% of these tests, they cause a large amount of radiation exposure, accounting for 74% of the total radiation dose in Austria. This is important because high radiation from medical imaging can be a health risk. The number of CT scans in Austria has more than doubled in the last 14 years and is higher than in nearby countries like Germany and Switzerland. [6]

Before a CT scan additionally to an informational conversation with the patients physicist, patients typically receive an paper-based informational sheet. The appearance and level of detail in the information of the sheet can vary depending on the provider of the informational sheet, but usually includes a section that explains the details of the CT procedure, as well as a section where patients are asked about their medical conditions. Additionally, patients are required to give their consent to the examination by signing the form. [7] [8] [9]

The growing population of non-German speakers in Austria, coupled with the rising frequency of CT scans and the persistent use of paper-based CT information sheets by healthcare providers, underscores the necessity for a more efficient and adaptable approach. Unlike traditional paper forms, digital solutions offer significant advantages in terms of flexibility. They are not only easily translatable into multiple languages, enhancing accessibility to vital medical information, but also capable of providing audiovisual feedback. This additional functionality can facilitate comprehension of complex medical procedures, ensuring patients are better informed and empowered to give fully informed consent.

To address this pressing issue, students from the Digital Healthcare department at the University of Applied Sciences St. Pölten developed the "MedBuddy" prototype during the academic year 2022/2023. This innovative project introduced a Mock-Up application designed to provide multilingual information about CT examinations and include a digital consent form for patients undergoing these procedures. Leveraging the adaptability of digital solutions, the prototype not only facilitates easy translation into various languages but also incorporates audiovisual feedback, enhancing patient comprehension of medical procedures and enabling truly informed consent. [10]

## 1.2 Motivation and Aim of this thesis

The aim of this thesis is to develop and evaluate an advanced prototype of the MedBuddy Mock-Up application, with the capability to store patient-inputted data in a database using an international standard for transferring healthcare data. The effectiveness of this prototype will be assessed through a randomized Controlled pilot trial, comparing it to traditional paper-based questionnaires to evaluate its impact on enhancing patients' understanding of CT procedures.

This thesis holds scientific significance as it investigates the practical application of digital technologies in healthcare and contributes to the broader discourse on the role of digitalization in optimizing patient care and safety. By developing and rigorously evaluating the MedBuddy prototype, this thesis aims to provide valuable insights for future advancements in healthcare technology and policy, making it a meaningful contribution to the field.

## 1.3 Research Question

This thesis deals with the following research question:

*"What is the estimated effect size of a digital computed tomography explanation application on knowledge gain, as measured by participants' Pre- and Post-Test scores, compared to conventional paper-based information sheets?"*

## 1.4 Structure

The next chapter will present the theoretical background of this thesis. Chapter 3 will detail the methodology, focusing on the development and evaluation of the prototype. Chapter 4 will present the experiment's outcomes and results. Finally, Chapters 5 and 6 will discuss the findings, interpreting their implications for the future of the healthcare system, and conclude by summarizing the entire thesis.

# 2 Background and Related Work

This chapter reviews the literature on language barriers in healthcare, examining their impact on patient care and satisfaction. It explores various studies that address the challenges these barriers present and discusses the effectiveness of strategies, including digital tools and translation technologies, in improving communication between healthcare providers and patients from diverse linguistic backgrounds.

## 2.1 Language barriers in healthcare

A language barrier is any obstacle that prevents clear communication due to differences in language or linguistic skills. It can arise from speaking entirely different languages, varying levels of proficiency, specialized jargon, cultural differences, or physical disabilities affecting speech or hearing. [11]

Al Shamsi et al. found in their study that language barriers in healthcare settings significantly affect the quality of healthcare delivery, patient safety, and the overall satisfaction of both patients and medical professionals. The review of 14 studies, encompassing a total of 300,918 participants across various countries, highlighted that miscommunication due to language differences is a critical issue in healthcare. This miscommunication often leads to misunderstandings between healthcare providers and patients, resulting in incorrect diagnoses, inappropriate treatments, and decreased adherence to prescribed medical regimens. Such errors not only compromise patient safety but also diminish the quality of care provided.

The presence of language barriers was also found to have a profound impact on patient satisfaction. Patients who cannot effectively communicate with their healthcare providers often feel alienated and misunderstood, which leads to frustration and dissatisfaction with the care they receive. This dissatisfaction can manifest in patients being less likely to seek medical help in the future, thus potentially exacerbating their health conditions. Medical professionals, on the other hand, experience significant challenges in delivering effective care when communication is hindered by language differences. This not only increases their stress levels but also leads to reduced job satisfaction, as they are unable to provide the level of care they strive for. [12]

## 2.2 Overcoming language barriers in healthcare through technology

While Al Shamsi et al. found that the implementation of online translation tools like Google Translate in healthcare settings led to a significant increase in satisfaction among both medical providers and patients, reaching a satisfaction level of 92%, a study by Patil et al. presents a more nuanced view, highlighting significant limitations in Google Translate's usefulness for medical communication. In 2013 Patil et al. found that Google Translate had an accuracy rate of only 57.7% when used for medical phrase translations, with many translations being completely incorrect. [12] [13]

Still technology can play a significant role in overcoming language barriers in healthcare settings, as Shouten et al. demonstrated in their research. [14]

Digital translation tools and multilingual eHealth applications offer innovative solutions to enhance communication between healthcare providers and patients from diverse linguistic backgrounds. These technologies extend beyond the confines of the consultation room, allowing for better preparation and education before and after medical consultations. For instance, eHealth applications with audiovisual capabilities are particularly beneficial for patients who are illiterate in their native languages, empowering them to participate more actively in their healthcare.

Shouten et al. found that patients using such tools, like multilingual question prompt lists and culturally sensitive patient narratives, were more engaged during consultations, leading to more comprehensive discussions about their health concerns. This increased engagement not only improves the quality of care but also fosters a more inclusive healthcare environment. Additionally, multimedia tools, such as patient education video animations tailored to specific cultural and linguistic needs, have shown positive affective effects, such as reducing anxiety among patients. These technological innovations hold great potential to bridge language gaps, improve patient participation, and ultimately enhance the overall quality of healthcare delivery. [14]

## 2.3 Using technology for patient education in computed tomography

Informed consent is a fundamental aspect of medical ethics and patient care, particularly in diagnostic procedures like Computed Tomography (CT) scans. It involves providing patients with comprehensive information about the procedure, including its purpose, potential risks, alternatives, and expected outcomes, allowing them to make an informed decision about their healthcare.

However, the effectiveness of this process can be influenced by several factors, including the patient's ability to recall the information provided and their overall satisfaction with the process. In their study, Vogele et al. explored these aspects in the context of CT scans, aiming to evaluate the current state of patient recall and satisfaction with the informed consent process and to identify potential areas for improvement. [7]

Vogele et al. conducted a survey-based study to measure patient recall and satisfaction with the informed consent process for CT scans. The study involved 512 patients who had undergone CT scans and were asked to recall specific details from the consent discussion. The key findings indicated a significant gap between the information provided during the consent process and what patients could remember afterward. The survey revealed that although most patients remembered general information, such as the radiation risks associated with CT scans, many had difficulty recalling specific details. Notably, 92% of participants did not recall being informed about alternative diagnostic options or the necessity of the procedure. [7]

In addition to examining patient recall and satisfaction, Vogele et al. also explored the potential for technological innovations to improve the informed consent process. The study found strong support among both patients and physicians for the use of digital tools, such as interactive videos and animations, to enhance the delivery of consent information. These tools were seen as a way to make the information more engaging and easier to understand, which could potentially improve patient recall and satisfaction. The study also noted the potential benefits of using tablets or PCs for patients to answer health-related questions, which could streamline the process and reduce the cognitive load on patients during the consent session. [7]

The findings of Vogele et al. concur with those of Schouten et al. regarding the importance of effective communication in healthcare and the potential of technological innovations to enhance patient understanding and satisfaction. Both studies emphasize that patient recall of information provided during medical consultations is often limited, and that this can negatively impact patient outcomes. Vogele et al. found that many patients struggle to remember key details from informed consent discussions. Similarly, Schouten et al. highlight the challenges faced by patients, particularly those from diverse cultural backgrounds, in fully comprehending medical information due to language and cultural barriers. Both studies suggest that incorporating digital tools, such as interactive videos and multilingual eHealth applications, can significantly improve patient engagement and comprehension. [7] [14]

## 2.4 The MedBuddy student project

Based on the findings of Vogele et al. and Schouten et al., which demonstrated that many patients struggle to understand and retain critical information during the informed consent process for CT scans, the MedBuddy project was initiated. This initiative, developed by a group of students at the University of Applied Sciences St. Pölten, including the author of this thesis, aims to address these challenges. [7] [14]

MedBuddy is a Mock-Up of a mobile application designed to enhance patient comprehension by providing detailed information about CT examinations in multiple languages. The application concept includes comprehensive explanations through text or video content available in the patient's preferred language, thereby improving accessibility and understanding.

Additionally, the MedBuddy Mock-Up features a digital consent form and a Frequently Asked Questions (FAQ) section, which addresses common patient concerns and inquiries. The primary objective of MedBuddy is to improve the informed consent process, ensuring that patients are more thoroughly informed and confident about their medical procedures. [10]

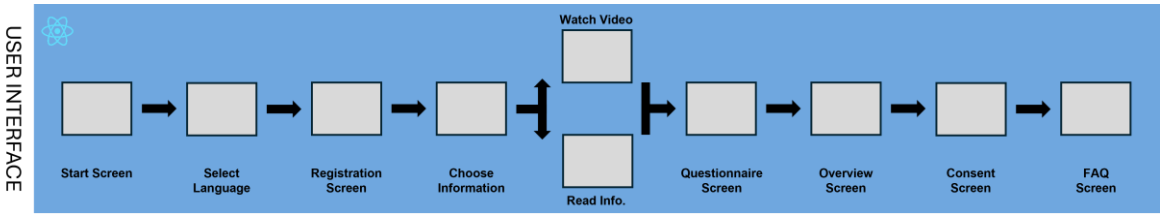


Figure 1 – In this figure the clickable Mock-Up architecture of MedBuddy is displayed, showing the user journey through language selection, registration, and information screens.

Figure 1 shows the Mock-Up architecture representing the process of clicking through the MedBuddy application. The Mock-Up was fully clickable, and the user journey proceeded as follows:

First, the Start Screen was displayed, featuring the MedBuddy logo. This screen acted as a safeguard to prevent accidental interactions and ensured the process started deliberately.

Next, users could choose one of nine languages for the application: German, English, Albanian, Bosnian, Croatian, French, Polish and Romanian. All the texts and translations used in the application come from official information sheets provided by the OERG. Once a language was selected, the entire interface adapted accordingly to provide a tailored experience. [15]

After selecting a language, the Registration Screen appeared, allowing users to enter basic information such as their name, age, and date of birth. Additionally, there was a placeholder for an insurance number. While not used in the Mock-Up, this field was included to simulate how, in future use cases, an easy link between the hospital's patient data and the application could be realized.

The journey continued to the Choose Information Path Screen, where users could decide how to learn about the CT examination. They could either watch an informational video or read a detailed text. Both options were functional, giving users flexibility in how they accessed the information.

The Video/Information Screen followed by the Questionnaire Screen was the main part of the application. Here, users received comprehensive details about the CT procedure, either through the video or written text. Afterward, they answered questions about their medical history, such as allergies, and reviewed their responses before digitally signing to simulate consent.

Finally, the FAQ Screen provided additional information about CT examinations. Users could access a list of frequently asked questions to deepen their understanding and address any concerns.

# 3 Requirements / Methods

The methodology of this thesis was divided into two main phases. In the first phase, a mobile application prototype for multilingual CT scan explanations was developed using modern frameworks and aligned with international healthcare data standards to ensure functionality and usability. In the second phase, the prototype was evaluated through a randomized controlled pilot trial to assess its effectiveness in improving patient knowledge compared to traditional paper-based methods. This structured approach was designed to examine both the technical feasibility and educational potential of the digital solution.

## 3.1 Development of the prototype

The prototype built upon the Mock-Up with significant enhancements. Development began with refactoring the codebase to improve maintainability and building the user interface (UI) using the React Native framework. The UI design was adapted from the previous MedBuddy project, ensuring a seamless and user-friendly experience. Next, the data structure was redesigned to align with the international Fast Healthcare Interoperability Resources (FHIR) standard for healthcare data exchange, enabling better organization and interoperability of information. Finally, a database was added to store user data in a structured format, paving the way for future integration with hospital systems. Each of these aspects, the UI development, data structuring, and database implementation, will be discussed in detail in the following chapters.

The source code for both the initial Mock-Up and the advanced prototype of this project have been made publicly available on GitHub to ensure transparency and reproducibility of the research. The repository for the Mock-Up includes the clickable UI design and early functionality concepts, accessible via https://github.com/mochsenhofer/MedBuddy_rn. The repository for the prototype features the fully developed codebase, structured in compliance with FHIR standards, and is available at https://github.com/mochsenhofer/med-buddy-expo-fhir

### 3.1.1 User Interface

As mentioned before the UI design was adapted from a template developed in the previous MedBuddy project by user-expericence designer Nadine Heckenast. The UI was built using the JavaScript framework React Native (RN), chosen for its versatility in creating cross-platform applications that run on Android, iOS, and web platforms. This made it an ideal choice for MedBuddy, which is intended for use on tablets in hospital environments.

The application's code was refactored to adhere to modern coding standards and best practices, with a focus on improving clarity, modularity, and maintainability. Drawing on principles outlined in BrowserStack's coding guide, particular attention was given to improving the readability of the code. [16]

For example, the *RegistrationScreen.js* file was optimized by reducing it from over 120 lines of code to approximately 20, thereby simplifying its structure. This reduction in code size not only minimized complexity but also ensured that the code was easier to understand and maintain by other developers.

Descriptive naming conventions were also prioritized to improve code clarity. Functions and variables were given names that explicitly reflected their purpose, reducing the likelihood of confusion or misinterpretation by others working on the project.

Version Control was managed through the use of GitHub, a platform that provides robust tools for collaboration and the tracking of changes over time. By employing a systematic version Control process, the development workflow was streamlined, and issues such as code conflicts and errors were minimized. This practice, which aligns with best practices for collaborative software development, ensured that the codebase remained organized and accessible throughout the project.

These improvements collectively strengthened the quality of the codebase, making it more robust, maintainable, and scalable. The reliance on BrowserStack's recommendations was helpful in refining the code to meet professional standards, ensuring the MedBuddy prototype was well-suited for hospital implementation while preserving the user experience envisioned in the original Mock-Up. [16]

The key changes to the user journey from the Mock-Up to the prototype included deactivating the informational video and the FAQ section, as well as limiting language options to German, English, and Polish. These adjustments were made to ensure experimental consistency, preventing the Intervention group from having an advantage over the Control group.

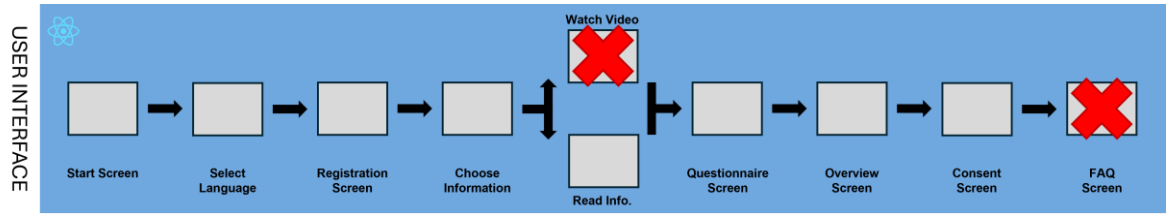


Figure 2 – This figure depicts the updated user journey in the prototype, highlighting the deactivated informational video and FAQ screens.

### 3.1.2 Data Structure

Health Level Seven International (HL7) is a global organization dedicated to developing standards for the exchange, integration, and retrieval of electronic health information. Founded in 1987, HL7 aims to improve healthcare delivery by enabling seamless communication between diverse healthcare systems. It provides a framework for interoperability, ensuring that healthcare information systems can function effectively together. HL7's standards include HL7 v2, HL7 v3, and the Clinical Document Architecture (CDA). HL7 v2, released in 1987, is widely implemented and supports the exchange of data such as laboratory results, patient demographics, and clinical observations through a flexible and straightforward messaging format. HL7 v3, developed later, is based on a formal model-driven methodology that offers more structure and consistency. [17]

CDA is a standard developed by HL7 to structure clinical documents so they can be shared easily between healthcare providers and systems. It is designed to make documents like discharge summaries and progress notes both readable by machines for automated tasks and understandable by humans for clinical use. CDA allows structured data, like coded medical information, to be combined with unstructured text for flexibility. This balance helps ensure that vital healthcare information can be shared in a consistent and adaptable way across different systems. [18]

Fast Healthcare Interoperability Resources (FHIR) is a next-generation standards framework created by HL7. FHIR combines the best features of HL7 v2, HL7 v3, and CDA while leveraging modern web standards. It emphasizes feasibility and uses technologies like RESTful APIs and JSON to enable fast and efficient healthcare information exchange. [19]

This prototype utilizes FHIR version 5, which introduces enhanced functionality, refined resource definitions, and advanced support for interoperability in healthcare systems.

Given these advantages, FHIR was selected as the most suitable standard for implementation in the prototype.

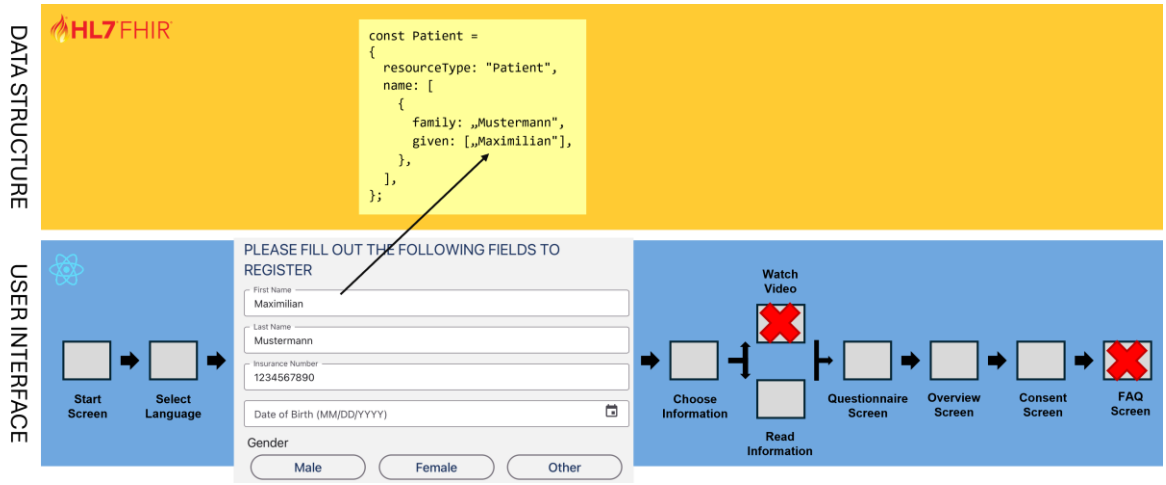


Figure 3 – The figure illustrates how user input is structured and formatted appropriately to align with the FHIR standard.

Figure 3 demonstrates how user input is structured and formatted to align with the FHIR standard. This ensures that the data adheres to the required structure for seamless integration and interoperability.

In FHIR version 5, there are 157 defined resources, serving as modular building blocks for healthcare data. These resources represent core concepts like patients, medications, and diagnoses, enabling standardized data exchange. Their flexibility allows them to be combined for various clinical and administrative workflows, ensuring seamless interoperability across healthcare systems. [20]

The specific FHIR used in the prototype were *Patient*, *Questionnaire*, and *QuestionnaireResponse*, which will be discussed in the following paragraphs.

The *Patient* resource in FHIR is designed to manage and store demographic and administrative information about patients. This includes details like the patient's name, gender, birth date, address, and contact information. For the prototype's requirements, the *Patient* resource was chosen as the best solution. Below is an example of how a patient's data, represented by the *Patient* resource, is structured in JSON format within the prototype's database. [21]

```
{
  "birthDate": "1950-08-10",
  "communication": [{"language": {"coding": [
   {"code": "de", "system": "urn:ietf:bcp:47"}
   ]}}],
  "gender": "male",
  "id": "-O3brLbXwjBYvCads2wf",
  "identifier": [{
    "system": "urn:oid:1.2.36.146.595.217.0.1",
    "type": {"coding": [{"code": "SS", "system":
"http://terminology.hl7.org/CodeSystem/v2-0203"}]},
    "use": "usual",
    "value": "1234567890"
  }],
  "name": [{"family": "Mustermann", "given": ["Max"]}],
  "resourceType": "Patient"
}
```

Code Snippet 1 - This JSON represents a FHIR Patient resource with details such as name ("Mustermann, Max"), birth date, gender (male), identifier, language preference (German), and a unique ID.

The Code Snippet 1 illustrates a typical FHIR *Patient* resource in JSON format, as used in the prototype system. This example contains structured patient data, identifying the individual as "Max Mustermann." The patient's gender is recorded as male, their birth date is noted as August 10, 1950, and their primary communication language is specified as German, following the IETF BCP 47 coding standards.

The *Questionnaire* resource of FHIR defines structured question sets for healthcare data collection, used in forms, surveys, or assessments like clinical trials or patient history intake. It ensures consistent data capture, crucial for analysis and interoperability in various healthcare scenarios. [22]

Given that the Mock-Up featured a form for patient information input, the *Questionnaire* resource was identified as a suitable choice for structuring the data in the prototype. The figure below illustrates the *Questionnaire* utilized in the prototype.

```
{
  "resourceType": "Questionnaire",
  "id": "en",
  "item": [{
    "linkId": "questionnaire",
    "type": "group",
    "item": [{
      "linkId": "q.2",
      "text": "Did you have one of these examinations before?",
      "type": "group",
      "item": [{
        "linkId": "q.2.1",
        "text": "Computer tomography (CT)",
        "type": "choice",
        "answerOption": [
          { "valueCoding": { "code": "Y", "display": "Yes", "system":
"http://terminology.hl7.org/CodeSystem/v2-0532" }},
          { "valueCoding": { "code": "N", "display": "No", "system":
"http://terminology.hl7.org/CodeSystem/v2-0532" }},
          { "valueCoding": { "code": "ASKU", "display": "asked but
unknown", "system": "http://terminology.hl7.org/CodeSystem/v2-0532" }}
        ]
      }]
    }]
  }]
}
```

Code Snippet 2 - This JSON represents a FHIR Questionnaire resource. It defines a structured questionnaire with grouped items, including a question about prior CT examinations and predefined answer options

Code Snippet 2 illustrates a FHIR *Questionnaire* resource, focusing on a specific segment within its hierarchical structure. This hierarchy begins with the root item, identified by the ID "questionnaire," which organizes a group of related questions. Within this group, the item with the ID "q.2" addresses whether the respondent has previously undergone certain medical examinations.

A sub-question, identified as "q.2.1," specifically asks about "Computer Tomography (CT)" and offers three possible answer options: "Yes," "No," and "Asked but unknown."

These options are encoded using standardized terminology from the HL7 system, ensuring consistency in data representation.

This structured, hierarchical format allows for clear mapping of nested questions and their corresponding answer options, facilitating accurate data capture. To record and store the responses to such a *Questionnaire*, the FHIR standard uses the *QuestionnaireResponse* resource. This resource plays a crucial role in capturing and preserving answers to predefined questions in a standardized format. By ensuring uniform data capture, the *QuestionnaireResponse* enables seamless data sharing and analysis across various healthcare systems. [23]

The *QuestionnaireResponse* resource from FHIR contains the corresponding Questionnaire resource. Code Snippet 3 below should illustrate the principal of how the FHIR system works.

```
{
  "resourceType": "QuestionnaireResponse",
  "status": "completed",
  "questionnaire": "en",
  "item": [{
    "linkId": "q.1",
    "text": "Please answer the following questions to the best of your
knowledge.",
    "item": [
      { "linkId": "q.1.1", "text": "Size (cm)", "answer": [{
"valueInteger": 180 }] },
      { "linkId": "q.1.2", "text": "Weight (kg)", "answer": [{
"valueInteger": 90 }] },
      { "linkId": "q.1.3", "text": "Is there a possibility of
pregnancy?", "answer": [{ "valueCoding": { "code": "N", "system":
"http://terminology.hl7.org/CodeSystem/v2-0532" } }] }
    ]
  }],
  "contained": [{
    "resourceType": "Questionnaire",
    "id": "en",
    "item": [{
      "linkId": "q.1",
      "text": "Please answer the following questions to the best of
your knowledge.",
      "type": "group",
      "item": [
        { "linkId": "q.1.1", "text": "Size (cm)", "type": "integer",
"maxLength": 3 },
        { "linkId": "q.1.2", "text": "Weight (kg)", "type": "integer",
"maxLength": 3 },
        { "linkId": "q.1.3", "text": "Is there a possibility of
pregnancy?", "type": "choice", "answerOption": [
          { "valueCoding": { "code": "Y", "display": "Yes", "system":
"http://terminology.hl7.org/CodeSystem/v2-0532" } },
          { "valueCoding": { "code": "N", "display": "No", "system":
"http://terminology.hl7.org/CodeSystem/v2-0532" } },
          { "valueCoding": { "code": "ASKU", "display": "asked but
unknown", "system": "http://terminology.hl7.org/CodeSystem/v2-0532" }
}
        ]}]
    }]}]
}
```

Code Snippet 3 - This JSON represents a FHIR QuestionnaireResponse resource linked to a contained Questionnaire. It captures user answers, such as height (180 cm), weight (90 kg), and pregnancy status. Metadata, grouped questions, and responses ensure consistency with FHIR standards for recording patient-provided information.

### 3.1.3 Database

For the application's database, it was essential to have features such as efficient data storage, easy retrieval, and real-time synchronization. This is why the Firebase Realtime Database was chosen. Firebase, a cloud-based service provided by Google, offers a comprehensive set of tools that simplify the process of building, managing, and scaling applications without the need to worry about the underlying infrastructure. [24]

One of the key reasons for choosing Firebase Realtime Database was its ability to store data in a JSON format, which is perfectly aligned with the FHIR standard, also based on JSON. This ensured that storing and retrieving data is both simple and efficient. Additionally, Firebase's real-time synchronization feature ensured that any updates are instantly visible to all healthcare providers connected to the database. This is particularly beneficial for future scenarios, such as allowing hospital staff to immediately access completed questionnaires, enabling timely monitoring of patients' health conditions.

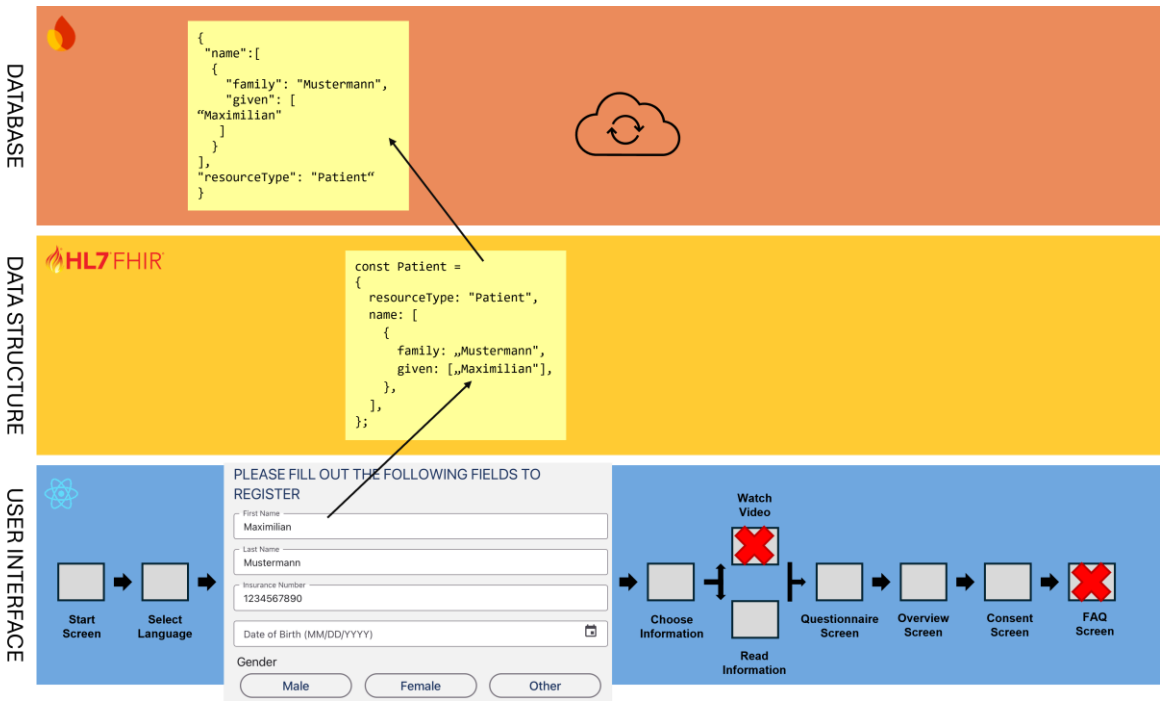


Figure 4 - The figure illustrates the process of transforming user input from the interface into the FHIR-compliant format, which is then automatically converted by Firebase from a JavaScript object to JSON for storage in the database.

Figure 4 illustrates the process of transforming user input from the Registration Screen into a FHIR-compliant format and storing it in Firebase as JSON.

For example, when a user enters their family name and given name in the Registration Screen, this data is structured in the FHIR format, such as family: "Mustermann" and given: ["Maximilian"]. Firebase then converts the JavaScript object into JSON and stores it in the database, ensuring the data remains properly formatted and accessible for future use. This process demonstrates the seamless flow from user interface input to structured, interoperable data storage.

## 3.2 Evaluation of the prototype

The evaluation of the prototype was conducted through a randomized controlled pilot trial (RCT) to assess its effectiveness in comparison to the traditional paper-based CT information sheets. The primary aim of the study was to estimate the impact of these two different methods on patients' understanding of CT examinations.

The experiment included 18 participants, who were randomly assigned to either the Control group or the Intervention group. The allocation was done using a 1:1 allocation ratio, ensuring an equal number of participants in each group. The random assignment was carried out using a random number generator, where participants were assigned to the Control group if the number 0 was generated and to the Intervention group if the number 1 was generated. This method ensured that the allocation to each group was entirely random, minimizing potential biases and enhancing the reliability of the results.

Participants were required to meet specific eligibility criteria to ensure alignment with the general population who could be patients in Austria. Eligible participants were those between 14 and 100 years old. Additionally, participants needed to have a first language of either German, English, or Polish and have at least a B2 level of proficiency in German. These criteria were implemented to ensure that participants could fully understand the study materials and procedures.

The participants were recruited through the social network from the author. The data was collected in October and November 2024 in multiple locations.

Due to the limited availability of participants with a primary language other than German, it was not possible to compare understanding across different languages. Consequently, the study focused solely on evaluating participants' comprehension of the content, without accounting for potential linguistic differences in interpreting the educational materials.

The experiment was structured into six phases as shown in Figure 5.

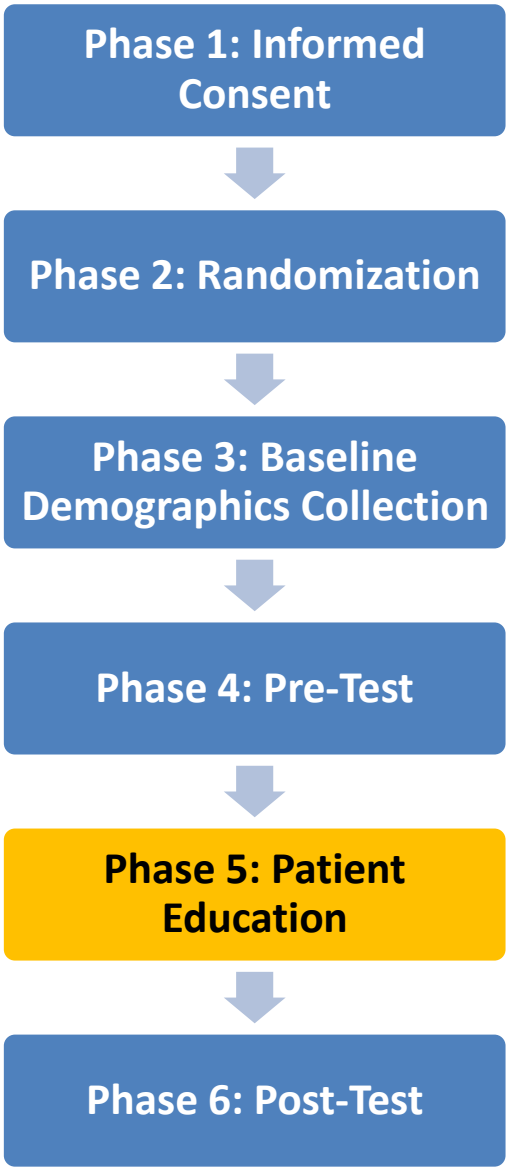


Figure 5 – This figure shows the experiment's six phases: informed consent, group assignment, demographic data collection, a Pre-Test, education via paper or iPad, and a Post-Test to assess knowledge gained.

In Phase 1, participants were asked to give informed consent, indicating their agreement to take part in the study. This step was essential to ensure that all participants fully understood the study's objectives, procedures, and their right to withdraw at any time.

In Phase 2 the participants were systematically randomized in either the Control group or the Intervention group, as mentioned before.

In Phase 3, baseline demographic information was collected from the participants. Specifically, participants were asked about their age, gender, first language, and highest degree of education. This phase was important to ensure that the two groups were comparable in terms of these key characteristics.

In Phase 4, participants completed an initial test to assess their baseline knowledge of CT examinations. The test consisted of nine quantitative and two qualitative questions, designed to evaluate understanding before any educational intervention. A maximum of 10 minutes was allowed for the quantitative questions, while no time limit was imposed for the qualitative ones. This phase ensured a consistent assessment of participants' prior knowledge.

Phase 5 focused on the patient education. Participants in the Control group (n = 9) reviewed traditional paper-based CT information sheets, while the Intervention group (n = 9) used the digital CT explanation prototype *MedBuddy* on an iPad. Both tools provided identical information about the CT examination process. Participants were allowed up to 10 minutes to interact with their assigned materials and could conclude the session at any time once they felt adequately informed. This approach replicated the experience of receiving information in a hospital setting while allowing flexibility in participant engagement.

In Phase 6, participants retook the test to measure knowledge gained after the intervention. The Post-Test included nine quantitative and three qualitative questions, enabling a comprehensive evaluation of knowledge acquisition. A maximum of 10 minutes was allowed for the quantitative questions, with no time tracking for qualitative ones. Overall, the entire process took around 20 to 25 minutes for most participants.

### 3.2.1 Development of the Test

The test was designed to evaluate participants' Pre-existing knowledge regarding CT examinations. The primary objective was to establish a baseline understanding of what participants knew before they were exposed to either the intervention or control conditions.

This baseline would then serve as a reference point to measure the knowledge gained after exposure to the respective conditions.

To ensure the test's content was both reliable and valid, a thorough literature review was conducted across several academic databases, including PubMed, Google Scholar, and ScienceDirect.

The focus of this search was to identify studies that had previously assessed patients' knowledge about their upcoming CT examinations. A crucial criterion for the selection of these studies was the availability of the questionnaires used in these assessments as supplementary material. This allowed for the inclusion of questions that had already been validated in similar contexts, thereby enhancing the reliability and validity of the test as an assessment tool.

Additionally, some of the test's questions were adapted to align with the information provided in both the paper-based CT information sheets and the informational content of the MedBuddy prototype. This adaptation ensured that the test was not only relevant but also directly related to the specific content that participants were exposed to during the study.

The test was composed of both single-choice and multiple-choice questions, offering a balanced approach to assessing various aspects of participants' knowledge about CT examinations. Each question was carefully selected from the validated sources identified during the literature review and subsequently translated into German using DeepL. This translation was essential to ensure the test was accessible and understandable for all participants. [25]

The scoring system was simple and objective. Each quantitative question was worth one point, with one point awarded for correct answers and zero for incorrect or incomplete responses. This binary method ensured consistent and unbiased evaluation of participants' knowledge. The test had a maximum score of nine points, representing the total number of quantitative questions. This approach allowed for a clear and accurate comparison of knowledge levels before and after the educational intervention.

The following Table 1 showcases the original questions with their German translations, with correct answers highlighted in bold font style for clear reference. The "Reference" column shows the original source from the question.

Table 1 - Original Questions from the identified studies and German Translations used in the CT Tests. The correct answers are displayed in bold.

| # | *English Question* | *German Translation* | *Reference* |
|---|---|---|---|
| *1* | A computed tomogram (CT or CAT scan) ____ .<br>a. Uses sound waves to make pictures<br>b. Evaluates how smart you are<br>**c. Uses X-rays and computers to look deep inside your body**<br>d. Measures heat created by abnormal body cells | Ein Computertomograph (CT oder CAT-Scan) ____ .<br>a. Verwendet Schallwellen zur Erstellung von Bildern<br>b. Bewertet, wie intelligent Sie sind<br>**c. Benutzt Röntgenstrahlen und Computer, um tief in Ihren Körper zu schauen**<br>d. Misst die von abnormen Körperzellen erzeugte Wärme | [26] |
| *2* | Which of this following radiological examinations involves exposure to ionizing radiation?<br>a. Ultrasound<br>**b. Computed Tomography**<br>c. Magnetic resonance | Welche der folgenden radiologischen Untersuchungen beinhaltet eine Exposition durch ionisierende Strahlung?<br>a. Ultraschall<br>**b. Computertomographie**<br>c. Magnetresonanztomographie | [27] |
| *3* | Radiography/CT is performed by doctors.<br>a. True<br>**b. False** | Die Radiographie/CT wird von Ärzten durchgeführt.<br>a. Richtig<br>**b. Falsch** | [28] |
| *4* | How dangerous is it to undergo radiological tests using ionizing radiation?<br>**a. Not very dangerous**<br>b. Quite dangerous<br>c. Very dangerous | Wie gefährlich sind radiologische Untersuchungen mit ionisierender Strahlung?<br>**a. Nicht sehr gefährlich**<br>b. Ziemlich gefährlich<br>*c.* Sehr gefährlich | [27] |
| *5* | *The purpose of injecting you with contrast media is to ___ .*<br>a. Keep you calm<br>b. Help the X-rays better penetrate your body<br>**c. Help brighten up differences between normal tissues and vessels and highlights disease** | *Der Zweck der Injektion von Kontrastmitteln ist es, ___ .*<br>a. Sie ruhig zu halten<br>b. den Röntgenstrahlen zu ermöglichen, Ihren Körper besser zu durchdringen<br>**c. die Unterschiede zwischen normalem Gewebe und Gefäßen hervorzuheben und Krankheiten zu erkennen** | [26] |

| | | | |
|---|---|---|---|
| *6* | Please pick from the following list one serious reaction that is NOT a possible complication from IV contrast material. | Bitte wählen Sie aus der folgenden Liste eine schwerwiegende Reaktion aus, die NICHT zu den möglichen Komplikationen bei der intravenösen Verabreichung von Kontrastmitteln gehört. | [26] |
| | **a. A stomach ulcer**<br>b. Shortness of breath<br>c. Drop in blood pressure<br>d. Cramps | **a. Ein Magengeschwür**<br>b. Atemnot<br>c. Abfall des Blutdrucks<br>d. Krämpfe | |
| *7* | The chance of a serious reaction from the injection of contrast material is closest to ___ . | Das Risiko einer schwerwiegenden Reaktion durch die Injektion von Kontrastmittel liegt bei ___. | [26] |
| | a. 1 in 100 (1%)<br>b. 1 in 1.000 (0,1%)<br>**c. 1 in 10.000 (0,01%)**<br>d. 1 in 100.000 (0,0001%) | a. 1 zu 100 (1%)<br>b. 1 zu 1.000 (0,1%)<br>**c. 1 zu 10.000 (0,01%)**<br>d. 1 zu 100.000 (0,0001%) | |
| *8* | Which of the following is a minor side effect to the IV contrast dye? | Welcher der folgenden Punkte ist eine geringfügige Nebenwirkung des intravenösen Kontrastmittels? | [29] |
| | a. Death<br>b. Kidney damage<br>**c. Rash**<br>d. Heart attack | a. Tod<br>b. Nierenschäden<br>**c. Ausschlag**<br>d. Herzinfarkt | |
| *9* | Which of the following is one of the most common side effects of IV contrast dye? | Welche der folgenden ist eine der häufigsten Nebenwirkungen von intravenösem Kontrastmittel? | [29] |
| | a. Death<br>**b. Nausea**<br>c. Kidney Damage<br>d. Heart attack | a. Tod<br>**b. Übelkeit**<br>c. Nierenschädigung<br>d. Herzinfarkt | |

In addition to the quantitative questions displayed in Table 1, qualitative questions were incorporated into the survey to capture participants' emotional responses and perceptions regarding their experience with CT explanation modalities.

Table 2 – This table presents the qualitative questions designed to assess participants' feelings about CT procedures and their satisfaction with the information provided. Each question is displayed with its corresponding numbers for the Pre- and Post-Tests. The two numbers indicate the question's position in each test. Since the Post-Test included one additional qualitative question compared to the Pre-Test, the numbering is different.

| *Pre/Post* | *English Question* | *German Translation* | *Reference* |
|---|---|---|---|
| *x/10* | Please rate your overall satisfaction with the way you were informed about IV contrast dye. | Bitte bewerten Sie, wie zufrieden Sie insgesamt mit der Art und Weise sind, wie Sie über das intravenöse Kontrastmittel informiert wurden. | [29] |
| | a. Poor<br>b. Fair<br>c. Good<br>d. Excellent | a. Schlecht<br>b. Ausreichend<br>c. Gut<br>d. Ausgezeichnet | |
| *10/11* | From CT examination, I have … | Vor der CT-Untersuchung habe ich ... | [30] |
| | a. No fear<br>b. Little fear<br>c. Great fear | a. Keine Angst<br>b. Wenig Angst<br>c. Große Angst | |
| *11/12* | From intravenous contrast material, I have … | Vor intravenösem Kontrastmittel habe ich ... | [30] |
| | a. No fear<br>b. Little fear<br>c. Great fear | a. Keine Angst<br>b. Wenig Angst<br>c. Große Angst | |

The question which assessed how well participants felt informed about intravenous contrast dye (Question x/10), was only included in the Post-Test, as it specifically evaluated their reflections after receiving the procedure and information. The other qualitative questions, addressing participants' levels of fear or comfort related to the CT examination and intravenous contrast material, were included in both the Pre-Test and Post-Test.

This design allowed the Pre-Test to focus on initial feelings of apprehension or comfort, while the Post-Test included an additional measure of satisfaction with the information provided, ensuring a holistic understanding of participants' experiences before and after the procedure.

# 4 Evaluation and Results

The results of the study are presented in this chapter. Initially, the baseline demographic characteristics of the participants are outlined to provide context. This is followed by the presentation of the primary outcome results, after which the secondary outcomes are analysed to offer a detailed comparison between the Control and Intervention group.

The study compared two methods of patient education for CT examinations. The Control group, which consisted of nine participants, received traditional paper-based information sheets to explain the CT procedure. This group included six males and three females. The majority of participants, eight out of nine, were between 17 and 25 years old, while one participant was in the age range of 26 to 35 years. Their educational backgrounds varied, with one participant holding a secondary school leaving certificate, five having a higher education entrance qualification, and three possessing bachelor's degrees. All participants in the Control group spoke German as their first language, although this was not a selection criterion.

The Intervention group, also comprising nine participants, used the prototype of the mobile application MedBuddy to receive information about the CT procedure. This group was composed of three males and six females. Six participants were between 17 and 25 years old, two were between 26 and 35 years old, and one participant was over 55 years old. Regarding educational attainment, six participants had a higher education entrance qualification, two held bachelor's degrees, and one participant had a master's degree. While German was the predominant first language in this group, spoken by eight participants, one participant reported a different first language.

The baseline demographics of both groups, as outlined in the following comparison in Table 3, provide a basis for analysing the similarities and differences between the two methods of patient education and assessing their respective impacts.

Table 3 - Comparison of baseline demographics, including gender, age, education, and first language, between the intervention and Control groups.

| | | *Intervention group* | *Control group* |
|---|---|---|---|
| *Variable* | Category | N | N |
| *Gender* | Male | 3 | 6 |
| | Female | 6 | 3 |
| *Age* | 17-25 | 6 | 1 |
| | 26-35 | 2 | 8 |
| | > 55 | 1 | 0 |
| *Education* | Secondary school leaving certificate | 0 | 1 |
| | Higher education entrance qualification | 6 | 5 |
| | Bachelor | 2 | 3 |
| | Master | 1 | 0 |
| *First Language* | German | 8 | 9 |
| | Other Language | 1 | 0 |

It was important to evaluate whether educational levels were distributed similarly between the intervention and Control groups. Ensuring comparability between groups minimizes the risk that any observed differences in knowledge gain are attributable to Pre-existing disparities rather than the intervention itself.

Given the small sample size and the 4x2 table structure with low expected frequencies, the Freeman-Halton extension of Fisher's Exact Test was used. This test is suitable for small datasets and accounts for all possible distributions of cell frequencies consistent with the observed marginal totals, providing a probability of observing the current distribution.

Since PSPP does not support this version of Fisher's Exact Test, an online tool from VassarStats.net was used to calculate the p-value. [31]

The analysis yielded a p-value of 0.525, indicating no statistically significant difference in the distribution of educational levels between the two groups.

# 4.1 Primary Outcomes

Participants in the Intervention group received information about CT procedures through the MedBuddy prototype, designed to improve comprehension and engagement. The table below presents the primary outcome data for this group, including their Pre-Test Scores, Post-Test Scores, and the Differences between the two. This data serves as the basis for statistical analysis to assess the intervention's effectiveness.

To evaluate the suitability of a paired t-test for assessing changes in scores, a Kolmogorov-Smirnov (KS) Test was conducted.

Table 4 - This table displays the achieved scores from the participants before and after the patient education phase as well as the calculated differences between the test scores in the Intervention group

| *Participant* | *Pre-Test Score* | *Post-Test Score* | *Difference Pre- and Post-Test Score* |
|---|---|---|---|
| *1* | 9 | 7 | -2 |
| *2* | 6 | 7 | +1 |
| *3* | 7 | 6 | -1 |
| *4* | 8 | 7 | -1 |
| *5* | 7 | 8 | +1 |
| *6* | 5 | 7 | +2 |
| *7* | 7 | 7 | 0 |
| *8* | 7 | 8 | +1 |
| *9* | 5 | 9 | +4 |

The Kolmogorov-Smirnov (KS) test, conducted using PSPP, resulted in a Z-value of 0.5 and a p-value of 0.931, indicating no significant deviation from normality in the distribution of paired differences in the Intervention group. This finding confirms that the assumption of normality was met, allowing a paired t-test, also calculated with PSPP, to be performed for further analysis.

The paired t-test results provided insights into the comparison of Post-Test and Pre-Test scores in the Intervention group. The maximum score achievable was 9, as the test consisted of 9 questions, each contributing 1 point to the total score.

The mean Post-Test score was 7.3, with a standard deviation of 0.9, while the Pre-Test mean score was slightly lower at 6.8, with a standard deviation of 1.3. This resulted in a mean difference of 0.5 points, showing a minimal increase of the score after the patient education phase.

The standard deviation of the paired differences was 1.8, reflecting the variation in score changes among participants. The standard error of the mean difference was calculated as 0.6.

The t-value for the test was 0.9, with 8 degrees of freedom, and the two-tailed p-value was 0.384. The null hypothesis for this test was that there is no difference in the mean scores of the Post-Test and Pre-Test, implying that the intervention had no effect. As this p-value exceeds the typical significance threshold of 0.05, the null hypothesis could not be rejected. Overall, while there was a slight increase in Post-Test scores, the difference was not statistically significant, and further investigation may be required to evaluate the intervention's impact.

Table 5 - Statistical Key findings in the Intervention group

| *Intervention group* | *Pre-Test-Scores* | *Post-Test-Scores* | *Difference* | *Effect Size* | *p-Value* |
|---|---|---|---|---|---|
| *Mean (M)* | 6.8 | 7.3 | 0.5 | 0.3 | 0.384 |
| *Standard Deviation (SD)* | 1.3 | 0.9 | 0.4 | | |

The effect size for the Intervention group, calculated using G*Power based on the paired t-test results from PSPP, was found to be 0.3. This value corresponds to Cohen's d and is classified as a small effect size according to conventional criteria.

Using the calculated effect size, a power analysis was conducted to determine the sample size required for achieving sufficient statistical power. To attain 80% power, a total of 88 participants would be necessary. For higher power levels, such as 90% and 95%, the required sample sizes increased to 117 and 144 participants, respectively. These findings emphasize the limitations of the study's current sample size of 18.

The following table presents the power levels and their corresponding total sample sizes, based on the effect size.

Table 6 - The table shows the required sample sizes to achieve specific power levels, calculated using G*Power based the calculated effect size of 0.3.

| *Power* | *Total Sample Size* |
|---|---|
| *0.95* | 144 |
| *0.90* | 117 |
| *0.80* | 88 |

Participants in the Control group received information about CT procedures using traditional paper-based materials in the patient education phase. The following Table 7, structured in the same format as the table for the Intervention group, summarizes the primary outcome data for this group, including Pre-Test Scores, Post-Test Scores, and the Differences between them. This data serves as the basis for statistical analysis and comparison with the Intervention group to evaluate the effectiveness of both methods.

As in the Intervention group, a Kolmogorov-Smirnov (KS) test was conducted to determine whether the differences between Pre-Test and Post-Test scores were normally distributed, to confirm if it was appropriate to perform a paired t-test for further analysis.

Table 7 - This table displays the achieved scores from the participants before and after the patient education phase as well as the calculated differences between the test scores in the Control group

| *Participant* | *Pre-Test Score* | *Post-Test Score* | *Difference Pre- and Post-Test Score* |
|---|---|---|---|
| *1* | 6 | 7 | +1 |
| *2* | 2 | 6 | +4 |
| *3* | 5 | 8 | +3 |
| *4* | 3 | 6 | +3 |
| *5* | 4 | 6 | +2 |
| *6* | 7 | 8 | +1 |
| *7* | 5 | 6 | +1 |
| *8* | 7 | 9 | +2 |
| *9* | 7 | 8 | +1 |

The Kolmogorov-Smirnov test calculated a Z-value of 0.8 and a two-tailed p-value of 0.582 indicating no significant deviation from normality. Because of the results of the Kolmogorov-Smirnov test a paired sample t-test was conducted to compare Pre-Test and Post-Test scores, like it was done in the Intervention group.

The Pre-Test scores in the Control group had a mean of 5.1 points and a standard deviation of 1.8, indicating moderate variability in participants' baseline knowledge.

The Post-Test scores showed a notable improvement, with a mean of 7.1 and a lower standard deviation of 1.2, reflecting reduced variability in performance after the intervention.

This resulted in a mean difference of 2.0, suggesting an average improvement of two points in the Post-Test. The standard deviation of the paired differences was 1.1, and the standard error of the mean difference was 0.4, providing a precise estimate of the observed improvement.

A strong positive correlation of 0.812 was found between Pre-Test and Post-Test scores, with a statistically significant p-value of 0.008. This indicates that participants' scores were consistently higher after the intervention.

The paired t-test resulted in a t-value of 5.4 with eight degrees of freedom, and the two-tailed p-value was 0.001. The 95 percent confidence interval for the mean difference ranged from 1.14 to 2.86, confirming the reliability and consistency of the observed improvement.

Table 8 - Statistical Key findings in the Control group

| *Control group* | *Pre-Test-Scores* | *Post-Test-Scores* | *Difference* | *Effect Size* | *p-Value* |
|---|---|---|---|---|---|
| *Mean (M)* | 5.1 | 7.1 | 2.0 | 1.8 | 0.001 |
| *Standard Deviation (SD)* | 1.8 | 1.2 | - 0.6 | | |

The Control group demonstrated a very large effect size of 1.8, requiring only 6 participants to achieve a power of over 0.9. These values were calculated in G*Power based on the paired t-test results. However, the high effect size should be interpreted with caution, as the sample size consisted of only nine participants. This small sample size increases the likelihood that the observed effect could be influenced by random variation or the presence of outliers.

A closer examination of the data distribution and individual participant scores is necessary to ensure that the effect size accurately reflects the underlying trend rather than being skewed by extreme values

Table 9 - Comparison of statistical key findings between the Control group and the Intervention group

| | *Pre-Test Mean* | *Pre-Test SD* | *Post-Test Mean* | *Post-Test SD* | *Mean Difference (Post–Pre)* | *Effect Size* | *p-Value* |
|---|---|---|---|---|---|---|---|
| *Control group* | 5.1 | 1.8 | 7.1 | 1.2 | 2.0 | 1.8 | 0.001 |
| *Intervention group* | 6.8 | 1.3 | 7.3 | 0.9 | 0.5 | 0.3 | 0.384 |

Table 9 provides a comparison of the Pre-Test and Post-Test results for the Intervention and Control group, highlighting key statistical measures such as mean scores (in points), standard deviations, effect sizes, and p-values. The tests, both Pre-Test and Post-Test, had a maximum achievable score of 9 points.

In the Control group the mean Pre-Test score was 5.1 points, with a standard deviation of 1.8. Following the patient education phase, their mean Post-Test score increased to 7.1 points, with a reduced standard deviation of 1.2. This resulted in a mean difference of 2.0 points. The effect size for the Control group was calculated as very large, at 1.8. A p-value of 0.001 indicated that this improvement was statistically significant.

In the Intervention group, the mean Pre-Test score was higher, at 6.8 points, with a standard deviation of 1.3. However, the Post-Test mean score increased only slightly, reaching 7.3 points, with a smaller standard deviation of 0.9. This corresponded to a mean difference of 0.5 points. The effect size for the Intervention group was small, at 0.3, and the p-value of 0.384 suggested that the change was not statistically significant.

The required sample sizes to achieve sufficient statistical power were calculated using G*Power software. For the Control group, the large effect size of 1.8 required only six participants to achieve a power of over 0.9. In contrast, the smaller effect size of 0.3 observed in the Intervention group would have required a sample size of approximately 117 (0.9) to 144 (0.95) participants to reach a similar level of statistical power.

The following boxplot visualization in Figure 6 highlights differences in Pre-Test and Post-Test scores between the Intervention and Control group.

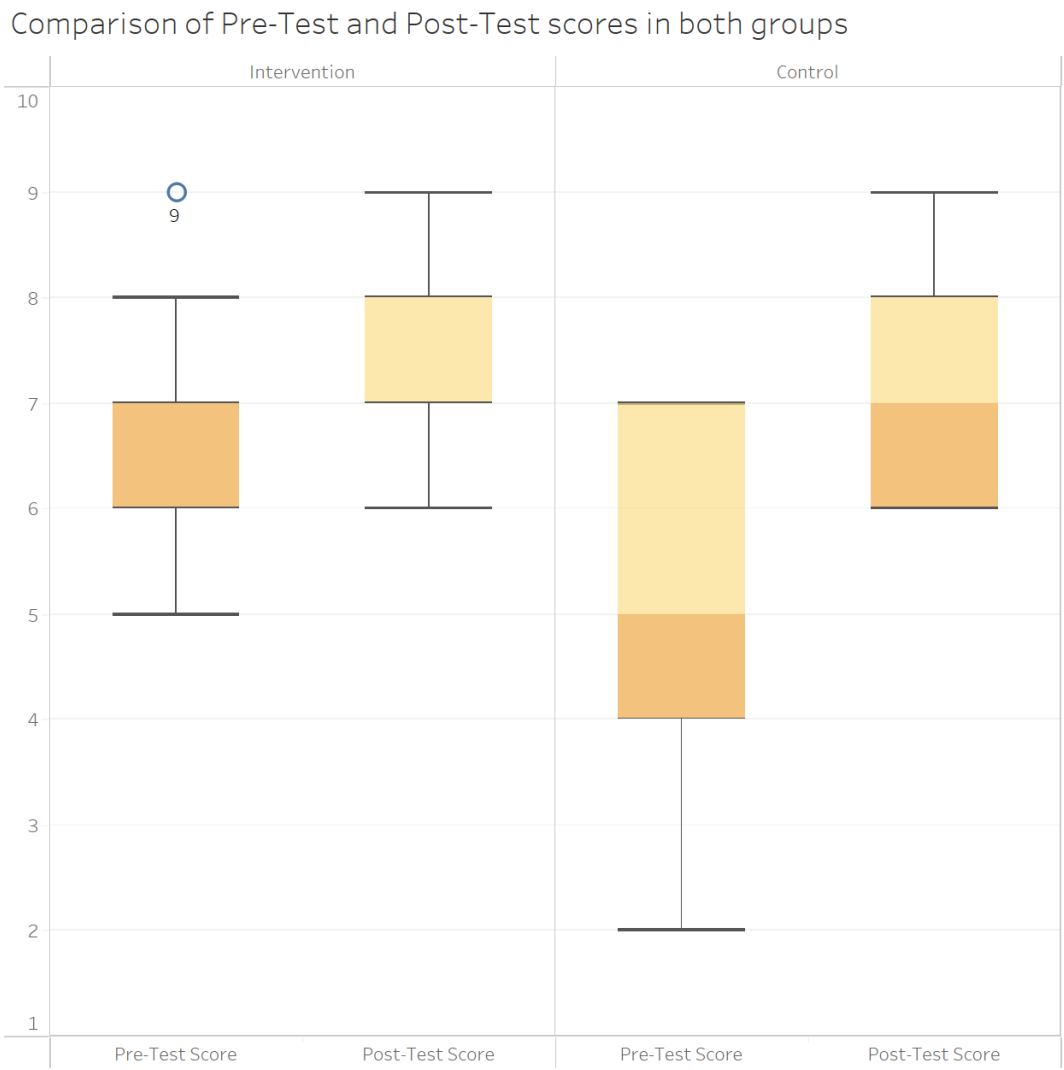


Figure 6 - Comparison of Pre-Test and Post-Test scores in the Intervention and the Control group

For the Pre-Test, the Intervention group showed a median score of 7.0 with an interquartile range between 6 and 7, indicating consistent baseline knowledge. This corresponds to its smaller variability, with a standard deviation of 1.3, and aligns with its higher mean score of 6.8 compared to the Control group. The Control group had a lower median of 5.0 and a broader interquartile range spanning 4 to 6, reflecting greater variability and a standard deviation of 1.8, consistent with its lower mean score of 5.1.

In the Post-Test, both groups showed increases in scores. The Intervention group's median remained at 7.0, with an interquartile range narrowing between 7 and 8, reflecting consistent performance. This aligns with its slightly higher mean score of 7.3 and smaller standard deviation. The Control group's median also rose to 7.0, with an interquartile range between 6 and 8. The broader score distribution observed in the Control group corresponds to its higher standard deviation and slightly lower mean score of 7.1 compared to the Intervention group, reflecting a greater variability in performance improvements.

Additionally to the Pre- and Post-Test Scores this thesis observed if the methodology was suitable to detect the effectiveness of the CT explanation prototype in comparison to the paper-based CT information sheet. Therefore the improvement from both groups on answering each question was observed.

The following Table 10 presents the number of participants (n = 9) in the Intervention group which correctly answered each question in the Pre-Test and Post-Test. A similar analysis was conducted in the Control group, presented in Table 11, to compare the two approaches.

Table 10 - Changes in correct answers for each question in the Intervention group (n=9), comparing Pre-Test and Post-Test performance.

| *Question* | *Correct answers (Pre-Test)* | *Correct answers (Post-Test)* | *Difference* |
|---|---|---|---|
| *1* | 4 | 6 | +2 |
| *2* | 5 | 7 | +2 |
| *3* | 8 | 5 | -3 |
| *4* | 7 | 9 | +2 |
| *5* | 9 | 9 | 0 |
| *6* | 7 | 7 | 0 |
| *7* | 4 | 7 | +3 |
| *8* | 9 | 7 | -2 |
| *9* | 8 | 9 | +1 |

Table 11 - Changes in correct answers for each question in the Control group (n=9), comparing Pre-Test and Post-Test performance.

| *Question* | *Correct answers (Pre-Test)* | *Correct answers (Post-Test)* | *Difference* |
|---|---|---|---|
| *1* | 7 | 7 | 0 |
| *2* | 3 | 7 | + 4 |
| *3* | 7 | 7 | 0 |
| *4* | 6 | 9 | + 3 |
| *5* | 7 | 8 | + 1 |
| *6* | 6 | 5 | - 1 |
| *7* | 2 | 7 | + 5 |
| *8* | 2 | 6 | + 4 |
| *9* | 6 | 8 | + 2 |

As shown in Table 10, changes in the number of correct answers were observed across several questions in the Pre-Test of the Intervention group. The largest increase occurred in Question 7, with a gain of +3 correct answers, while the largest decrease was noted in Question 3, with a drop of -3. No change was recorded for Questions 5 and 6. Question 5 was answered correctly by all nine participants of the Intervention group in the Pre-Test.

In the Control group, most questions showed an increase in the number of correct answers. The largest improvements were observed in Questions 7, 2, and 8, with gains of +5, +4, and +4 correct answers, respectively. A slight decrease was noted in Question 6, while no changes were observed for Questions 1 and 3. During the Pre-Test, Questions 1, 3, and 5 were correctly answered by 7 participants, making them the most well-known or familiar questions among the group prior to the education phase.

When comparing both groups, Question 5 was the most familiar across participants, with 16 correct answers combined during the Pre-Test with 9 correct answers from the Intervention group and 7 from the Control group.

While the Intervention group displayed both increases and decreases in correct answers across questions, the Control group demonstrated more consistent improvements in knowledge.

Statistical analysis using the Wilcoxon signed-rank test showed differences in performances between the groups.

In the Intervention group, five questions showed an increase in the number of correct answers from the Pre-test to the Post-Test, with an average rank of 3.60 and a total rank sum of 18.00. Two questions showed a decrease in the number of correct answers, with an average rank of 5.00 and a total rank sum of 10.00. Two questions remained unchanged, contributing to tied ranks. The test statistic for this group was $Z = -0.69$, with a p-value of 0.490, indicating that the observed changes in correct answers across questions were not statistically significant.

In the Control group, six questions showed an increase in the number of correct answers, with an average rank of 4.42 and a total rank sum of 26.50. One question exhibited a decrease, with an average rank of 1.50 and a total rank sum of 1.50. Two questions remained unchanged, contributing to tied ranks. The test statistic for the Control group was $Z = -2.12$, with a p-value of 0.034. This indicates statistically significant increases in the number of correctly answered questions in the Post-Test compared to the Pre-test.

# 4.2 Secondary Outcomes

As described in chapter 3.2.1, qualitative questions were included with the quantitative ones to assess participants' mood and emotional responses. These questions formed the basis for evaluating the secondary outcomes of both the Intervention and Control groups, offering insights into participants' perceptions and emotional engagement with the respective educational materials.

The following table presents the responses of participants (n = 9) from the Intervention group, comparing their reported fear levels before and after the patient education phase. The questions aimed to capture changes in participants' feelings about CT examinations and intravenous contrast material, providing insight into the psychological impact of the mobile application-based educational approach.

Table 12 – Intervention group participants' feelings about CT examinations and intravenous contrast material before and after the patient education phase (n = 9). Note that in the Post-Test phase, an additional question (Question 10) was included, which caused the subsequent questions to shift one order back compared to the Pre-Test phase

| | *Pre-Test* | | *Post-Test* | |
|---|---|---|---|---|
| *Question* | *10. From CT examinations, I have …* | *11. From intravenous contrast material, I have …* | *11. From CT examinations, I have …* | *12. From intravenous contrast material, I have …* |
| *No Fear* | 5 | 7 | 7 | 7 |
| *Little Fear* | 3 | 0 | 2 | 2 |
| *Great Fear* | 1 | 2 | 0 | 0 |

In the Intervention group, 5 participants initially expressed no fear of CT scans, 3 reported little fear, and 1 expressed great fear. After the patient education phase, the number of participants with no fear rose slightly to 7, while those with little and great fear decreased.

Regarding intravenous contrast material in the Intervention group, 7 participants initially reported no fear, while 2 experienced great fear. Post-intervention, there was no change in the number of participants reporting no fear, but the great fear category disappeared, with 2 participants shifting to little fear.

Table 13 – Control group participants' feelings about CT examinations and intravenous contrast material before and after the patient education phase. The data reflect responses from 8 participants (n = 8) due to one non-respondent.

| | *Pre-Test* | | *Post-Test* | |
|---|---|---|---|---|
| *Question* | *10. From CT examinations, I have …* | *11. From intravenous contrast material, I have …* | *11. From CT examinations, I have …* | *12. From intravenous contrast material, I have …* |
| *No Fear* | 5 | 4 | 6 | 4 |
| *Little Fear* | 3 | 4 | 2 | 4 |
| *Great Fear* | 0 | 0 | 0 | 0 |

In the Control group, Table 13 shows the Pre-Test and Post-Test responses of participants regarding fear of CT examinations and intravenous contrast material. For CT examinations, there was a slight increase in participants reporting "No Fear" in the Post-Test. However, responses to intravenous contrast material remained unchanged, indicating minimal variation in fear levels for this procedure.

In addition to these ratings, participants in both groups were also asked in the Post-Test to evaluate how well they felt informed about intravenous contrast material. The results are shown in the following Table 14.

Table 14 - The table displays participant responses to Post-Test question 10 regarding satisfaction with IV contrast dye information. The Intervention group includes 9 responses, while the Control group has 8 responses due to one non-respondent

| | *Intervention group* | *Control group* |
|---|---|---|
| *Poor* | 0 | 1 |
| *Fair* | 1 | 3 |
| *Good* | 6 | 4 |
| *Excellent* | 2 | 0 |

The table presents the responses to Post-Test question 10, which asked participants: *"Please rate your overall satisfaction with the way you were informed about IV contrast dye."* The responses are categorized as Poor, Fair, Good, and Excellent for the Intervention group and the Control group. Both groups originally consisted of 9 participants, but one participant from the Control group did not respond, resulting in 8 responses for that group and 9 for the Intervention group. In the Intervention group, no participants selected Poor, one chose Fair, six chose Good, and two chose Excellent. In the Control group, one participant selected Poor, three chose Fair, four chose Good, and none selected Excellent. Comparing the two groups, more participants in the Intervention group rated their satisfaction as Good or Excellent, while the Control group had higher numbers in the Poor and Fair categories.

In addition to assessing patients' emotional responses to their groups' educational tools, the time taken by participants to complete the Pre-test and Post-Test was recorded as a secondary outcome as well. The following tables, Table 15 and Table 16, present the time required for each test in seconds. To enable statistical analysis, the normal distribution of the data was evaluated using the Kolmogorov-Smirnov test. For the Intervention group, the mean time difference was -58.00 seconds, with a standard deviation of 42.8. The KS test yielded a Z- value of 0.54 and a p-value of 0.931, indicating that the data were normally distributed. Similarly, for the Control group, the mean time difference was -56.22 seconds, with a standard deviation of 44.6. The KS test produced a Z of 0.68 and a p-value of 0.744, confirming normality.

These results allowed for a paired t-test to be conducted in each group, as the assumption of normal distribution was satisfied for both groups.

Table 15 - Pre- and Post-Test durations with differences, highlighting changes in Intervention group participants' performance.

| *Participant* | *Pre-Test Duration (s)* | *Post-Test Duration (s)* | *Difference in Duration (s)* |
|---|---|---|---|
| *1* | 119 | 108 | -11 |
| *2* | 159 | 135 | -24 |
| *3* | 113 | 94 | -19 |
| *4* | 118 | 62 | -56 |
| *5* | 124 | 55 | -69 |
| *6* | 84 | 53 | -31 |
| *7* | 128 | 52 | -76 |
| *8* | 239 | 95 | -144 |
| *9* | 194 | 102 | -92 |

Table 16 - Pre- and Post-Test durations with differences, showing changes in performance for Control group participants.

| *Participant* | *Pre-Test Duration (s)* | *Post-Test Duration (s)* | *Difference in Duration (s)* |
|---|---|---|---|
| *1* | 149 | 69 | -80 |
| *2* | 97 | 90 | -7 |
| *3* | 107 | 121 | 14 |
| *4* | 221 | 145 | -76 |
| *5* | 190 | 114 | -76 |
| *6* | 194 | 68 | -126 |
| *7* | 213 | 125 | -88 |
| *8* | 110 | 89 | -21 |
| *9* | 156 | 110 | -46 |

The Pre-Test and Post-Test durations for both the Intervention and Control groups are summarized in Table 15 and Table 16.

In the Intervention group, consistent reductions in duration were observed, ranging from a decrease of 11.0 seconds to 144.0 seconds. Notably, Participant 8 showed the largest reduction of 144.0 seconds. In contrast, the Control group's data revealed mixed results. Most participants showed decreases in duration, such as Participant 6 with a 126.0-second reduction, but Participant 3 displayed an increase of 14.0 seconds.

The differences in test durations between the Pre-Test and Post-Test for each group were analysed using a paired t-test in PSPP. In the Intervention group, the mean Post-Test duration was 84.0 seconds with a standard deviation of 29.7 seconds. The mean Pre-Test duration was 142.0 seconds with a standard deviation of 47.7 seconds. This resulted in a mean difference of -58.0 seconds. This reduction in duration was statistically significant, with a t-value of -4.1 and a p-value of 0.004.

For the Control group, the mean Post-Test duration was 103.4 seconds with a standard deviation of 26.2 seconds. The mean Pre-Test duration was 159.7 seconds with a standard deviation of 47.4 seconds. This yielded a mean difference of -56.2 seconds. This reduction was also statistically significant, with a t-value of -3.8 and a p-value of 0.005.

Both groups demonstrated significant reductions in test durations. Detailed statistical findings are presented in Table 17. While the mean differences between groups were similar, the analysis focused on within-group changes. These results highlight reductions in the duration within both the Intervention and Control groups in completing the Post-Test compared to the Pre-Test.

Table 17 – This table summarizes the Pre- and Post-Test means, standard deviations, mean differences, and statistical significance, highlighting notable reductions in test durations for both groups.

| | *Mean Pre-Test Duration (s)* | *Pre-Test SD* | *Mean Post-Test Duration (s)* | *Post-Test SD* | *Mean Difference in Duration (s)* | *p-Value* |
|---|---|---|---|---|---|---|
| *Control group* | 159.7 | 47.4 | 103.4 | 26.2 | -56.2 | 0.005 |
| *Intervention group* | 142.0 | 47.7 | 84.0 | 29.7 | -58.0 | 0.004 |

# 5 Discussion

This section summarizes the key findings of the experiment. The study assessed the effectiveness of a mobile application prototype, *MedBuddy*, designed to explain CT procedures, by comparing it to traditional paper-based CT information sheets. The aim was to find the application's effect on knowledge acquisition and the suitability of the methodology for future research, contributing to the development of accessible and effective patient education tools.

A randomized controlled pilot trial was conducted to estimate the effect size and to validate the methodology. Knowledge acquisition was assessed through Pre- and Post-Test scores, enabling direct comparison between the two educational methods. Participants were randomly assigned to either the Control group (n = 9), using paper-based CT information sheets, or the Intervention group (n = 9), using the *MedBuddy* prototype.

The research question was: *"What is the estimated effect size of a digital application for explaining computed tomography procedures on knowledge gain, as measured by Pre- and Post-Test scores, compared to conventional paper-based information sheets?"*

The findings revealed distinct differences in the outcomes between the two groups. Participants in the Control group, who utilized traditional paper-based materials, demonstrated a significant mean increase of 2.0 points in test scores, corresponding to a very large effect size of 1.8. This result was statistically significant, as indicated by a p-value of 0.001, highlighting the effectiveness of paper-based materials in enhancing understanding of CT procedures.

By contrast, participants in the Intervention group, who interacted with the digital application, showed a modest mean score increase of 0.5 points, corresponding to a small effect size of 0.3. This improvement was not statistically significant ($p = 0.384$), suggesting that the digital application, as implemented in this pilot trial, had a limited impact on knowledge acquisition.

The observed effect sizes must be interpreted cautiously, particularly given the small sample size of the study. A power analysis based on the observed effect size of 0.3 indicated that 88 participants per group would be required to achieve 80% power at a significance level of 0.05. To achieve 90% and 95% power, the required sample sizes increased to 117 and 144 participants per group, respectively.

These calculations underscore the limitations of the current study's sample size of nine participants per group, which was insufficient to detect significant differences for a small effect size. This limitation, while common in randomized controlled pilot trials, restricts the generalizability of the findings. Consequently, the results should be considered exploratory and foundational for future, adequately powered investigations.

The methodology itself could benefit from refinements to improve its ability to measure knowledge gain effectively. The test used in this study consisted of nine questions, which may not have been sufficient to fully capture differences in participants' understanding. Expanding the test to include a broader range of topics and more detailed questions would provide a more comprehensive assessment of knowledge acquisition. Furthermore, certain questions that were answered correctly by a majority of participants in the Pre-Test (for example Question 5) could be revised or removed. This adjustment would ensure that the test focuses on areas where knowledge gaps are more pronounced and meaningful improvement is more likely to be observed.

The Pre-Test scores in the Intervention group were notably higher than those in the Control group. The mean score in the Intervention group was 6.8, compared to 5.1 in the Control group. This suggests that participants in the Intervention group may have had greater baseline knowledge about CT procedures, which likely reduced the potential for measurable improvement during the study. This higher starting point may have resulted in a ceiling effect, limiting the ability to observe larger knowledge gains in the Intervention group.

Another important factor is the use of standardized content in both groups. The information sheet provided to the Control group and the text displayed in the MedBuddy digital application were identical, as both were sourced from the Austrian Society for Radiology.

This ensured that participants in both groups received high-quality, validated content. However, it also raises the possibility that the observed differences in knowledge gains were influenced more by the method of delivery than by the content itself. Since the same information was used in both conditions, it is possible that the results would have been reversed if participants had been randomized into the opposite group. This makes it difficult to attribute knowledge gains to either the digital or traditional method with certainty.

Lastly, the effectiveness of the digital application may have been limited by the deactivation of its interactive features. Key elements such as multimedia explanations and frequently asked questions were excluded to standardize the experimental conditions. These features are widely recognized for improving user engagement and comprehension. Their absence likely reduced the digital application's ability to achieve its intended educational impact.

The limitations of this pilot trial, including the small sample size, the higher baseline knowledge in the Intervention group, the use of identical content across groups, and the reduced functionality of the digital application, make it challenging to draw definitive conclusions. Future studies should aim to recruit a larger and more diverse sample to improve the generalizability of findings. Interactive features should be fully incorporated into the digital application to evaluate its potential more effectively. Additionally, the use of varied content between groups could help to better isolate the impact of the delivery method on knowledge gains. These adjustments would provide a clearer understanding of the intervention's effectiveness and its ability to enhance patient knowledge about CT procedures.

The secondary outcomes of the study, focusing on participants' emotional responses and satisfaction with the educational tools, provided additional descriptive insights. In the Intervention group, 7 participants reported no fear of CT procedures after the education phase, compared to 5 participants before the intervention. Similarly, for intravenous contrast material, 7 participants reported no fear in both the Pre-Test and Post-Test, with 2 participants shifting from great fear to little fear. In the Control group, 6 participants reported no fear of CT procedures after the education phase, up from 5 in the Pre-Test.

However, fear levels regarding intravenous contrast material remained unchanged in this group, with 4 participants reporting no fear both before and after the intervention. Regarding satisfaction, in the Intervention group, 6 participants rated their experience as "Good," and 2 rated it as "Excellent," while in the Control group, 4 participants rated their experience as "Good," and none rated it as "Excellent."

These results suggest that while the digital application may have offered a user-friendly experience, its emotional impact and participant satisfaction levels differed slightly from the traditional approach. As no statistical analysis was performed on these secondary outcomes, these findings are presented descriptively and should be interpreted cautiously.

An additionally secondary outcome of the study was the significant reduction in test durations observed in both the intervention and control groups. These findings provide insights into participant engagement and behaviour during the testing process. In the intervention group, the mean Pre-test duration was 142 seconds, which decreased to 84 seconds in the Post-test. This reduction of 58 seconds was statistically significant ($p = 0.004$). Similarly, in the control group, the mean Pre-test duration of 159.7 seconds decreased to 103.4 seconds in the Post-test, with a mean reduction of 56.2 seconds, also statistically significant ($p = 0.005$).

These results suggest that participants in both groups became more efficient in completing the test over time. This reduction may be attributed to increased familiarity with the test content and structure, as participants had encountered the same set of questions during the Pre-test. The repetition likely allowed them to anticipate and recall answers more quickly, thereby reducing completion times.

Additionally, emotional factors may have influenced these reductions. Participants might have experienced impatience or frustration due to the repetitive nature of the testing process, which could have led them to prioritize speed over careful reflection during the Post-test. However, it is also possible that the educational materials contributed to a better understanding of the content, enabling more confident and efficient responses.

While the reductions in durations were statistically significant, they should be interpreted with caution, as they may reflect a combination of learning effects, behavioural adaptations, and emotional responses. Future research could further investigate the underlying reasons for these time reductions and their implications for evaluating educational interventions.

Comparisons from the outcomes with existing literature reveal both alignment and divergence. Studies by Vogele et al. and Schouten et al. emphasize the critical role of effective communication tools in healthcare, particularly for overcoming language barriers. While the paper-based materials in this thesis achieved significant knowledge gains, the prototype’s limited success highlights the challenges of translating theoretical advantages into practical outcomes. [7] [14]

There are limitations of this thesis extend beyond the small sample size and the deactivation of features in the digital application. The demographic homogeneity of the participants, who were predominantly young adults with higher levels of education, restricts the generalizability of the findings to broader patient populations. A more diverse sample, including older adults, individuals with varying levels of digital literacy, and speakers of additional languages, would allow for a more comprehensive evaluation of the intervention's effectiveness.

In addition, the controlled experimental setting does not reflect the complexities of real-world healthcare environments. Participants engaged with the materials in isolation, free from the typical distractions, time constraints, and pressures experienced in clinical settings. In actual practice, healthcare professionals often supplement paper-based information sheets with direct conversations to clarify and expand on the material provided. In this study, however, participants interacted with the materials independently, which likely affected the depth of their understanding. Testing the application in real healthcare environments, where professionals engage with patients alongside digital or traditional tools, could provide more ecologically valid insights into its effectiveness and usability.

In conclusion, while MedBuddy did not outperform traditional materials in this pilot study, its development marks an important step toward modernizing patient education. The findings confirm the value of well-designed paper forms while highlighting the potential of digital tools to complement and enhance traditional methods. With iterative improvements and expanded testing, applications like MedBuddy could play a pivotal role in advancing informed consent processes.

Future research should focus on reactivating and refining multimedia features, improving usability, and evaluating the tool in diverse, real-world settings. A hybrid approach, integrating both digital and traditional methods, may offer a more effective solution, allowing digital tools to play a transformative role in advancing patient education and empowerment.

# 6 Conclusion

This thesis examined the effectiveness of a digital computed tomography (CT) explanation prototype compared to traditional paper-based CT information sheets in enhancing patient knowledge. The research aimed to estimate the effect size of the prototype on knowledge gain, as measured by Pre- and Post-Test scores, relative to the conventional paper-based method. The findings revealed that the digital application achieved a small effect size (Cohen's d = 0.3) with a mean knowledge gain of 0.5 points. In contrast, the paper-based approach demonstrated a very large effect size (Cohen's d = 1.8) with a mean increase of 2.00 points. These results suggest that the digital tool, in its current form, did not outperform the traditional method in this pilot study.

Several limitations likely influenced these findings. The small sample size (n = 18) reduced the statistical power and limited the generalizability of the results. Furthermore, the Intervention group had a higher baseline knowledge (mean Pre-Test score: 6.8) compared to the Control group (mean Pre-Test score: 5.1), which likely resulted in a ceiling effect that restricted measurable improvements in the digital group. While the digital application included multimedia features, these were deactivated to ensure parity between groups, potentially reducing the tool's impact. Additionally, participants interacted with the materials independently, unlike real-world scenarios where healthcare professionals provide supplemental support with paper-based materials.

Despite these limitations, the development of the digital application represents a significant step toward modernizing patient education and addressing communication barriers.

Future research should activate multimedia features, making the tool easier to use, and testing it in different real-life situations. Combining digital and traditional methods might be an advanced solution, helping digital tools improve patient education and support.

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# List of Figures

# List of Tables

# Appendix

## A. Informed Consent

Forschungsvorhaben: Masterarbeit mit dem Arbeitstitel *„Digital Vs. Traditional - Development And Evaluation Of An FHIR Conformant Computed Tomography Explanation Application In Comparison To Traditional Paper-based Information Sheets”*

Die Datenerhebung wird durchgeführt von Markus Ochsenhofer, dh221802

Teilnehmer/in:

.....

**Einverständniserklärung**

Hiermit bestätige ich, dass ich über das Forschungsvorhaben ausreichend informiert wurde und dass offene Fragen meinerseits von der Forscherin/dem Forscher zu meiner Zufriedenheit beantwortet wurden. Es ist mir bewusst, dass meine Teilnahme an der Datenerhebung freiwillig ist und ich diese jederzeit ohne Angaben von Gründen beenden kann. Ich bin damit einverstanden, dass ich einen Fragebogen ausfülle, der sowohl quantitative als auch qualitative Fragen enthält. Die erhobenen Daten werden anonymisiert und ausschließlich für wissenschaftliche Zwecke verwendet.

 Ich gebe meine Zustimmung zur anonymisierten Verwendung meiner Antworten im Rahmen des oben genannten Forschungsvorhabens. Persönliche Informationen, die ei-ne Identifikation ermöglichen könnten, werden weder veröffentlicht noch an Dritte weitergegeben.

.....

Name und Unterschrift

.....

Ort und Datum

Bei Fragen zur Datenerhebung wenden Sie sich bitte an die/den Verantwortlichen der Untersuchung.

# B. Demographic Questionnaire

**1. Welchem Geschlecht fühlst du dich zugehörig?**

- Männlich
- Weiblich
- Divers

**2. Wie alt bist du?**

- Unter 16
- 17 – 25
- 26 – 35
- 36 – 45
- 46 – 55
- Über 55

**3. Wie lautet dein höchster Bildungsabschluss?**

- Kein Abschluss
- Hauptschulabschluss
- Realschulabschluss
- Fachhochschulreife
- Allgemeine Hochschulreife
- Berufsausbildung
- Bachelor
- Master
- Promotion

**4. Welche ist deine Muttersprache?**

- Deutsch
- Englisch
- Polnisch
- Andere Muttersprache

# C. Pre-Test

**1. Ein Computertomograph (CT oder CAT-Scan) ____ .**

 Verwendet Schallwellen zur Erstellung von Bildern

 Bewertet, wie intelligent Sie sind

 Benutzt Röntgenstrahlen und Computer, um tief in Ihren Körper zu schauen

 Misst die von abnormen Körperzellen erzeugte Wärme

**2. Welche der folgenden radiologischen Untersuchungen beinhaltet eine Exposition durch ionisierende Strahlung?**

 Ultraschall

 Computertomographie

 Magnetresonanztomographie

**3. Die Radiographie/CT wird von Ärzten durchgeführt.**

 Richtig

 Falsch

**4. Wie gefährlich sind radiologische Untersuchungen mit ionisierender Strahlung?**

 Nicht sehr gefährlich

 Ziemlich gefährlich

 Sehr gefährlich

**5. Der Zweck der Injektion von Kontrastmitteln ist es, ___.**

 Sie ruhig zu halten

 den Röntgenstrahlen zu ermöglichen, Ihren Körper besser zu durchdringen

 die Unterschiede zwischen normalem Gewebe und Gefäßen hervorzuheben und Krankheiten zu erkennen

**6. Bitte wählen Sie aus der folgenden Liste eine schwerwiegende Reaktion aus, die NICHT zu den möglichen Komplikationen bei der intravenösen Verabreichung von Kontrastmitteln gehört (kreisen Sie nur eine Antwort ein).**

- Ein Magengeschwür
- Atemnot
- Abfall des Blutdrucks
- Krämpfe

**7. Das Risiko einer schwerwiegenden Reaktion durch die Injektion von Kontrastmittel liegt bei ___.**

- 1 zu 100 (1%)
- 1 zu 1.000 (0,1 %)
- 1 zu 10.000 (0,01%)
- 1 zu 100.000 (0,0001%)

**8. Welcher der folgenden Punkte ist eine geringfügige Nebenwirkung des intravenösen Kontrastmittels?**

- Tod
- Nierenschäden
- Ausschlag
- Herzinfarkt

**9. Welche der folgenden ist eine der häufigsten Nebenwirkungen von intravenösem Kontrastmittel?**

- Tod
- Übelkeit
- Nierenschädigung
- Herzinfarkt

Zeit stoppt! Benötigte Zeit: ___ min ___ s

**10. Vor der CT-Untersuchung habe ich ...**

□ Keine Angst

□ Wenig Angst

□ Große Angst

**11. Vor intravenösem Kontrastmittel habe ich ...**

□ Keine Angst

□ Wenig Angst

□ Große Angst

# D. Post-Test

**1. Ein Computertomograph (CT oder CAT-Scan) ____ .**

 Verwendet Schallwellen zur Erstellung von Bildern

 Bewertet, wie intelligent Sie sind

 Benutzt Röntgenstrahlen und Computer, um tief in Ihren Körper zu schauen

 Misst die von abnormen Körperzellen erzeugte Wärme

**2. Welche der folgenden radiologischen Untersuchungen beinhaltet eine Exposition durch ionisierende Strahlung?**

 Ultraschall

 Computertomographie

 Magnetresonanztomographie

**3. Die Radiographie/CT wird von Ärzten durchgeführt.**

 Richtig

 Falsch

**4. Wie gefährlich sind radiologische Untersuchungen mit ionisierender Strahlung?**

 Nicht sehr gefährlich

 Ziemlich gefährlich

 Sehr gefährlich

**5. Der Zweck der Injektion von Kontrastmitteln ist es, ___.**

 Sie ruhig zu halten

 den Röntgenstrahlen zu ermöglichen, Ihren Körper besser zu durchdringen

 die Unterschiede zwischen normalem Gewebe und Gefäßen hervorzuheben und Krankheiten zu erkennen

**6. Bitte wählen Sie aus der folgenden Liste eine schwerwiegende Reaktion aus, die NICHT zu den möglichen Komplikationen bei der intravenösen Verabreichung von Kontrastmitteln gehört (kreisen Sie nur eine Antwort ein).**

- Ein Magengeschwür
- Atemnot
- Abfall des Blutdrucks
- Krämpfe

**7. Das Risiko einer schwerwiegenden Reaktion durch die Injektion von Kontrastmittel liegt bei ___.**

- 1 zu 100 (1%)
- 1 zu 1.000 (0,1 %)
- 1 zu 10.000 (0,01%)
- 1 zu 100.000 (0,0001%)

**8. Welcher der folgenden Punkte ist eine geringfügige Nebenwirkung des intravenösen Kontrastmittels?**

- Tod
- Nierenschäden
- Ausschlag
- Herzinfarkt

**9. Welche der folgenden ist eine der häufigsten Nebenwirkungen von intravenösem Kontrastmittel?**

- Tod
- Übelkeit
- Nierenschädigung
- Herzinfarkt

Zeit stoppt! Benötigte Zeit: ___ min ___ s

**10. Bitte bewerten Sie, wie zufrieden Sie insgesamt mit der Art und Weise sind, wie Sie über das intravenöse Kontrastmittel informiert wurden.**

- Schlecht
- Ausreichend
- Gut
- Ausgezeichnet

**11. Vor der CT-Untersuchung habe ich ...**

- Keine Angst
- Wenig Angst
- Große Angst

**12. Vor intravenösem Kontrastmittel habe ich ...**

- Keine Angst
- Wenig Angst
- Große Angst