Design of a Prototype for an App-based Patient Briefing for CT-Examinations:

Usability for and Acceptance of Visually Impaired People in a Fictitious Setting

Master Thesis

For attainment of the academic degree of
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Declaration

I declare that I have developed and written the enclosed Master Thesis completely by myself and have not used sources or means without declaration in the text. Any thoughts from others or literal quotations are clearly marked. This work was not used in the same or in a similar version to achieve an academic grading or is being published elsewhere.

....

Place, Date Signature

Preface

I would like to thank my advisor

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for inspiration, motivation, patience and support

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for giving me the opportunity to present the prototype
and spreading the call to participate in the survey

all subjects

who took their time to participate

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my beloved wife

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for supporting me during the whole studies
and more than ten years of my life

and my beloved daughter

Daria

for welcome distraction
and lots of fun while doing nonsense

Abstract

Computed tomography (CT) is an imaging technique to detect structural diseases as well as to monitor the progression / digression after an executed treatment. To illustrate certain organs and structures during a scan, an intra-venous contrast medium is administered to patients before undergoing a CT-examination. In order to be able to estimate the risks of such a contrast medium, the patient is asked to fill out a questionnaire concerning special risk factors. For people with impaired vision reading these documents can be difficult.

With today's technological devices like tablet computers, it is feasible to increase the patients' self-determination by creating applications containing an interactive questionnaire.

The aim of this thesis was to develop a prototype for such an interactive questionnaire based upon the informed consent by the OERG[1] [1], [2] following specific guidelines for people with impaired vision [3] and guidelines for user interface design [4].

Twenty subjects with impaired vision were requested to imagine that they are attending a computed tomography and that they would have to fill out such an informed consent on a tablet computer. After testing the prototype, the subjects had to fill out an evaluation questionnaire to assess the interface of the prototype as well as to answer questions about their sociodemographic and technical background.

Data were visualized with bar charts to show how the prototype's usability scored with respect to gender, age, and other attributes.

The results show that the usability of the prototype was very high. The font size and the size of the on-screen-buttons were just right. The color combination of text to background as well as the color combinations of the on-screen-buttons were comfortable for the subjects. The posed questions were at least equally comprehensible on the prototype and on the paper-based form. The app-based questionnaire was the preferred interrogation method for the majority of the subjects.

[1] http://www.oerg.at

Kurzfassung

Die Computertomographie ist ein bildgebendes Untersuchungsverfahren zur Erkennung struktureller Erkrankungen sowie zur Verlaufskontrolle nach erfolgter Behandlung. Um die Aussagekraft vieler CT-Untersuchungen zu erhöhen, muss Kontrastmittel in eine Vene gespritzt werden. Um die Risiken einer Kontrastmittelgabe besser abschätzen zu können, werden die PatientInnen gebeten, vor der Untersuchung einen Fragebogen auszufüllen, in dem nach bestimmten Risikofaktoren gefragt wird. Für Personen mit eingeschränktem Sehvermögen kann das Lesen des Fragebogens ein Problem darstellen.

Mit den heutigen technischen Errungenschaften wie Tablet Computern, ist es möglich die Selbstbestimmtheit der Patienten zu stärken, indem eine Applikation (App) mit einem interaktiven Fragebogen erstellt wird.

Basierend auf dem Fragebogen [1], [2] der OERG[2] wurde ein Prototyp entwickelt, der nach den Richtlinien für Personen mit eingeschränktem Sehvermögen [3] und Richtlinien für die Gestaltung einer Benutzeroberfläche [4] erstellt wurde.

Zwanzig Personen mit eingeschränktem Sehvermögen wurden anschließend gebeten sich vorzustellen, dass sie eine Computertomographie durchführen lassen und den Fragebogen auf einem Tablet PC ausfüllen müssen. Nach dem Test des Prototyps füllten die ProbandInnen einen Fragebogen aus, um die Benutzeroberfläche des Prototyps zu bewerten.

Die erhobenen Daten wurden mittels Balkendiagrammen visualisiert um die BenutzerInnenfreundlichkeit (Usability) des Prototyps darzustellen. Außerdem wurde gezeigt, wie einzelne Attribute (Geschlecht, Alter, ...) der Testpersonen eine Rolle in der Akzeptanz spielen.

Die Ergebnisse zeigen eine sehr hohe BenutzerInnenfreundlichkeit des Prototyps. Schriftgröße und Größe der Schaltflächen am Bildschirm waren genau richtig. Die Farbkombination von Text zu Hintergrund und die Farbkombination der Schaltflächen waren angenehm für die Testpersonen. Die Verständlichkeit der gestellten Fragen war beim Prototyp zumindest gleich verständlich wie auf dem bisherigen Formular auf Papier. Die Mehrheit der Testpersonen würde eine App-basierte Befragung zukünftig bevorzugen.

[2] http://www.oerg.at

Table of Content

1 Introduction

Computed tomography (CT) is an imaging technique to detect structural diseases as well as to monitor the progression / digression after an executed treatment. During the last decades, the number of radiological examinations increased; especially the amount of examinations with computed tomography. The percentage of CT scans of all radiological examinations in 2015 was about 11 % in Austria [5]. To increase the significance of many CT examinations, an intravenous contrast medium is administered prior to the examination.

Before attending a computed tomography, an informed consent form has to be filled out by the patient [6]. On the front side of this informed consent, information about computed tomography and contrast medium is provided. On the rear page, questions about foregone examinations with contrast medium including occurred side-effects to it are posed, as well as questions concerning special risk factors like asthma, allergies, kidney damages or thyroid diseases [2].

Reading the explanations on the printed patient information sheets and filling out the questionnaires can be hard for people with vision impairment. Bourne et al. have shown that “globally, of the 7.33 billion people alive in 2015, an estimated 216.6 million people had moderate to severe visual impairment” [7]. In 2015, 3 % of the Austrian population, older than 15 years was affected by visual impairment [8].

Estimated 1.8 billion people lived with presbyopia in 2015, which is about 25 % of the world’s population. 826 millions of whom have a near vision impairment because no or inappropriate vision correction is given [9]. In ICD-11 for Mortality and Morbidity Statistics by the WHO, presbyopia is defined as “the normal decreasing elasticity of the crystalline lens that leads to loss of accommodation” [10]. “The term Vision Impairment compromises category 1 for mild vision impairment, category 2 for moderate vision impairment and category 3 for severe vision impairment” [11]. The loss of acuity is a normal ageing process from almost everybody will be affected [12].

Vision impairment affects people when having examinations with computed tomography, because a patient briefing questionnaire has to be filled out to make

sure that the patient is informed about the procedure of the examination and to ensure, that the intravenous contrast medium administration is safe for the patient. Patients with visual impairment rely on someone else to explain the examination to them, to read out the questions and answer them correctly for them. This carries a certain risk or uncertainty, because the patient himself / herself cannot review what the other person has written.

Nowadays, tablet computers can be found in various clinical settings and can be used for patient information managing, to look at x-ray images, to access health records, etc. [13], as an educational tool [14], as well as a platform to communicate between the members of medical disciplines as shown by Vetter et al [15]. It can also be used for communication between patients and healthcare staff where information about medication and the care team can be shown [16].

Another use case is to fill out an informed consent [17]–[19]. Schlechtweg et al. used an iPad application which was created by an expert software programmer for this purpose [17], [18]. The majority of the subjects would prefer an iPad briefing over a paper-based consent [18].

An iPad is a tablet computer created by the company Apple which was first released in 2010. Depending on the specific model, it has a touch display with a diagonal length of 7'' to 12.9''. The operating system for the iPad is Apple's iOS [20]. As Schlechtweg et al. have claimed, the intuitive and uncomplicated interface is appreciated by customers [17].

However, this application and the relating studies were designed for magnetic resonance imaging (MRI), and the content of the iPad application was a one-to-one transformation of the paper-based patient briefing [17].

The aim of this thesis was to create a prototype for a questionnaire for an examination with computed tomography. The prototype will be interactive instead of a one-to-one transformation of the paper-based briefing. Guidelines for people with vision impairment [3] will be implemented as well as the guidelines for user interfaces by Apple [4]. This will make the use of the application look familiar to other applications people know from every day use. Guidelines concerning product usability [21], [22] will be considered as well.

The focus will be on the process before attending a computed tomography and make use of the possibility to create an interactive way through the questionnaire. For instance, if a patient has never received contrast medium before, it does not make sense to ask for side effects after the contrast medium administration. By that, the number of questions can be reduced for the patient, which would be easier

for people with vision impairment because they do not have to read more than the minimal necessary questions on the one hand, and on the other hand, the whole process before the examination can be shortened in these cases.

A big step towards patient empowerment and self-determination would be, to be able to fill out these questionnaires for people with visual impairment on their own.

The usability and acceptance of such an application for people with impaired vision will be evaluated by a usability test with subjects and a subsequent questionnaire. Figure 1 shows the key points of this work.

Figure 1 Evolution of the master thesis

2 Theoretical Background

This chapter provides basic knowledge concerning visual impairment and the difficulties when attending a computed tomography. Fundamentals in computed tomography and the frame conditions for a CT examination will be provided as well as the relating legal requirements. Basics in usability are described in the last part of this chapter.

2.1 Visual Impairment

Visual impairment is defined as a defect or malfunctioning of the eye which is diagnosed by a medical doctor and covers a range from total blindness to low vision [23, p. 253]. The level of visual impairment is defined by the International Statistical Classification of Diseases and Related Health Problems (ICD) by the World Health Organization (WHO) [11]. The 11th revision of the ICD was released in December 2018.

The majority of visual impaired people is older than 65 years [23, p. 5]. The ability to see small objects decreases with increasing age is a result of the aging and the blurring of the lenses as well as the smaller pupil. The declining visual acuity affects the ability to read [23, p. 6].

The biggest age group attending a computed tomography according to the statistic evaluation of the Gesundheit Österreich GmbH [5] is between 65 and 84 years of age, which is just representing the group of people with decreasing visual acuity [23, p. 6].

Figure 2 simulates the impression visually impaired people get from the informed consent [2] by the OERG. The simulation was created with the GNU Image Manipulation Program (GIMP)[3] using the Gaussian Blur Overlay.

[3] https://www.gimp.org

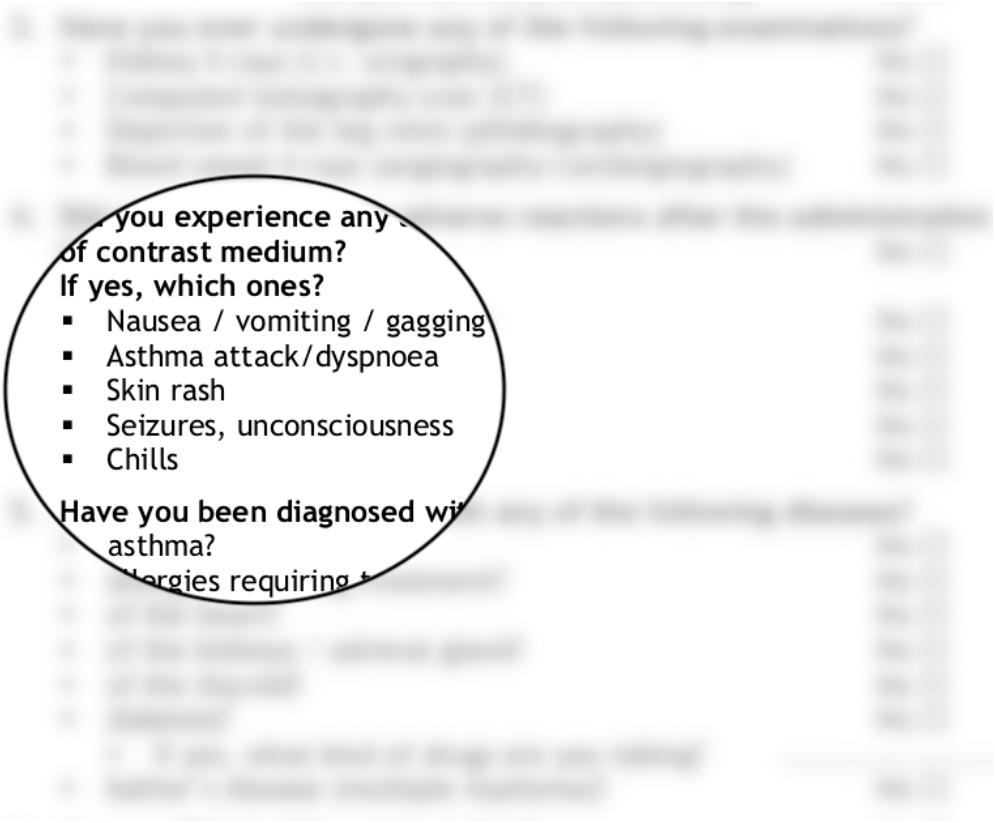

Figure 2 Symbolic illustration of reduced visual acuity compared to normal vision (circled)

2.2 Fundamentals in Computed Tomography

Computed Tomography (CT) is an imaging technique where cross-sectional images are created by rotating an x-ray source 360 ° around an object with a detector positioned directly opposite the radiation source. It is a well-established technique to differ a variety of tissue types, such as cardiovascular system, renal tract, liver, bones, tumors, etc. [24] with an increasing number of examinations [24] [5].

During a CT scan, a series of images is created where the human body is figuratively cut in slices. Every single CT-image shows a cross-sectional image of the human body. It is looked at, if the patient lies on his / her back, pointing with his / her feet to the viewer. Therefore, on the CT-images, all organic structures inside the human body are situated on the opposite side. Taking the liver as an example, Figure 3 shows that the liver is situated on the left side of the image and the spleen on the right side which is directly opposite to the real anatomic position.

Different types of body tissue can be differentiated through their different ability to extenuate x-rays (e.g. bones and internal organs). To distinguish similar types of

body tissues (e.g. liver and a tumor) can be difficult. Therefore, contrast medium is used and is often required to make certain structures visible or examine the function / performance of organs. The contrast medium must attenuate the radiation from the x-ray tube more than the surrounding tissue. As an element of choice, Iodine is used [24].

Figure 3 shows the difference between the arterial and the venous phase of contrast enhancement in the abdomen. On the left part, one slice through the abdomen in arterial phase is shown. The structure in the liver appears lighter than the surrounding tissue, the abdominal aorta is well contrasted and shines very bright. On the right part, a slice of the venous phase can be seen where the structure appears darker than the surrounding tissue. As well as the aorta is not filled with contrast medium anymore, that's why it is as dark as the other tissues in the abdomen.

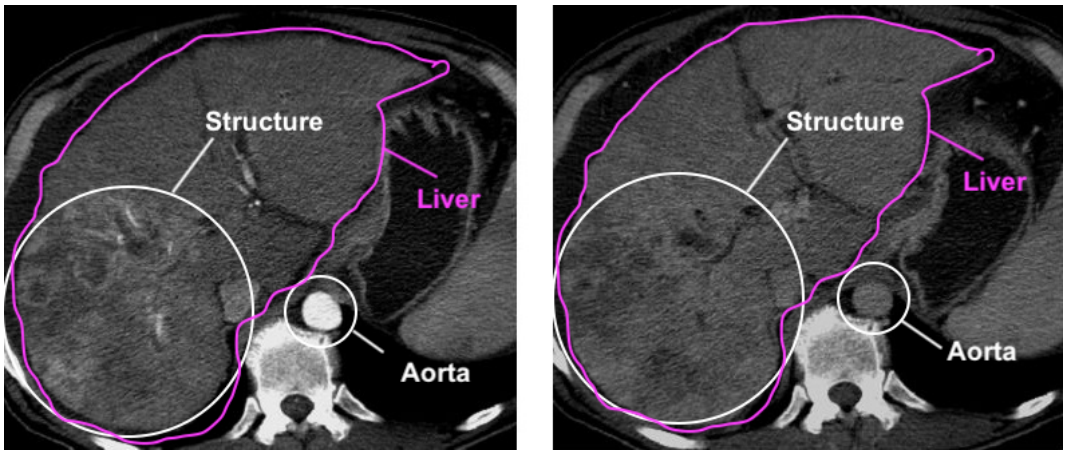

Figure 3 Arterial and Venous Phase of an abdomen CT – created by Kristie Guite, Louis Hinshaw and Fred Lee [25] and Mikael Häggström, MD released under the Creative Commons Attribution 3.0 Unported License [26] used with permission, labels added by Gerald Wagner

Before the contrast medium can be injected, the values of serum creatinine [27], [28] and the thyroid stimulating hormone (TSH) [29] should be collected. The serum creatinine value should be present because side effects like contrast medium-induced nephropathy can occur, especially to people with existing kidney malfunctions. To avoid this, the European Society of Urogenital Radiology (ESUR) has published guidelines [27] for the administration of contrast medium concerning the creatinine value [28]. The value for the TSH should be present because contrast medium application may lead to thyrotoxicosis due to the small amounts of free iodine [29].

2.3 Legal Requirements

Before the computed tomography can be executed, the patient gets an information sheet where the examination process is explained. This information sheet contains questions about foregone examinations with contrast medium, any occurred side effects to contrast medium as well as questions concerning the general state of health, like the proper function of kidneys and thyroid gland as well as questions about asthma, allergies, heart diseases and diabetes. After answering these questions, the patient has to give his / her consent with his / her signature. An informed consent is mandatory before the beginning of a treatment (or an examination) because the patient has to agree with it, otherwise the performer is guilty of a criminal offence as written in § 110 in the Austrian Penal Code [6]. Every radiographer is legally bound to document all performed actions as legally required through § 11a Section # 1 in the professional law for members of the medical-technical staff [30].

Referring to the framework conditions above, a patient information sheet was created by the Austrian Roentgen Society (OERG). On the front page, general information about the CT examination is provided as shown in Figure 4. On the rear page, a questionnaire can be found to capture all required data for a safe administration of the contrast medium as shown in Figure 5.

Allergic reactions to contrast medium are very rare, but have to be checked carefully by questions about foregone examinations with contrast medium and possible occurred reactions to it [31].

When the patient has answered all the questions on the questionnaire, he / she has to sign to give his / her consent to the examination.

CT **PATIENT INFORMATION SHEET**
for the COMPUTED TOMOGRAPHY (CT) SCAN

OERG

englisch

Dear patient!

Your physician has referred you for undergoing a computed tomography (CT) examination. For your information, kindly read the text below and answer the questions that follow. This document has been designed to provide basic information. If you have any other questions, please do not hesitate to ask the medical technical staff or the examining physician.

What is a computed tomography scan?
A computed tomography (CT) scan is a special type of X-ray examination used to create cross-sectional images of the body. This allows the collection of important information about the position of the focuses of a disease which is often crucial for the further treatment.

What is the procedure like?
The examination takes approximately 10 to 20 minutes. In the CT room you will be resting on a special table top which will slowly move through the opening of the CT device during the examination. It is very important that you remain calm during the examination, avoid movements and strictly follow the breathing commands given to you. You will be monitored by specialists throughout the entire procedure.

Why is contrast medium being administered?
Depending on the examination, it may be necessary to administer a contrast medium injection or infusion into your arm. This may be necessary to illustrate certain organs and anatomical structures of the body and to help recognise pathological alterations. The relevancy of a number of examinations can be enhanced with contrast medium.

Are complications expected?
Similar to any other injection, tenderness, a haematoma and rarely an infection may occur at the injection site. One of the known reactions to **contrast medium** includes a sensation of warmth during the injection or bitter taste in the mouth. Intolerability-induced reactions can also occur after the administration of the **contrast medium:** a minor drop in blood pressure and associated minor complaints as well as nausea or tenderness have been reported in rare cases. Serious adverse reactions such as dyspnoea, sudden drop in blood pressure, arrhythmia or seizures are very rare.

In rare cases, the contrast medium exits the injection site in the arm during the infusion of the contrast medium into the vein. This causes painful swelling which may last for several days and requires treatment in some cases. If you feel pain and swelling of the arm during the infusion of the contrast medium, please immediately notify the physician during the examination.

Scientific studies[1] indicate that contrast medium is well tolerated by 97% of patients. The incidence of serious adverse reactions is reported to be 0.04 %. Similar to almost any medically indicated diagnostic procedure, a life-threatening complication is possible, albeit highly unlikely.

Therefore, the risk associated with the examination is very low compared to the achieved benefits. However, if any adverse reactions arise, medical care will be available immediately.

To be able to evaluate your potentially increased risk for adverse reactions to contract medium, we ask that you kindly answer the questions provided overleaf by checking the appropriate answer.

If you are uncertain about how to answer any of the questions provided overleaf, please seek clarification from the medical technical staff or the physician.

[1] KATAYAMA study, report investigating the safety of contrast media based on 300,000 cases (Radiology 1990, 175, p. 621 – 628)

Figure 4 Front page of the patient information sheet by the OERG in English

CT

1. **Height:** ..... **Weight:** .....
2. **For women:** **Are you pregnant?** No ☐ Yes ☐
   Are you currently breastfeeding? No ☐ Yes ☐
3. **Have you ever undergone any of the following examinations?**
   - Kidney X-rays (i.v. urography) No ☐ Yes ☐ .....
   - Computed tomography scan (CT) No ☐ Yes ☐ .....
   - Depiction of the leg veins (phlebography) No ☐ Yes ☐ .....
   - Blood vessel X-rays (angiography/cardangiography) No ☐ Yes ☐ .....
4. **Did you experience any adverse reactions after the administration of contrast medium?** No ☐ Yes ☐
   If yes, which ones?
   - Nausea / vomiting / gagging No ☐ Yes ☐ .....
   - Asthma attack/dyspnoea No ☐ Yes ☐ .....
   - Skin rash No ☐ Yes ☐ .....
   - Seizures, unconsciousness No ☐ Yes ☐ .....
   - Chills No ☐ Yes ☐ .....
5. **Have you been diagnosed with any of the following diseases?**
   - asthma? No ☐ Yes ☐ .....
   - allergies requiring treatment? No ☐ Yes ☐ .....
   - of the heart? No ☐ Yes ☐ .....
   - of the kidneys / adrenal gland? No ☐ Yes ☐ .....
   - of the thyroid? No ☐ Yes ☐ .....
   - diabetes? No ☐ Yes ☐ .....
     - if yes, what kind of drugs are you taking? .....
   - Kahler's disease (multiple myeloma)? No ☐ Yes ☐ .....
6. **Are you fitted with a pace maker?** No ☐ Yes ☐ Make:.....
   (only relevant for patients undergoing chest CT's)

By signing below, I confirm that I have read and understand the text of this form and that I have answered the questions concerning my person to the best of my knowledge. **I consent to the conduct of the proposed examination.** My other questions were adequately answered during a personal conversation.

☒

Patient's and/or legal guardian's signature	Physician's name and signature
Date / time	Med. tech. employee's name and signature

☞ **Please hand this form to the assistant prior to the examination.**

Physician's remarks about the briefing:

.....

.....

.....

Patient's name:

The patient agrees to undergo the examination **Yes ☐ / No ☐**

If the patient refuses to undergo the examination, s/he was informed about the potentially resulting negative impact.

.....

Compiled by the following working group: Med. director Dr. W. Küster – Med. director Prof. Dr. G. Mostbeck – S. Möritz-Kaisergruber, B.S., M.I.M. – Prof. Mag.iur.Dr.H.Ofner, LLM (Vienna University) – associate Prof. Mag. iur. Dr.med. A. Resch-Holeczke – Med. director lecturer Dr. W. Schima, MSc

Figure 5 Rear page of the patient information sheet by the OERG in English

2.4 Usability

Usability cannot be defined as an aspect because it depends on the intended use case [22]. It is marked by certain attributes as usefulness, efficiency, effectivity, learnability and accessibility [21, pp. 4, 5] [22]. The target audience must be considered by posing questions about who the users of the product will be, what they need and how they can be supplied [22]. It is important to “speak the user’s language” [32] as claimed by Nielsen and Molich. The user’s physiology and psychology should also be taken into account [33]. It is a difference if a system will be used professionally as imaging software by photographers or as a billing system by accountants in everyday use for example, where it is possible to learn how the system works, or if the user just gets in contact with the system once and has to use it without training.

“To be usable, a product or service should be useful, efficient, effective, satisfying, learnable, and accessible.” [21, p. 4] Efficiency can be described as the quickness in which the user can fulfill the task. Effectiveness means, that the product behaves the way the user expects. Satisfaction refers to the user’s opinion found out by an interrogation. Learnability has to do with the user’s ability to operate the system after some training. Accessibility can be quoted as the possibility to use the product with disabilities [21, pp. 4, 5].

For the development of interactive prototypes for informed consents, it must be considered, that the system users may not be firm with technical devices. Simple and intuitive handling must be ensured.

A common way to assess the usability of a product is the “System Usability Scale” developed by John Brooke in 1986. This scale contains ten statements where a Likert scale with five gradings is used [34].

3 Methodology

First, a prototype was created using MarvelApp[4] – a web based prototyping tool. The user interface was designed regarding specific guidelines for usability and accessibility. In the next step, an evaluation questionnaire was generated to assess the usability and acceptance of the prototype. The subjects were chosen upon specific criteria of impaired vision. In the last step a procedure was created to perform the usability test of the prototype and the evaluation of it every time in the same way.

3.1 The Prototype

Referring to Bernstein, a prototype is a tool to understand requirements and to build up an evaluation process on it. It's a simplification of the communication process between designer and user because their needs can be better understood. The prototype acts as a demonstration tool to show what is feasible and allows to integrate future users in the design process which may lead to more creative and forward looking inputs [35]. Ferre et al. describe a prototype as valuable for usability testing in early development phases [22].

Nelson et al. distinguish between low-fidelity and high-fidelity prototypes. Low-fidelity prototypes are sketches on paper while high-fidelity interactive prototypes look like the finished products [36].

For this master thesis a high-fidelity interactive prototype was created. The program flow had to be developed since the prototype should not be a direct transformation of the paper-based consent but an interactive guide through the questions.

After the creation of the flowchart, the next step was the design of the user interface which is based upon single screens created with Apple Keynote[5]. The EBU-Guidelines [3] and the Human Interface Guidelines for iOS by Apple [4] served as a basis for the design regarding font types, font sizes, buttons, etc.

[4] https://marvelapp.com

[5] https://www.apple.com/keynote/

To make the prototype usable for the target audience, key points of usability were considered and implemented.

The final step to create a functional prototype was finished when all the different screens of the user interface were linked together, so that the result was a clickable prototype which leads the users through the flow of the questions.

3.1.1 Flowchart

Before the prototype was created, a flow-chart was drawn using draw.io[6] to make a graphical overview on the walkthrough progress.

In the paper-based version of the informed consent, the patient must read through all the questions one after another, even if the response to the posed questions is not necessary. For example, if the patient has never received contrast medium before, he / she should not be bothered with reading questions about occurred reactions to contrast medium.

With the possibilities of an interactive porotype this block of questions concerning contrast medium can be skipped as shown in Figure 6, which can fasten up the whole process.

[6] https://www.draw.io

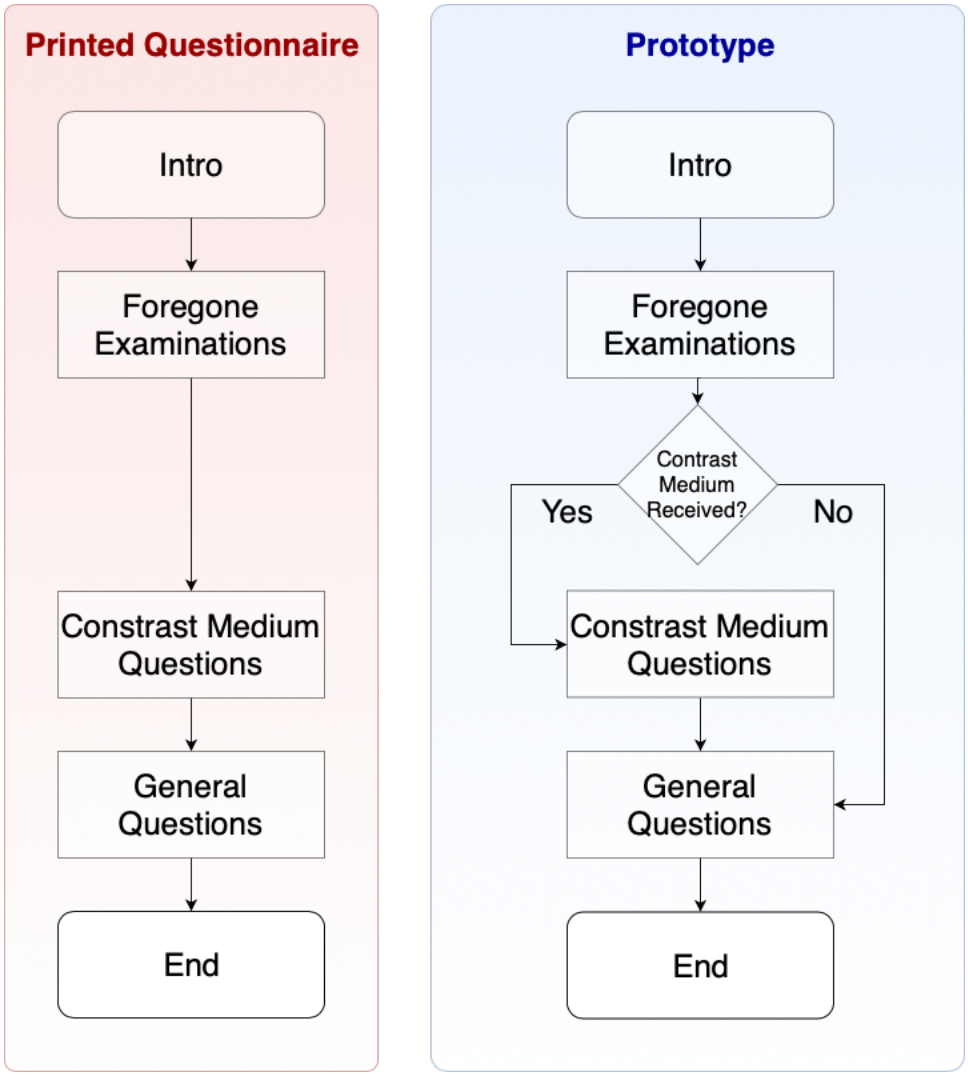

Figure 6 Different flows between printed questionnaire and prototype

3.1.2 Usability

Key points like target group, accessibility, effectivity, efficiency, learnability and the task to accomplish were considered for the creation of the prototype [21, pp. 4, 5], [22].

The system users would be patients attending a computed tomography which is an exceptional situation. They may not be firm with technical devices and are forced to answer the questions on the questionnaire in any way (paper-based / tablet-application). Regarding accessibility, the prototype must be usable for people with vision impairment.

To fulfill effectivity and efficiency, it was the aim to provide a simple intuitive user interface with clear buttons and captions where all the needed questions can be answered as fast as possible.

Regarding learnability, it was necessary to create a system which is usable with a minimum amount of introduction, because no training is provided like done with other application software. As the prototype is not intended for everyday use, users can ignore the tool after the CT examination.

To fill out the questionnaire correctly was the task to accomplish. Clear instructions, clear feedback and a clear and easily understandable user interface had to be provided to support the user. Audio-based support was implemented through the possibility to get the on-screen text read out. The possibility to undo false inputs was provided with a “back button”.

3.1.3 Design of the Screens

To create the screens of the prototype, the software Keynote, which ships with every Apple computer as part of the iWork office suite, was used. Basis of the design sketches were the EBU Clear Print Guidelines [3]. These guidelines, published by the EuroBlindUnion[7] constitute an example of the Universal Design (Inclusive Design) principles [3, p. 3]. Since the prototype was designed for an Apple iPad, the other source for creating the screens for the prototype were the Human Interface Guidelines for iOS [4] provided by Apple[8].

3.1.3.1 Written Content

Since the participants of the study would have German as a mother tongue, the content was based upon the German version of the paper-based informed consent provided by the OERG shown in Figure 7 [1]. The written text in the prototype was changed due to various reasons.

The introduction / explanation was shortened because it was for a prototype and not for use in a real clinical setting, so there could not be any harm to the test subjects by cutting the given information.

Personal data such as name, birthdate, gender, size, weight, etc. were not queried. In a real clinical setting, there should be no need to enter the data, because it should be provided through the interface to the Radiology Information System

[7] http://www.euroblind.org

[8] https://apple.com/

(RIS). This interface could also be used to skip the question for pregnancy, if the user's gender is male.

Since the answer of the question leads to the next slide, it was necessary to repeat the context of the question all the time. So instead of "Have you ever had one of the following examinations?" with the choice of yes and no for every examination, the text was changed to "Have you ever had a computed tomography?" (yes / no), "Have you ever had an angiography?" (yes / no), etc.

After the block of questions with foregone examinations, the question for contrast medium is asked "Have you received contrast medium into your veins during one of the examinations mentioned before?". This is, where the split comes: If the user's answer is "no", the block with the questions concerning contrast medium will be skipped as shown in Figure 6. If the user answers this question with "yes", he / she will be led to the block with questions about contrast medium. These questions were adapted as well.

The question "Have there been any side effects to contrast medium? If so, which ones?" was removed. One reason for this was the limitation of the prototyping tool, concerning the input of manual text. The other one was the simplicity in design. In this block the questions were adapted as well, repeating the context to contrast medium all the time, so there cannot be any confusion if the questions for skin rash or asthma for example, are general questions or refer to the application of contrast medium.

Combined questions like "Have you ever had nausea / vomiting / retching" were split in single questions like "Did you have nausea caused by contrast medium?", "Did you have to vomit because of contrast medium?" and "Did you have retching caused by contrast medium?". The same scheme was used for the block with the general questions.

The questions for the name of diabetic medications was removed. For one thing, because the question is not necessary for the user acceptance and on the other hand, diabetic medications like Metformin are only relevant in combination with kidney diseases [27]. This question could be linked to the question for diabetes and the question for kidney diseases in a real time scenario and linked to the creatinine level and the glomerular filtration rate (GFR) through the various interfaces with the Hospital Information System (HIS) and the Radiology Information System.

The question for the cardiac pacemaker and its manufacturer was removed as well as the field where the patient should sign to give his / her consent.

Österreichische Röntgengesellschaft,
Gesellschaft für Medizinische
Radiologie und Nuklearmedizin

AUFKLÄRUNGSMERKBLATT
Computertomographie (CT)

1. **Größe (cm):** _____ **Gewicht (kg):** _____
2. **Für Frauen:**
   Besteht die Möglichkeit einer Schwangerschaft? ☐ Nein ☐ Ja _____
3. **Haben Sie schon einmal eine dieser Untersuchungen gehabt?**
   - Computertomographie (CT) ☐ Nein ☐ Ja _____
   - Gefäßröntgen (Angiographie / Herzkatheter) ☐ Nein ☐ Ja _____
   - Nierenröntgen (Urographie) ☐ Nein ☐ Ja _____
   - Darstellung der Beinvenen (Phlebographie) ☐ Nein ☐ Ja _____
4. **Traten bei Ihnen nach der Gabe von Kontrastmittel Nebenwirkungen auf?** ☐ Nein ☐ Ja
   Wenn ja, welche? _____
   - Übelkeit / Erbrechen / Würgegefühl ☐ Nein ☐ Ja _____
   - Asthmaanfall / Atemnot ☐ Nein ☐ Ja _____
   - Hautausschlag ☐ Nein ☐ Ja _____
   - Krampfanfälle, Bewusstlosigkeit ☐ Nein ☐ Ja _____
   - Schüttelfrost ☐ Nein ☐ Ja _____
5. **Leiden Sie an einer der folgenden Erkrankungen?**
   - Allergien, die einer Behandlung bedürfen? ☐ Nein ☐ Ja _____
   - des Herzens ☐ Nein ☐ Ja _____
   - der Niere / Nebenniere? ☐ Nein ☐ Ja _____
   - der Schilddrüse? ☐ Nein ☐ Ja _____
   - Zuckerkrankheit (Diabetes)? ☐ Nein ☐ Ja _____
     Wenn ja, welche Diabetes-Medikamente nehmen Sie? _____
   - Myasthenia gravis? (spezielle Muskelerkrankung) ☐ Nein ☐ Ja
6. **Tragen Sie einen Herzschrittmacher?**
   (nur relevant bei Thorax-CT-Untersuchung) ☐ Nein ☐ Ja Fabrikat: _____

Durch meine Unterschrift bestätige ich, dass ich den Text dieses Formulars gelesen und verstanden habe. Ich habe die Fragen nach bestem Wissen beantwortet. In einem persönlichen Gespräch wurden mir die Risiken erklärt und meine weiteren Fragen sind ausreichend beantwortet worden. Ich stimme der Durchführung der vorgeschlagenen Untersuchung zu.

Unterschrift der Patientin/des Patienten und/oder des gesetzlichen Vertreters	Name und Unterschrift der Ärztin/des Arztes
Datum / Uhrzeit	Name und Unterschrift der/des MTD

Wir bitten Sie, dieses Formular vor der Untersuchung dem Sie betreuenden medizinsch-technischen Fachpersonal zu übergeben.

Ärztliche Anmerkungen zum Aufklärungsgespräch		
Die Patientin/der Patient stimmt der Untersuchung zu	Ja ☐	Nein ☐

Im Fall der Ablehnung der Untersuchung wurde die Patientin/der Patient über die sich ergebenden möglichen Nachteile informiert.

Figure 7 Rear page of the patient information sheet by the OERG in German

3.1.3.2 Color Scheme

Glare affects the majority of people with low vision. [3] As written in the Encyclopedia of Blindness and Vision Impairment by Jill Sardegna, photophobia, also called fear of light means that pain may occur in the eyes when looking at light which also leads to blinking and squinting. It is not a disease itself but a symptom or result of a multitude of ocular disease or disorder [23, p. 182]. For that reason, a black background with light fonts was used as suggested by the EBU Guidelines [3].

Apple provides a set of all needed interface components as buttons, fonts, colors, etc. for developers as a Keynote presentation in their Apple Design Resources [37].

The color scheme of the dark version, shown in Figure 8 was used to create the screens. For the titles, the standard text and the text on the buttons, white was used as a color except for the “back button”, where the font color orange was used as shown in the template provided by Apple.

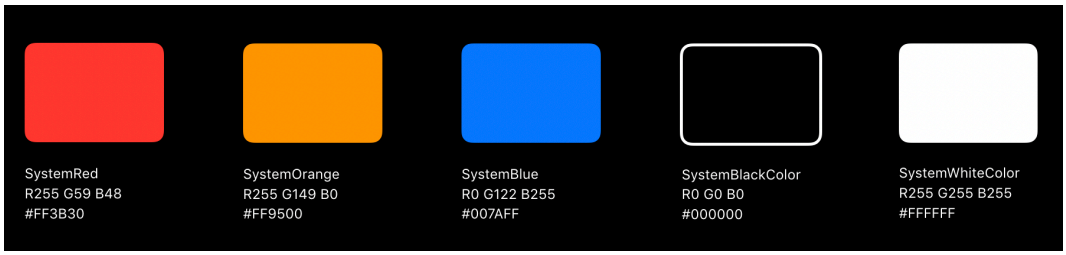

Figure 8 Dark color scheme for iOS provided by Apple

For the “no” button, the color red was chosen as a color, because “there is a general societal association between red and danger where negative possibilities are salient, such as stop signs or warning signals” [38]. Thinking of a traffic light, green would be the expected opposite color to red. Green is used as an opposite color to red in several color models and has some general associations with approaching motivation as described by Elliot and Maier in their setup for their first experiment to test the effect of red on intellectual performance [38]. Since this app should be designed for people with vision impairment, where colorblindness (and green blindness) belong to as well, the combination of red and green was avoided, and blue was used instead of green, because a person with green blindness sees reds, oranges, and greens as much the same shade and cannot distinguish between them [23, p. 44].

3.1.3.3 Design Elements

The user interface has to be simple, not cluttered, reduced to the essentials and of aesthetic and minimalist design [32], [39]. To provide good legibility of the content, the font type was set to San Francisco (SF) which is the standard font in Apple's iOS [4]. It is a serif-less font type as proposed in the EBU Clear Print Guidelines [3]. Relying on these guidelines left alignment was used and setting the font to bold was done for highlighting important words [3]. The EBU Clear Print Guidelines recommend font sizes between 14 pt. and 18 pt. [3]. To take advantage of the 9.7-inch screen size of the iPad, the font size was set to 110 pt. for on screen text and to 100 pt. for the labels of the "yes" and "no" buttons.

On top of the screen a navigation bar was designed to provide the users a hint on where they are during their walkthrough process of the app as suggested by Thompson and Kemp [39]. The segmentation was just for the three blocks mentioned in chapter 3.1.3.1. In this prototype, it was not possible to realize a variating display of numbers as it would have been needed due to the variable count of total questions. As shown in Figure 6, it is possible to skip a block of questions. Also, a "back button" with a font size of 40 pt. was created to provide the opportunity to go back to the previous question for the user.

In the middle of the screen, an image of a speaker in size 500 pt. by 500 pt. was placed. The image source is an SVG vector graphic provided by Wikipedia[9] under the public domain license. The color of the icon was changed to the same shade of grey as used in the color scheme of SoundCloud[10] to provide that the button for the playable audio file will integrate well in the user interface.

Figure 9 shows all of the used design elements except the button for the playable audio file.

[9] https://www.wikipedia.org

[10] https://soundcloud.com/

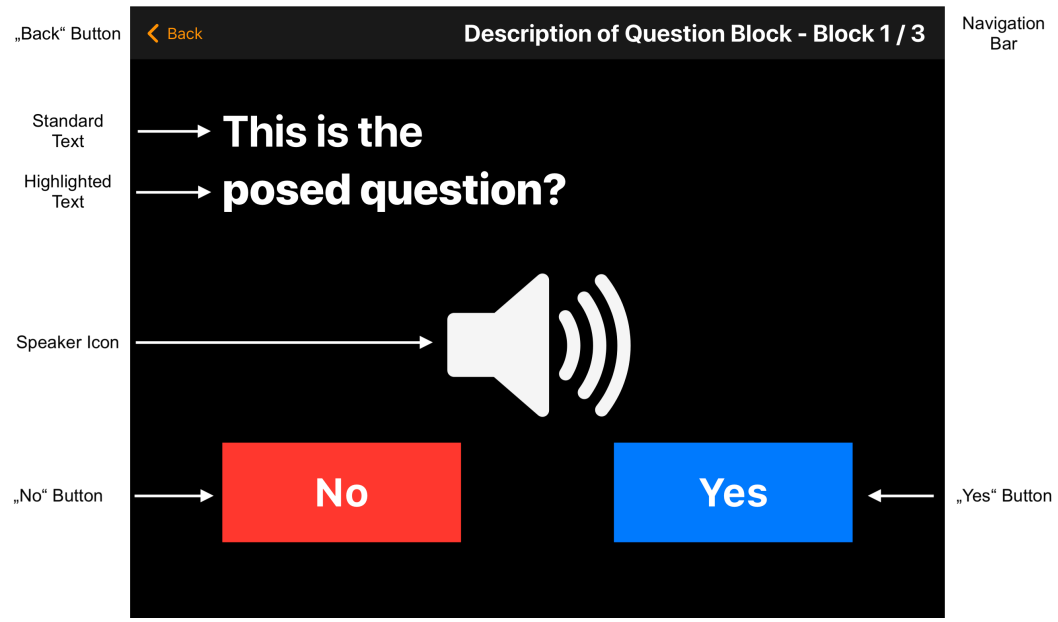

Figure 9 Design elements used in the prototype

3.1.4 Creating an Interactive Prototype

After the design of the user interface was finished, a tool was needed to create a clickable, respectively tap-able prototype which should behave like a native iOS application. After some research which prototyping environment would fit best, MarvelApp was chosen.

3.1.4.1 Hot Linking

To make the prototype behave like a native iOS application, it was necessary to export the slides as PNG files. These images were uploaded to the MarvelApp creating tool which is a web application.

To make it feel like a real application, it was necessary to draw so called hotspot areas. The buttons of the slides were marked, and the target image must be

selected as shown in Figure 10. The screens do not follow sequentially one after the other, the user's choice makes the difference in the progress.

Figure 10 Hot linking the "no button" with MarvelApp: A hotspot area is drawn over the "no button" and links to the next screen.

For the "back button", a preset value can be used to link to the last visited image as shown in Figure 11.

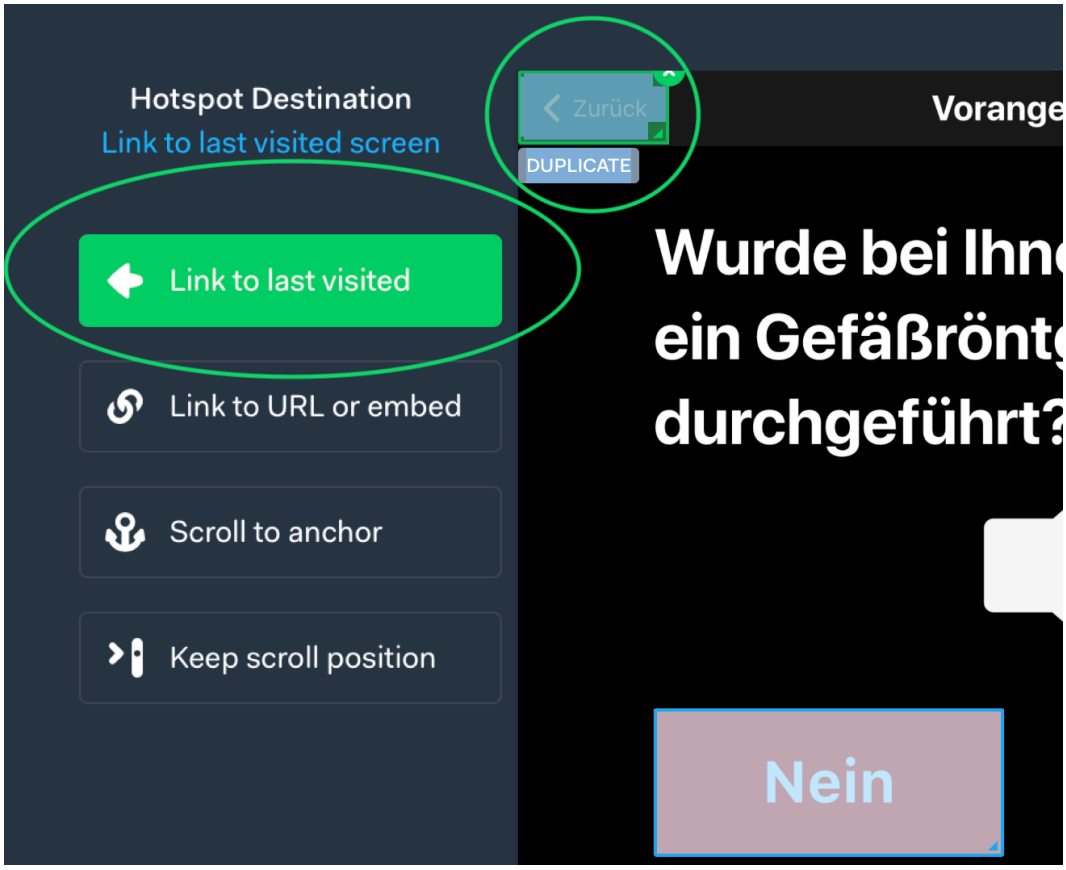

Figure 11 Hot linking the “back button” with MarvelApp: A hotspot area is drawn over the “back button” and the destination is set to the last visited screen.

3.1.4.2 Sound Files

To support people with vision impairment, and even illiterate people, the instructions and questions can be read out by the prototype application.

The read-out questions were recorded by using Audacity[11] as shown in Figure 12. Audacity is released under the GNU General Public License (GPL). The recorded audio files were exported as ogg-vorbis. A SoundCloud[12] account for artists was created where the audio files could be uploaded. Due to limitations of the prototyping tool, this was the only way to implement sound files as shown in Figure 13.

[11] https://www.audacityteam.org/

[12] https://soundcloud.com/

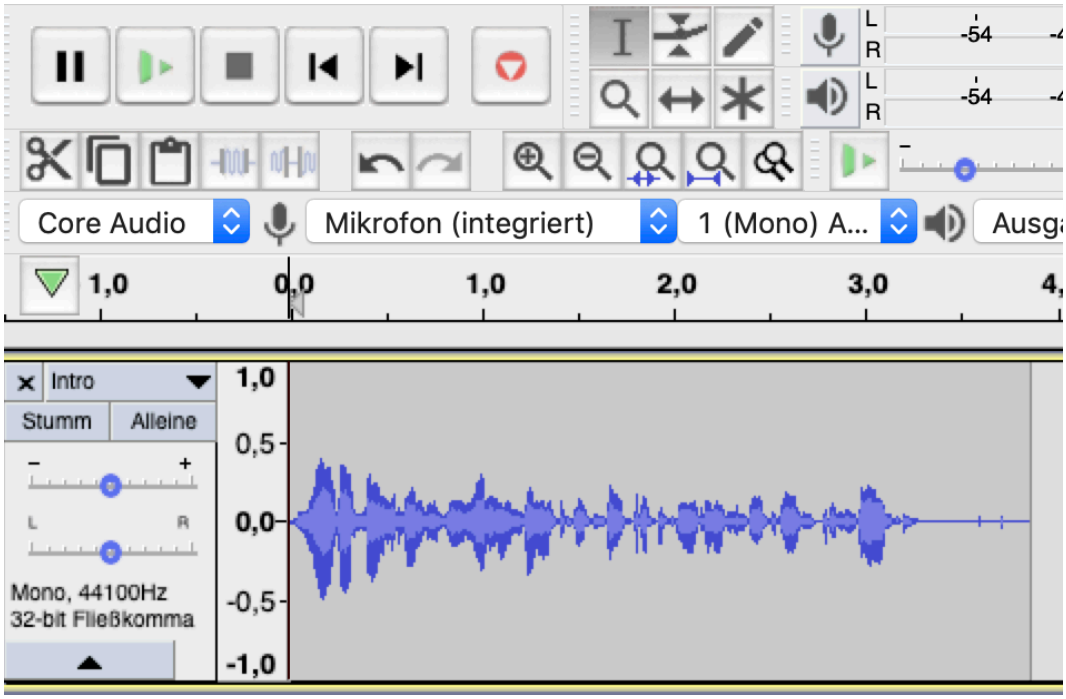

Figure 12 Recording of a read-out question with Audacity

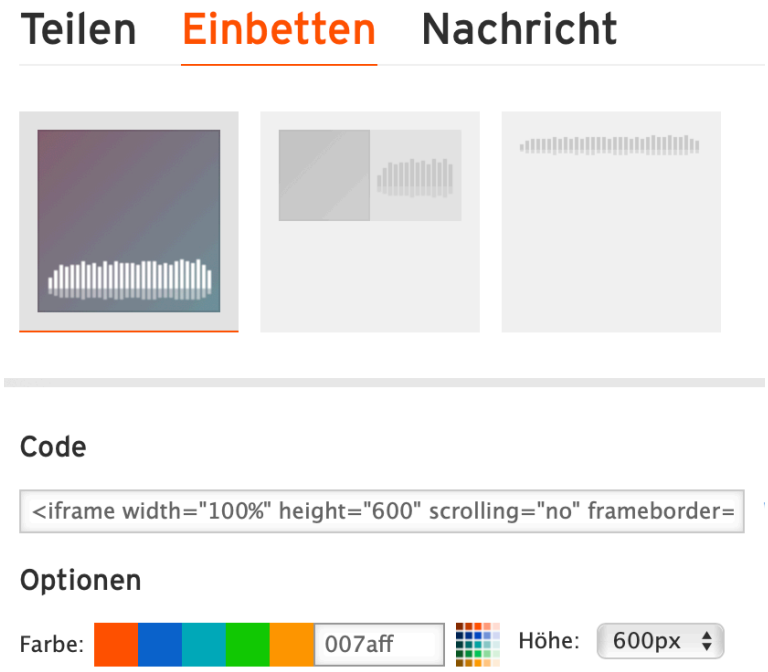

Figure 13 Embedding with SoundCloud. The code is used for integrating in MarvelApp.

The hotspot area which includes the embedded SoundCloud player was downsized to the absolute minimum, so it just looks like a “play-button”, which

should be an established symbol. The link to the cookie policy could not be removed due legal requirements by SoundCloud.

The standard SoundCloud player has a certain visual appearance which had to be adapted using some settings in the html source code of the embedded link [40].

This is what an original embed code looks like:

```
<iframe width="100%" height="600" scrolling="no" frameborder="no"
allow="autoplay"
src="https://w.soundcloud.com/player/?url=https%3A//api.soundcloud.com
/tracks/568986807%3Fsecret_token%3Ds-
qEvM3&color=%23f6f4f5&auto_play=true&hide_related=false&show_comments=
true&show_user=true&show_reposts=false&show_teaser=true&visual=true"><
/iframe>
```

This is what the adapted code looks like (highlighted):

```
<iframe width="100%" height="600" scrolling="no" frameborder="no"
allow="autoplay"
src="https://w.soundcloud.com/player/?url=https%3A//api.soundcloud.com
/tracks/568986807%3Fsecret_token%3Ds-
qEvM3&color=%23007aff&auto_play=true&hide_related=true&show_comments=f
alse&show_user=false&show_reposts=false&show_teaser=false&visual=false
"></iframe>
```

The color of the play-button was changed to the same shade of blue as used in the other design elements in the prototype, following the Apple developer guidelines, changing the value after the part `color=%23` to `007aff`. To eliminate most of the content that would disturb the user experience, the value for `hide_related` was set to `true` and the values `show_comments`, `show_user`, `show teaser` and `visual` were set to `false`. The result of the adaption is shown in Figure 14.

To do this for all embed-codes together, all the links were written into a text file and the values mentioned above were changed with the search and replace function of the text editor.

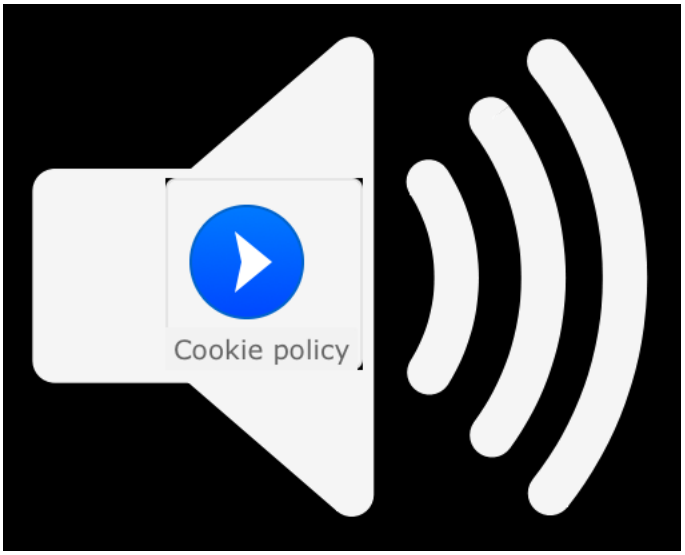

Figure 14 Play-button on the speaker image, “cookie policy” cannot be removed due legal requirements by Sound Cloud

3.2 The Evaluation Questionnaire

To evaluate if the prototype is useable and accepted by people with impaired vision, a questionnaire was created using QuestionPro[13] with the student’s license of the St. Pölten University of Applied Sciences. The questionnaire was designed to be best viewable with the Apple iPad. An example of the overall look is provided in Figure 15. The complete questionnaire can be found in Appendix E.

[13] https://www.questionpro.com/

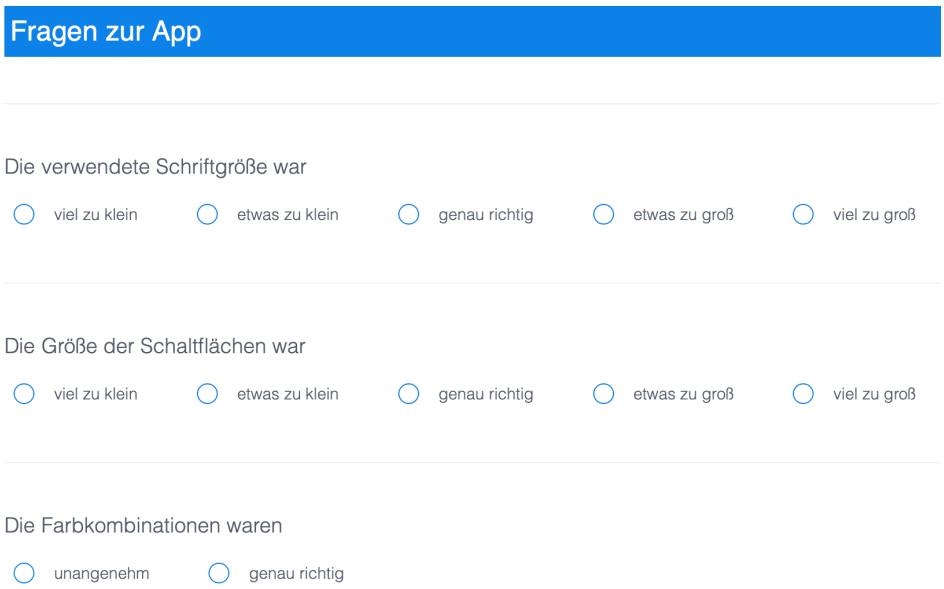

Figure 15 Example of an extract of the QuestionPro questionnaire

To assess the usability of a product the “System Usability Scale” developed by John Brooke is very common. This scale contains ten statements where a Likert scale with five gradings is used [34].

The ten statements are:

1. I think that I would like to use this system frequently.

2. I found the system unnecessarily complex.

3. I thought the system was easy to use.

4. I think that I would need the support of a technical person to be able to use this system.

5. I found the various functions in this system were well integrated.

6. I thought there was too much inconsistency in this system.

7. I would imagine that most people would learn to use this system very quickly.

8. I found the system very cumbersome to use.

9. I felt very confident using the system.

10. I needed to learn a lot of things before I could get going with this system.

[41, p. 192]

Taking a closer look at these statements, they do not fit to evaluate the prototype because the system will not be used frequently by the users [22]. Statement 5 and 6 are too technical to be answered by the prototype users. It does not “speak the user's language” [32] as claimed by Nielsen and Molich. The usability test itself should fulfil the key points of usability and therefor the usability part of the evaluation questionnaire was adapted regarding the prototype and the target audience.

The ”system usability scale” evaluation scheme could not be used because no statements were used with answer possibilities from "do not agree" to "strongly agree" where scores are awarded. Instead, eight questions were posed regarding the personal feeling and experience while using the prototype. The evaluation score was defined as follows: every time the given answer “just right” / “helpful” / “clear” / “app” was the most chosen, a score of 5 points was assigned. When the given answer “a little bit too small” / “a little bit too large” was the most chosen one, a score of 3 points were assigned. When the given answer was “much too small” / “much too large” / “uncomfortable” / “unnecessary” / “complicated” / “paper-based form” was chosen the most, 0 points were given. A theoretical maximum of 40 points could be reached. These points were multiplied by 2.5 to scale the total maximum to 100 points.

Inspired by “Item Benchmarks for the System Usability Scale” by Lewis and Sauro, who showed the curved grading scale to interprete the “system usability scale” with a grading system from A+ to F (A+, A, A-, B+, B, B-, C+, C, C-, D, F) [42], an adapted version regarding to the five Austrian grades was used as shown in Table 1.

Table 1 Usability Score with equivalent in Austrian grades and interpretation

Score	Grade	Grade Name	Interpretation
78.9 - 100	1	Very good	Very usable
72.6 - 78.8	2	Good	Usable
62.7 - 72.5	3	Satisfactory	Usable with improvement
51.7 - 62.6	4	Sufficient	Hardly usable
0 - 51.6	5	Unsatisfactory	Unusable

The content of the questionnaire is as well inspired by the “Handbook of Usability Testing” by Jeff Rubin and Dana Chisnell [21, pp. 197–198] and “SUPR-Qm: A Questionnaire to Measure the Mobile App User Experience” by Jeff Sauro and Pareezad Zarolia [43]. The questionnaire was structured in four blocks of questions (prototype itself, comparison between prototype and paper-based form, subject’s personal background, subject’s technical background). A challenge for creating the questionnaire was the fact that usability tests are mostly developed for applications people use voluntarily and not in a kind of necessity like a medical examination.

To provide a short briefing for the participants, an introduction screen was created. The title of the master thesis project was mentioned as well as the hint given, that the participation is voluntarily and confidential. The participant was informed that a dropout is possible all the time. To provide a significant result, it was necessary to make most of the questions mandatory. The participant was made aware that questions marked with an asterisk (*) must be answered. To prepare the participant for the duration of the questionnaire, the overall number of questions (18) and the estimated time to complete (ten minutes) were provided as well.

Block 1: seven questions about the **prototype itself**.

Question 1 asked for the font size.

Question 2 asked for the size of the buttons.

There were five response options. The participant could choose from much too small, a little bit too small, just right, a little bit too large and much too large.

Question 3 asked for the color combination of text color to background color.

Question 4 asked for the color combination of text color to button color.

Question 5 asked for the color combination of the two buttons which where red and blue.

These questions could be answered as uncomfortable or just right.

Question 6 asked if the voice output was helpful or unnecessary.

Question 7 was about the navigation; if it was complicated or clear.

Block 2: two questions to find out the **preferred interrogation method**.

Question 8 was about the wording of the questions in the prototype. Participants could choose if the prototype, the paper-based form or both are equally comprehensible.

Question 9 was about the preference, asking which kind of questionnaire the participants would prefer in the future, or if there is no preference between the app and the paper-based form. It further aims to show if the application is accepted by the target audience. This question was the pivotal question to evaluate the acceptance of the prototype.

Question 10 was the only voluntarily question in the whole questionnaire and is not assignable to a question block. It was the text field where the subjects could write what features they would like to have in such an app in the future.

Block 3: four questions to collect **sociodemographic data**.

Question 11 asked about the gender (male / female).

Question 12 asked for the age category (18-29 / 30-39 / 40-49 / 50-59 / 60+).

Question 13 asked for the top graduation (none / mandatory school / completed apprenticeship / general higher education/vocational school / university degree). Due to the difference in the Austrian / UK / US school systems, the translation of the types of schools might not be accurate. The used terms in the evaluation questionnaire were: kein Schulabschluss / Pflichtschule / Lehrabschluss / AHS/BHS / FH/Universität.

Question 14 was a self-assessment concerning the visual impairment using a three-step scale (light / moderate / heavy).

Block 4: four questions to examine the **technical background**.

Each question in this block could only be answered with yes or no.

Question 15 asked if the subject is experienced in dealing with personal computers.

Question 16 asked if the subject works a lot with personal computers.

Question 17 asked if the subject owns a smartphone.

Question 18 asked if a tablet computer is used privately.

After completing the questionnaire, a thank-you page was displayed, so the participant was informed that the questionnaire and the usability test are finished.

3.3 Subjects

A call to participate in the study was created and spread in the authors' family environment, work environment and via the online platform of the St. Pölten University of Applied Sciences as well as via e-mail to the "Hilfsgemeinschaft der Blinden und Sehschwachen Österreichs"[14]. Persons who were interested in participating had to write an e-mail to make an appointment for the usability test.

The group of subjects consisted of 20 individuals (7 males, 13 females). All subjects were older than 18 years. The majority (65 %) was older than 40 years. Self-assessed visual impairment was especially medium to heavy with a total of 85 %. All subjects had at least a completed apprenticeship (20 %), the majority had a university degree (45 %). The others (35 %) graduated from a general higher education / vocational school. Nearly all subjects (95 %) were experienced in dealing with personal computers. The majority (85 %) also works a lot with personal computers. Nearly all subjects (95 %) use smartphones. About half of the subjects (55 %) use a tablet computer privately. A detailed graphical breakdown can be found in Figure 16.

[14] https://www.hilfsgemeinschaft.at

General Sociodemographic Background

	Count	
Gender	n = 20	
male	7	35%
female	13	65%
Age Category	n = 20	
18-29	2	10%
30-39	5	25%
40-49	4	20%
50-59	4	20%
60+	5	25%
Top Graduation	n = 20	
none	0	0%
Mandatory School	0	0%
Completed Apprenticeship	4	20%
General Higher Education / Vocational School	7	35%
University Degree	9	45%
Visual Impairment (self assessment)	n = 20	
light	3	15%
moderate	11	55%
heavy	6	30%

Technical Background

Experienced in Dealing with Personal Computers	n = 20	
yes	19	95%
no	1	5%
Working a Lot with Personal Computers	n = 20	
yes	17	85%
no	3	15%
Owns a Smartphone	n = 20	
yes	19	95%
no	1	5%
Uses a Tablet Computer Privately	n = 20	
ja	9	45%
nein	11	55%

Figure 16 Sociodemographic key facts of the subjects

Inspired by the classification of the WHO for people with vision impairment, where a value of 6/12 / 20/40 presenting distance visual acuity is defined as mild vision impairment and the value worse than N6 with existing correction presenting near vision acuity [11], [44], the inclusion criteria were defined as follows: people who

cannot read the paper-based questionnaire by the OERG, which is printed in font size 6 pt. / 8 pt., within a distance of 40 cm were included in the study.

To evaluate the prototype, subjects who match the criterion of vision impairment tested the prototype and answered a questionnaire about it. The usability test and the interrogation were done from February to End of March 2019.

3.4 Procedure of the Study

This study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by the ethics committee of the federal state Lower Austria.

In the meeting, the subjects were asked, if they can read the content of the paper-based questionnaire of the OERG [1], [2]. If he / she could read it, the subject was excluded for the study, otherwise he / she could participate.

After the explanation of the handling of the collected survey data, the subject had to sign an informed consent (Appendix F). If he / she decided that he / she would not like to sign, the subject was excluded. The inclusion or exclusion process is shown in Figure 17. After that, the real part of the usability testing of the prototype and the following evaluation with the questionnaire could start.

The iPad was disinfected in front of the subjects' eyes before it was handed to him / her. After the usability test and the evaluation, it was disinfected again. Isopropanol wipes (Clinell ® by GAMA Healthcare Ltd., Watford, UK) were used to minimize germ transmission as investigated by Albrecht et al [45]. The subject used the iPad prototype once or many times if he / she wanted to try out certain possibilities again. The paper-based questionnaire by the OERG [1], [2] is handed to the subject again to compare the way the questions were posed.

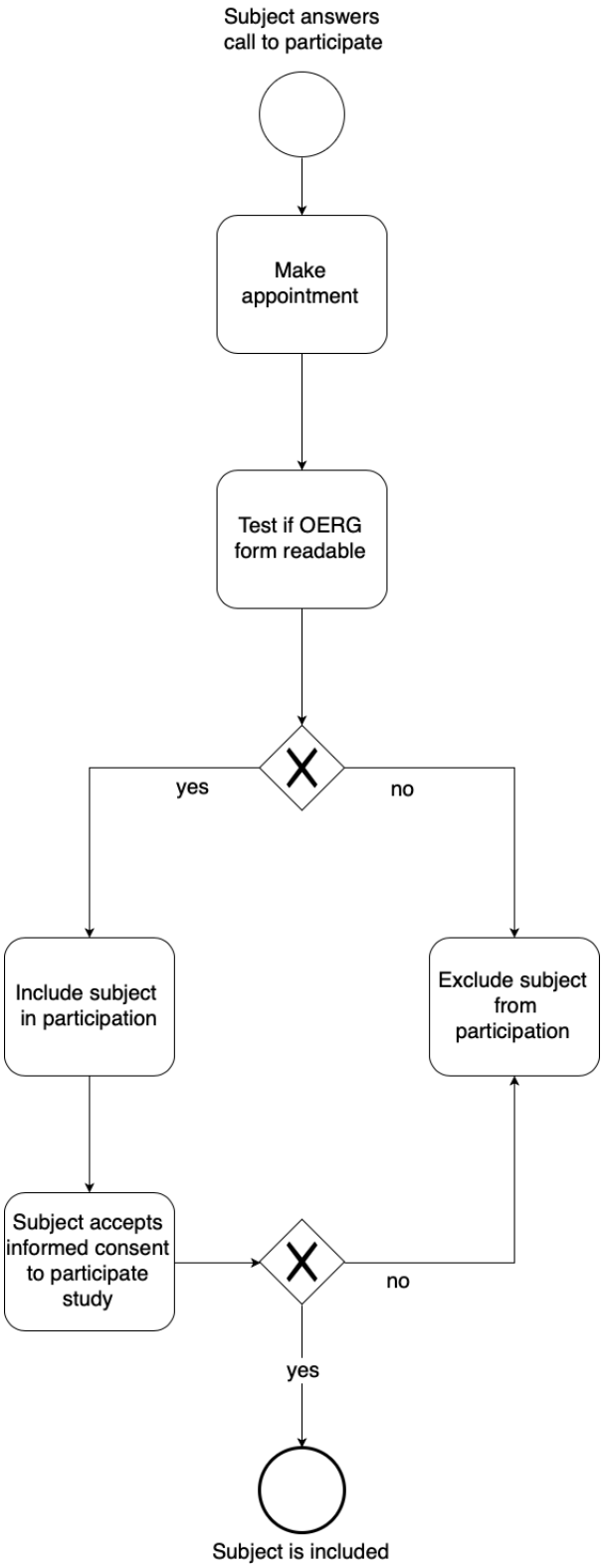

Figure 17 Inclusion / exclusion process

To make sure every subject is put in the same fictitious setting, every time the same text (Appendix A / B) was read out to him / her. After that, the printed questionnaire of the OERG [1], [2] was handed to the subject to make him / her aware of the particular issue.

A short briefing on the iPad was done to make sure every subject can handle the iPad in the same way. Every time the same text (Appendix C / D) was read out to him / her.

To assess the prototype, the designed evaluation questionnaire was filled out by the subjects with help where needed.

After this last step, the usability test and the evaluation process were finished as shown in Figure 18.

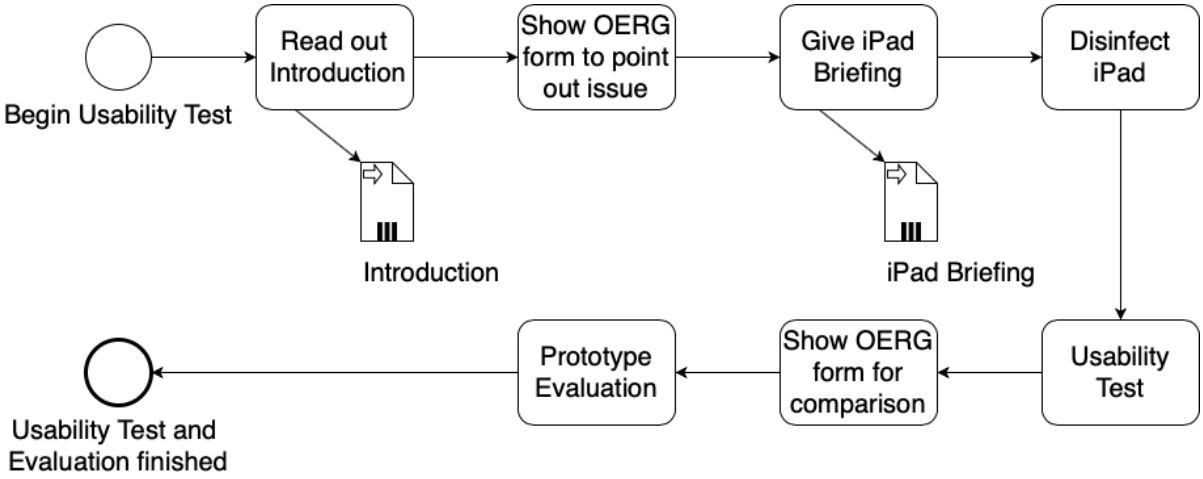

Figure 18 Process of the usability test and evaluation process

4 Evaluation Results

Usability and acceptance will be evaluated in this chapter. The quantitative results will be shown in bar charts and tables. The qualitative feedback of the subjects will be presented in a table.

No subject dropped out of the evaluation questionnaire.

The used font size was evaluated as “just right” by 70 % of the subjects, 20 % found it “a little bit too small” and 10 % rated it “a little bit too large”. Therefore 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

The size of the buttons was “just right” for 80 % of the subjects, 15 % found it “a little bit too large” and 5 % claimed it “a little bit too small”. Therefore, 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

The color combination of text color to background color was “just right” for 95 % of the subjects and uncomfortable for 5 %. Therefore, 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

The color combination of text color to background color was “just right” for 100 % of the subjects. Nobody claimed it as “uncomfortable”. Therefore, 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

The color combination of the buttons to each other (red / blue) was “just right” for 100 % of the subjects. Nobody claimed it as “uncomfortable”. Therefore, 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

The voice output was “unnecessary” for 65 % of the subjects and “helpful” for 35 %. Therefore 0 points are given for this question.

The navigation was “clear” for 100 % of the subjects. Nobody rated it as “complicated”. Therefore 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

The graphical results of the evaluation of the prototype itself are shown in Figure 19.

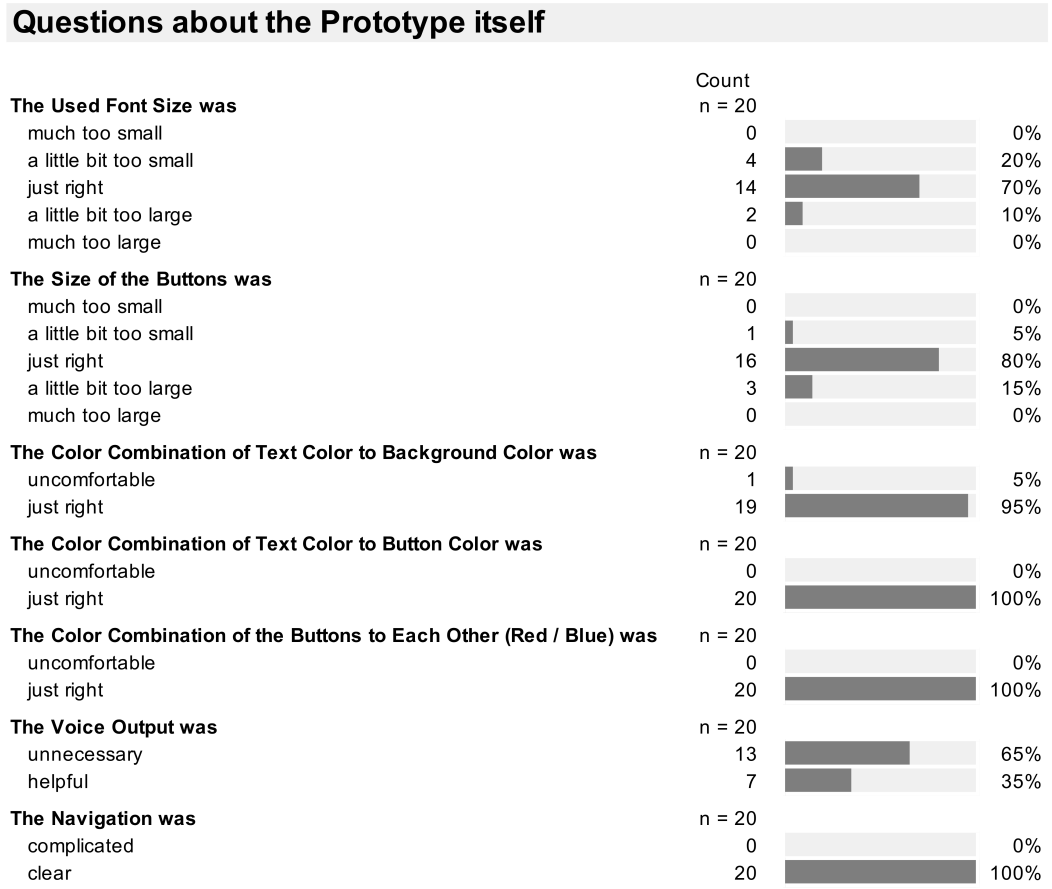

Figure 19 Questions about the Prototype itself including seven out of eight questions about the usability

The comprehensibility of the questions was better in the application, as claimed by 65 % of the subjects, or at least equally comprehensible like the paper-based form as selected by 35 %. Therefore, 5 points are given for this question. Multiplied by factor 2.5, the total score is 12.5.

Table 2 shows the calculated score of the usability questions.

Table 2 Evaluation of the usability including the most chosen answers and the score multiplied by factor 2.5 as explained in chapter 3.2

#	Question	Most chosen answer	Percentage	Score
1	Font Size	just right	70 %	12.5
2	Size of Buttons	just right	80 %	12.5
3	Color Combination Text-Background	just right	95 %	12.5
4	Color Combination Text-Button	just right	100 %	12.5
5	Color Combination Buttons (red / blue)	just right	100 %	12.5
6	Voice Output	unnecessary	65 %	0.0
7	Navigation	clear	100 %	12.5
8	Wording of the Questions	app	65 %	12.5
			Total Score	**87.5**

The comparison between prototype and paper is shown in Figure 20. The application is the preferred interrogation method by 75 % of the subjects. “No preference” was selected by 25 %. Nobody preferred the paper-based form which shows the acceptance of the prototype as proved.

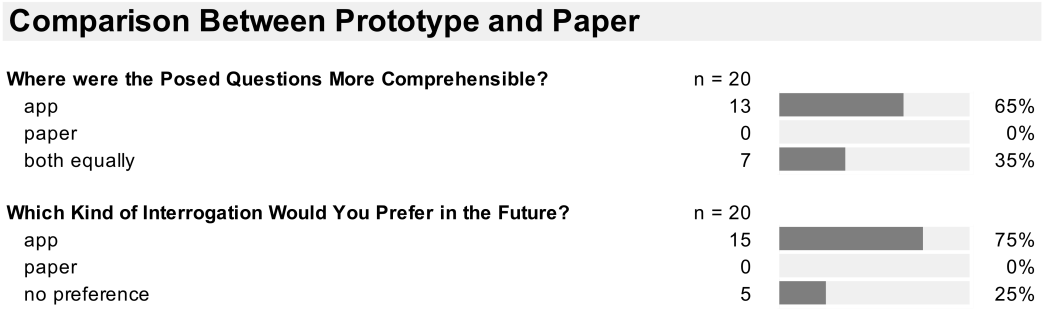

Figure 20 Comparison between prototype and paper

Only 5 subjects (25 %) used the text field for individual feedback and proposes for the application. Table 3 shows the German statements and an analogous English translation of the individual statements of the subjects. Spelling and typing errors were corrected. Nevertheless, many subjects spoke their thoughts out loudly while

answering the evaluation questionnaire. Though, all subjects were instructed to choose the answers that fit best for them, many subjects chose the voice output as helpful, because the voice output maybe helpful for other people and they did not want to label it “unnecessary”. Otherwise, the high number of subjects who claimed the voice output as “unnecessary”, could be a clue that the font size and chosen colors are helpful and usable enough to use the application without a voice output as shown through the questions regarding these key points.

Table 3 Individual text feedback of the subjects in German original and an English translation

German Original	**English Translation**
Die Antwortmöglichkeit: Weiß nicht.	The response option: don’t know
Schriftgröße variieren. Größer oder kleiner. Fix besser als Papier	Variable font size. Larger or smaller. Definitely better than paper-based
Orange – „zurück“ – ist nicht sehr optimal, schlechter Kontrast Schaltfläche „nicht bekannt“ z. B. Allergien fehlt Die App ist eine gute Idee und sollte bald umgesetzt werden, da es die Selbstständigkeit der Patientinnen fördert	Orange – “back” – is not very optimal, bad contrast Button “unknown” e.g. Allergies is missing The application is a good idea and should be implemented soon, because it empowers the self determination of the patients
App auf eigenem Smartphone vorhanden und daraus resultierende Datenübermittlung	Application on own smartphone and resulting data transmission
Kontrasthintergrund Einstellung Schriftart Einstellung Schriftgröße Einstellung	Contrast background setting Font type setting Font size setting

5 Discussion

As the usability test was done outside a real clinical setting, psychological factors like nervousness or anxiety which could influence people while doing the app-based questionnaire, were not given. For a significant result, the number of participants should be increased. An application like this should also be usable for people without visual impairment. No comparison was done with people with unimpaired sight.

Through the heterogeneous and small group of subjects, no strong relations comparing attributes like gender, age, visual impairment, etc. with the posed questions for usability and acceptance could be found.

Nearly all subjects (95 %) were experienced in dealing with personal computers and 85 % of the subjects work a lot with personal computers. This technical background could be a reason why the prototype was the preferred interrogation method for 75 % of the subjects, but a similar result was shown by Alikhani et al. where 83 % of the subjects preferred an electronic briefing over the paper-based form [46].

A relation between gender and acceptance (preferred interrogation method) can be suggested as shown in Figure 21. All subjects preferred the app or did not have any preference. No subject preferred the paper-based form. All male subjects had a strong preference for the app because none stated to not have a preference. About 60 % of the female subjects preferred the app while about 40 % did not have any preference. This could be because of the technical affinity of men as shown through a study of the Verbrauchs- und Medienanalyse (VuMA) in 2019 which evaluated the statement “I like to try out new technical devices” where about 47 % male respondents (totally) agreed while only about 18 % female respondents (totally) agreed [47].

Gender & Preferred Interrogation Method

Which Kind of Interrogation Would You Prefer in the Future?	Gender	n = 20	
app	female	8	40%
app	male	7	35%
both equally	female	5	25%
both equally	male	0	0%
paper	female	0	0%
paper	male	0	0%

Figure 21 All male subjects have a definitive preference for the app

A coherence between age of the subjects and the acceptance (preferred interrogation method) can be suggested as shown in Figure 22. 80 % of the subjects older than 60 years preferred the application, while 10 % had no preference. 100 % of the subjects in the age category 50-59 years preferred the application as well as 100 % of the subjects in the age category 18-29.

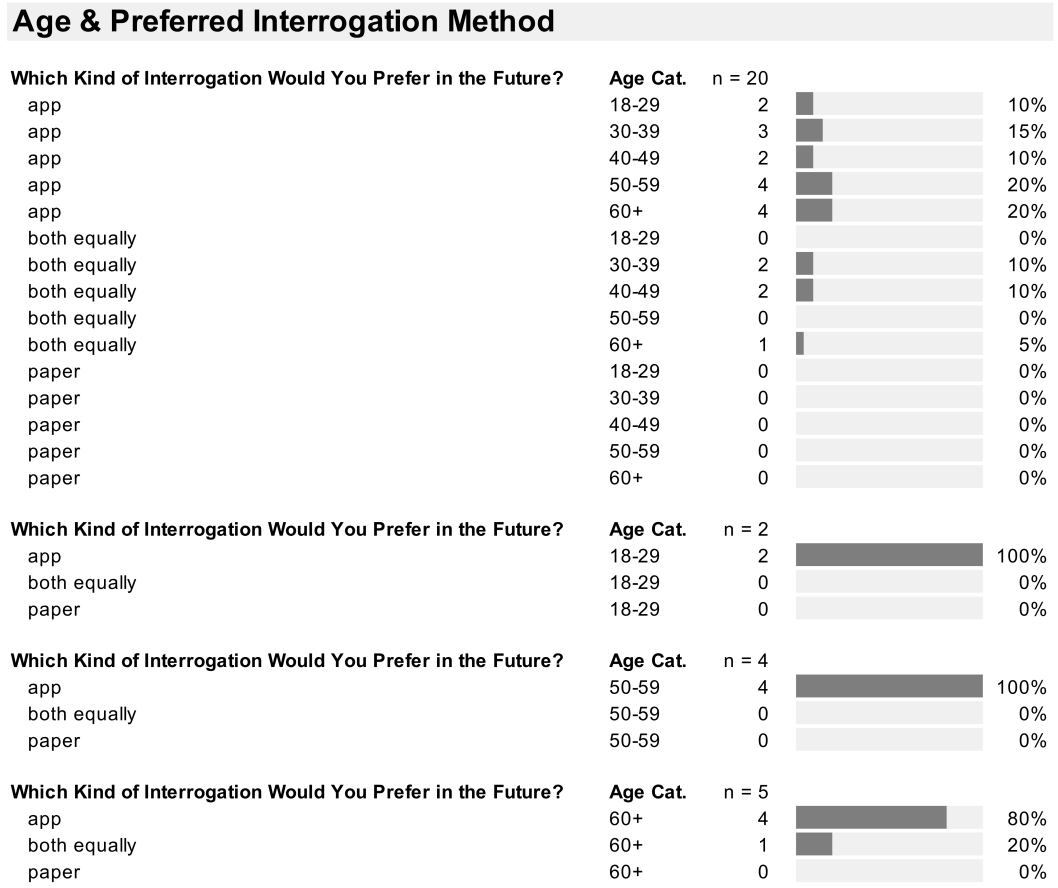

Figure 22 Acceptance of the app and preference for the app in the age category older than 50 years and younger than 30 years

Schlechtweg et al. claimed that the completion of an electronic version of the patient briefing takes longer to complete than the paper-based form [17]. This is true if the transformation of the paper-based patient briefing is done one-to-one. With the possibility of an interactive design, the amount of time for completion can be minimized as shown in Figure 6 and was realized in this prototype. On the other hand, a reduction of time was shown by Alikhani et al., where the whole process of electronic patient briefing took only half the time of the paper-based form, especially concerning background processes as archiving papers in contrast to the immediate digital transfer of the patient information into the digital archive [46]. Another reason for the shorter completion time of paper-based forms is already

shown in the study by Schlechtweg et al. themselves. The possibility to skip parts of the questionnaire and hand in incomplete forms is only given in paper-based forms. On an iPad application, the patient is only allowed to proceed to the next step/question when an answer is given. Incomplete forms are a well-known practice of patients and produce additional work for medical employees [18].

One subject suggested to provide the patient briefing on the user's smartphone and transfer data from there. This was also considered by Schlechtweg et al. as a possibility to react early to problematic constellations as renal diseases [17].

Another benefit of electronic patient questionnaires and informed consents is the elimination of illegible handwritings of the patients [18]. This applies as well for medical employees who use iPads. Vilstrup et al. stated in their study about the iPad use of nurses in home care that it was to be expected, regarding the societal use of technology as well as it represented professionalism. One of the participants in this study stated that "it seems as if things are under control" and "believes that it's better than writing Post-it's" and "it feels reassuring" [48]. Regarding these statements, another benefit in the use of iPads for patients as well as medical employees can be suggested: the perceived professionalism gives the patients an additional feeling of trust and security and might have a calming effect before an examination.

Electronic patient briefings would offer the possibility to add multimedia content like videos or images. No subject requested it, which matches the results of Schlechtweg et al. [17] in 2013. In the subsequent study of 2014, only 3 % of the participants wished to have multimedia content [18].

As already claimed by Schlechtweg et al., tablet computers like an iPad can serve as an alternative to paper-based patient briefing [17]. The acceptance of digital patient briefing was proved by Alikhani et al. regarding patients as well as medical employees and radiographers [46].

6 Rethinking the Prototype

After the usability test was done, it was time to critically review the prototype. Limitations of the prototype will be mentioned in this chapter as well as some aspects regarding the colors of the user interface. This was also done with a side look at Google's Android operating system which holds 88 % of the global market share while Apple's iOS holds 11.9 % in the second quarter of 2018 [49].

Some limitations of the prototype had to be accepted and were tolerated because it was no real application.

The dependency on SoundCloud (or Spotify[15]), as the only way to implement sound files made it necessary to rely on the small play button. A better solution would be to tap anywhere on the speaker sign to play the sound file.

Instead of pre-recorded sound files, a screen reader could be used if the screens were real text with descriptions instead of graphics, which would make the application usable for blind people.

The colors of the prototype were not switchable and changeable in an easy way. A color style switcher as shown in Figure 28, would not simply change the colors in the prototype, because for every color option, an own screen would have to be created which would lead to seven versions of each screen.

A possibility of visual feedback after pressing a button could not be created in a reasonable achievable amount of work.

There was no possibility to review questions and, no need for it, because it was a usability test of the user interface and in no real clinical setting.

Although, only one aspect (text color to background color) of the color scheme was criticized by only one subject, the whole set of used color combinations was analyzed based upon the Web Content Accessibility Guidelines (WCAG) 2.0 [50] of the World Wide Web Consortium (W3C) [51].

Regarding the contrast relation of the WCAG, the ratio between text and background should be at least 4.5 : 1, except for large text which should be 3 : 1

[15] https://www.spotify.com/

[52]. The application “Colour Contrast Analyser” by “The Paciello Group”[16] which is a member of the W3C was utilized to check the used color combinations.

Referring to the Apple Design Resources [37], the following colors shown in Table 4 were used.

Table 4 Color palette of the prototype

What	Color	Color Name by Apple	Hex-Color
Background		SystemBlack	#000000
Navigation Bar on Top		none	#1B1B1B
Font of Back Button		SystemOrange	#FF9500
Font of Written Text on Screen		SystemWhite	#FFFFFF
Background of No Button		SystemRed	#FF3B30
Background of Yes Button		SystemBlue	#007AFF

As shown in Table 5, the used color combinations were set into relation and checked by the tool “Colour Contrast Analyser”.

Table 5 Evaluation result of the color combinations

Foreground Color	Background Color	Contrast Ratio	Result
SystemWhite	SystemBlack	21 : 1	passed
SystemWhite	SystemRed	3.5 : 1	failed*
SystemWhite	SystemBlue	4 : 1	failed*
SystemOrange	Dark grey	7.8 : 1	passed

The main text and the text of the back button passed the test as shown in Figure 23.

[16] https://developer.paciellogroup.com/resources/contrastanalyser/

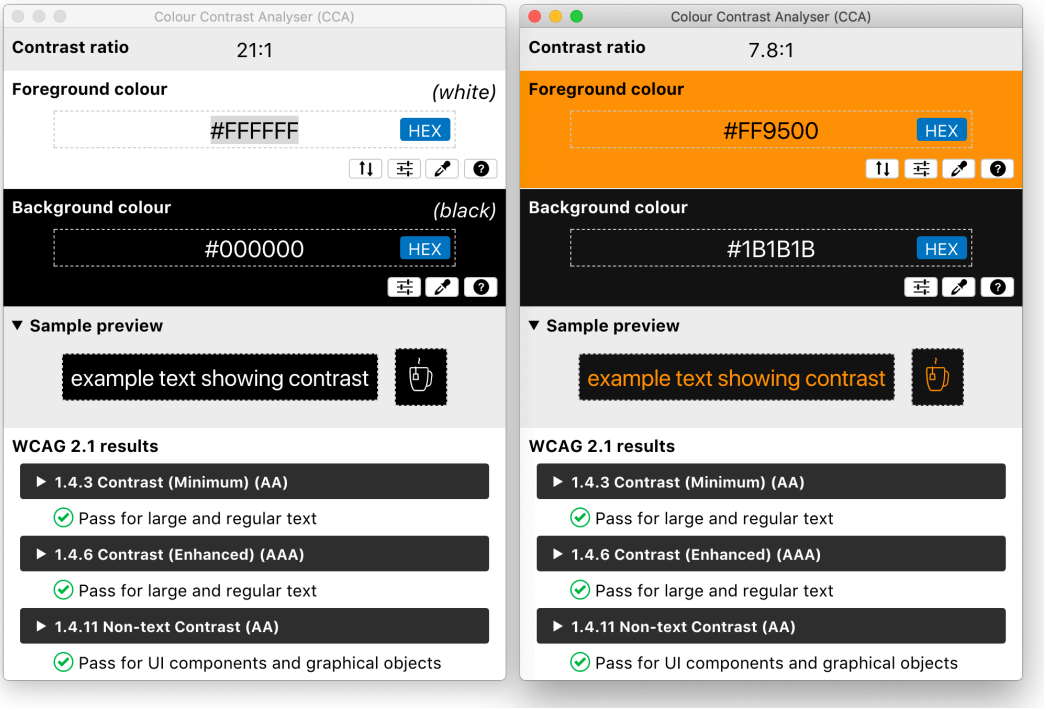

Figure 23 Colour Contrast Analyser: Main text and back button text

At first sight, the two contrast ratios regarding the white font text on the button colors fail as shown in Figure 24.

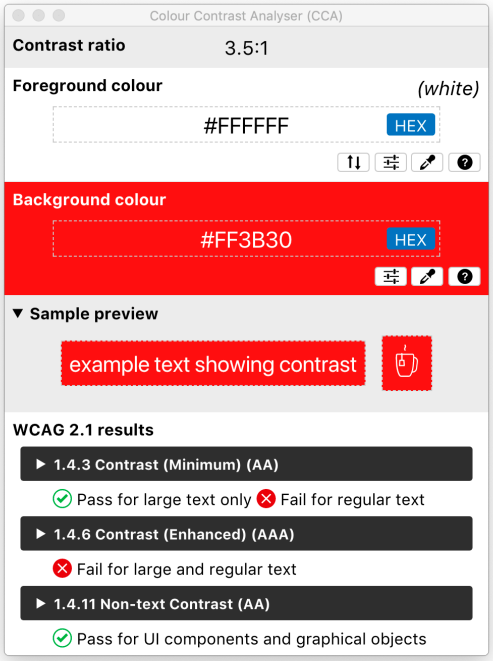

Figure 24 Colour Contrast Analyser: White text on red background

With a closer look at the explanation shown in Figure 25 it turns out that the fail is just meant for small and regular texts. In the prototype the used font size for the buttons was 100 pt.

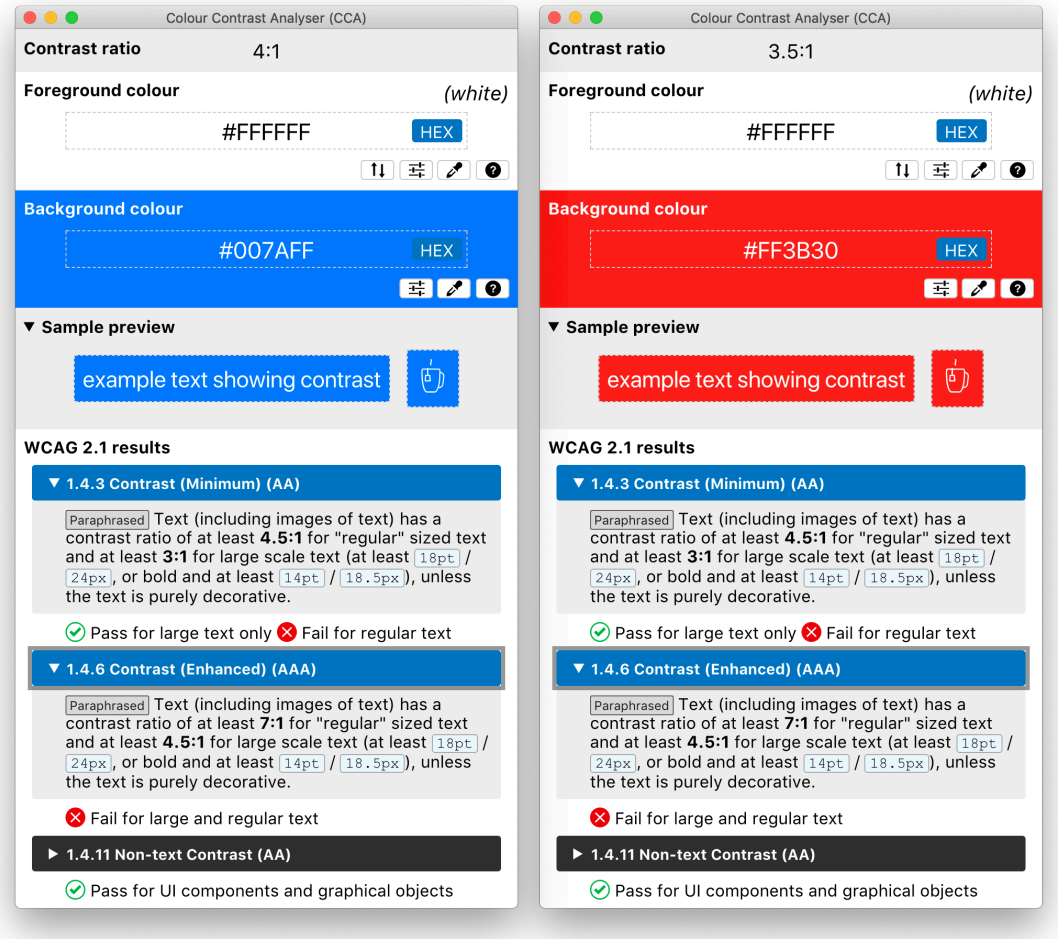

Figure 25 Colour Contrast Analyser: Explanation of the results

Theoretically the failed contrast ratio should be neglectable. Nevertheless, another test was done, this time with a side look at Google and it's Android operating system, where the color and design resources can be found at Material Design[17] in the section "The Color System" within the subsection "Color Theme Creation" [53]. The colors were taken from the baseline Material color theme. For red in this theme, the hexadecimal code `#B00020` is used. Blue is not provided in this theme, instead two different shades of violet are provided; the test was done with both. The primary violet color's hexadecimal code is `#6200EE` and the variant of the primary violet color's hexadecimal code is `#3700B3`. As shown in Figure 26, all

[17] https://material.io

colors used in the Material color theme, passed the contrast ratio test. Therefore, it could be envisaged to use an alternative color palette instead of the scheme provided by Apple.

Figure 26 Colour Contrast Analyser: Testing with Material Color Resources

7 Outlook

After showing a high acceptance of an app-based patient briefing, the next logical step would be the implementation into a real application with interfaces to the Radiology Information System. Looking at the information sheet, provided by the OERG [1], [2], again, a step-wise analysis should be done to determine where interfaces related to conditions can be used to simplify and fasten up the process.

It can be discussed, if patients, who attend a computed tomography every three months, really have to read the information about the examination itself and the contrast medium each time, or if there could be a possibility to skip the introduction with a warning, that it is the patient's own risk to skip the introduction. If the introduction text has changed since the last attendance, there should not be the possibility to skip it.

The patient's name and date of birth can be taken from the master patient data of the Radiology Information System; no need to be filled out by the patient himself / herself.

Body height and body weight could be recorded in the master patient data and of course be reused by other examination modalities as well (e.g. Magnetic Resonance Imaging (MRI)).

The question for pregnancy could be conditional by two factors. The gender of the patient, which is also included in the master patient data, as well as the date of birth are conditions if the question is displayed or not. No male patient will ever see this question. And no woman, who is younger than 12 years or older than 60 years will get this question displayed; a safety range upwards and downwards from realistic ages is recommendable.

The next step concerning pregnancy could be the connection to the recorded medical history. For female patients who had a hysterectomy, the question could be skipped as well.

Linking to foregone examinations of the patient, there should be no need to ask about a certain examination again, as the answer cannot be negative. The remaining examinations should be asked again, because the patient could have been attending one of them in another institution.

For safety reasons, the questions for side effects of contrast-medium should always be asked, because of the possibility of an examination which is not yet recorded in the inhouse patient data.

The questions for general diseases should be asked every time as well because of the possibility that diseases have occurred since the last examination.

It can be discussed if the questions for kidney diseases and for diabetes and the resulting question of the diabetes medication is necessary if the blood values of creatinine and GFR are within the limits for safe administration of contrast medium. The intake of Metformin is just important to know if the eGFR is less than 30 ml / min / 1.73 m^2 [27].

The blood values for creatinine could be transferred via standardized interfaces like HL7 from a medical laboratory to the Radiology Information System, which can be accessed by the app-based questionnaire. With the use of an e-medication service, the data about any drugs containing Metformin could be taken from there which would make the question for these drugs pointless.

It could be discussed further, if there is a need to ask for a thyroid disease if the blood value for TSH is within the limits. The blood values should be provided as mentioned above.

The question for a cardiac pacemaker and its manufacture is only relevant for examinations of the thorax. Linking to the examination in the RIS, this question can be hidden if the patient attends any other examinations than a computed tomography of the thorax.

If there was a digital implant pass, the information about the manufacture and the suitability for the thorax CT could be linked as well as the possibility to reuse this captured data for MRI examinations. When attending an MRI examination with an implanted cardiac pacemaker, the Radiology Information System could put a warning on the screen as suggested by Schlechtweg et al. [17].

Instead of inserting date and time by the patient himself / herself, a timestamp could be generated when the patient finishes the questionnaire with his / her signature on the tablet computer's display and by pressing a "finish button".

The doctor's name and signature as well as the radiographer's name and signature can be taken out of the staff database linking to the responsible radiologist and the radiographer who logs into the consent discussion.

After filling out the questionnaire, the tablet computer could be used to give further information to the patients like the instructions for emptying the bladder or to drink water.

Linking to the worklist in the Radiology Information System and the time of the patient's appointment, an estimated waiting time for the examination could be displayed. These first considerations are shown in

Figure 27.

The link to the worklist could as well be useful to provide an overview for the radiographers of all patient briefings that are currently in progress as done by the software E-ConsentPro[18] by Thieme Compliance [46].

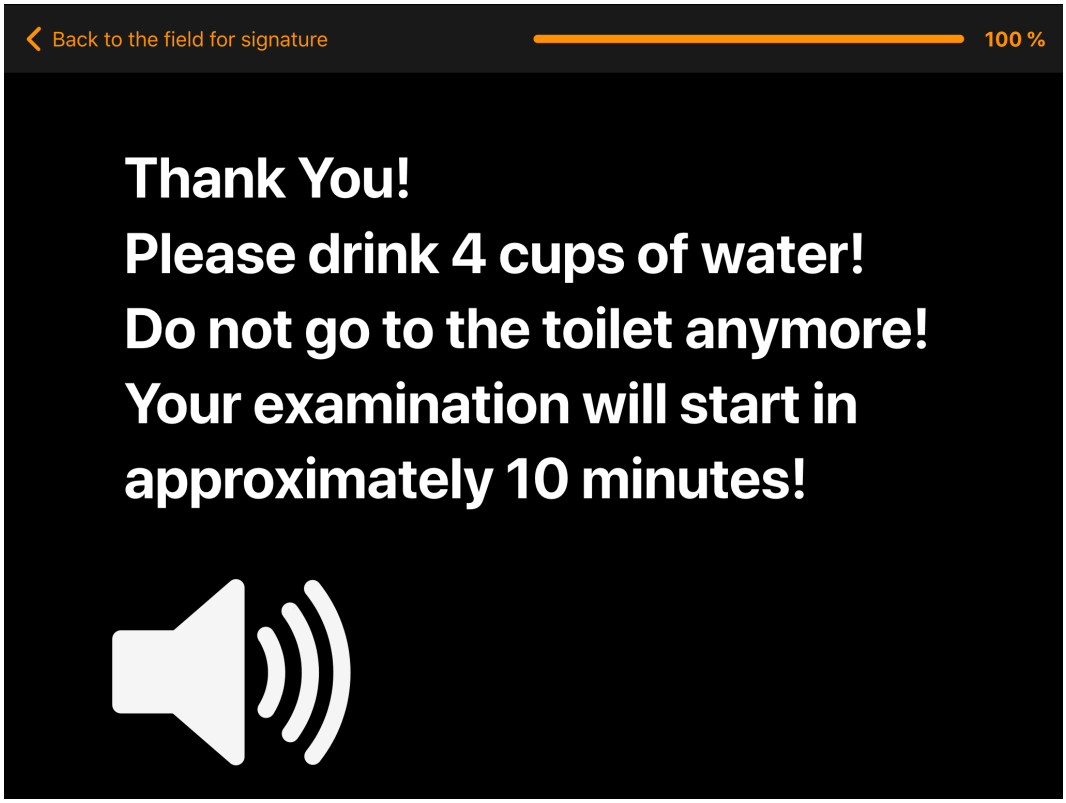

Figure 27 Adapted status bar on top right corner, instructions for the patient and estimated waiting time until the start of the examination

Visible feedback, which button was pressed should as well be provided as the possibility to do a complete review of all the given answers.

[18] https://thieme-compliance.de/de/e-consentpro/

It could be considered if the buttons should be removed and an intuitive gesture control should be used. The response option for “no” could be a tap on the left half of the tablet computer’s screen and the response option for “yes” could be a tap on the right half of the screen while the possibility to step back is provided by a swipe gesture from the left to the right. The application could then be used for blind people as well.

The space saved on top and bottom could be used to implement a style switcher as included in the WCAG 2.0 [54] for colors and contrast and change the font size as shown on the website of the Hilfsgemeinschaft der Blinden und Sehschwachen Österreichs (Austrian Association in support of the blind and visually impaired) [55] which served as a basis for Figure 28.

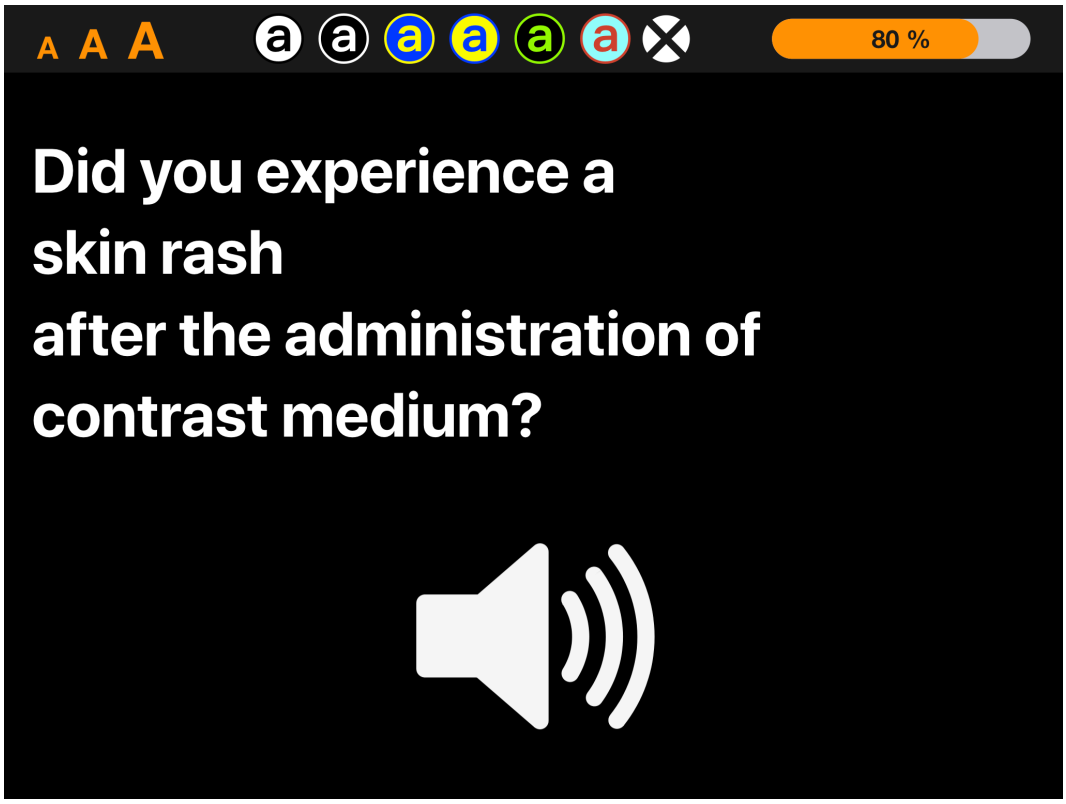

Figure 28 Font size switcher in the top left corner, style switcher on the top middle, status bar in the top right corner and removed buttons

8 Conclusion

The development of the prototype as a replacement for the paper-based form of an informed consent for examinations with computed tomography led to the result that it was accepted by and usable for people with visual impairment.

The evaluation results show that the prototype was chosen as the preferred interrogation method over a paper-based questionnaire and informed consent.

These findings suggest that a future use of app-based questionnaires and informed consents could ease the mandatory completion of these documents. It increases self-determination of the patients who could fill out questionnaires on their own without relying on someone else.

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Appendix

A. Introduction to the Situation

Stellen Sie sich vor, Sie lassen eine Gesundenuntersuchung durchführen. Im Rahmen dieser Gesundenuntersuchung wird auch ein Ultraschall des Bauches durchgeführt. Bei der Ultraschalluntersuchung wird eine unklare Struktur in Ihrer Leber entdeckt. Zur weiteren Abklärung dieser Struktur wird eine Computertomographie notwendig sein. Um herauszufinden, um welche Art Struktur es sich handelt, wird es erforderlich sein, Kontrastmittel in Ihre Vene zu spritzen um die Struktur einerseits besser vom umgebenden Gewebe abgrenzen zu können, andererseits um zu untersuchen, wie sich die Struktur in den einzelnen Phasen des Kreislaufes verhält (ohne Kontrastmittel, arterielle Phase, venöse Phase). Um eventuelle Risiken für die Kontrastmittelapplikation abschätzen zu können, ist es notwendig Ihnen einige Fragen bzgl. Ihres Gesundheitszustandes und vorangegangener Untersuchungen mit Kontrastmittel zu stellen. Zu diesem Zweck gibt es derzeit ein standardisiertes Formular von der Österreichischen Röntgengesellschaft. Basierend auf diesem Formular habe ich einen Prototyp entwickelt, der speziell auf die Bedürfnisse von Personen mit eingeschränktem Sehvermögen zugeschnitten sein soll. Nochmals zur Erinnerung: es findet hier keine echte Untersuchung statt, auch Ihre Antworten, die Sie auf die gestellten Fragen geben, werden nicht gespeichert. Es handelt sich um eine reine Simulation!

B. Introduction to the Situation (English)

Imagine, you are attending a preventive medical checkup. As part of this examination, a sonography of your abdomen is performed. As a result, an undefined structure is detected in your liver. In order to further clarification of that structure, a computed tomography will be necessary. To find out what exact structure this is, it will be necessary to inject contrast medium into your veins. On the one hand, it helps to mark out the structure from the surrounding tissue and on the other hand, it will be possible to examine how the structure behaves in the single phases of the blood circuit (native phase, arterial phase, venous phase). To reduce potential risks of the contrast medium application, it is necessary to pose you some questions regarding your personal state of health and foregone examinations with contrast medium. For this purpose, a standardized form of the Austrian Radiologic Society (OERG) is used. Based upon this questionnaire, a prototype was developed especially designed for the needs of people with impaired vision. Once again, a reminder: you are not attending a real examination and your answers to the questions will not be saved. It is just a simulation!

C. Introduction for the iPad

In Ihren Händen halten Sie nun einen Tablet-Computer der Firma Apple - genannt „iPad“. Um die Verbreitung von Keimen möglichst gering zu halten, wird das iPad mit einem für die Spitalshygiene zugelassenen Tuch desinfiziert. Ihnen werden nun Fragen in schriftlicher Form gestellt. Wenn Sie auf den dreieckigen „Play-Knopf“ drücken, der sich auf dem Lautsprecher befindet, wird Ihnen die Frage vorgelesen. Diesen Vorgang können Sie beliebig oft wiederholen. Links unten befindet sich eine rote Schaltfläche. Drücken Sie diese Schaltfläche, wenn Sie die Frage mit „nein“ beantworten möchten. Rechts unten befindet sich eine blaue Schaltfläche. Drücken Sie diese Schaltfläche, wenn Sie die Frage mit „ja“ beantworten möchten. Die farbliche Unterteilung in rot und blau dient zur besseren Unterscheidung für Personen, die eine Rot-Grün-Sehschwäche aufweisen. Ganz oben links ist ein kleiner, oranger Knopf, wo „zurück“ draufsteht. Drücken Sie diesen Knopf, um zurück zur vorigen Frage zu springen. Wenn Sie Fragen haben, stellen Sie diese bitte jetzt, (oder während des Testdurchlaufs). Wir werden jetzt beginnen.

D. Introduction for the iPad (English)

In your hands you are holding a tablet computer by the company Apple, which is called “iPad”. To reduce germ transmission, the iPad will be disinfected with a wipe which is approved for the purpose of hospital hygiene. You will be asked written questions. When you press the triangular “play-button” which is placed upon the speaker symbol, the question will be read-out. You may repeat this procedure as often as you like. On the bottom left, you find a red button. Press this button if you want to answer a posed question with “no”. On the bottom right, you can find a blue button. Press this button, if you want to answer a posed question with “yes”. The division in red and blue is for better differentiation for people with red-green color blindness. On the top left you can see a small orange button, which is labeled “back”. Please press this button to jump back to the foregone question. If you have any further questions, please do not hesitate to ask. We will start right now.

E. Evaluation Questionnaire

Prototyp-Evaluierung

Umfrage abbrechen

4%

Sehr geehrte Probandin, sehr geehrter Proband!

Vielen Dank, dass Sie an der Evaluierung meines Protoyps für meine Masterarbeit

„Design eines Prototyps für eine App-basierte PatientInnenaufklärung für CT-Untersuchungen:
Akzeptanz von Personen mit eingeschränktem Sehvermögen in einem fiktiven Setting“

“Design of a Prototype for an App-based Patient Briefing for CT-Examinations:
Acceptance of Visually Impaired People in a Fictitious Setting”

teilnehmen!

In diesem Fragebogen werden Ihnen **18 Fragen gestellt** werden.
Die Beantwortung wird vermutlich **10 Minuten** dauern.

Ihre **Teilnahme** ist **freiwillig**, Ihr Einverständnis dazu haben Sie bereits in der **Einverständniserklärung** bestätigt.

Sollten Sie sich dennoch entschließen die Befragung abzubrechen, haben Sie jederzeit die Gelegenheit dazu.
Rechts oben befindet sich eine Schaltfläche "**Umfrage abbrechen**".

Bitte beachten Sie, dass mit einem **Stern (*) markierte Fragen beantwortet** werden **müssen**!

Die **Ergebnisse** der Befragung werden **vertraulich** behandelt!
Wenn Sie Fragen haben, stellenSie sie bitte jetzt!

Bitte starten Sie die Befragung durch drücken der Schaltfläche "**Weiter**"!

Weiter

Unterstützt von QuestionPro

Figure 29 Introduction screen

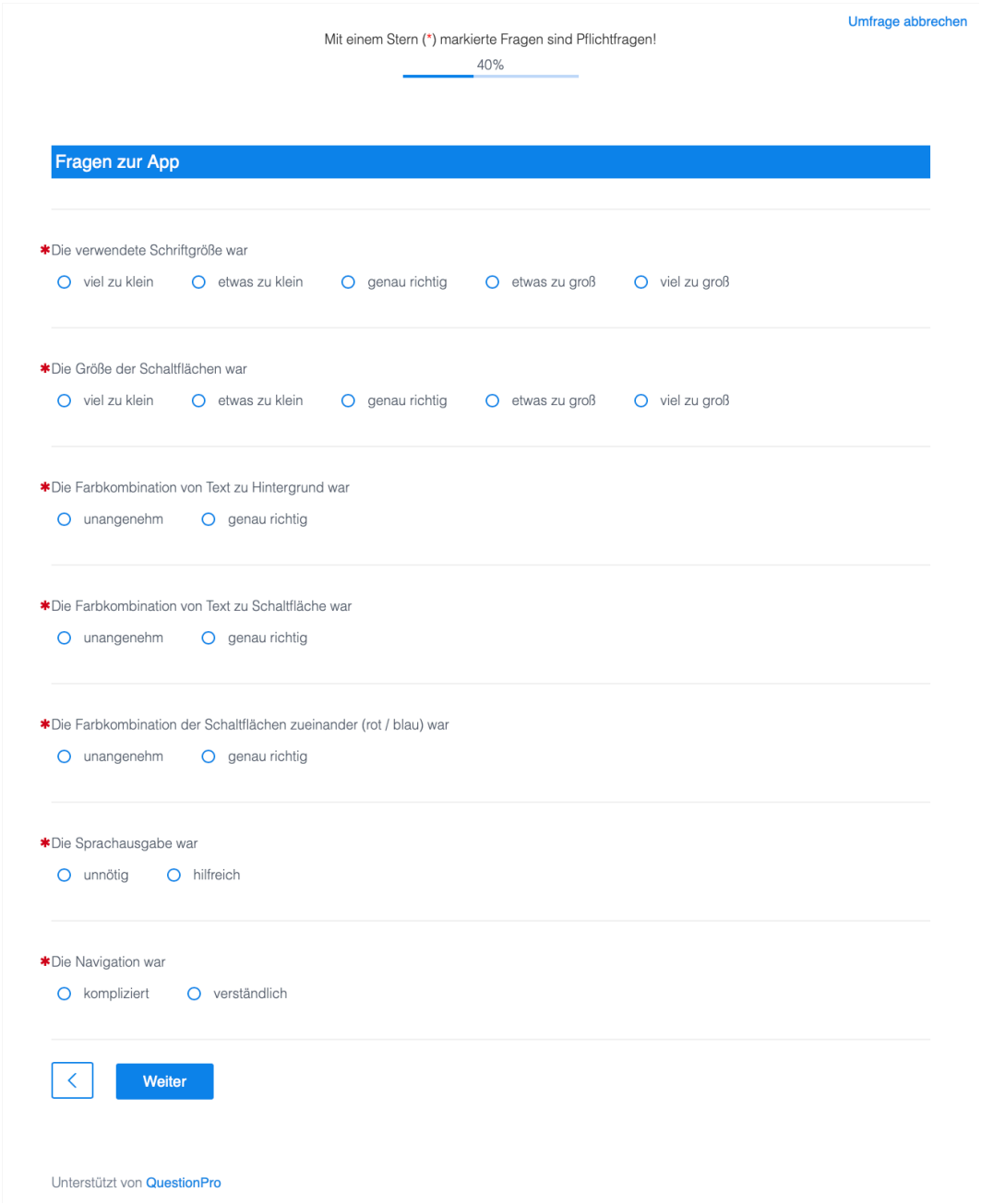

Figure 30 Questions about the prototype itself for evaluation of the usability

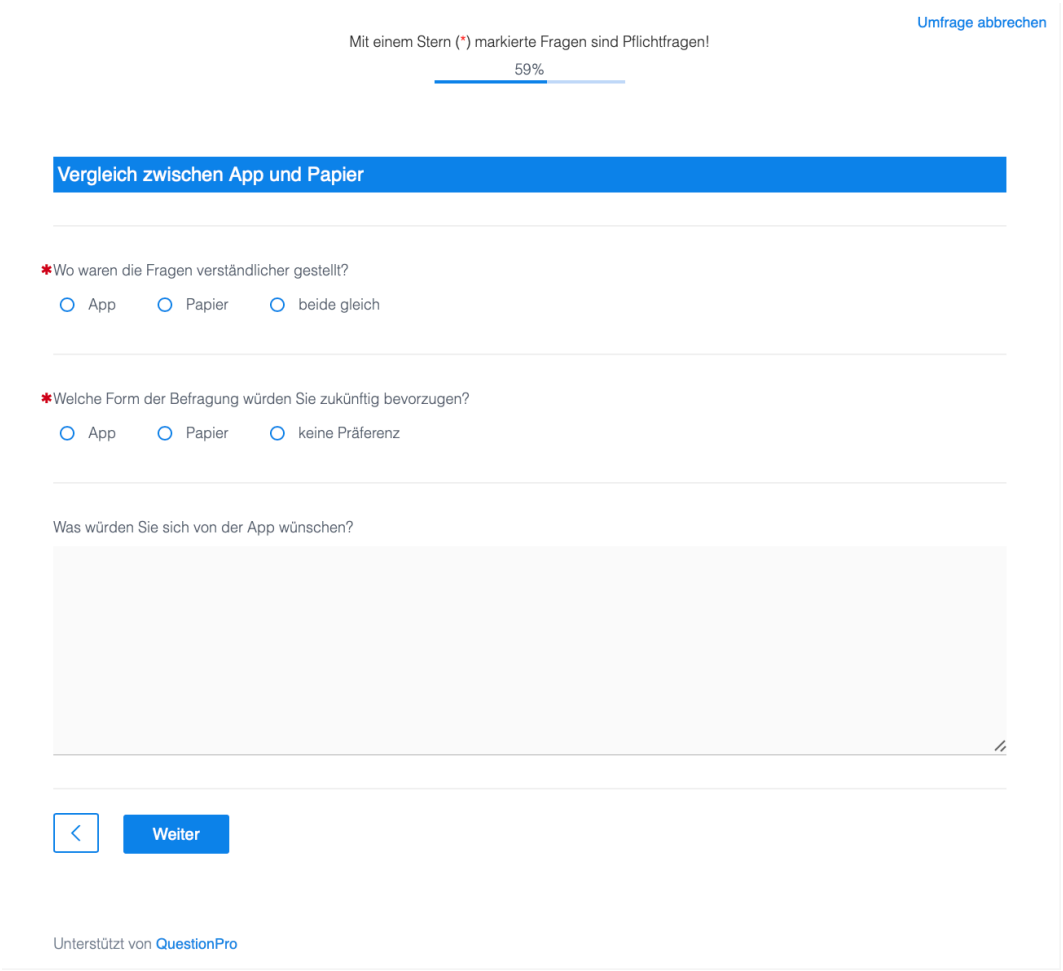

Figure 31 Comparison between prototype and paper including the possibility to write individual feedback and the pivotal question which interrogation method is preferred in the future to show the acceptance of the prototype

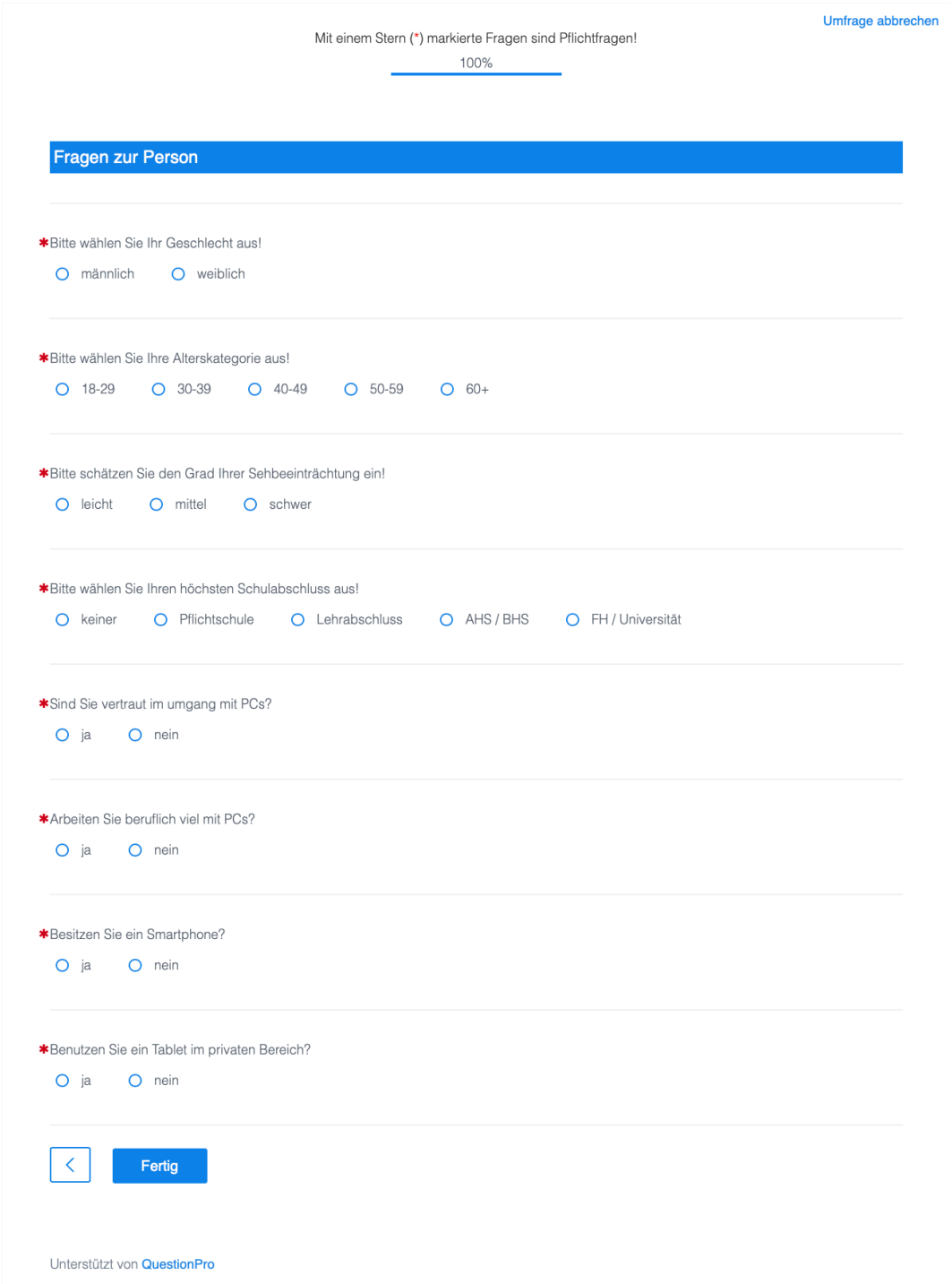

Figure 32 Questions about sociodemographic data including the subjects‘ technical background

F. Informed Consent for Participation

ProbandInneninformation & Einwilligungserklärung zur Teilnahme an der Pilotstudie

„Design eines Prototyps für eine App-basierte PatientInnenaufklärung für CT-Untersuchungen: Akzeptanz von Personen mit eingeschränktem Sehvermögen in einem fiktiven Setting“

“Design of a Prototype for an App-based Patient Briefing for CT-Examinations: Acceptance of Visually Impaired People in a Fictitious Setting”

Sehr geehrte(r) ProbandIn!

Ich lade Sie ein, an der oben genannten Pilotstudie im Rahmen meiner Master Thesis teilzunehmen.
Unverzichtbare Voraussetzung für die Durchführung einer Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme schriftlich erklären.
Die zuständige Ethikkommission hat festgestellt, dass für die Durchführung dieser Studie kein vollständiger Ethikantrag notwendig ist, wie er zum Beispiel bei medizinischen Studien benötigt wird.
Bitte lesen Sie den folgenden Text als Ergänzung sorgfältig durch.

Vielen Dank!

1. **Allgemeine Informationen zur Studie**

   Die Studie beschäftigt sich mit der Akzeptanz einer digitalen Einverständniserklärung für Personen, die eine Untersuchung mittels Computertomographie durchführen lassen müssen. Diese digitale Einverständniserklärung könnte in Zukunft den Fragebogen auf Papier ersetzen, wie es derzeit Standard ist. Dieser Fragebogen ist üblicherweise sehr klein gedruckt und daher nicht für alle Personen lesbar. Für die Studie wird der Prototyp einer solchen Einverständniserklärung entwickelt und im Anschluss durch TesterInnen hinsichtlich BenutzerInnenfreundlichkeit und Akzeptanz mittels eines Fragebogens ausgewertet. Die digitale Einverständniserklärung wird als Programm (App) auf einem Tablet laufen. Die Benutzeroberfläche der App soll insbesondere für Personen mit eingeschränktem Sehvermögen gut benutzbar sein. Die App ist eine reine Simulation, die keinerlei Daten erfasst, speichert, oder auswertet.

2. **Ziel der Studie**

   Ziel der Studie ist, herauszufinden, ob diese Form der PatientInnenaufklärung bei Personen mit eingeschränktem Sehvermögen auf Akzeptanz stößt.

3. Auswahl der StudienteilnehmerInnen

In die Studie werden Personen eingeschlossen, die die Einverständniserklärung der Österreichischen Röntgengesellschaft (OERG) in einem Abstand von 40 cm nicht mehr lesen können. ProbandInnen müssen kognitiv in der Lage sein, die Informationen auf der Einverständniserklärung zu verstehen. ProbandInnen müssen in der Lage sein, ein Tablet (iPad) alleine zu bedienen. Die Kenntnis der deutschen Sprache ist essenziell. Minderjährige sind von der Teilnahme ausgeschlossen.

4. Freiwilligkeit der Teilnahme

Die Teilnahme an dieser Studie ist freiwillig. Wenn Sie auf die Teilnahme an dieser Studie verzichten, haben Sie keine Nachteile zu erwarten. Das gleiche gilt, wenn Sie Ihre gegebene Einwilligung zu einem späteren Zeitpunkt widerrufen. Diese Möglichkeit haben Sie jederzeit ohne Angabe von Gründen. Die bis zu diesem Zeitpunkt erhobenen Daten dürfen für die Studie verwendet werden.

5. Studienablauf

- Es wird nochmals darauf hingewiesen, dass es sich um ein fiktives Setting handelt, das heißt, es wird keine echte Untersuchung mittels Computertomographie durchgeführt. Auch die App erhebt keinerlei Daten. Alle ProbandInnen erhalten eine kurze Erklärung, was eine Computertomographie ist und warum es notwendig ist, eine Einverständniserklärung für diese auszufüllen.
- Alle ProbandInnen erhalten ein Tablet (iPad).
- Alle ProbandInnen erhalten eine kurze Einschulung für das Tablet.
- Die ProbandInnen beantworten die Fragen, die Ihnen mit dem Tablet gestellt werden.
- Die ProbandInnen bekommen die Einverständniserklärung der OERG, wie sie dzt. in Papierform verwendet wird, zur Ansicht
- Die ProbandInnen füllen den Fragebogen zur Evaluierung der iPad-App aus.

6. **Nutzen**

   Generell sind weder ein unmittelbarer Nutzen noch Nachteile oder Gefahren für die ProbandInnen zu erwarten.

7. **Risiken und Unannehmlichkeiten**

   Die iPad-App und der Evaluierungsfragebogen bergen kein signifikantes Risiko.

8. **Vertraulichkeit der Daten**

   In der Studie werden persönliche Daten von Ihnen erfasst.
   Diese Daten werden nicht an Dritte weitergegeben. Nach Beendigung dieser Master Thesis, werden alle erhobenen Daten vernichtet.

9. **Vergütung / Entschädigung für die Teilnahme an der Studie**

   Durch Ihre Teilnahme an dieser Studie entstehen für Sie keine zusätzlichen Kosten. Sie erhalten im Gegenzug auch keine Entschädigung oder Vergütung Ihrer Aufwände.

10. **Abbruch**

    Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden.

11. **Kontaktperson:**

    Gerald Wagner
    Tel: **********
    E-Mail: dh171809@fhstp.ac.at

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie Art und Ablauf der Pilotstudie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen.

Einwilligungserklärung

Ich (Name, Vorname, Geburtsdatum in Blockbuchstaben)

.....

stimme ausdrücklich zu, dass meine personenbezogenen Daten, in Form von einer **Fragebogenerhebung** im Rahmen der Master Thesis - Pilotstudie

"Design of a Prototype for an App-based Patient Briefing for CT-Examinations: Acceptance of Visually Impaired People in a Fictitious Setting",

bzw. deutscher Arbeitstitel:

„Design eines Prototyps für eine App-basierte PatientInnenaufklärung für CT-Untersuchungen: Akzeptanz von Personen mit eingeschränktem Sehvermögen in einem fiktiven Setting"

verarbeitet werden.

In wissenschaftlichen Veröffentlichungen werden **keine personenbezogenen Daten** bekannt gegeben, um gegenüber Dritten sicherzustellen, dass es nicht zu einer Identifizierung der Person führen kann.

Es gelten die nationalen und internationalen **datenschutzrechtlichen Bestimmungen**. Nach Beendigung der Studie werden die erhobenen Daten („Rohdaten") unwiderruflich vernichtet.

Ich behalte mir das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile entstehen. Ein Widerruf kann formfrei jederzeit bei der Kontaktperson der Studie eingebracht werden.

Sollte ich meine Teilnahme an dieser Studie widerrufen, so willige ich ein, dass die bis zu diesem Zeitpunkt erhobenen Daten weiterhin verwendet werden dürfen, soweit dies erforderlich ist, um sicherzustellen, dass meine schutzwürdigen Interessen nicht beeinträchtigt werden

Ich stimme zu, dass meine Daten für weitere Forschungsprojekte („Sekundärforschung") von der Fachhochschule St. Pölten GmbH als auch von FH St. Pölten GmbH verwendet werden dürfen.

.....
(Datum und Unterschrift des/der Teilnehmenden)