EXPLORING THE EXPECTATIONS AND INFORMATION NEEDS OF DUTCH CITIZENS AGED 45-75 FOR THE IMPLEMENTATION OF THE URIMON DISEASE WARNING SYSTEM IN THE DUTCH HEALTHCARE MARKET

MASTER HEALTH SCIENCES

DOROTHY KWIDAMA
URIMON DISEASE WARNING SYSTEM
The University of Twente, The Netherlands

29 August 2022

Title page

Title:	Exploring the expectations and information needs of Dutch citizens aged 45-75 for the implementation of the Urimon disease warning system in the Dutch healthcare market
Author:	Dorothy Kwidama
Student number:	s2562332
Location:	University of Twente Hallenweg 15, 7522 NH Enschede The Netherlands
Date:	29/08/2022
Study program:	Health Sciences (Master)
Company:	You2Yourself-Urimon
Master Student:	D.N. Kwidama (Dorothy); BSc Biology and medical laboratory research d.n.kwidama@student.utwente.nl
First coordinator:	dr. J.A. van Til (Janine); Professor Health Sciences j.a.vantil@utwente.nl
Second coordinator:	dr. R. Wolkorte (Ria); Researcher at University of Twente r.wolkorte@utwente.nl
Supervisor :	mr. A.G.J. de Moor (Bram); Project leader Urimon bdemoor@live.nl

Declaration

I declare that this thesis is original and composed by myself. The work and data analysis contained herein is my own expect where explicitly stated otherwise with the use of referencing in the text. I certify that this thesis is submitted for the master's degree of Health Sciences at the University of Twente and has not been submitted to any other University or institution.

Signed on the 10th of July 2022

Acknowledgements

I would like to express my great gratitude and sincere thanks to my supervisor and coordinators: dr. J.A. van Til, dr. R. Wolkorte and mr. A.G.J. de Moor for providing me with valuable and patient guidance, enthusiastic encouragement, useful and regular feedback on this thesis. I would also like to extend my gratitude to the participants who showed up and actively participated in my focus group sessions. Without their support this endeavour would not have been possible. I would also like to thank the Urimon team for offering me assistance and guidance in the office at the beginning of my master assignment. I had the pleasure of working with other students and graduates who also share the similar passion for health care. I would be remiss in not mentioning that this course and topic researched broadened my view and increased my knowledge in general on healthcare and its processes. Therefore, I would also like to thank the other professors and lecturers who are part of the Health sciences faculty, chair and committee, who aided my understanding of different topics in this course. I would also like to express my indebtedness to my lovely parents and siblings for their support and encouragement throughout the entirety of my study. I would also like to acknowledge the people who participated in my mock focus group sessions for their support. Lastly, I would like to thank my friends for their support while writing this thesis.

- Dorothy Kwidama

Abstract

Background

In the Netherlands (NL) one in five people aged from 65 to 74 has more than one chronic illness. In due course, chronic illness causes significant increase of mortality and morbidity in the elderly. Early detection of disease can reduce patient burden, improve cure prospects and possibly lower healthcare costs, if Direct-To-Consumer Genetic-Testing (DTC-GT) are used. Accordingly,different companies such as Urimon want to satisfy the public's need for genetic information by providing DTC-GT. However, information about these tests is not always available or understood by the consumer. In addition, it is unclear if the expectations of consumers align with what these companies want to provide. If this remains unclear; it could hinder implementation of DTC-GT. Therefore, the aim of this research is to support the implementation of the Urimon disease warning system in the market by exploring consumers expectations of genetic test, how they should be implemented in clinical practice, and their expectations in terms of information needs before and after taking a test.

Methodology

The study population was a mixed gender population which included 24 individuals living in NL between the ages of 45 and 75. A qualitative research approach was used in this explorative research to elicit end-users' expectations and information needs. This approach concisted of a narrative systematic review (NSR) and a classical content analysis of three emergent-systematic focusgroups. The NSR was carried out during March of 2022, to create a semi-structured moderator guide. This guide was generated based 15 scientific articles; here the questions were divided in three main topics. These topics are: *expectations*, *information needs*, and *conditions*. The content analysis was executed with ATLAS.ti and the fragments where inductively coded.

Result

Possible early adopters of DTC-GT expect that a general practitioner (GP) should be involved in the DTC-GT process. Besides the involvement of a GP, the participants stated that DTC-GT should be accessible for the entire society, provided either as a population screening method, in their healthcare package, free of costs. Furthermore, participants expect clear information about what is being researched and what services they can expect from DTC-GT test such as the Urimon disease warning system. Moreover, participants expect general and specific information about the Urimon product and process prior and after using their services, which could increase the likelihood of uptake of this technology. Participants also showed great interest in the financing aspects of Urimon which could pose a barrier for implementation.

Conclusion

My advice for Urimon would be to first provide clarity about the essence of the disease warning system so that consumers know what to expect from this service. Secondly, Urimon is advised to involve a GP in their care process. Thirdly, Urimon should lower the price of ~€500 that the future end-user will have to pay out of pocket as much as possible by collaborating with health insurances. To conclude, Urimon should explore the requirements for their innovation as a population screening method. By doing this individuals in NL could be screened free of cost. This would remove the barrier surrounding the financing aspects that has emerged in this research. Therefore, I would advise Urimon to present their services to the Dutch Health council or the Minister of Health, Welfare and Sport to facilitate implementation.

Research topic: Direct to consumer genetic testing (DTC-GT).
Keywords: Direct to consumer genetic testing (DTC-GT), Expectations , Information needs, conditions, (Early) HTA, Focus groups, end-user perspective

Lists/glossary

List of abbreviation

WHO	**W**orld **H**ealth **O**rganization
DTC GT	**D**irect **t**o **C**onsumer **G**enetic **T**esting
NGS	**N**ext **G**eneration **S**equencing
NL	The **N**ether**l**ands
HBM	**H**ealth **B**elief **M**odel
UTAUT model	**T**heory of **A**cceptance and **U**se of **T**echnology
(Early) HTA	**Early H**ealth **T**echnology **A**ssessment
HTA	**H**ealth **T**echnology **A**ssessment
DCE	**D**iscreet **C**hoice **A**nalysis
SLR	**S**ystematic **L**iterature **R**eview
COREQ	**C**ons**o**lidated Criteria for **Re**porting **Q**ualitative Studies
ISO	**I**nternational **O**rganization for **S**tandardization
IEC	the **I**nternational **E**lectrotechnical **C**ommission
IEEE	the **I**nstitute of **E**lectrical and **E**lectronics **E**ngineering
BMS	**B**ehavioural **M**anagement and **S**ocial Sciences
HSS	Domain **H**umanities and **S**ocial **S**ciences
NSR	**N**arrative **S**ystematic **R**eview
CEFR	**C**ommon **E**uropean **F**ramework of **R**eference for Languages
TRA	**T**heory of **R**easoned **A**ction

List of figures

List of tables

List of definitions

Topic definition

DTC-GT

Genetic testing service without the need of providing a prescription or license to obtain personal genetic test results(3, 7). This service is available online to the consumer via private companies(7).

Keywords definitions

Urimon study

The Urimon study is a study in where the participants deliver urine every three months for two years, deliver blood once a year and fill in questionnaires every three months with questions regarding their health status. The initial duration of the current clinical trial is two years) (8). During the study nothing is measured. We wait until the participant indicate that they have become ill by the three-monthly questionnaires; then we ask the diagnosis from the General Practitioner. When cancer or cardiovascular disease is diagnosed, the sample will be analysed to look in hindsight how well and how early we could have detected the disease. In this study samples of healthy people are used as controls. These control samples are only a limited number that do not surpass the disease case numbers Therefore, the purpose of this study is to proof that the Urimon disease warning system can give a warning on a disease that is being developed.

Urimon disease warning system

In this research proposal the Urimon system is referred to as a disease warning system where it is aimed to warn participants in the future of the development of a disease preferably in the early stages of disease development. This is done by periodically collecting biological samples also referred to as liquid biopsies of the patients. In the Urimon disease warning system participants should deliver urine every three months for 1 year to establish their baseline, after this year the participant should deliver urine every six months and deliver blood once a year to detect deviations in microRNA levels.(8).

Information needs**

From the participants perspective this is a need from the participant regarding information that the participant may need to participate in a procedure in this case in the Urimon study. To understand information needs of a participant it is also essential to understand the participants personal situation as it has been proven that information needs can be predominantly influenced by social factors. In addition, information needs can be the driving force that will motive the participant to seek information. All in all information needs represent the starting point and motivation that brings a participant to undertake the process of information seeking(11).

From a health care professionals perspective this is a need to have information including different factors such as e.g. a participants education, care and curiosity to be able to provide the participants with summarized information about the research that they could need. Further, information needs of health care professionals can be defined as following(12);

1. Information that is already known by health care professional and that is also needed for decision making this is referred to as ‘’currently satisfied needs’’
2. Information that is unknown by the health professional, however the health care professional does recognize this information to be applicable for decision making. This is referred to as ‘’consciously recognized needs’’

3. Information that is needed for the current circumstances. However, the health professional does not see or realize that this information is needed. This is referred to as ‘’unrecognized needs’’.

Expectations

Expectations are not to be confused with information needs described above, as expectations are the standards people, in this case participants, have for others but also for themselves or conditions in their lives(13). Having insights in what the expectations are for health care systems or in this case a disease warning system is essential in improving the satisfaction and delivery of care to participants of a health related research(14). However, It is important to note that standards participants have may or may not be realistic(13).

Conditions

Factors that can be relatable to expectations and information need that may have a significant influence on the attitude of the end-user to consider using the Urimon service. Examples of conditions are: costs, willingness to pay and privacy.

Focus groups

A focus group a research methodology where the researcher gathers participants from the target group in question to discuss a topic or issue to collect qualitative data. The main goal of the focus group is for the researcher to gain a better grasp of the participants perspective on the topic discussed(17).

End-user* perspective

A particular way the person who uses a company’s services after it has been fully marketed and developed views thing. This way of viewing things depends on the individuals experience and personality(19, 20). The word end-user* separates the end user for whom the product is developed from other users who enable the end user to utilize the product(21).

End-user* requirements

This describes what the person using the company’s services after it has been fully marketed and developed expects from the system. It also dictates the performance levels that are necessary for a technical system(22, 23). Moreover, requirements are referred to as “a condition or capability that must be met or possessed by a system, system component, product, or service to satisfy an agreement, standard, specification, or other formally imposed documents” according to ISO/IEC/IEEE 24765(24, 25).

End-user* health oriented individual. In this research these health oriented individuals were people that currently participate in the Urimon research

Information needs** In this research we are focused on the information needs from the participants perspective.

Contents

1.Introduction & rationale

1.1. Background

In the Netherlands (NL) one in five people aged 65-74 has more than one chronic illness, and one in three people aged 75+ have a comorbidity. In due course, chronic illness causes significant increase of mortality and morbidity in the elderly(26). Disease progression normally remains unnoticed until physical difficulties arise. Therefore, early detection of disease can reduce patient burden, improve cure prospects and possibly lower healthcare cost(27). Disease can be detected early with genetic testing resulting in new possibilities for predicting and enhancing health.

According to Hellemond et al. (2011), individuals have great expectations of genetics' potential advantages and are becoming more interested in understanding their genetic profile(28). Accordingly, different companies want to satisfy the public's need for genetic information by providing Direct-To-Consumer Genetic-Testing (DTC-GT)(28), which is a service that enables individuals to have their genetic profile examined without the consultation of a healthcare provider(3). DTC-GT can often be ordered online, where the consumers take their sample at home, which usually is mouth cells or saliva. This sample is then send back to the respective company where the DNA is isolated from the sample to be able to carry out genetic testing. Thereafter, the consumers receive their results at home without interference of a healthcare professional(29, 30).

DTC-GT is widely offered with the promise of generating predictive genetic risk assessment for a range of health diseases as well as providing information on response and/or side-effect of medications(7). In addition, according to the RIVM the concept of DTC-GT is that, based on its predictive results, the consumers will choose to lead a healthier lifestyle. This choice can also reduce their risk of having a disease by consulting health care professionals sooner(29). However, if DCT-GT really improves health by e.g., living a healthier lifestyle remains unknown.

Commercial firms usually only provide the consumers with the possible advantages of DTC-GT without disclosing potential disadvantages(2). Therefore, providing insufficient information about crucial aspects of what they offer to consumers e.g., about the reliability or possible implications of the test results. Which often results in objective quality information not being provided to the consumer. In addition, support by, e.g., a decision aid or the possibility of consulting with an independent advisor is not offered. This makes it more difficult for the consumer to make an informed decision on whether to use the technology or not(29).

1.2. Narrative systematic literature review

There is limited information on expectations and information needs of DTC-GT among Dutch citizens. Therefore 15 articles, which were conducted in high income countries, and which are relevant to the scope of my research have been selected and reviewed. Most of the articles reviewed, are articles that can also be found in the systematic research of Ozdemir et al.(2022), in which 38 articles were included. Specific attention was given to this article since it is the first systematic review that compiled key study elements of attribute-based stated preference studies on genetic testing. The article of Ozdemir et al.(2022), reviews the benefits, cost and potential disadvantages before deciding on whether or not to use genetic tests; by reviewing discreet choice experiment (DCE) and conjoint analysis studies on genetic testing, including genomic tests. According to Ozdemir et al.(2022), choosing to take up genetic testing is a complicated

decision for consumers. Since the awareness of being at risk or having a disease can have an impact on the consumer and their family. Especially, when an indication of illness does not result in treatment or prevention of the disease (9). An example of such disease is Alzheimer. Furthermore, the article of Ozdemir et al.(2022)discusses the possible concerns that consumers of DTC-GT can have. These concerns are: the potential difference in accessibility of health care, where the presence of disease may lead to an increased healthcare premium or reimbursement denial. And, the concern that DTC-GT results will be shared with employers, as employers can refuse to employ sick individuals (9).

The article by Yeyang Su et al.(2011), is the only second study focused on studying DTC-GT users' perspectives(6). The study of Yeyang Su et al.(2011), has shown that there are five themes of expectations towards DTC-GT(6). These are themes related to curiosity, fascination, genealogy, health, contributing to research and recreation. Health related expectations according to the study of Yeyang Su et al.(2011), refer to ''*improve the quality of health and live longer*'', ''*learn about medical history*'' and ''*address concerns for certain diseases*''(6).

Opening question	
What have you heard of similar tests like Urimon?	
Expectations	
What do you expect from a service like Urimon wants to offer in the future?	Rafiq M et al.,2015 (2) Ruhl GL et al.,2020(3) Genet Med.2016 (4) Ritger T. et al., 2020 Horton R. et al., 2016(5) Yeyang Su et al. 2011 (6)
What are your main reasons for using a such a service?	
To what extend do you expect using such service will lead to earlier detection of diseases?	
To what extend do you think that using such service will lead to a longer or better life?	
Information need	
What for information do you want to have before you can decide if you will use such a service?	Rafiq M et al.,2015 (2) Ruhl GL et al.,2020 (3) Genet Med.,2016 (4) Ritger T. et al., 2020 (1) Semra Ozdemir.et al.,(2022) (9) Qian X et al.,2019 (10)
What for information would you like after handing in your sample?	
Do you expect that a company like Urimon will inform you about steps you need to take after receiving an abnormal result ?	
Do you expect that a company like Urimon will inform you about the different diseases that the test will detect?	
Conditions	
What do you expect to pay for a service like Urimon?	Rafiq M et al.,2015 (2) Ruhl GL et al.,2020 (3) Semra Ozdemir.et al.,2022(9) Hall MA et al.2000, (15) Chong KJ,et al.,2018 (16) Tong T.,2013, (18)
Is it a hindrance for you if you have to pay for such a service?	
Should a service like Urimon be covered by your health insurance?	
How do you think that a company like Urimon treats your personal information and your genetic material ?	
Can a company like Urimon provide their services to employers	

Figure 1. Key focus group questions

According Horton R. et al.(2016), and Rafiq M et al.(2015), end-users of DTC-GT may expect that their result will be a prediction of their future health(5). In addition, it is also expected that DTC-GT can help consumers with their concerns regarding history of family diseases (5, 6). This results in a sense of empowerment for the consumer, as they can take ownership of their own health. The latter is what most DTC-GT companies promote (2).

In literature, it is mentioned that consumers should be well informed on the specifics of the genetic test (2, 4, 5). However, what the information needs of consumers of DTC-GT are, remain unknown. Based on what is known of DTC-GT and the aforementioned findings, early adopters of DTC-GT should be asked the following key questions in figure 1, where the respective articles from which the question is drawn are given; to gain better insights on their expectations and information needs of DTC-GT. This table is divided in three topics: expectations, information needs and conditions.

Expectations are the standards consumers, have for others but also for themselves or conditions in their lives(13). Having insights in what the expectations are for DTC-GT is essential in improving the satisfaction and delivery of care to consumers of a health related research(14). However, it is important to note that standards consumers have may or may not be realistic(13). Information needs from the

consumers perspective is the need regarding information that the consumer may need to participate in a process. To understand information needs of a consumer it is also essential to understand the consumers personal situation as it has been proven that information needs can be predominantly influenced by social factors. In addition, information needs can be the driving force that will motive the consumer to seek information. All in all, information needs represent the starting point and motivation that brings a consumer to undertake the process of information seeking(11). An additional topic besides expectations and information needs was introduced in this research, which is conditions, to better understand expectations and information needs. Conditions are factors that can be relatable to expectations and information need that may have a significant influence on the attitude of the end-user to consider using the a DTC-GT service. Examples of conditions are costs, willingness to pay and privacy. (See Appendix D, page 55, for a more extensive table in Dutch of figure 1.)

1.3. Urimon

Urimon is an emerging DCT-GT company that wants to provide consumers with a disease warning system in the future. The Urimon disease warning system, which is the end-product of Urimon, here after referred to as system, focusses on early detection of all types of cancers, diseases of the central nervous system and cardiovascular diseases. Urimon aims to base the detection of disease on MicroRNA (miRNAs), which are biomarkers found in blood and urine that serve as an indicator for specific diseases(31). Urimon's concept is that the system will determine the concentration of these biomarkers with the use of next generation sequencing (NGS). After having achieved a proof of concept, Urimon aims to implement their system in the Dutch healthcare market. Companies and individuals who make use of this system can then have insights on their health by being informed of diseases that they might be developing. In the first year that an individual makes use of the system, a baseline of their MiRNA concentration is established (32). In the subsequent years the samples of the individuals will be compared with their own baseline concentrations, which makes Urimon unique and different from other DTC-GT companies, as other companies do not compare your sample with your own previous samples. Nonetheless, just like other DTC-GT genetic testing companies, Urimon should provide the necessary information to their future customers, to ensure that they can make an informed decision on whether to use Urimon services.

1.4. Dutch health care market

Dutch healthcare has been regulated since 2006 via the Health Insurance Act (Enthoven & Van de Ven 2007) (33). This law obliges everyone who is above the age of 18 and lives in NL to take out health insurance. The paid health insurance premiums forms part of the collectively financed Dutch health care. The direct financing through insurance premiums is supplemented by the government through taxes. The basic health insurance package in the Netherlands reimburses a wide range of care such as the most commonly used, necessary medical care, medicines and medical aids(33). The content of the basic health insurance package changes almost every year on the basis of new advice and insights of the National Health care institute, new medicine and technological advances. The Minister of Health, Welfare and Sport annually compiles the basic package for the following year on the basis of these recommendations(33).

According to the report by Eric C. Schneider et al.(2021), which compares health care in the United States with other high-income countries; The Netherlands, together with Norway and Australia, is one of the best performing countries in healthcare(34). However, the high quality of care in NL results in rising premiums for its citizens. These high healthcare costs causes a lot of dissatisfaction among Dutch citizens as a large part of their income is spent on healthcare(35). In total, an average of €6.660,- per person was

spent on healthcare in 2020 via the government, insurance and personal payments(36). Therefore, people who live in NL could be less willing to pay extra for additional health related services that is not included in their insurance package.

1.5. Relevance

In order to support the implementation of genetic tests provided by companies such as Urimon; the information needs of the potential users of these kind of test should be met. In addition, the expectations and conditions should match with what Urimon wants to provide in the future. Therefore, it is important to assess the information needs expectations and possible conditions that potential end-users may have

However, at present, there is limited insights on the information needs, the expectations and conditions of consumers with regard to DTC-GT. This could impact the implementation of emerging DTC-GT companies such as Urimon.

If the expectations of potential buyers are not met and if they are not adequately informed, these individuals could be disappointed. This could be a contributing factor for the unfortunate event of people refusing to use e.g., Urimon as a DTC-GT tests. Which can result in the possible ramification of decrease in revenue and reflect badly on the reputation of the company. Hence, additional research is needed to investigate the aforementioned phenomenon, especially among Urimon participants, aged 45-75, which is the target group of my study. Considering, that the Urimon participants are most likely to be the early adopters of the Urimon system.

1.6. Research Question

The aim of this research is to support the implementation of the Urimon disease warning system by providing the developers with information of the consumer expectations and information needs regarding a system such as the one Urimon wants to provide. This information can help Urimon developers better understand their target audience which can lead to better implementation of their system in the Dutch health care market. Besides, this research can fill the existing knowledge gap regarding expectations and information needs on DTC-GT. My research aim can be facilitated by answering the following research question:

What are the expectations and information needs of potential users of the Urimon disease warning system and to what extent do these influence the decision of citizens aged 45-75 years in the Netherlands to use this technology?

2.Theoretical framework

2.1. Product life cycle

This research is an explorative research that explores the expectations and information needs from the end-user perspective. In figure 2, the different steps in the life cycle of the Urimon disease warning system are given. All the steps in figure 2 lead to implementation. Urimon currently performs clinical trials to generate a proof of concept. However, prior to conducting clinical trials, user research needs to be done. In this case both the clinical trials and user research is being done simultaneously.

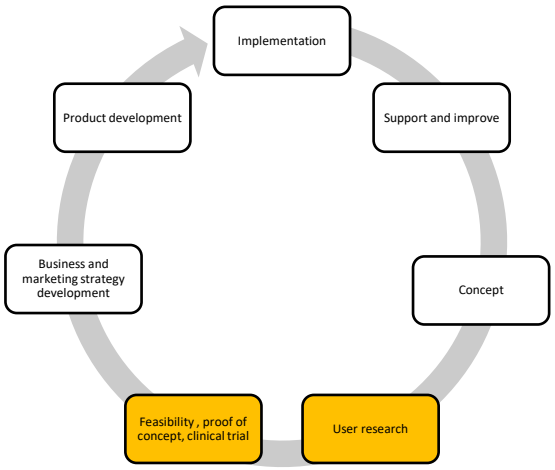

Figure 2. Product life cycle

2.2. Early health technology assessment

Studies that focus on determining user needs early in the development of a technology, are part of an early health technology assessment ((Early) HTA). (Early) HTA is used to provide the needed information about the management and design of new medical technologies. With this assessment you can evaluate the possible obstacles perceived by the public but also in the industry, which is also related to market access. In addition, performing (Early) HTA in studies is essential in providing companies with information regarding the possible success of their company. This allows companies to stop development early if preliminary results suggest that the product in question will be unsuccessful(37).

During (Early) HTA researchers can thus anticipate the extent of acceptance of their innovation, address uncertainty and possibly improve research evaluation efficiency. Moreover, an important aspect in (Early) HTA is to include end-user perspectives in further advancements in medical devices (38). This is done to fulfil and measure end-user requirements of an innovation during the development process of a medical device. Which subsequently, will result in a more successful product that improves device effectives, reduce additional modifications and improve user safety (39).

In this paper, user research is being done in the early phases of the technology.This allows Urimon to make adjustments to their end-product, with the possibility introducing a product to the market which will have better success. Therefore, this study can also be considered as a component of a (Early) HTA.

2.3. Health belief model

To investigate the causes of limited participation in preventive programs, Rosenstock and colleagues crea ted the Health Belief Model(HBM) in the 1950s(40).The HBM is based on psychological and behavioural theory, with the two components of health-related behaviour being the desire to avoid illness and the believe that a specific health action will prevent or cure illness. However, the action that the individual takes generally depends on the perceptions of the barriers and benefits related to the health behaviour (41). A person is likely to undertake action if the benefits outweigh the perceived barriers(42). The HBM is usually used to predict whether or not the end-user will adopt a health behaviour based on four factors of individual believes (22, 24).

In addition to the four individual believes the model included different demographic variables which are the modifying factors. The modifying factors can influence the other factors in the HBM and thus also the outcome. This outcome is the individual behaviour of a person and the likelihood for this individual to take a specific action. Referring to the benefits outweighing the barriers to take action (40, 42).

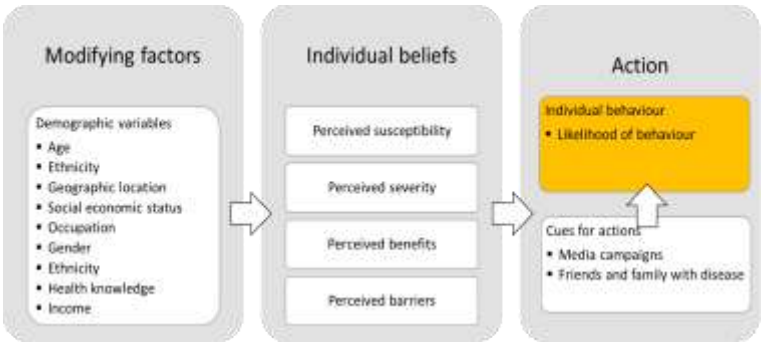

Figure 3: Health Believe Model

For this reason , the HBM model has been used to discuss the findings of this research to be able to structure the expectations of the target population. In this research the action would refer to using the Urimon disease warning system. The HBM is visualised in figure 3 Below the 4 individuals beliefs are explained(40):

- Perceived susceptibility: A person's perception of their vulnerability to a specific illness or condition, such as, Alzheimer
- Perceived severity: The perception of the disease's in question seriousness if the person contracts is or does not receive treatment for it .
- Perceived benefits: The idea that taking preventative measures will reduce the chance of developing a disease is known as perceived benefits.
- Perceived barriers: what the individual believes to be an obstacle that hinders them from acting preventively

In addition to the four individual beliefs factor, cues for action/ stimuli can trigger a reaction. There are internal and external cues. Internal cues refer to physiological stimuli such as symptoms and external cues care motivation such as media campaigns to part take in the preventive program for example

2.4. Theory of reasoned action

The theory of reasoned action (TRA) was developed in 1975 by Fishbein and Ajzen (1). This theory explains behaviour based on individuals intentions and adoption of a specific behaviour. According to this theory, individuals act rationally to attain desired outcomes and to avoid disappointing others by confounding their expectations (1). Furthermore, the behavioural intention of the individual is established by their subjective norms and their attitude towards that behaviour, which determines the behaviour which is expressed. In figure 4. the theory of reasoned action is visualized.

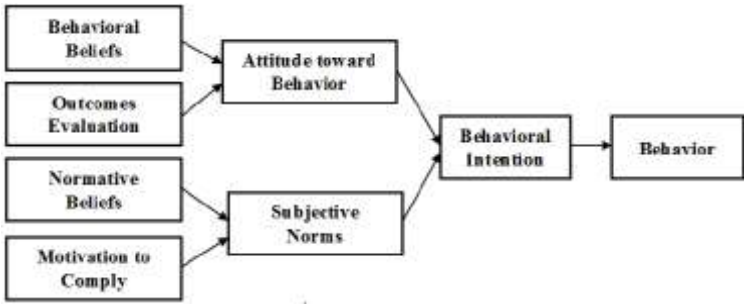

Figure 4. Theory of Reasoned Action – TRA by Fishbein & Ajzen, 1975(1)

2.5. Unified theory of acceptance and use of technology

The UTAUT model was developed and first introduced by Venkatesh et al.(2003), based on eight Technology Acceptance competing models(43). This was done to consolidate research in technology acceptance literature. The eight competing models were the : ''Theory of Reasoned Action (TRA), the Technology Acceptance Model (TAM), the Motivational Model (MM), the Theory of Planned Behaviour (TPB), a model combining the Technology Acceptance Model and the Theory of Planned Behaviour (C-TAM-TPB), the model of PC utilization, the Innovation Diffusion Theory (IDT), and the Social Cognitive Theory (SCT)'' (43). Despite the numerous research models in Technology Acceptance, the research of Venkatesh et al.,(2003) and Dwivendi showed that the UTAUT model outperformed the other acceptance models by explaining 70% of variance in behavioural intention and 50% in technology use(44-46). In addition, the UAUT theory is settled on four theoretical constructs which are: facilitating conditions, effort expectancy , performance expectancy and social influence. These theoretical constructs serve as the reason a person will choose to use a product (use behaviour) or has the intention to use a product (intention to use), which play a pivotal role in technology acceptance. According to A.Akinnuwesi et al. (2022), the decision to consider using DTC-GT would be in line with ones' personal values(47). Besides the theoretical constructs on which the UTAUT model is established, the theory contains factors that moderate the relation between the aforementioned constructs and the intention to use. These moderating factors are: experience, age, gender and voluntariness of use(43).

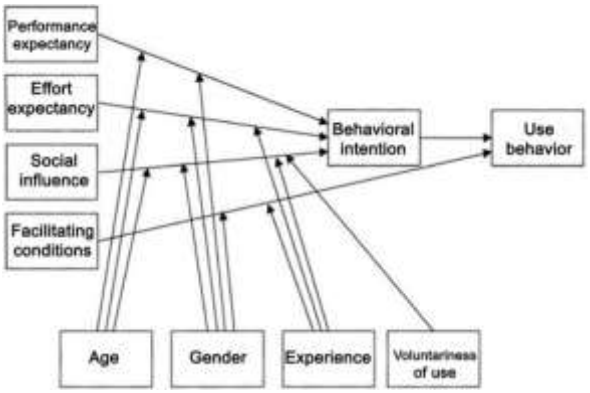

Figure 5: UTAUT model by Venktates et al. (2003)

2.4. Qualitative research

This study consists of a qualitative research approach which is a method designed to reveal the behaviour and perception of the target population in regards to the topics researched. There are numerous types of qualitative research methods such as: focus groups, content analysis, interviews, ethnographic research and participant observation(48, 49). Qualitative research is an exploratory scientific method of observation to gather non-numerical data. Rather than determining 'counts or measures' as in quantitative research, qualitative research involves a description of things, related characteristics and meanings, and basic observations and interpretations. Some of the common approaches to conducting qualitative research include interviews, participant observation, and focus group discussions(49).

The qualitative research approach used in this research are focus groups. A classical content analysis will be performed with the data obtained from the focus group discussions. Moreover, this research consists of a narrative literature based on literature which discusses the expectations and information needs for genetic testing technology. This narrative literature review will be a supportive data set to gather inspiration and knowledge on assembling the semi structured discussion guide for the focus groups. The primary emphasis will remain on the results from the qualitative data set in this case. With the results from the aforementioned approach, implementation could be improved with the collaborative implementation strategy. This strategy is intended to provide perspectives and contexts of the involved parties e.g., in this case Urimon and its end-users. Here both parties can provide their perspectives in order to align them and mutually improve their knowledge on how to improve implementation (50).

2.4.1. Focus group

In medical and health research, focus groups are emerging. A focus group is a research methodology where the researcher gathers participants from the target group in question to discuss a topic or issue to collect qualitative data. The main goal of the focus group is for the researcher to gain a better grasp of the participants perspective on the topic discussed(17). According Hennink et al.(2019), two to three focus groups are sufficient to capture 80% of themes discussed, including the most frequent themes, and three to six focus groups are needed to capture for 90% of themes in a homogenous population where a semi-structured discussion guide was used in the focus group(51). The recommended sample size for a focus group is eight to ten people (52). A narrative literature review has been done on the main topics of this thesis to form a discussion guide for the focus groups.

2.4.2. Narrative literature review

A narrative literature review is a traditional literature review which is critical, comprehensive and gives an objective analysis on present knowledge on a topic. It assists with identifying trends and patters in the literature to facilitate the identification of gaps or inconsistencies of knowledge(53). In addition, narrative refers to an approach to a systematic review of findings from deferent studies that primarily relies on the text to explain and summarize the findings(54).

2.4.3.Tape- based analysis

The data from the focus group will be analysed with a tape-based analysis. In this analysis the researcher will listen to the tape recorded during the discussion and thereafter create an abridged transcript. An abridged transcript is more condensed than a full transcript. This type of analysis for the qualitative data is chosen for this proposed research because it will help the researcher focus on the research question of the thesis and transcribe only the parts of the discussion that assists the researcher to gain better understanding of the essential aspect discussed(55).

2.4.4. Classical content analysis

The qualitative data retrieved from the focus groups should be also quantified to organize and condense the data even further. This is possible with a classical content analysis which is a quantitative research method. This method can establish the amount certain themes, words or concepts have been mentioned within qualitative data; in this case the abridged transcript derived from the focus group discussion(56). The aim of this analysis is to systematically transform the text into a highly concise and organized summary of key results. This should be done following these steps(57):

1. Re-read the abridged transcript to understand what the participants are talking about in order know the main ideas or topics expressed by the participants.
2. Divide the text into smaller meaning units to condense the text further
3. Label the condensed meaning units with the use of formulated codes (coding scheme)
4. Group the codes into categories; these categories can be visualized in graphs and tables with the use of Excel.

3.Methodology

3.1. Study design

A qualitative research approach was used to elicit Urimon participants expectations and information needs. This approach concisted of a narative systematic review (NSR) and a content analysis from three emergent-systematic focusgroups. The NSR was carried out during March of 2022, to create a semi-structured discussion guide with the use of excel/ATLAS.ti. The NSR was based on qualitative studies which researched the expectations and information needs for genetic testing, especially DTC-GT. The findings of the NSR have been used to create a semi-structured discussion guide for the three emergent-systematic focus group sessions.

3.2.Study population and sample size

3.2.1. Population

The population was a mixed gender population (female and male) which included 24 people living in the NL between the ages of 45 and 75. Participants of this research were people who participated in the Urimon research. The population had a stable health status, since this was an inclusion criteria for the Urimon study. However, this was not necessarily an inclusion criteria for my study considering, that this would not affect my research. Below the inclusion and exclusion criteria for the participants of this research are given.

3.2.1.1. Inclusion criteria

- Individuals between the ages of 45 and 75 (8).
- Individuals who are able to read and communicate in Dutch with minimum proficiency level of B1, according to the Common European Framework of Reference for Languages (CEFR) (58).
- People without cognitive limitations
- People who can access the University of Twente with their own transportation

3.2.1.2. Exclusion criteria

- Criteria's that contradict the inclusion criteria described above.

3.4. Description of focus groups

The focus group sessions were held at the University of Twente on the following respective days: 9th of May 2022, 16th of May 2022 and 20th of May 2022. Three focus groups were held to reach saturation of the topics being researched (55). The focus groups contained approximately twelve people including the researchers/ moderator, assistant moderators and the note taker. The total duration of the individual focus group discussions were approximately 120 minutes consisting of three 30-minute discussion rounds with the following topics:

- Expectations – to elicit the expectations of the future end-users regarding the Urimon disease warning system
- Information needs - to elicit information the end-user may need in order to make a choice to buy or make use of the services Urimon wants to provide in the future
- Conditions – includes sub-topics regarding costs and privacy, e.g. how much do future end-users want to pay for the services that Urimon wants to introduce to the market.

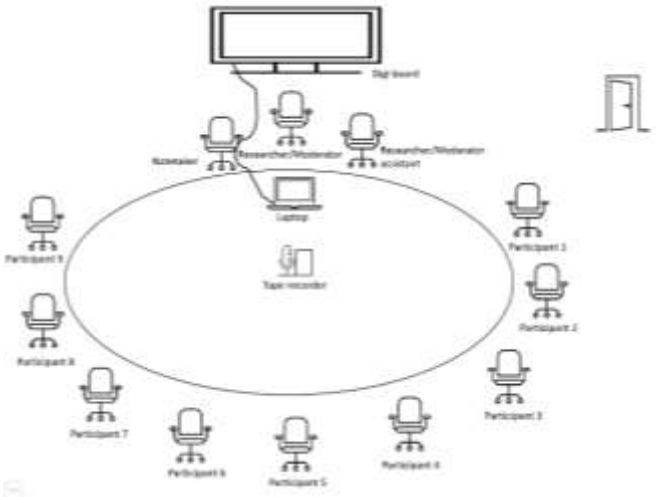

Figure 6. Focus group seating arrangement

The seating arrangement visualized in figure 6. facilitated the discussions. During the discussions a simple PowerPoint slide was presented on the Digi-board to help participants stay focused on the specific topic being discussed at that moment, which also assisted the discussions.

3.4.1. Discussion moderator guide development

The focus group questions for the moderator guide was generated based on the NSR. Since different topics where discussed in literature, three main topics, hereafter also referred to as general codes where made. These are: expectations, information needs and conditions. The questions were reviewed for content and meaning behind the question and further narrowed down to more concise questions. To ensure consistency in the questions asked, a semi-structured questioning route was used. This questioning method allowed some flexibility in accordance to the participation level of the participants and the topics and questions raised during the different discussions. Before initiating the discussion, participants were asked to share their name, age and current occupation. This was done to help the participants feel at ease during the discussions. To help participants start discussions, an opening question was asked followed by general questions regarding the three main aforementioned topics (see figure 1. Key focus group questions). This was followed with more specific questions to gain better insights on the topics being discussed. (The complete discussion guide with additional questions can be found in the appendix C, page 51-54)

3.5. Data analysis and materials

The focus group session were recorded and a tape-based analysis was performed to analyse the data derived from the focus group recordings. In this analysis an abridged transcript was created with the use of the Microsoft 365 transcription tool. Thereafter, a classical content analysis was performed based of the abridged transcript and notes taken during the discussions. The content analysis was conducted to find patterns of topics that were discussed during the focus group discussions (qualitative data)(56). This qualitative data analysis was analysed with ATLAS.ti. The codes in ATLAS.ti were created inductively as they were based on the content of the fragments in the transcripts and were not created in advance. The main codes and sub codes were used to code the fragments. After the fragments where coded, overarching themes were created that aggregated subcodes. (See figure 7 for the inductive coding steps that were followed. To provide credibility for the qualitative research to be executed in this research with aforementioned focus groups, the Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines was used to facilitate a comprehensive and explicit reporting of the focus groups(59). (See appendix B, page 49-50 for the COREQ guidelines)

Step 1:
- *The focus group transcripts were read*

Step 2
- *Segments of information were identified per focus group*

Step 3
- *First level codes were created by labelling segments for each focus group*

Step 4
- *Redundant codes were removed*

Step 5
- *Broader codes where created by aggregating first level*

Figure 7. Inductive coding steps

3.6. Sample recruitment & ethical considerations

Urimon participants voluntarily signed-up via a newsletter to be approached for follow-up research regarding enhancement of the Urimon end-product. Therefore, the sampling method that was used was convenience sampling, as there was a pool of respondents available at Urimon. The participants have been recruited via phone calls and emails. (See appendix A, call protocol and email for participants, page 41-44)

This study was conducted according to the principles of the BMS/HSS ethical committee of the University of Twente. Participants could contact the researcher at any time with questions by e-mail or phone. Prior to participating in the focus group the participant should have read and signed a consent form. (See appendix A: consent form, page 47). There was no direct benefit from this study for the participants. The future benefit for the population could be the further development of a disease warning system, which enables early detection of disease resulting in less burdening treatments, and lower health care costs for society. Additionally, the implementation of such system is also improved. The incentive for participating in this research were gift cards with a value of €10, free lunch and travel expenses covered.

4. Results

4.1. Focus group demographics

In total there were twenty-four participants in the focus groups (twelve females and twelve males), with a mean age of 67. All focus group participants were currently participating in a research project, in which the aim is to demonstrate proof of concept of the Urimon service. Most of the participants were retired. In each focus group, one or more individuals had a background in health care. The characteristics of the focus groups are shown in table 1.

Table 1: Characteristics of focus group participants

Table with all participants	Nr of participants	Nr of females	Nr of males	Nr of participants that are retired	Past or current occupation	Average age
Focus group A	**9**	**5**	**4**	**4**	*-Sales manager* *-Medical analyst/clinical analyst* *-Coach* *-Highschool teacher* *-Pharmacy assistant* *-Housewife*	**68.3**
Focus group B	**8**	**4**	**4**	**5**	*-Functionary* *-Chemical analyst* *-Medical analyst* *-Social gerontologist* *-Logistics* *-Municipality government function*	**63.4**
Focus group C	**7**	**3**	**4**	**6**	*-Beer brewer* *-Works in healthcare* *-Family hotel business* *-Corporate social worker* *-Midwife* *-Automation* *-Househusband* *-Housewife*	**69.5**
Total	**24**	**12**	**12**	**15**		**Average=67**

4.2. Expectations of consumers to use Urimon services in the future

The product and process expectations of the Urimon system is given in table 2. The initial expectation that the participants have of a service like Urimon is that it will detect diseases in an earlier stage, given that the service is presented as a preventive examination method. *''I just think it is a preventive examination and you should get your expectations out of that.''*

Participants expressed that they do not think that participation in a service like Urimon will lead to a longer or better life. A participant argued that a person should be intrinsically motivated to take care of their own health. *''The services presented can function as a mirror, where your supposedly mindful and healthy living practices can be affirmed or debunked''*. Other participants agreed with this statement. Therefore, they do not expect Urimon to provide the benefit of promoting a healthy lifestyle, because they view Urimon as an external motivator that can only provide them with feedback regarding their health.

The main expectation for the Urimon process is that a GP should be involved in the procedure to e.g. provide consumers with their genetic results and give further advice related to these results. In addition, participants expect Urimon to give advice regarding their health status to the consumers GP. Participants stated that they view their GP as a confidant as well as a knowledgeable person that can understand and interpret test results. Moreover, some participants suggested that Urimon could offer consumers the option to receive the information either through their own GP, a generic GP or directly through Urimon.

According to the participants, insurances should also be involved in Urimon's system process. Because, insurances can possibly cover consumers expenses when using DTC-GT services like Urimon. The majority of participants stated that the services presented should be included in the basic insurance, whereas some participants expressed that these services could be included in the extended insurance package. Overall, participants agreed that it should be affordable and accessible for everyone. The focus group discussions also revealed that participants are more likely to use Urimon services if their services are presented as a population screening method.

Furthermore, participants expect that Urimon services are made available to the younger population; allowing possible end-users to start using the services at a young age. The reason they give for this expectation, is that the younger population can also be susceptible to the specific illnesses Urimon wants to detect in an early stage in the future. Therefore, participants stated that there should not be an age limit for using the presented services. *"I think when you talk about a preventive method, that you should do something at a young age, I think, because so much is already happening in old age.'' ''I hope that Urimon can ensure that, in fact, without an age limit, those studies can be done.''*

Participants also shared that they expect Urimon to be the sole organization that is responsible for what happens to the information and data they provide to Urimon. *''Based on principle, shared responsibility means that no one is responsible. If several authorities are responsible at that time, then no one is responsible and that is why it is very important that the information comes together at one point. Because that is precisely why someone is responsible and only he is passing on and writing for the information, but where several organizations are responsible, no one can be held accountable.''*

Participants also suggested that a motivating factor for participation, would be to receive some form of incentive such as e.g., receiving points for every time you hand in urine. In addition, it would also motivate participants if they can receive feedback from people that have been using the Urimon services, to inform them about their achieved results and progress, to determine for themselves if Urimon is successful or not. *"They should make a success list available because with that we can determine that it works."*

Table 2. Product and process expectations coding scheme

	Product expectations	
Theme	**Category and** *subcodes*	**Description**
Can Urimon benefit individuals and the Dutch society by facilitating health and/or healthy behaviour?	**Urimon facilitates health** *Healthy lifestyle* *Health check system* *Life expectancy*	Urimon can benefit individuals and the Dutch society by facilitating health and/or healthy behaviour by keeping individuals health in check
	Preventive services *Prevention* *Population screening* *Disease detection* *Early detection*	Participants expect a research that is preventive, that will detect diseases in Urine
	Process expectations	
Theme	**Category and** *subcodes*	**Discription**
Cooperation with health professionals, preferably the GP, is necessary for responsible communication of test results.	**Communication of test result** *GP should be involved* *Health care professional should be involved* *Genetic literacy* *Inform about health* *Urimon should give feedback to GP* *Responsibility*	Involvement of a GP in the Urimon process is important for their possible future costumers
	Perception of GP *GP should be involved* *Personal believe*	A GP is perceived as a knowledgeable and trustworthy health professional.
	Offer options *Option* *Choice*	Urimon participants expect that they can choose who will provide them with information regarding their health, either Urimon, a specialist or a GP.
"A preventive service like URIMON should be affordable and accessible to all"	**Health insurance** *Urimon should be included in the basic insurance package* *Work with insurances*	The service could be a part of an insurance package, either in the basic insurance or in an extended package.
	Dutch Government *Population screening*	The servie should be offered within the national screening program.
	Affordable *Cost*	It would be unfair to exclude people from having access to a service like Urimon because they cannot afford it.
	Accessibility -General *Difference in accessibility* *Accessibility*	Urimon services should be 23ccessible for everyone
	Accessibility- Age *Accessibility* *Age limit*	Urimon services should not have an age restriction

"Contact with and/or sharing of experiences of current and past users of the Urimon service would offer potential users better insight about what to expect.	**Feedback from users** *Recommendation*	Participants would appreciate receiving feedback from Urimon users to know their progress
	Past successes *Recommendation*	Participants expect that Urimon presents them with succes stories.
	Incentives/ motivation *Recommendation*	Urimon should give its users insetives as a motivation to continue using their product.
Users find it important to know when they will receive feedback about their results	**When will I receive an reaction /feedback** *Fast results* *Questions about service*	Participants expect Urimon to give them information on when they can receive feeback.

The expectations of the participants have been divided in process expectations and product expectations. The general code for this table is expectations. The categories which are the different expectations; regarding the way in in which a DTC-GT service like Urimon should be offered to society **or** individual consumers **or the benefit that using a DTC-GT service like Urimon can have**, **was formed by grouping related *subcodes*. The different categories have been categorized in overarching themes to facilitate comprehension of the results**.

4.3. Information needs of Urimon participants

Information need of the Urimon product and process are given in table 3. Participants shared that there are still a lot of uncertainties about Urimon product and process. Therefore, participants have stated that they want clear information which is easy to understand for a layman about Urimon and about what is being researched in the samples to be able to determine if they will make use of the system

In addition, they would also want information about which diseases Urimon can detect. *''What can they detect?''* Moreover, they would want to know where they can get this information. Besides that, they would like to be informed on; to what extend Urimon can provide preventive services. Participants revealed that if evidence for the latter can be generated, this could be an indication for them to make use of the system. *''If a clear explanation is provided, which is the advantage of participating in this research. Then yes, then you will be able to keep people on track.'' ''If it turns out to have a preventive function, this has yet to be proven, that will be an indication to participate, yes, but there are still so many uncertainties.''* They would also want to be informed about the costs of the Urimon system prior to using their services.

Participants shared that they expect to be informed about their test results after using the presented services, together with a positive or negative feedback as this feedback can motivate them to continue using Urimon services. Few participants expressed that they do not need to receive information and/or feedback from a GP if there are no adverse events present when receiving their results. However, the majority still prefers to be contacted by a healthcare professional. Furthermore, participants expect Information about the trustworthiness regarding the reliability and accuracy of the product, and how the information obtained should be managed. Reliability was defined by the participants as how good ''correct'' the system can detect disease, in other words the trustworthiness of the test ; and accuracy was defined by how precise the test would be in the results.

Another expectation that the participants had about information of the product was, the infromation about how the genetic material of the consumers is managed with respect to privacy. *''You can also write a piece about the privacy: if we continue with the investigation, if we find something, if we use your genetic material, things like that should be included ''.*

Furthermore, participants stated that they would like to be informed on how to monitor their process within the Urimon system. Therefore, some participants suggested that sharing information about their data and progress with graphs in an online platform would be useful. *''I think a website is also important, for example, for people who want to know more or want to watch newsletters.'' ''Some might also like to be able to access their own data online. With graphics or something? If it takes that many years, then that is fun.''*

Table 3. Information need of the product and process coding scheme

Information need of the product		
Theme	**Category and** *subcodes*	**Description**
Information that users expect prior to using DTC-GT	**General user needs** *Where to get information* *When to expect results* *Which disease is researched* *Does Urimon have approval/ quality mark* *Accuracy of test* *Quality of test*	General information needs, not specific to the exact service participants are going to choose. Such as information that would allow them to judge the credibility of the company that offers the service
	Specific user needs *What is being researched in the Urine* *When to expect results* *Is there support with interpretation* *Who gives information about the test to consumers* *Costs*	Information specific to the service participants are going to choose. e.g what is being researched in the urine samples at Urimon, what are the costs of the service?
How information about Urimon should be communicated to its users its users	**Digital and/or physical information sheets should be available.** *Digitalisation* *Where to get information*	Urimon participants want to know where they can get information regarding Urimon but also about their services. Participants made suggestions that they could receive information via their GP, local library and pharmacy
	Information should be correct and clear but also easy to understand *Genetic literacy* *Easy to understand* *Clarity* *Honesty*	Participants want information that is easy to understand, in simple language
Information that users expect after to using DTC-GT, who should provide this information	**Information after analysis** *Gp should not be involved* *Feedback/Motivation*	What information is expected after the analysis; particpants shared that they would like to receive feedback wether their result is positive or negative. This feedback can also motivate them to continue using the Urimon system and increase likelihood of adherence
Information about the trustworthiness of product and How the genetic and/or private information obtained from Urimon users should be managed	**Trustworthiness of product** *Reliability* *Accuracy*	Participants want to know how reliable the Urimon system is. In addition, the reliability should be tested by another independent research group. Participants also

		expect that Urimon should have approval of the government *Participants what to know how accurate the Urimon system is* This means how precise the research will be
	Data management *Privacy* *Responsibility*	Participants expect information about how Urimon guarantees to keep participants genetic and personal information private.
Information need of the process		
Theme	**Category and** *subcode*	**Description and/ or quote**
Process monitoring , validity of results and its specifications	**What are the test procedures** *Length of participation*	Participants want information regarding how long they should make use of Urimon services
	How long are results valid *Test value*	Participants want information about the time frame they can attach a value to the results of their test

The information needs of the participants have been divided in process information needs and product information needs. The general code for this table is information needs. The categories which are the different expectations; regarding the information that a service like Urimon will offer to its consumers before and after using their services, and information about the process of their service was formed by grouping related *subcodes*. The different categories have been categorized in overarching themes to facilitate comprehension of the results.

4.4. Conditions of Urimon participants

Facilitating conditions and conditions that could pose a barrier for the uptake of Urimon are given in table 4. All participants who were present agreed to wanting to know what diseases they might be developing and some participants shared that they have a family member or a family history of disease, which could be a facilitating condition; If the services are presented to people with family members with disease or who have a disease history in their family. *''My parents and my sister died of cancer and on my mother's side of the family, the whole family has blood vessel problems. So I think that for me it is useful to keep a close eye on this.* ''

When the participants were questioned about how much they are willing to pay for such a service Urimon wants to provide, a variety of perspectives were expressed. In the first focus group participants shared that they would be willing to pay approximately €100,-. However, in the other focus groups that followed, participants were unable to answer as they expressed that they do not exactly know what Urimon can provide and thus do not know what to expect. Some participants indicated that if Urimon can save costs in society; their services should be free of cost. Nonetheless, the participants compared Urimon frequently with Pre-scan which can be seen as a similar company to Urimon. The general shared opinion of the participants about the costs of Pre-scan were that their prices are too high.

However, after the price that Urimon expects to set for their services was shared with the participants, which is approximately €500 for the first year, some felt that €500 could pose a problem for a lot of people. *''Yes, then I think that if you pay € 500 every year for a whole lot of People, it could be a problem.''* While others considered that if they can detect a disease early, as Urimon proposes, it should be worth this price. Moreover, a participant expressed that they could pay the price now but do not know if they could pay this when they are retired.'' *And now I can afford it, but soon I will have my old age pension and then I may not be able to pay it.''*

As a remark to the price, participants also expressed that the cost could result in a difference in accessibility for using the Urimon services, especially for people who are unable to pay. Therefore, the majority of participants agreed with the statement that Urimon services should be provided through the Dutch basic health insurance. When asked, if it is an hindrance to pay for such a service, the majority agreed that it is indeed a hindrance for them personally. However, other participants indicated that they do not know if it is a hinderance, but rather see it as a threshold.

When asked if a company like Urimon can provide their services to third parties like employers, the participants were unanimous in the view that this should not be done. Especially if the employers can obtain information of the employees' health status. *''Per definition you cannot trust your employer''* Expressing great concern, they stated that they are afraid that their private information can be used against them. For instance, employers basing their selection procedures on the health status of the individuals. *'' If I'm sure the company is not going to do anything with my data, but if not I don't agree with a company investigating something to be able to use it against me, while I can't do anything about it myself.''* Furthermore, they see this practice as a violation to their privacy. *''I do not think that is privacy anymore''.*

Table 4: Facilitator and barriers coding scheme

Facilitating conditions		
Theme	**Category and *subcodes***	**Description**
Why an individual would be interested in their genetic information; to know which diseases they may have or are predisposed to.	**Individuals desires to be informed on their health status** *Do I want to know which diseases I may or may not have?* *Family member with disease* *family history of disease* *Reasons to buy the product* *Prevention*	wanting or not wanting to know for which disease a participant may be at risk
Conditions that can be a possible barrier		
Theme	**Category and *subcodes***	**Description**
How and in what way will the Urimon service be financed	**Financing aspects** *Cost* *Work together with health Insurance*	Willingness to pay of the participants, what the participants are willing to pay for Urimon services.
To what extend do participants expect that information shared with Urimon will be not be shared with third parties	**Share information with employers** Reasons not to buy the product Privacy	Participants expect that information will not be shared with their employers

This table contains the facilitating conditions and conditions that can be a barrier to a service like Urimon. The ***subcodes*** which are the facilitating factors and factors that could pose a barrier, have been grouped in categories. These were factors mentioned by the focus group participants. That would make them, or other people more likely to use a service like Urimon.

5.Discussion

This research aimed to support the implementation of the Urimon disease warning system by exploring consumers expectations and information needs, regarding the use of the technology. In this study, we uncovered two major expectations, several information needs and conditions. The most evident expectation of our study is that participants expect that a genetic test such as the Urimon system will be made available as a population screening method, or within their basic healthcare package, free of costs. This is directly in contrast with how Urimon is currently developing this service at the moment and how it aims to implement the service. It is also in contrast with how other DTC-GT are implemented, which is by offering them directly to consumers, to be paid out of their own pocket. Not meeting participants expectations of providing Urimon as a population screening method can be a barrier according to the HBM, as this is not the implementation scenario that Urimon is pursuing for the time being. This could impact Urimon's success along with not meeting the other expectations of the participants. However, fulfilling this expectation could be interpreted as a facilitating condition according the UTAUT model, which directly relates to ''Use behaviour'', where consumers are more likely to use the technology. We can think of multiple reasons for why Dutch citizens expect this service to be offered free of cost. One of these reasons could be because a wide range of healthcare are reimbursed in the Netherlands, and people do not want to pay out of pocket for additional health related services(33).

Another major expectation of our study is that participants expect the involvement of a GP in the Urimon system process. To primarily help participants with understanding their results and give them advice and counselling based on their genetic test results. Therefore, not involving an GP in the Urimon process can also be perceived as a barrier according the HBM, which could be an obstacle for consumers to make use of the Urimon system. This finding was unanticipated since when discussing DTC-GT you would expect participants to be aware that DTC-GT is a service that is provided without the interference of a healthcare professional and would thus not expect involvement of a GP. However, It has been reported by a DTC-GT survey targeted to DTC-GT web pages, commissioned by the European Parliament, that many companies providing DTC-GT services do not provide the necessary information to consumers about the essence of the test. This includes how to interpret results and the implications that may arise from the test (60).Therefore, it has been recommended by Rafiq M et al.(2015), to provide consumers with genetic counseling to help them understand their test results due to the possible low genetic literacy of the consumers (2). This is consistent with findings regarding information need in our research. A finding that is not consistent with literature is the statement of participants indicating Urimon services cannot lead to a longer or better life. As this outcome is contrary to that of Yeyang Su et al.(2011), who found that health expectations towards DTC-GT are *''improve the quality of health and live longer''.*

Before Dutch citizens can decide on whether they want to participate in a preventive screening program such as Urimon, they need to get their information needs met. For instance, we found that participants expressed that they do not need to receive information from a GP if there are no adverse events present when receiving their results. This contradicts the aforementioned expectation of involving of a GP in the process. Therefore, if looked at the results more closely, we can discuss that the participants may only want the involvement of a GP to disclose results and give advice when these are unfavourable. And to inform them about which steps they need to take after receiving an abnormal result. This occurrence could be explained by the TRA, where individuals could have a subjective norm of wanting

support and/or approval for adverse test results by a heath care professional, which could influence their behaviour towards the results.

Moreover, the participants indicated that they need general and specific information about the service that is easy to understand. The results regarding information needs corroborate with the findings of the previous work in the article of Rafiq M. et al.(2015) and Bermseok Oh, (2019) (2, 30). Who state that DTC-GT users could need information regarding scientific evidence of the benefits of genetic testing along with the explanation of the scientific basis upon which genetic testing is carried out. This should be provided in a simplified manner for the general public (2). This explanation should contain information regarding privacy concerns, e.g.; who will own the genetic material, personal information and how it will be protected. Additionally, clear guidance about what the genetic test can or cannot indicate to the end-user in the present and future should be disclosed to the consumer (30). An noticeable condition of this research is how Urimon will be financed. In the first focus group participants shared that they would be willing to pay approximately €100,-. However, in the other focus groups that followed, participants were unable to answer as they expressed that they do not exactly know what Urimon can provide, and thus do not know what to expect.

Further, the article of Rafiq M et al.(2015), states that DTC-GT companies advertise them self in such a way that their benefits outweigh their disadvantages. Hence, the disadvantages and limitations of the test should also be made clear to the consumer to be transparent(2). Not being transparent about the trustworthiness of the product and management of data could pose a threat to the likelihood of uptake of the service, which could affect the success of Urimon; as this can be perceived as a barrier according to the HBM for the potential buyers to purchase the presented service. These results are in accord with recent studies indicating that it is important that DTC-GT test result reports of the consumer indicate the specifics of the laboratory's accreditations(2, 4, 5). Ensuring that the laboratories who perform these highly technical and complex tests adhere to the strict guidelines and standards for clinical testing. In accordance with the results, previous studies have also demonstrated that, possible obstacles for using genetic tests are accessibility concerns, which can lead to differences in healthcare. Including the concern of sharing information with third parties(9). This study demonstrated that this is a great concern among the Dutch population as participants made clear that they do not thrust their employers. This finding is especially important for Urimon because, the main stake holders of the Urimon disease warning system will include health-oriented individuals and companies offering health programs to employers

Since three focus groups were carried out I can discuss that 80% of saturation has been reached in this study. However, according to McKenna et al.(2016), 8 focus group sessions should be held to reach 100% saturation(61). Although, according to Guest et al.(2016), 3 to 6 focus groups in a homogenous study population using a semi- structured discussion guide can result in 90% saturation(61). It is apparent that it is still unclear what saturation is, and what influences saturation for different qualitative methods data, according to different papers discussed in the article of Guest et al.,(2016)(61). Concerns regarding researchers claiming to have attained saturation in qualitative studies without adequately describing or justifying how saturation was determined or achieved is growing in the qualitative research community(51). According Hennink et al.2019, future research is needed to examine the levels of saturation in qualitative research also in the different types of data, research approaches and data collection methods (51). Therefore, the possible saturation level of 80% should be interpreted with caution

5.1. Strengths & limitations

The strength of this study is that it is one of few studies that researched expectations and information needs of Dutch citizens regarding the use of DTC-GT technology with focus groups as a qualitative research method. However, the results of this study have to be interpreted in light of its limitations. There are three main limitations to the study design and outcome.

First, we collected data using focus groups and it is common to analyse qualitative results with a minimum of two independent researchers. In this study, there was one researcher who did the data analysis. This could have resulted in inconsistent use of codes when analysing the data set(62).

Second, during the different focus groups there were either working or retired healthcare professionals present. These participants posed an authority bias among the other participants. Resulting in non-healthcare professional participants to possibly agree with the views of the healthcare professional -participants; which I think could have caused other participants to withhold their expressions and believes. Especially when jargon was used by these healthcare professionals.

Third, the topics discussed in the three focus groups were different. This might have been caused by the presence of different discussion leaders in the three focus groups. Specifically, one of the project leaders of the Urimon company was present during the first focus groups, and actively engaged in the discussion. This might have resulted in authority bias. One example of this was, that this was the only focus group, in which participants assigned an actual number to their willingness to pay for the test. Also, overall, in this focus group participants were more positive that those in other focus groups. Participants had the tendency to respond in a manner that would feel socially appropriate this is also known as conformity bias (63). In addition, it can also be discussed that there was an anchoring bias present in focus group A. Where when one person agreed on being willing to pay an amount, others also anchored their response based on what was previously stated(63).

Due to the different biases present in the first focus group which are: conformity, confirmation and authority bias, as well as fewer topics that answer my research question being discussed during this focus group session; the reliability of the results of this focus group could have be limited. Making focus group B and C, despite also having authority bias due to the presence of authoritative figures, more reliable. Nevertheless, the combination of all three focus groups give a clear picture of the expectations, information needs and conditions of the participants.

5.2. Implications

5.2.1. Theoretical implications

This study contributes to understating expectations and information needs that users may have for using DTC-GT. To my knowledge, there is no substantial research on these topics especially, within the specific target group demographics of this research. Making this article the first article that explores the expectations and information needs of Dutch citizens aged 45-75 to consider using DTC-GT. Additionally , the findings of my research align to those of other scholars, everything considered, as discussed in chapter 4, which strengthens the previous findings in literature. Furthermore this article highlights consumers thoughts in NL to some extent, on their willing ness to pay for additional health related services.

5.2.2. Practical & policy implications

The direct impact that this study has on Urimon is to inform the Urimon team, project leader and eventual future managers on what type of information needs potential end- users may have to use the Urimon system. In addition, what the potential end-users expect with different conditions is also made clear in this research. The Urimon team could asses how they are going to implement their service in the Dutch health

care market with the findings in this research. This could be done not only to meet the needs and expectations of their potential buyers but also to ensure a higher rate of success for their company. There is still a lot of uncertainties and questions among participants, not only regarding the Urimon disease warning system but also the current ongoing Urimon research. It is important for Urimon to make their research clear to the participants and also what they can expect from the disease warning system in the future. Participants are in great need of e.g. clear information of Urimon and which diseases Urimon aims to detect in their system. By not providing this information in an easy to understand manner, participants are then unsure if they would be willing to pay for the presented service. This can possibly deter potential customers from considering using this system.

My advice for Urimon would also be involve a general practitioner in their care process. This general practitioner should deliver the test results to the end-users and also support users with information regarding their test results after the result has been delivered. This was also recommended by a DTC-GT survey commissioned by an European Parliament; to provide consumers with genetic counselling to help them understand their test results due to the possible low genetic literacy of the consumers(2). I would also advice Urimon to lower the price that the future end-user will have to pay out of pocket as much as possible by collaborating with health insurances, who will possibly cover a part of the expenses. Urimon should be transparent about this and thus provide evidence of this to their end-users. The price that Urimon wants to charge for e.g. the first year which is ~€500,- could deter the general population that is between the ages of 45 to 75 to make use of this system. As there is a high number of people who are retired in this population, it is important to mention that; more than half of the Dutch (60%) do not know whether they will have enough income after retirement to pay all their expenses. Only four out of ten people in NL have a good idea of what their finances will look like after retirement(64).

What would make the Urimon services even more attractive to potential end-users would be to implement Urimon as part of the national Dutch population screening. By doing this individuals in NL could be screened free of cost. This would remove the barrier surrounding costs that has been presented in this research. Therefore, I would advise Urimon to present their services to the Dutch Health council or the Minister of Health, Welfare and Sport. The Minister of Health, Welfare and Sport is ultimately responsible for the National Population Screening Program and decides on the introduction and possible adjustment of a population screening (65). A national population screening is only introduced or adapted if it meets the criteria for responsible screening and if the advantages outweigh the disadvantages. In doing so, the minister uses the advice of the Health Council. Aspects such as the financing of the population screening also play a role in the decision(65). (See appendix D for the criteria for responsible screening, page 53-54), Currently Urimon does not meet these criteria, as there is no proof of concept. However, Urimon is aiming to analyze the first sample series of prostate cancer and heart and vascular diseases next year.

The Minister of Health, Welfare and Sport determines the preconditions and, if necessary, issues permits for the performance of a population screening. The Health council assesses bases on scientific evidence if its desired to implement, expand or adapt the population screening. In addition, the Health council considers whether there are benefits that outweighs possible risks for participants(65). The Health council uses the criteria of Wilson and Junger 1968 and additional criteria of the WHO to get to its advice. The criteria of Wilson and Junger 1968 are the international criteria to determine whether a screening is justified(66, 67).Furthermore, the Health council advices on the target group, the nature and cut-off value of the screenings test, the number of screening rounds, frequencies and quality. To be part of a population screening, a WBO (''Wet op het bevolkingsonderzoek''), law on the population screening permit is also required(65).

Sometimes there is still insufficient data to establish if a medical research meets the criteria to eventually be considered a part of the population screening. When this is the case, trial population studies, pilots, additional research often take place under the guidance of ZonMw. ZonMw is a Dutch health research and care innovation organization; that finances health research and encourages the use of the knowledge developed to improve healthcare(68). The results of this collaboration are used for further assessment by the Council on whether or not to introduce the new medical research in the population screening(65).

5.3. Recommendations for future research.

To develop a full picture of the expectations, information needs and conditions that possible end-users may have to use the Urimon system, additional focus groups, ~eight, should be held in different locations within NL. The inclusion criteria for the target group should not be limited to 45-75 years old, if Urimon aims to eventually make their services available for the entire Dutch population. Furthermore, I would also recommend to include people in who are not already Urimon participants in the focus groups to avoid possible confirmation bias among participants. It is also recommended to do additional studies that involve another qualitative data collection method e.g., interviews to reduce the different biases among participants explained in chapter 4. Another independent researcher should analyse the data to reduce confirmation bias among the researcher executing the research. In addition, for future research a stake holder analysis can be performed to see what kind of people would make use of the Urimon system. This could be done to research the adoption and uptake of the technology.

Urimon could perform a qualitative research such as a DCE to reveal and quantify the different facilitator and barriers of participatory rate and use for their services and how individuals value the different attributes related to genetic testing(9, 69).A good example of such research can be seen in the systematic review article by Ozdemir et al(2022), who aimed to carry out a systematic review of DCE and conjoint analysis on genetic testing(9).

I would also recommend to carry out a systematic literature review (SLR) of the main topics discussed in this thesis as a follow up research. The steps that should be taken to be able to perform a systematic literature review are shown in the appendices. (See appendix B, supplementary information, systematic review, page 44).

For future research, the participants should be screened according to their profession to reduce the risk of including additional ''experts'' that can influence the other participants. However, I would not limit the target group to only health oriented individuals. As companies who offer health programs to; employers, private clinics and health insurance companies are also stake holders of Urimon. A further study with more focus on the different stake holders is therefore suggested. This research also made clear that GP should be involved in the care process of Urimon; this makes a GP also a possible new stakeholder for Urimon. Participants suggested that focus group sessions should be held with GPs to elicit their views on the Urimon system.

Additionally, researchers should aim for a more ethnically diverse sample size which is a representative of the population in the Netherlands. Since Enschede only has a population consisting of 17,5 % non-western immigrants and 12,8% western immigrants. Whereas, when compared to the west these numbers are significantly low. See table in the appendixes. However, it is important to mention that the available data from the CBS is limited, as it is data that is already two years old. In this year 2022, the CBS will publish a new classification of the population by origin(70).

I will also recommend to not include directly involved company personnel in the research, especially focus group sessions.

6. Conclusion

This qualitative research discussed the various expectations, information needs and conditions that possible end-users may have to consider using the Urimon system in the future. Overall, this study has shown that the main expectation of possible end-users is that it should detect diseases in an early stage. Furthermore, they expect that a GP would be involved in the process of the presented service. Additionally, they expect a DTC-GT company as Urimon to collaborate with insurances to possibly lower the cost that they would otherwise have to pay out of pocket. This study has also revealed that participants are more likely to use Urimon services if their services are presented as a population screening method. In respect of the information needs, participants expect clear information about what is being researched and thus what services they can expect from DTC-GT test such as the Urimon disease warning system. To conclude, the participants took great interest in discussing the cost of Urimon which is clearly a condition for them to consider using Urimon services.

Bibliography

1. Octav-Ionut M. Applying the Theory of Planned Behavior in Predicting Pro- environmental Behaviour: The Case of Energy Conservation. Acta Universitatis Danubius Œconomica. 2015;11:15-32.
2. Rafiq M, Ianuale C, Ricciardi W, Boccia S. Direct-to-consumer genetic testing: a systematic review of european guidelines, recommendations, and position statements. Genet Test Mol Biomarkers. 2015;19(10):535-47.
3. Ruhl GL, Hazel JW, Clayton EW, Malin BA. Public Attitudes Toward Direct to Consumer Genetic Testing. AMIA Annu Symp Proc. 2020;2019:774-83.
4. Direct-to-consumer genetic testing: a revised position statement of the American College of Medical Genetics and Genomics. Genet Med. 2016;18(2):207-8.
5. Horton R, Crawford G, Freeman L, Fenwick A, Wright CF, Lucassen A. Direct-to-consumer genetic testing. BMJ. 2019;367:l5688-l.
6. Su Y, Howard HC, Borry P. Users' motivations to purchase direct-to-consumer genome-wide testing: an exploratory study of personal stories. J Community Genet. 2011;2(3):135-46.
7. S Morrison MS CGC JAMFaJCMC. Direct-to-Consumer Genetic Testing 2020 [cited 2022 18-02-2022]. Available from: https://geneticseducation.ca/educational-resources/gec-ko-on-the-run/direct-to-consumer-genetic-testing/#:~:text=Generally%2C%20DTC%2DGT%20is%20marketed,(e.g.%20clopidogrel%2C%20statins).
8. Rooij Jd. Urimon, study of blood and urine for health monitoring Protocol. 2019 21-11-2019.
9. Semra Ozdemir JJL, Isha Chaudhry & Remee Rose Quintana Ocampo A Systematic Review of Discrete Choice Experiments and Conjoint Analysis on Genetic Testing. The Patient - Patient-Centered Outcomes Research. 2022;15:39-54.
10. He K, Huang S, Qian X. Early detection and risk assessment for chronic disease with irregular longitudinal data analysis. Journal of Biomedical Informatics. 2019;96:103231.
11. Naumer C, Fisher K. Information needs. 2017.
12. Liverman C, Ingalls C, Fulco C. Understanding the information needs of health professionals. Toxicology and Environmental Health Information Resources: The Role of the National Library of Medicine. 1997;4.
13. Psychology A, 周泳伶临床心理诊所, psychology c. Reflections from therapy Needs vs Expectations 2021 [cited 2022 24/03/2022]. Available from: https://www.annabellepsychology.com/needs-vs-expectations.
14. El-Haddad C, Hegazi I, Hu W. Understanding Patient Expectations of Health Care: A Qualitative Study. J Patient Exp. 2020;7(6):1724-31.
15. Hall MA, Rich SS. Patients' fear of genetic discrimination by health insurers: the impact of legal protections. Genet Med. 2000;2(4):214-21.
16. Wong XY, Groothuis-Oudshoorn CG, Tan CS, van Til JA, Hartman M, Chong KJ, et al. Women's preferences, willingness-to-pay, and predicted uptake for single-nucleotide polymorphism gene testing to guide personalized breast cancer screening strategies: a discrete choice experiment. Patient Prefer Adherence. 2018;12:1837-52.
17. P WL. Focus group discussion: a tool for health and medical research Medical Education 2008;49(3):256-61.
18. Tong R. Ethical concerns about genetic testing and screening. N C Med J. 2013;74(6):522-5.
19. Press CU. Perspective: Cambridge Dictionary; 2022 [cited 2022 28/03/2022]. Available from: https://dictionary.cambridge.org/dictionary/english/perspective.

20. TechTerms. End User: Sharpened Productions; 2022 [cited 2022 28/03/2022]. Available from: https://techterms.com/definition/enduser.
21. TechTarget. End user 2022 [cited 2022 28/03/2022]. Available from: https://whatis.techtarget.com/definition/end-user.
22. Klaus Witrisal CA-H, Thomas Wilding. Inclusive Radio Communication Networks for 5G and Beyond2021.
23. Backledget JM. Principles of Software Engineering. Digital Signal Processing 2006;2:299-363.
24. (OBP) OBP. ISO/IEC/IEEE 24765:2017(en)
Systems and software engineering — Vocabulary 2017 [cited 2022 30/03/2022]. Available from: https://www.iso.org/obp/ui/#iso:std:iso-iec-ieee:24765:ed-2:v1:en.
25. Kwidama D, López Chávez A, Tintin G, Arevalo Ramirez J. Glutrans Telemedicine and Data analysis for monitoring. 2022 04/02/2022.
26. Zantinge EM, Wilk EAvd, Wieren Sv, Schoemaker CG. Gezond ouder worden in Nederland. RIVM; 2011.
27. You2Yourself 2022 [cited 2022 17-02-2022]. Available from: https://you2yourself.com/.
28. Van Hellemondt RE, Hendriks AC, Breuning MH. Regulating the Use of Genetic Tests: Is Dutch Law an Example for Other Countries with Regard to DTC Genetic Testing? Amsterdam Law Forum. 2011;3(1):13.
29. Rigter T, Jansen ME, Kruijff IEvK-d, Onstwedder SM. Kansen en risico's van DNA-zelftesten. Bilthoven, The Netherlands 2020.
30. Oh B. Direct-to-consumer genetic testing: advantages and pitfalls. Genomics & Informatics. 2019;17(3):e33.
31. Condrat CE, Thompson DC, Barbu MG, Bugnar OL, Boboc A, Cretoiu D, et al. miRNAs as Biomarkers in Disease: Latest Findings Regarding Their Role in Diagnosis and Prognosis. Cells. 2020;9(2):276.
32. Ashaqa S. A preliminary cost-effectiveness analysis of the You2yourself health monitor for earlier detection of lung cancer: University of twente 2021.
33. F.R.M. portrait BvdB. The willingness of the Dutch to pay for mental health
care. Tijdschrift voor Psychiatrie. 2016(10):759-65.
34. Eric C. Schneider AS, Michelle M. Doty, Roosa Tikkanen, Katharine Fields, Reginald D. Williams II. Reflecting Poorly: Health Care in the U.S. Compared to Other High-Income Countries 2021.
35. Kuijper K. Zorg in Europa: Nederland behoort tot duurste én beste 2016 [Available from: https://www.zorgwijzer.nl/zorgverzekering-2017/zorg-europa-nederland-behoort-tot-duurste-en-beste.
36. CBS. Zorguitgaven, inclusief steunmaatregelen, stegen in 2020 met 8,3 procent 2021 [Available from: https://www.cbs.nl/nl-nl/nieuws/2021/26/zorguitgaven-inclusief-steunmaatregelen-stegen-in-2020-met-8-3-procent#:~:text=In%20totaal%20werd%20via%20de,28%20procent%2C%20circa%20340%20euro.
37. Ijzerman MJ, Koffijberg H, Fenwick E, Krahn M. Emerging Use of Early Health Technology Assessment in Medical Product Development: A Scoping Review of the Literature. PharmacoEconomics. 2017;35(7):727-40.
38. Markiewicz K. Health Technology Assesment of Medical Devices during Development: University of Twente; 2017.
39. Martin JL, Murphy E, Crowe JA, Norris BJ. Capturing user requirements in medical device development: the role of ergonomics. Physiological Measurement. 2006;27(8):R49-R62.
40. McFarland D. Associations of demographic variables and the Health Belief Model constructs with Pap smear screening among urban women in Botswana. International Journal of Women's Health. 2013:709.
41. LaMorte WW. The Health Belief Model 2019 [Available from: https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/behavioralchangetheories2.html.

42. McKellar K, Sillence E. Chapter 2 - Current Research on Sexual Health and Teenagers. In: McKellar K, Sillence E, editors. Teenagers, Sexual Health Information and the Digital Age: Academic Press; 2020. p. 5-23.
43. Ahmad M. Unified Theory of Acceptance and Use of Technology (UTAUT): A Decade of Validation and Development2014.
44. Dwivedi YK, Rana NP, Jeyaraj A, Clement M, Williams MD. Re-examining the Unified Theory of Acceptance and Use of Technology (UTAUT): Towards a Revised Theoretical Model. Information Systems Frontiers. 2019;21(3):719-34.
45. Venkatesh V, Thong JYL, Xu X. Consumer Acceptance and Use of Information Technology: Extending the Unified Theory of Acceptance and Use of Technology. MIS Quarterly. 2012;36(1):157-78.
46. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. MIS Quarterly. 2003;27(3):425-78.
47. Akinnuwesi BA, Uzoka F-ME, Fashoto SG, Mbunge E, Odumabo A, Amusa OO, et al. A modified UTAUT model for the acceptance and use of digital technology for tackling COVID-19. Sustainable Operations and Computers. 2022;3:118-35.
48. software Qs. Qualitative Research: Definition, Types, Methods and Examples 2022 [cited 2022 10-07-2022]. Available from: https://www.questionpro.com/blog/qualitative-research-methods/.
49. Shah DS. 7 Biases to avoid in qualitative research 2019 [cited 2022 09 June]. Available from: https://www.editage.com/insights/7-biases-to-avoid-in-qualitative-research.
50. ZonMw. Tabel met implementatiestrategieën en voorbeelden van activiteiten op niveau van een project. 2019.
51. Hennink MM, Kaiser BN, Weber MB. What Influences Saturation? Estimating Sample Sizes in Focus Group Research. Qual Health Res. 2019;29(10):1483-96.
52. University CCS. Helpful Hints for Conducting a Focus Group [Available from: https://www.ccsu.edu/oira/assessment/files/FocusGroupsHints.pdf.
53. University CS. Literature Review: Traditional or narrative literature reviews [Available from: https://libguides.csu.edu.au/review/Traditional.
54. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, et al. Guidance on the Conduct of Narrative Synthesis in Systematic Reviews 2006 [Available from: https://www.lancaster.ac.uk/media/lancaster-university/content-assets/documents/fhm/dhr/chir/NSsynthesisguidanceVersion1-April2006.pdf.
55. Onwuegbuzie AJ, Dickinson WB, Leech NL, Zoran AG. A Qualitative Framework for Collecting and Analyzing Data in Focus Group Research. International Journal of Qualitative Methods. 2009;8(3):1-21.
56. Center CUIM. Content Analysis 2019 [Available from: https://www.publichealth.columbia.edu/research/population-health-methods/content-analysis#:~:text=Content%20analysis%20is%20a%20research,words%2C%20themes%2C%20or%20concepts.
57. Erlingsson C, Brysiewicz P. A hands-on guide to doing content analysis. Afr J Emerg Med. 2017;7(3):93-9.
58. Dutch language levels CEFR (A1/A2/B1/B2/C1/C2): Incompany-dutch.nl; 2022 [cited 2022 08/06/2022]. Available from: https://incompany-dutch.nl/en/dutch-language-levels/.
59. Booth A, Hannes K, Harden A, Noyes J, Harris J, Tong A. COREQ (Consolidated Criteria for Reporting Qualitative Studies). Guidelines for Reporting Health Research: A User's Manual2014. p. 214-26.
60. parliament E. Science and Technology Options Assessment Annual Report 2012 2012.
61. Greg Guest EN, Kevin McKenna. How Many Focus Groups Are Enough? Building an Evidence Base for Nonprobability Sample Sizes. Sage Journals. 2016.
62. Busetto L, Wick W, Gumbinger C. How to use and assess qualitative research methods. Neurological Research and Practice. 2020;2(1):14.

63. Metrix. 6 types of bias that can derail your research 2021 [cited 2022 09 June]. Available from: https://metrixconsulting.com.au/News/6-types-of-bias-that-can-derail-your-research.
64. Warnaar AvdSeM. Rapport De Nederlanders en hun pensioen 2015.
65. Volksgezondheid Rv, Milieu e, Ministerie van Volksgezondheid, Sport We. Voorbereiding: betrokken overheidspartijen 2012 [cited 2022 9th Juli]. Available from: https://www.rivm.nl/bevolkingsonderzoeken-en-screeningen/bevolkingsonderzoek-organisatie/voorbereiding-betrokken-overheidspartijen#:~:text=De%20Gezondheidsraad%20beoordeelt%20op%20basis,tegen%20eventuele%20risico's%20voor%20deelnemers.
66. Jungne JMGWG. Principles and Practice of screening for disease World Health Organization 1968
67. Volksgezondheid Rv, Milieu e, Ministerie van Volksgezondheid, Sport We. Criteria voor verantwoorde screening 2012 [cited 2022 9th June]. Available from: https://www.rivm.nl/bevolkingsonderzoeken-en-screeningen/screening-theorie/criteria-voor-verantwoorde-screening.
68. ZonMw. 2022 [Available from: https://www.zonmw.nl/nl/.
69. Terris-Prestholt F, Neke N, Grund JM, Plotkin M, Kuringe E, Osaki H, et al. Using discrete choice experiments to inform the design of complex interventions. Trials. 2019;20(1):157.
70. Netherlands C-S. Hoeveel mensen met een migratieachtergrond wonen in Nederland? : CBS-Statistics Netherlands; 2020 [cited 2022 9th of June]. Available from: https://www.cbs.nl/nl-nl/dossier/dossier-asiel-migratie-en-integratie/hoeveel-mensen-met-een-migratieachtergrond-wonen-in-nederland-.

Appendix

Appendix A: Sample recruitment

1. Call protocol

This call protocol is written in Dutch since the language that will be spoken during the entire research is Dutch to make communication easier and more comfortable with the participants. Since it is a Dutch target group.

Goedemorgen/middag, u spreekt met Dorothy van het Urimon onderzoek. Ik ben op zoek naar de heer/mevrouw [naam].
Ik bel u, omdat u deelneemt aan het Urimon onderzoek en zich heeft aangemeld via de nieuwsbrief om ideeën uit te wisselen om Urimon onderzoek te verbeteren. Ik wil graag een aantal mensen uitnodigen voor een bijeenkomst. Heeft u op dit moment tijd, zodat ik hier wat over uit kan leggen?

Nee, geen interesse → Hartelijk dank voor uw tijd en het feit dat u meedoet aan het Urimon onderzoek. Heeft u daar nog vragen of opmerkingen over? Zo ja, beantwoord de vraag/ vragen, dan wens ik u nog een prettig dag!

Nee, geen tijd → Is er een ander moment waarop het zou schikken?
Ja → ga door met het volgende:

In het Urimon onderzoek wordt een systeem ontwikkeld. Met dit systeem hopen we in de toekomst bepaalde ziektes sneller op te kunnen sporen en mensen te kunnen waarschuwen als ze een ziekte aan het ontwikkelen zijn. Voordat dit systeem echt op de markt kan worden gebracht, moeten we beter begrijpen wat mensen hiervan verwachten en wat voor informatie behoeftes men heeft om een bewuste keuze te maken om dit systeem te gebruiken. Dit wil ik onderzoeken door middel van een bijeenkomst met ongeveer 8 tot 10 Urimon deelnemers waar we in een groep hierover gaan praten. Bij deze bijeenkomst zullen er ook twee onderzoekers aanwezig zijn.

Tijdens de bijeenkomst zullen er een paar onderwerpen aan bod komen. Dit gaat over wat mensen denken dat het Urimon onderzoek kan ondersteunen voor implementatie in de nederlandse zorgmarkt, dus denk daarbij aan : Wat verwacht u van het Urimon-ziektewaarschuwingssysteem ?

Dit doen we om het onderzoek beter aan te laten sluiten bij de wensen van deelnemers om implementatie te kunnen bevorderen. Voor de bijeenkomst hoeft u geen speciale kennis te hebben en u hoeft ook niets voor te bereiden. De bijeenkomst zal plaatsvinden op de Universiteit Twente en er staat uiteraard een reiskostenvergoeding tegenover. Heeft u hier wellicht interesse in?

Nee → Hartelijk dank voor uw tijd en dan wens ik u nog een prettig dag!

Ja → Ga door met het volgende:
Voordat ik verder ga met de data, heeft u op dit moment nog vragen?

Ja → Vragen beantwoorden (mogelijke antwoorden op vragen)

- [Eenmalige bijeenkomst, duurt twee uur , 8 tot 10 andere deelnemers aan het Urimon project, er zullen twee onderzoekers van de Universiteit Twente bij aanwezig zijn, kleine onkostenvergoeding (reiskosten en een bon van 10 euro)]
- Indien vragen niet beantwoord kunnen worden: Helaas kan ik deze vraag nu niet beantwoorden, maar ik kom er op terug via email.

Nee → Ga door met het volgende:
Op dit moment staan deze bijeenkomsten gepland op:

Maandag 9 Mei van 13:00 tot 15.00 uur
Maandag 16 Mei van 18.00 tot 20:00 uur
Vrijdag 20 Mei van 10:00 tot 12:00 uur

Zit hier een datum bij die u zou schikken? [bij de bijeenkomst zal ook catering geregeld worden, 's middags koffie/thee, 's avonds een broodje]

Nee → Dat is jammer. Mag ik uw gegevens noteren voor het geval er een nieuwe datum wordt toegevoegd, zodat we u dan opnieuw kunnen vragen?

Ja → Dan plan ik u in op deze datum. Ik zal u een bevestiging van de afspraak sturen, en wat extra informatie samen met de routebeschrijving via email. Ook staan hier mijn contactgegevens in, zodat als u vragen heeft, u te allen tijde contact kan opnemen met mij.

Klopt dit email adres [email adres gegeven in de lijst]?

- **Noteer naam van deelnemer om email te versturen na het telefoon gesprek**

Heeft u op dit moment nog vragen?

Ja → Vragen beantwoorden

- [Eenmalige bijeenkomst, anderhalf uur, 8 tot 10 andere deelnemers aan het Urimon project, er zullen twee onderzoekers van de Universiteit Twente bij aanwezig zijn, kleine onkostenvergoeding (reiskosten en een VVV-bon van 10 euro)]
- Indien vragen niet beantwoord kunnen worden: Helaas kan ik deze vraag nu niet beantwoorden, maar ik kom er op terug via email.

Nee → Hartelijk dank voor uw tijd en dan wens ik u nog een prettig dag!

2. Email for participants

This concept e-mail is written in Dutch since the language that will be spoken during the entire research is Dutch to make communication easier and more comfortable with the participants.

Geachte heer/mevrouw, [naam]

Zo juist heb ik u gebeld met de vraag of u deel wilt nemen aan een bijeenkomst voor mijn onderzoek. In deze bijeenkomst ga ik onderzoeken wat mensen van het Urimon ziekte waarschuwingsysteem verwachten, wat voor informatie behoeftes ze hebben en wat de redenen zijn om dit systeem wel of niet te gaan gebruiken.

Allereerst hartelijk dank voor uw interesse. In deze email vind u een informatie brief voor deelnemers aan het onderzoek:

Verkenning van de barrières en facilitators van het Urimon-ziektewaarschuwingssysteem voor implementatie in de Nederlandse zorgmarkt.

Verder vind u in de bijlagen van deze e-mail een toestemmingsformulier die u ingevuld mag mee nemen naar de bijeenkomst. Er zullen exemplaren van dit formulier ook aanwezig zijn bij de bijeenkomst die u ter plekke kan ondertekenen. Lees graag voor de bijeenkomst allebei de formulieren goed door.

Tijdens deze bijeenkomst zullen er een paar onderwerpen aan bod komen. Dit gaat over wat mensen denken dat het Urimon onderzoek kan ondersteunen voor implementatie in de gezondheidszorg. Tijdens deze bijeenkomst gaat u samen met ongeveer 7 andere deelnemers en de onderzoeker praten over deze onderwerpen.

De bijeenkomst waar u zich voor heeft opgegeven vind plaats op:
Maandag 9 Mei van 13:00 tot 15.00 uur/ Maandag 16 Mei van 18.00 tot 20:00 uur / Vrijdag 20 Mei van 10:00 tot 12:00 uur

De bijeenkomst zal plaats vinden op de campus van de universiteit Twente in Enschede. Echter, is de ruimte waar deze bijeenkomst zal plaatsvinden nog niet bekend. Enkele dagen voor de bijeenkomst ontvangt u van ons informatie over de ruimte waar de bijeenkomst zal plaatsvinden inclusief een routebeschrijving.

Als u nog vagen heeft kunt u uiteraard contact opnemen. Dit kan per e-mail d.n.kwidama@student.utwente.nl of per telefoon : 085-0220268.

3. Participant information letter

Informatie brief voor deelnemers aan de focusgroep

Informatieblad voor onderzoek 'Verkennen van de informatiebehoefte en -verwachtingen voor de implementatie van het Urimon-ziektewaarschuwingssysteem in de Nederlandse zorgmarkt.'

Doel van het onderzoek
Dit onderzoek wordt geleid door Dorothy Kwidama.
Het doel van dit onderzoek is om de implementatie van Urimon, een opkomend Direct to Consumer Genetic Testing (DTC-GT) bedrijf, in de Nederlandse zorgmarkt te ondersteunen. De onderzoekgegevens zullen worden gebruikt voor een wetenschappelijk manuscript.

Hoe gaan we te werk?
U neemt deel aan een onderzoek waarbij we informatie zullen vergaren door: focus groep discussies.

Gedurende deze bijeenkomst zullen er een paar onderwerpen aan bod komen. Dit gaat over wat u denkt dat het Urimon onderzoek kan ondersteunen voor implementatie in de Nederlandse zorgmarkt. Tijdens deze bijeenkomst gaat u samen met ongeveer 8 tot 10 andere Urimon deelnemers samen met 2 onderzoekers hierover praten. Uw antwoorden tijdens deze discussie worden opgenomen via een audio-opname en er zal ook een transcript worden uitgewerkt van deze audio-opname. Verder word uw non-verbale communicatie tijdens de focus groep sessie geobserveerd.

Beschrijving van het onderzoek
Dit onderzoek is een verkennend marktonderzoek dat aspecten van een (Early) HTA betrekt en de verwachtingen en informatiebehoeften verkent vanuit het perspectief van de eindgebruiker. De bevindingen van mijn onderzoek kunnen ten goede komen aan het bedrijf Urimon, om de implementatie van hun ziektewaarschuwingssysteem te bevorderen. Dit word gedaan door inzicht te krijgen in de verwachtingen en informatie behoeftes die deelnemers nodig hebben om een bewuste keuze te kunnen maken om het Urimon-ziektewaarschuwingssysteem te gebruiken. Dit kan van invloed zijn op de implementatie van het Urimon-ziektewaarschuwingssysteem. Doormiddel van het organiseren van focus groepen met Urimon deelnemers, kan ik inzicht krijgen in deze aspecten. Dit onderzoek is belangrijk omdat het probleem rond het onderwerp *''Direct to Consumer Genetic Testing'' (DTC-GT*) is dat er beperkte inzichten zijn in de informatiebehoeften en de verwachtingen van gebruikers, en dit zou van invloed kunnen zijn op de implementatie van opkomende DTC-GT-bedrijven.

Hoelang duurt dit onderzoek
Dit onderzoek duurt 120 minuten.

Plaats en tijdstip:
Maandag 9 Mei van 13:00 tot 15.00 uur
Maandag 16 Mei van 18.00 tot 20:00 uur
Vrijdag 20 Mei van 10:00 tot 12:00 uur
Alle drie bijeenkomsten nemen plaats op de campus van Universiteit Twente plaats bij de Gallery, ruimte: de vijzel 1.18.

U dient alleen 1 bijeenkomst bij te wonen op de datum die u had aangegeven via de telefoon.

Potentiële risico's en ongemakken
Er zijn geen fysieke, juridische of economische risico's verbonden aan uw deelname aan deze studie. U hoeft geen vragen te beantwoorden die u niet wilt beantwoorden. Uw deelname is vrijwillig en u kunt uw deelname op elk gewenst moment stoppen.

Vergoeding
U ontvangt voor deelname aan dit onderzoek een vergoeding van €10 als waardering voor uw deelname.

Wat word er verwacht van de deelnemers
Er word verwacht dat de deelnemers actief deelnemen met de discussie tijdens de bijeenkomst.

Vertrouwelijkheid van gegevens
De bevindingen uit de bijeenkomst, zoals uw verwachtingen en informatie behoeftes worden gedeeld met Urimon en de Universiteit van Twente. Wij doen er alles aan uw privacy zo goed mogelijk te beschermen. Er wordt op geen enkele wijze vertrouwelijke informatie of persoonsgegevens van of over u naar buiten gebracht, waardoor iemand u zal kunnen herkennen.
Voordat onze onderzoeksgegevens naar buiten gebracht worden, worden uw gegevens zoveel mogelijk geanonimiseerd, tenzij u in ons toestemmingsformulier expliciet toestemming heeft gegeven voor het vermelden van uw naam, bijvoorbeeld bij een quote.

In een publicatie zullen anonieme gegevens of pseudoniemen worden gebruikt. De audio-opnamen, formulieren en andere documenten die in het kader van deze studie worden gemaakt of verzameld, worden opgeslagen op een beveiligde locatie bij de Universiteit Twente en op de beveiligde (versleutelde) gegevensdragers van de onderzoekers.
De onderzoeksgegevens worden bewaard voor een periode van [10 jaar]. Uiterlijk na het verstrijken van deze termijn zullen de gegevens worden verwijderd of worden geanonimiseerd zodat ze niet meer te herleiden zijn tot een persoon.
De onderzoeksgegevens worden indien nodig (bijvoorbeeld voor een controle op wetenschappelijke integriteit) en alleen in anonieme vorm ter beschikking gesteld aan personen buiten de onderzoeksgroep.

Tot slot is dit onderzoek beoordeeld en goedgekeurd door de ethische commissie van de faculteit BMS(domain Humanities & Social Sciences) / EU / NWO / anderszins.

Data verzameling , opslag , opslag duur
Er word een (audio)-opname gemaakt van de bijeenkomst zodat de onderzoekers later terug kunnen luisteren wat er gezegd is. Deze opname wordt bewaard op het beveiligde netwerk van de Universiteit Twente en zal niet verder verspreid worden. De opgeslagen data word na het analyseren vernietigd.

Deelname beëindigen
De deelname aan deze studie vindt plaats op vrijwillige basis waarvoor u zelf zich had aangemeld om deel te nemen aan dit onderzoek. Echter, kunt u op elk moment weigeren om deel te nemen aan de studie en op elk ogenblik terugtrekken uit de studie zonder dat u hiervoor een reden moet opgeven en zonder dat dit op enige wijze een invloed zal hebben op uw deelname van de Urimon studie.

Kosten
Uw deelname aan deze studie brengt geen extra kosten voor u

Vergoedingen
Er word een vergoeding voorzien van €10,- in de vorm van VVV-bonnen, verder worden uw reiskosten vergoed.

Schade ten gevolge van deelname aan onderzoek
De waarschijnlijkheid dat u door deelname aan deze studie enige schade ondervind is extreem laag.

Vrijwilligheid
Deelname aan dit onderzoek is geheel vrijwillig. U kunt als deelnemer uw medewerking aan het onderzoek te allen tijde stoppen, of weigeren dat uw gegevens voor het onderzoek mogen worden gebruikt, zonder opgaaf van redenen. Het stopzetten van deelname heeft geen nadelige gevolgen voor u of de eventueel reeds ontvangen vergoeding.
Als u tijdens het onderzoek besluit om uw medewerking te staken, zullen de gegevens die u reeds hebt verstrekt tot het moment van intrekking van de toestemming in het onderzoek gebruikt worden.
Wilt u stoppen met het onderzoek, of heeft u vragen en/of klachten? Neem dan contact op met de onderzoeksleider.

Naam onderzoeker: Dorothy Kwidama
E-mail : d.n.kwidama@student.utwent.nl

Bedrijf: Urimon
E-mail:info@urimon.nl
Telnr. 085-0220268

Voor bezwaren met betrekking tot de opzet en of uitvoering van het onderzoek kunt u zich ook wenden tot de Secretaris van de Ethische Commissie / domein Humanities & Social Sciences van de faculteit Behavioural, Management and Social Sciences op de Universiteit Twente via ethicscommittee-hss@utwente.nl. Dit onderzoek wordt uitgevoerd vanuit de Universiteit Twente, faculteit Behavioural, Management and Social Sciences.
Indien u specifieke vragen hebt over de omgang met persoonsgegevens kun u deze ook richten aan de Functionaris Gegevensbescherming van de UT door een mail te sturen naar dpo@utwente.nl.

Tot slot heeft u het recht een verzoek tot inzage, wijziging, verwijdering of aanpassing van uw gegevens te doen bij de Onderzoeksleider.

4. Consent form

Door dit toestemmingsformulier te ondertekenen erken ik het volgende:

1. Ik ben voldoende geïnformeerd over het onderzoek door middel van een separaat informatieblad. Ik heb het informatieblad gelezen en heb daarna de mogelijkheid gehad vragen te kunnen stellen. Deze vragen zijn voldoende beantwoord.
2. Ik neem vrijwillig deel aan dit onderzoek. Er is geen expliciete of impliciete dwang voor mij om aan dit onderzoek deel te nemen. Het is mij duidelijk dat ik deelname aan het onder-zoek op elk moment, zonder opgaaf van reden, kan beëindigen. Ik hoef een vraag niet te beantwoorden als ik dat niet wil.

Naast het bovenstaande is het hieronder mogelijk voor verschillende onderdelen van het onderzoek specifiek toestemming te geven. U kunt er per onderdeel voor kiezen wel of geen toestemming te geven. Indien u voor alles toestemming wil geven, is dat mogelijk via de aanvinkbox onderaan de stellingen.

3. Ik geef toestemming om de gegevens die gedurende het onderzoek bij mij worden verzameld te verwerken zoals is opgenomen in het bijgevoegde informatieblad. Deze toestemming ziet dus ook op het verwerken van gegevens betreffende mijn gezondheid/ras/etnische afkomst/politieke opvattingen/religieuze en of levensbeschouwelijke overtuigingen/lidmaatschap van vakbond/seksueel gedrag/seksuele gerichtheid en/of over mijn genetische gegevens/biometrische gegevens.	JA ☐	NEE ☐
4. Ik geef toestemming om tijdens het interview opnames (geluid / beeld) te maken en mijn antwoorden uit te werken in een transcript.	☐	☐
5. Ik geef toestemming om mijn antwoorden te gebruiken voor quotes in de onderzoek publicaties.	☐	☐
6. Ik geef toestemming om mijn echte naam te vermelden bij de hierboven bedoelde quotes.	☐	☐
7. Ik geef toestemming om de bij mij verzamelde onderzoeksdata te bewaren en te gebruiken voor toekomstig onderzoek en voor onderwijsdoeleinden.	☐	☐
Ik geef toestemming voor alles dat hierboven beschreven staat.	☐	

Naam Deelnemer: Naam Onderzoeker:

Handtekening: Handtekening:

Datum: Datum:

5. Declaratieformulier

Declaratieformulier

Naam:		IBAN:	
Adres:			
Telefoon:		Periode:	
E-Mailadres:			

Declaratie reiskosten

Datum	Omschrijving	Aantal km's	Vergoeding per km		Bedrag
		0			
			Totaal te declareren		

Akkoord door budgethouder

Naam:	
Handtekening:	
Datum:	

Appendix B: Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

For further information about the COREQ guidelines, please see Tong *et al.*, 2017: https://doi.org/10.1093/intqhc/mzm042

No.	Item	Description	Section #
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Title page (1)
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	Title page (1)
3.	Occupation	What was their occupation at the time of the study?	Title page (1)
4.	Gender	Was the researcher male or female?	female
5.	Experience and training	What experience or training did the researcher have?	tings with supervi
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	no
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? *E.g. Personal goals, reasons for doing the research*	he goals of Urimo
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? *E.g. Bias, assumptions, reasons and interests in the research topic*	N/A
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and theory	What methodological orientation was stated to underpin the study? *E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	content analysis
Participant selection			
10.	Sampling	How were participants selected? *E.g. purposive, convenience, consecutive, snowball*	convenience
11.	Method of approach	How were participants approached? *E.g. face-to-face, telephone, mail, email*	elephone and ema
12.	Sample size	How many participants were in the study?	24
13.	Non-participation	How many people refused to participate or dropped out? What were the reasons for this?	
Setting			
14.	Setting of data collection	Where was the data collected? *E.g. home, clinic, workplace*	niversity of Twent
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	, Urimon interns an

16.	Description of sample	What are the important characteristics of the sample? E.g. demographic data, date	demographic data
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	ested in the specifi
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	yes, three
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	yes, audio
20.	Field notes	Were field notes made during and/or after the interview or focus group?	yes
21.	Duration	What was the duration of the interviews or focus group?	120 minutes
22.	Data saturation	Was data saturation discussed?	yes
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	no
Domain 3: analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	1
25.	Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26.	Derivation of themes	Were themes identified in advance or derived from the data?	erived from the dat
27.	Software	What software, if applicable, was used to manage the data?	ATLAS.ti
28.	Participant checking	Did participants provide feedback on the findings?	no
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? *E.g. Participant number*	no
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	yes
31.	Clarity of major themes	Were major themes clearly presented in the findings?	yes
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	yes

Appendix C: Focus group discussion moderator guide

Focus groep gids voor: ''Verkennen van de verwachtingen en informatiebehoefte voor de implementatie van het Urimon-ziekte waarschuwingssysteem in de Nederlandse zorgmarkt''

Ontvangst, basisinformatie en voorstelronde

30 minuten

Deelnemers verwelkomen en plaats laten nemen. Ingevulde toestemmingsformulieren laten ondertekenen/verzamelen, koffie en thee uitdelen.

We gaan het hebben over genetische testen die direct aan de consument aangeboden worden, wat Urimon in de toekomst ook wil aanbieden en op de markt zetten voor de volgende twee uren. Het Urimon ziektewaarschuwingssysteem is een systeem dat u kan waarschuwen wanneer u een ziekte aan het ontwikkelen bent. Dit zorgt ervoor dat u in een vroeg stadium behandeld kan worden door uw arts, wat voor minder last en kosten voor u zorgt. Het is wel belangrijk om het Urimon onderzoek en het Urimon-ziektewaarschuwingssysteem niet met elkaar te verwarren. Het Urimon onderzoek is het onderzoek waar u ook nu aan meedoet, waar u elke 3 maanden urine inlevert samen met een vragen lijst en bloed 1 keer per jaar laat prikken. Wanneer een persoon ziek wordt, wordt het materiaal geanalyseerd om te kunnen bewijzen dat Urimon in een vroeg stadium die ziekte kon aantonen. Als dit bewezen is kan het Urimon-ziektewaarschuwingssysteem op de markt. Hiervoor is het dus belangrijk dat ik de verwachtingen en informatiebehoefte van u in kaart kan brengen

Allereerst wil ik jullie bedanken om aanwezig te zijn en we kunnen beginnen met een korte voorstel ronde om kennis te maken met iedereen die vandaag aanwezig is. Hiervoor kan je je naam, je huidige functie, als je dat wenst te delen, en de reden waarom je vandaag me doet met deze bijeenkomst met ons delen.

(Onderzoeker stelt zichzelf eerst voor samen met andere onderzoekers of extra personen die aanwezig zijn)

Algemene vraag: **Wat hebben jullie van soortgelijke testen als Urimon gehoord?** (Dit beantwoordt niet mijn onderzoeksvraag maar is een opening vraag)

Verwachtingen van genetische testen die direct aan de consument aangeboden worden

30 minuten

Links of rechts beginnen met aanwijzen van mensen die aan bod kunnen komen. Ongeveer 6 mensen aan bod laten komen (3 minuten per persoon)

Vragen:

1. Wat verwacht u van een service zoals Urimon in de toekomst wil aanbieden?
2. Wat zou voor u de belangrijkste reden zijn om gebruik te maken van een soortgelijke service?
3. In hoeverre denkt u dat gebruik maken van een dergelijke service zal leiden tot eerdere opsporing van ziekten?
4. In hoeverre denkt u dat gebruik maken van een dergelijke service zal leiden tot een langer of beter leven?

Topics die kunnen opkomen tijdens de discussie:

(Verwachtingen) Besproken tijdens focusgroep sessie?	Ja/nee
Persoonlijke waarschuwing, risico op verdere ontwikkeling van ziekte (hoge positieve voorspelling kan ook voorkomen) maar Urimon voorspelt niet.	
Het vroeg opsporen van verschillende ziekten	
Vergelijking met de reguliere screening	
-betrouwbaarheid	
-beter voor de consument (is liquid biopsy meer gewenst?)	
Kwaliteit, hoe accuraat de test is en validiteit van de test	
Rust en zekerheid (vooral voor mensen met een ziektegeschiedenis in de familie)	
Empowerment (jouw gezondheid in eigen handen hebben)	
Ondersteuning bij interpretatie van resultaten	
Ondersteuning bij het leiden van een gezondere levensstijl	
Hogere levensverwachting	

Pauze 10 minuten

Koffie , thee en eten uitdelen

Informatiebehoefte

Deze vragen kunnen ook verwachtingen van de informatiebehoefte inhouden**

30 minuten ☐

Ongeveer 6 mensen aan bod laten komen (3 minuten per persoon)

Vragen:

1. Welke informatie zou u willen hebben, voor u kunt besluiten of u gebruik zou maken van een dergelijke service?
    a. Hoe zou u deze informatie het liefst ontvangen? *
2. Wat voor informatie zou u willen hebben na het inzenden van uw materiaal?
    a. Wie zou deze informatie moeten verstrekken? *
    b. Hoe snel verwacht je informatie terug te krijgen? (Levertijd)*
        i. Wie zou deze informatie moeten verstekken*
3. Verwacht u dat een bedrijf als Urimon u ook zal informeren over wat de volgende stappen zijn na een mogelijke afwijkende (“foute”) uitslag? **
    a. Zo ja, welke informatie wilt u dan vooral hebben*
    b. Wie zou deze informatie moeten verstrekken? *
4. Verwacht u dat een bedrijf als Urimon u ook zal informeren over de verschillende ziektes die de test zal opsporen? **
    a. Zo ja, welke informatie wilt u dan vooral hebben? *

* Alleen vragen als het nog niet is opgekomen tijdens discussie

Topics die kunnen opkomen tijdens de discussie:

(Informatiebehoefte) besproken tijdens de focusgroep sessie?	Ja/nee
Hoeveelheid en wat voor soort ziekten er allemaal worden onderzocht	
Gepersonaliseerde informatie (ziekten die gerelateerd zijn aan geslacht, leeftijd, leefstijl of etniciteit.	
Voor- en nadelen van genetische testen die direct aan consumenten aangeboden worden	
Mogelijke kosten en voor wie de kosten zijn	
Mogelijke ondersteuning bij interpretatie van resultaten	
Kwaliteit, validiteit en hoe accuraat de test is	
Verantwoordelijkheid. Wie is er uiteindelijk verantwoordelijk voor de genetische test resultaten	
Rechten als consument	
Klanttevredenheid	
Preventie	
Advies - Van Urimon of van zorgprofessional? - Wat kunt u zelf doen (na het verkrijgen van ongewenste resultaten) - Voorkomen van ziektes (preventie) - Behandelingstraject	
Genetische geletterdheid (informatie in een makkelijke taal verstrekken)	
Opname van technologie	

Randvoorwaarden
Kosten en privacy vragen
Extra vraag**

15 minuten

Ongeveer 5 mensen aan bod laten komen (2 minuten per persoon)

1. Wat verwacht u te moeten betalen voor een service als Urimon?
2. Is dit een belemmering voor u om gebruik te maken van deze service?
3. Zou een service als Urimon vergoed moeten worden door uw ziektekostenverzekering?
4. Hoe denkt u dat een bedrijf als Urimon omgaat met uw persoonlijke informatie en uw genetisch materiaal?
    a. Is dit een belemmering voor u om gebruik te maken van deze service?
5. Zou Urimon zijn services aan werkgevers kunnen aanbieden? **
    a. Hoe denkt u hierover? *

* Alleen vragen als het nog niet is opgekomen tijdens discussie

Topics die kunnen opkomen tijdens de discussie:

(Randvoorwaarden) besproken tijdens de focusgroep sessie?	Ja/nee
Verschil in toegankelijkheid in de zorg	
Mogelijk discriminatie in het werkveld/ zorgen hierover	
Hoe de kosten betaald worden -maandelijks/jaarlijks, abonnement?	
Wie betaald de kosten	
Door die worden de kosten vergoed, verzekeringen	
Ethiek	
Verantwoordelijkheid -privacy	
Klanttevredenheid	
Genetische geletterdheid	
Sociaaleconomische status/ persoonlijke omstandigheden	
Afschrikking	

Afsluiting **5 minuten**	☐

Afsluiting. Vragenronde, deelnemers bedanken en VVV-bonnen uitdelen samen met de reiskostenvergoeding formulier.

Appendix D: Focus group questions in Dutch

Verwachtingen :	**Literatuur**
▪ *Wat verwacht u van een service zoals Urimon in de toekomst wil aanbieden?*	Rafiq M et al.,2015 (2) Ruhl GL et al.,2020(3) Genet Med.2016 (4) Ritger T. et al., 2020 Horton R. et al., 2016(5) Yeyang Su et al. (6)
▪ *Wat zou voor u de belangrijkste reden zijn om gebruik te maken van een soortgelijke service?*	
▪ *In hoeverre denkt u dat gebruik maken van een dergelijke service zal leiden tot eerdere opsporing van ziekten?*	
▪ *In hoeverre denkt u dat gebruik maken van een dergelijke service zal leiden tot een langer of beter leven?*	
Information need:	
▪ *Welke informatie zou u willen hebben, voor u kunt besluiten of u gebruik zou maken van een dergelijke service?*	Rafiq M et al.,2015 (2) Ruhl GL et al.,2020 (3) Genet Med.2016 (4) Ritger T. et al., 2020 (1) Semra Ozdemir.et al.,(2022) (9) Qian X.et al,2019 (10)
○ *Hoe zou u deze informatie het liefst ontvangen?**	
▪ *Wat voor informatie zou u willen hebben na het inzenden van uw materiaal?*	
○ *Wie zou deze informatie moeten verstrekken?**	
○ *Hoe snel verwacht je informatie terug te krijgen ? (levertijd)**	
▪ *Wie zou deze informatie moeten verstekken**	
▪ *Verwacht u dat een bedrijf als Urimon u ook zal informeren over wat de volgende stappen zijn na een mogelijke afwijkende (“foute”) uitslag? ***	
○ *Zo ja, welke informatie wilt u dan vooral hebben**	
○ *Wie zou deze informatie moeten verstrekken?**	
▪ *Verwacht u dat een bedrijf als Urimon u ook zal informeren over de verschillende ziektes die de test zal opsporen? ***	
○ *Zo ja, welke informatie wilt u dan vooral hebben?**	
Condition:	
▪ *Wat verwacht u te moeten betalen voor een service als Urimon?*	Rafiq M et al.,2015 (2) Ruhl GL et al.,2020 (3) Semra Ozdemir.et al.,2022(9) Hall MA et al.2000, (15) Chong KJ,et al.,2018 (16) Tong T.,2013, (18)
▪ *Is dit een belemmering voor u om gebruik te maken van deze service?*	
▪ *Zou een service als Urimon vergoed moeten worden door uw ziektekostenverzekering?*	
▪ *Hoe denkt u dat een bedrijf als Urimon omgaat met uw persoonlijke informatie en uw genetisch materiaal?*	
○ *Is dit een belemmering voor u om gebruik te maken van deze service?*	
▪ *Zou Urimon zijn services aan werkgevers kunnen aanbieden?***	
○ *Hoe denkt u hierover? **	