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BMJ Open Usability assessment of an interactive health technology for kidney living donors: protocol for a prospective cross-sectional survey

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ABSTRACT

Introduction Several web portals for kidney patients are available, but assessments of their performance are scarce. A crucial aspect of living donation is to provide standardised information about the risks of the procedure. This is of particular interest among candidates for kidney living donation. In 2019, the Digital Care Path for Living Kidney Donor Candidates was launched in Finland as part of the Health Village portal, containing information about the donation process and facilitating communication between clinicians, transplant coordinators and patients. The performance of this eHealth service has not yet been studied. The present study will investigate living donor candidates' experience with the Health Village and Digital Care Path for Living Kidney Donor Candidates. Participants' general attitudes towards the use of eHealth services will also be explored as a secondary objective.

Methods and analysis A prospective cross-sectional survey study will take place. Participants will be kidney donor candidates who have used the digital care path since its implementation in January 2019 up to 1 March 2021 (N=122). The surveys will include demographic data, electronic device ownership and digital health literacy. Platform's ease of use will be assessed with the System Usability Scale. Open-ended questions will be used to gather suggestions.

Ethics and dissemination The research protocol has been approved by the Helsinki University Hospital ethical committee (HUS/501/2021) to ensure that the work is done in accordance with the declaration of Helsinki and Declaration of Istanbul. Recruitment will start during the first semester of 2021. Initial results are expected during the second semester of 2021.

Trial registration number NCT04791670; Pre-results.

INTRODUCTION

Worldwide, between 2006 and 2016, there has been a 28% increase in deaths due to chronic kidney disease.¹ Kidney transplantation is the treatment of choice for these patients, offering better quality of life, prolonged survival at much less costs.² In 2017, over 88000 patients with chronic kidney disease started kidney replacement treatment in Europe alone.³ The most common causes for

Strengths and limitations of this study

- The use of quantitative and qualitative methods with different standardised tools allows for a multidimensional analysis of the phenomena.
- Participant recruitment and informed consent process mediated by the digital platform increases participation.
- The generalisation of results of the study regarding digital care path is limited to our institution and is only available in Finnish language. However, since the platform used is representative for the Finnish population, the impact is still relevant.
- The use of the eHealth Literacy Scale tool has not yet been validated in the Finnish language.
- The use of the web as platform may have intrinsic biases against the visually impaired, people with learning disabilities or poor access to technology.

kidney transplantation are diabetic nephropathy, glomerulonephritis and hypertension; patients with dialysis having higher mortality risk than patients with lung, prostate or breast cancer.² The risk of death in kidney transplant patients is 88% lower than in patients in dialysis, as a nationwide study from Finland shows.⁴ Despite the survival and quality of life benefit of kidney transplantation, the majority of these patients are not listed for kidney transplantation.⁵ The main source of kidney allografts is from deceased donors. Because the number of patients needing a kidney transplant is increasing, waiting times for a new kidney are growing alarmingly. A suggested strategy to expand the donor pool is promoting kidney living donation.⁶

Rates of living kidney transplantation vary greatly throughout the world. In the Nordic countries, for example, only 13% of kidney transplants in Finland were from living donors in 2019, while that number reached 33% in Denmark.⁷ In Finland, the Ministry of Social Affairs and Health partially funded a National Action Plan on Organ Donation

and Transplantation, to promote online health information and eHealth tools. The Virtual Hospital 2.0 was established to create a series of digital healthcare services called 'Health Villages', which included different hubs designed for specific diseases or patient cohorts.⁸ The initiative was explored through a survey conducted by the University of Kuopio in Northern Finland, with preliminary data showing a willingness to use digital care services, but these data were not validated after launching the Health Village project.⁹

The Helsinki University Hospital (HUS) created the Digital Care Path for Living Kidney Donor Candidates as part of the Kidney hub as an open web-based portal in December 2018. The objective of the digital care path was to increase the number of living kidney donors by making clear and standardised information available any time, any place, proving a secure messaging pathway between patients and health providers, and enabling teleconsultation options. The experience of living donor candidates of using the digital care path has not yet been investigated.

OBJECTIVES

This study aims to investigate living donor candidates' experience with the Kidney hub and digital care path. The secondary aim is to investigate the attitudes of living donor candidates to eHealth services.

METHODS AND ANALYSIS

Study design

A prospective survey study will be conducted in the HUS, Department of Nephrology. Participants will answer sets of questionnaires meant to collect general information, digital health literacy profiles, and to assess the experience with the digital care path.

A general information survey, to gather demographics, sex, age, work status, income, education level, electronic device ownership and type of use (online supplemental annex 1).

The eHealth Literacy Scale (eHeals), an 8-item scale that measures perceived skills at finding, evaluating and applying electronic health information to health problems¹⁰ (online supplemental annex 2). The instrument has proved to be a reliable and easy-to-use self-reporting tool to assess digital health literacy.¹¹ The scale is based on a model that distinguishes between six types of literacy skills: traditional literacy, health literacy, information literacy, scientific literacy, computer literacy and media literacy.

Finally, to assess the Digital Care Path for Living Kidney Donor Candidates, an ad-hoc survey was created based on the Technology Acceptance Model (TAM).¹² The TAM proposes that the primary factors that influence users' decisions are perceived usefulness and perceived ease of use. The System Usability Scale (SUS) in its positive version, to explore the platform's ease of use. The

SUS is a 10-item short questionnaire with five response options for respondents (from strongly agree to strongly disagree) that provides a 'quick and dirty', reliable tool for measuring a product's usability.¹³ Also, an open-ended question will be presented asking suggestions for any information that the participants think is missing and should be added to the digital path (online supplemental annex 3).

Patterns of user activity of the digital care path over time will be aggregated per user and described. Adherence will be estimated with the frequency of weekly use throughout the tracking period.

Setting

The HUS is the biggest healthcare provider and the second-largest employer in Finland. It encompasses 17 hospitals in Helsinki, Espoo and Vantaa, and has all major medical specialties represented. Approximately 680 000 patients receive medical care annually. Also, the treatment of many rare and severe diseases is nationally centralised to HUS. As of September 2020, over 500 patients have received dialysis treatment, 108 of whom are on the waiting list for a kidney transplant. Near 1030 kidney transplant patients are followed up at this institution.

Living donation process and digital care pathway

Up until 2018 and the creation of the digital care path, the living kidney donation process consisted of two semiannual educational group meetings at HUS, where patients waiting for a kidney transplant and family members were briefed on the benefits, risks and transplantation process overall. In these in-person meetings, potential donors and recipients had the chance to interact with individuals who have already gone through the process of kidney transplantation. One-on-one interviews were made available with the kidney transplantation coordinator for follow-up information. Potential donors would meet with a transplant nephrologist for initial clinical evaluation and further discussions.

The donation process changed in January 2019 with the introduction of the digital care path as part of the Health Village portal. The kidney transplantation coordinator invites potential donors to use the Kidney hub site, and they are registered to use the Digital Care Path for Living Kidney Donor Candidates. Prospective donors are required to sign-in using Finland's secure strong mobile identification process. On successful login, the system unlocks an informative section for them to explore. The content that used to be presented during the semiannual educational meetings is now available as part of the Digital Care Path for Living Kidney Donor Candidates. Online materials include descriptions of the procedure, information about short and long-term risks following nephrectomy, economic and social impact of donation together with videos with living donors sharing their experiences after donation. Once candidates have reviewed the available information, they must confirm electronically their willingness to become kidney donors.

In case of a positive answer, a second part of the path is unlocked where they can schedule an outpatient clinic appointment with a nephrologist, and complete a short-structured survey. The system provides an automatically generated schedule of consultation visits and the required laboratory tests, appointments are shown in the donor's personal calendar. The system also displays specific information about required preparations and the location where radiological and laboratory tests would take place. A messaging feature is also present, allowing easy and secure exchange with the transplant coordinator. Tele-consultations can also be arranged through the digital care path itself.

Recruitment

We will invite all kidney donor candidates who have used the digital care path since its implementation in January 2019 up to 1 March 2021 (N=122) to participate in the study. We will approach the participants by phone, text messaging and/or email, considering participants' preferences. Surveys will be available on paper and digital versions. The study will take place during the first semester of 2021.

Statistical analysis

The present study is descriptive, and sample size calculation is not needed because the entirety of the users will be invited to participate. Quantitative analysis will take place following the instruments' scoring system and the 5-point Likert item response will be used for the ad-hoc surveys. Qualitative analysis will be used on the open-ended question. Independent t-tests will be used to compare differences between groups on continuous item responses. χ^2 and Mann-Whitney U tests will be used to examine differences in responses to categorical data. Annual rate of living donation after the launch of the Kidney hub will be compared with the rate before the implementation of the digital services in Helsinki. The patterns of use of all users of the living donor digital care path cohort will be analysed with Power BI statistics.

Descriptive statistics will be used to summarise participants' backgrounds and characteristics. Categorical variables will be presented as absolute and relative frequencies. Continuous variables will be presented as mean and SD or median with the IQR depending on the distribution. A p value of less than 5% will be considered statistically significant. Statistical analysis will be performed using STATA V.15.

Data handling

Access to personal information will be restricted to the investigators of the study, health authorities, the Research Ethics Committee and the monitors and auditors of the study. They will be subject to the duty of secrecy inherent to their profession, when necessary, to verify the data and procedures of the study, but always maintaining the confidentiality according to the current legislation. Data will be pseudonymised and data protection impact assessment has been performed, following institutional procedures. Participants may exercise their rights of access, rectification, cancellation

and opposition of data according to the European Union General Data Protection Regulations.

The information and personal data of the participants will be kept in a completely confidential form with all the rigour of the law.

ETHICS AND DISSEMINATION

The ethical research guidelines of the University of Oulu¹⁴ and HUS¹⁵ will be followed. This research protocol has been approved by the HUS ethical committee (HUS/501/2021) to ensure that the research is done in accordance with the declaration of Helsinki 2013, the Declaration of Istanbul 2008 and in line with the current local legislations from the respective authorities.

The participants will be informed about the nature of the research project; the reasons for their subjectability; risks, benefits and alternatives associated with the research; and their rights as research subjects before agreeing to participate. Steps will be taken to ensure that data gathered from participants will be kept under strict security and privacy.

Initial results are expected during the second semester of 2021. Outcomes will be published in peer-reviewed medical journals and presented at international conferences.

DISCUSSION

The current study presents the work intended to examine the acceptability and usability of eHealth services provided by the digital care path for kidney donor candidates developed by the Health Village web portal.

In 2018, according to Statistics Finland, 89% of adults were internet users and 80% had a smartphone.¹⁶ Results of the 'Adults health, wellbeing, and services' survey performed by the Finnish Health Ministry in 2018 showed that good digital competence and positive attitude towards the use of eHealth predicted the use of eHealth services, irrespective of users' age.¹⁷ Twenty-three per cent of the respondents believed that eHealth can support self-management. Another study performed in northern Finland showed that patients' experience with eHealth was mostly related to prescription renewals (90%), checking lab results (60%), reading the content of their medical records (66%) or scheduling a medical appointment (60%).⁹

Different eHealth portals for kidney patients have been developed, converting print media to digital content like 'The Talking About Live Kidney Donation Social Worker Intervention';¹⁸ However, despite their rapid growth, it is still uncertain the impact on patients' outcomes in the long term.¹⁹ The case of the iChoose Kidney Aid eHealth platform for patients with end-stage kidney disease shows that despite patients' knowledge increased significantly, it failed to increase access to kidney transplantation.¹⁹ Further assessment of portals for kidney patients is required.

A crucial aspect of living kidney donation is to provide standardised information about the risks of the procedure, particularly but not only when the living donor candidate is not completely healthy. The concept 'extended living

donor criteria' is applied in case of older age, obesity, hypertension, vascular multiplicity, women of childbearing age and minors as donors, and may be considered controversial contraindications.²⁰ Despite the increasing popularity in kidney living donation, informed consent procedures vary per country, per centre, and even per individual healthcare professionals.²⁰ Initiatives to go deeply into this problem already exist, such as the research protocol called Process of Informed Consent Evaluation project study. It is a prospective, multicentre cohort study in The Netherlands that is still ongoing.²⁰

Elements to be included in a standardised informed consent procedure proposed by Kortram have guided the development of the digital care path for living donor candidates presented in our research. This digital tool is aimed to standardise the information provided to potential donor candidates and to facilitate the communication between clinicians, transplant coordinators and patients.

It is challenging to measure how online portals can be as means to promote kidney donation, as several factors are at play. The nature of these platforms offers one way communication as information channels. Relying only on system usage statistics may misrepresent the true usage of the platform. Individuals may be visiting the platform simply seeking knowledge about the donation process. In our study, we propose to evaluate an interactive platform not only through quantitative data assessment but also by qualitative means.

LIMITATIONS

There are inherent limitations to the proposed study that needs to be taken into consideration. The generalisation of results of the study regarding digital care path is limited to the institution that adopted this digital tool. The living donor digital path is available only in the Finnish language for the moment; thus, results will apply only to participants fluent in Finnish. However, since the platform used is representative of the Finnish population the impact is still relevant. Similarly, the use of the eHEALS tool has not yet been validated in the Finnish language. Further, the use of the web as the platform may have intrinsic biases against the visually impaired, people with learning disabilities, or poor access to technology.

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Annex 1. General information

Participant ID

1. Date of birth:
2. Gender:
3. Level of education:

Primary	Secondary	Tertiary	University	Prefer not to answer
---------	-----------	----------	------------	----------------------
4. Income category (yearly):

less than 20000€	20000€ - 40000€	40000€ - 60000€	over 60000€	Prefer not to answer
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5. Working status:

student	unemployed	working	retired	other
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6. Do you live alone? yes - no
7. Do you own any of the following items? – Mark all that apply.
 - a. Computer
 - b. Smart mobile phone
 - c. Tablet
 - d. None
 - e. Prefer not to answer
8. If you own a mobile device (phone or tablet), please mark if you use it for any of the following. Mark all that apply.
 - f. Send/Receive text messages
 - g. Instant messaging (Whatsapp, etc)
 - h. Send/Receive emails
 - i. Take photos or videos
 - j. Navigating in the Internet
 - k. Social Media (WhatsApp, Facebook, Twitter, Instagram, etc)
 - l. Use of health apps (Fitbit, Nike+, etc)
 - m. Use other apps
 - n. Prefer not to answer
9. If you use the internet, how often do you use it?

	Every day	Several days a week	About once a week	Less often	Never
Read e-mails					
Search information (Google or similar)					
Read newspapers					
Watch movies or TV					
Social Media					
Play games					

Annex 2. eHealth Literacy Scale

We would like to ask you for your opinion and about your experience using the Internet for health information. For each statement, tell me which response best reflects your opinion and experience *right now*.

1. How **useful** do you feel the Internet is in helping you in making decisions about your health?

 Not important at all Not important Unsure Important Very important

2. How **important** is it for you to be able to access health resources on the Internet?

 Not important at all Not important Unsure Important Very important

3. I know **what** health resources are available on the Internet

 Strongly disagree Disagree Undecided Agree Strongly Agree

4. I know **where** to find helpful health resources on the Internet

 Strongly disagree Disagree Undecided Agree Strongly Agree

5. I know **how** to find helpful health resources on the Internet

 Strongly disagree Disagree Undecided Agree Strongly Agree

6. I know **how to use** the Internet to answer my questions about health

 Strongly disagree Disagree Undecided Agree Strongly Agree

7. I know how to use **the health information** I find on the Internet to help me

 Strongly disagree Disagree Undecided Agree Strongly Agree

8. I have the skills I need to **evaluate** the health resources I find on the Internet

 Strongly disagree Disagree Undecided Agree Strongly Agree

9. I can tell **high quality** health resources from **low quality** health resources on the Internet

 Strongly disagree Disagree Undecided Agree Strongly Agree

10. I feel **confident** in using information from the Internet to make health decisions

 Strongly disagree Disagree Undecided Agree Strongly Agree

Thank you!

Annex 3. Query about the Digital Care Path for Living Donors

Participant ID (researcher fulfills):

- Have you searched in the internet information about kidney donation before your first call to the nephrology outpatient clinic or transplant coordinator? Yes / No
- Have you already donated a kidney? Yes / No

Evaluate the next affirmations from a scale from 1 to 5

(1: strongly disagree, 2: disagree, 3: neutral, 4: agree, and 5: strongly agree)

Technical section (easy of use)

- | | |
|--|--------------------------|
| 1. I think that I would like to use this website frequently ----- | <input type="checkbox"/> |
| 2. I found the website to be simple ----- | <input type="checkbox"/> |
| 3. I thought the website was easy to use ----- | <input type="checkbox"/> |
| 4. I think that I could use the website without the support of a technical person ---- | <input type="checkbox"/> |
| 5. I found the various functions in this website were well integrated ----- | <input type="checkbox"/> |
| 6. I thought there was a lot of consistency in this website ----- | <input type="checkbox"/> |
| 7. I would imagine that most people would learn to use this website very quickly --- | <input type="checkbox"/> |
| 8. I found the website very intuitive ----- | <input type="checkbox"/> |
| 9. I felt very confident using the website ----- | <input type="checkbox"/> |
| 10. I could use the website without having to learn anything new ----- | <input type="checkbox"/> |

Medical section (utility)

- | | |
|---|--------------------------|
| 1. The kidney transplant section of the Kidney hub provided useful general information about kidney donation ----- | <input type="checkbox"/> |
| 2. The information I received through the digital treatment path about kidney donation was easy to understand ----- | <input type="checkbox"/> |
| 3. The digital treatment path contains valuable information about the risks related to kidney donation ----- | <input type="checkbox"/> |
| 4. I received enough digitalized information about the process and tests concerning kidney donation ----- | <input type="checkbox"/> |
| 5. It was easy to be in contact with the living donor team using the digital treatment path ----- | <input type="checkbox"/> |
| 6. The digital treatment path helped me to make my decision about kidney donation ----- | <input type="checkbox"/> |

Is there anything you wish kidney donors should be warned you about that you were not?