

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

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USABILITY OF AN INTERACTIVE HEALTH TECHNOLOGY FOR KIDNEY LIVING DONORS ASSESSMENT: PROTOCOL FOR A PROSPECTIVE CROSS SECTIONAL SURVEY

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ABSTRACT

Introduction. Several web portals for kidney patients are available, but an assessment of their performance is scarce. This is of particular interest among candidates for kidney living donation. A crucial aspect of living donation is to provide standardized information about the risks of the procedure. 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 1.3.2021 (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.

Registration in ClinTrials.gov: NCT04791670

Keywords: kidney disease; kidney transplant; user-centered design; usability; eHealth; living donation

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The use of quantitative and qualitative methods with different standardized tools allows for a multidimensional analysis of the phenomena.
- Participant recruitment and informed consent process mediated by the digital platform increases participation.
- The generalization 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 eHEALS 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

INTRODUCTION

Worldwide, between 2006 and 2016 there has been a 28% increase in deaths due to chronic kidney disease¹. Kidney transplantation is the treatment of choice for these patients, offering better quality of life, prolonged survival at much less costs². In 2017, over 88,000 patients with chronic kidney disease started kidney replacement treatment in Europe alone³. The most common causes for kidney transplantation are diabetic nephropathy, glomerulonephritis and hypertension; with dialysis patients having higher mortality risk than patients with lung, prostate or breast cancer². The risk of death in kidney transplant patients is 88% lower than in patients in dialysis, as a nationwide study from Finland shows⁴. Despite the survival and quality of life benefit of kidney transplantation, the majority of these patients are not listed for kidney transplantation⁵. 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 donation⁶.

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 Denmark⁷. 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 with different hubs designed for specific diseases or patient cohorts⁸. 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 this data was not validated after launching the Health Village project⁹.

The Helsinki University Hospital 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 standardized information available any time, any place, providing 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 their attitude of living donor candidates to eHealth services.

METHODS AND ANALYSIS

STUDY DESIGN

A prospective survey study will be conducted in the Helsinki University Hospital, 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 (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 (Annex 2). The instrument has proved to be a reliable and easy-to-use self-reporting tool to assess digital health literacy¹¹. 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 usability¹³. 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 (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 Helsinki University Hospital (HUS) is the biggest health care 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 centralized 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 semi-annual educational meeting groups 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, prospective 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 banking codes or mobile ID strong identification process. On successful login, the system unlocks an informative section for them to explore. The content that used to be presented during the semi-annual 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. Teleconsultations 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 March 1st 2021 (N=122) to participate in the study. We will approach the participants by phone, text messaging, or e-mail, 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. Chi-square and Man-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 analyzed with Power BI statistics.

Descriptive statistics will be used to summarize participants' backgrounds and characteristics. Categorical variables will be presented as absolute and relative frequencies. Continuous variables will be presented as mean and standard deviation or median with the interquartile range depending on the distribution. A p-value of less than 5% will be considered statistically significant. Statistical analysis will be performed using STATA v15.

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 pseudonymized 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 rigor of the law.

ETHICS AND DISSEMINATION

The ethical research guidelines of the University of Oulu¹⁴ and Helsinki University Hospital¹⁵ will be followed. This research protocol has been approved by the Helsinki University Hospital 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 smartphone¹⁶. 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' age¹⁷. Twenty-three percent 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 transplantation¹⁹. Further assessment of portals for kidney patients is required.

A crucial aspect of living kidney donation is to provide standardized 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 contraindications²⁰. Despite the increasing popularity in kidney living donation, informed consent procedures vary per country, per center, and even per

individual health care professionals²⁰. Initiatives to go deeply into this problem already exists, such as the research protocol called PRINCE project study (Process of Informed Consent Evaluation). It is a prospective, multicentre cohort study in The Netherlands that is still ongoing²⁰.

Elements to be included in a standardized 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 standardize 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 generalization 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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AUTHOR CONTRIBUTIONS

Fernanda Ortiz led overall study design. Guido Giunti led the drafting of the manuscript.

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COMPETING INTERESTS STATEMENT

None declared

DATA AVAILABILITY STATEMENTS

All data relevant to the study are included in the article or uploaded as supplementary information.

PATIENT AND PUBLIC INVOLVEMENT

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

WORD COUNT

3426