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BMJ Open

Multicentre, randomised, economic evaluation of a web-based interactive education platform, simple or enhanced, for patients with end-stage renal disease: the PIC-R trial protocol

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ABSTRACT

Introduction End-stage renal disease (ESRD) affects 84 000 persons in France and costs an estimated €4.2 billion. Education about their disease empowers patients and allows improved management of their disease and better health outcomes. This study aims to explore whether the addition of an interactive web-based platform to patient education is effective and cost-effective and additionally whether complementing the platform with social functions and features improves its performance.

Methods and analysis Patients with severe, ESRD or post-transplant will be randomised 1:1:1 to either standard therapeutic education; or education using a specific application; or the enhanced interactive app with social features. The total follow-up duration is 18 months. Primary endpoint is the cost utility of using app-based therapeutic intervention; secondary endpoints are: compliance with treatment guidelines, app use (professionals and patients), patients' satisfaction, budget impact analysis.

Ethics and dissemination The findings will inform the deployment and reimbursement of the application. The study has ethical approval by the Ile de France ethics committee. Dissemination of the results will be presented at conferences and in peer-reviewed publications.

Trial registration number NCT03090828.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study uses a multicentre randomised design.
- ⇒ The web-based intervention can be customised to meet the need of each participating centre.
- ⇒ Participants cannot be blinded to the interventions.
- ⇒ The length of the questionnaires may affect the retention of participants.

INTRODUCTION

Background and rationale

In addition to its effects on mortality and morbidity, end-stage renal disease (ESRD) affects 84 000 persons in France with an annual estimated cost of €4.2 billion.[1–7] Effective management of ESRD relies in part on the ability of patients to understand their disease and to identify complications or disease worsening at an early stage. To that aim, web-based educational materials have been developed, and prove to improve patients' empowerment and prognosis.[8–11] With recent advances in eHealth, there has been increased interest in the use of web-based platforms for patients to receive information and updates about their disease, interact with the care team and among themselves.[12–15] For patients with ESRD, this would allow better prevention of symptom deterioration, disease monitoring, and earlier intervention from the care team when needed. Use of web-based platforms may reduce the need for emergency hospitalisations and ultimately delay disease progression. Our objective was to assess the benefits of an interactive social platform for patients with ESRD.

The interactive social platform for patients with ESRD, named PIC-R (for Plateforme Interactive Communautaire—dialyse et transplantation Rénale), offers to patients the option of receiving information and accessing a discussion forum at a time and place of their choice, using a computer, tablet or smartphone. The PIC-R application is a Software service platform aiming at enabling therapeutic infoeducation and coaching of patients by their care givers in between medical consultations. Various functions enable caregivers to push key information to their patients either as fixed content or dynamic coaching news and alerts

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Table 1 Interactive web-based education platform for patients with ESRD, named PIC-R

	PIC features	PIC component
F1	Information on therapeutic patient education	Patients' therapeutic education
F2	News, advice, texts, emails	
F3	Tests and quiz	
F4	Social features (« likes», share, friends)	Social network
F5	Moderated forum and interest groups	
F6	Chat room for patients and professionals	

ESRD, end-stage renal disease; PIC-R, Plateforme Interactive Communautaire—dialyse et transplantation Rénale.

via email and/or SMS (Short Message Service) when required. Educational quizzes are automatically proposed to targeted patients as 'serious games' and patients can interact with each other or with their care-givers through comments or a question and answers interactive section.

Each hospital unit benefits from a personalised interface while software and technical infrastructure are shared . Content and functions can be either shared with other hospitals or personalised; each unit controls the content proposed to its patients. Table 1 describes the platform's functions.

Choice of comparator

The control arm receives the recommended patients' therapeutic education (PTE), according to the guidelines published by the national health authority (HAS).[16] The content of the recommended PTE is described in the treatment guidelines produced by HAS.[17] It is provided in person by trained professionals and includes the following steps: (1) understanding patients' needs, expectations and abilities; (2) customising the educational programme based on the patients' therapeutic objectives and competency; (3) planning individual or collective PTE sessions which take place on average 2–4 times per year and include 4–8 patients; (4) using patients' feedback to adapt the programme.

Randomised controlled trials (RCTs) of web-based interventions have been shown to be feasible and maximise the internal validity of the comparison.[18]An RCT represents the gold standard to evaluate PIC R efficacy and cost-effectiveness in ESRD, prior to implementation and financing by the social health insurance The research question addressed by PIC-R is whether the addition of an interactive web-based platform to standard patient education is effective and cost-effective and additionally whether complementing the platform with social functions and features improves its performance.

The research hypotheses are that (1) the use of a web-based educational programme will help reinforce the timeliness of the PTE information and provide additional content as per needed by the patients, (2) that the social functions and features will allow to require peer support or professional opinion as per needed by the patients and (3) that it is cost effective.

METHODS

We used the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) (Chan, 2013)[19]

Trial design

The PIC-R study is an investigator initiated, three-arm, open-label RCT exploring the quality of life and satisfaction of ESRD patients. Randomisation will be performed as block randomisation with a 1:1:1 allocation. Participants are randomised at the level of the individual to receive either usual therapeutic education or usual therapeutic education supplemented with access to the platform without enhanced social functions and features (functions 1–3 only in table 1) or with enhanced social functions and features (functions 1–6 in table 1).

Setting

Patients treated in 12 departments of nephrology in tertiary care hospitals in France.

Eligibility

Patients are screened by their attending nephrologist, invited to sign consent and to log in the platform to complete an initial questionnaire (M0). Formal inclusion and randomisation occur after the completion of the initial questionnaire. The study flow is presented in figure 1.

- Inclusion criteria are:
- Aged ≥18 years old.
- Ability to provide fully informed written consent for participation in the study.
- Eligible for social health insurance coverage
- Severe, ESRD or post-transplant.
- Ability to read and to understand French.
- Ability to complete an online questionnaire in French (computer literacy and Internet access).
- Completion of the initial (M0) questionnaire online.

Patients who do not complete the questionnaire 1 month after the screening visit receive a reminder per email and are excluded if they do not respond after another month.

Trial interventions

Participants in the control arm will continue to receive therapeutic education according to the procedures in the nephrology department where they receive their care. Participants randomised to the intervention arm will be offered access to the platform either without or with enhanced interactive educational content. The content was initially built by the principal investigator of this trial, in collaboration with patients' representatives, and tested in a pilot centre (Hôpital Saint-Louis), which did not include patients in this trial. The content available on

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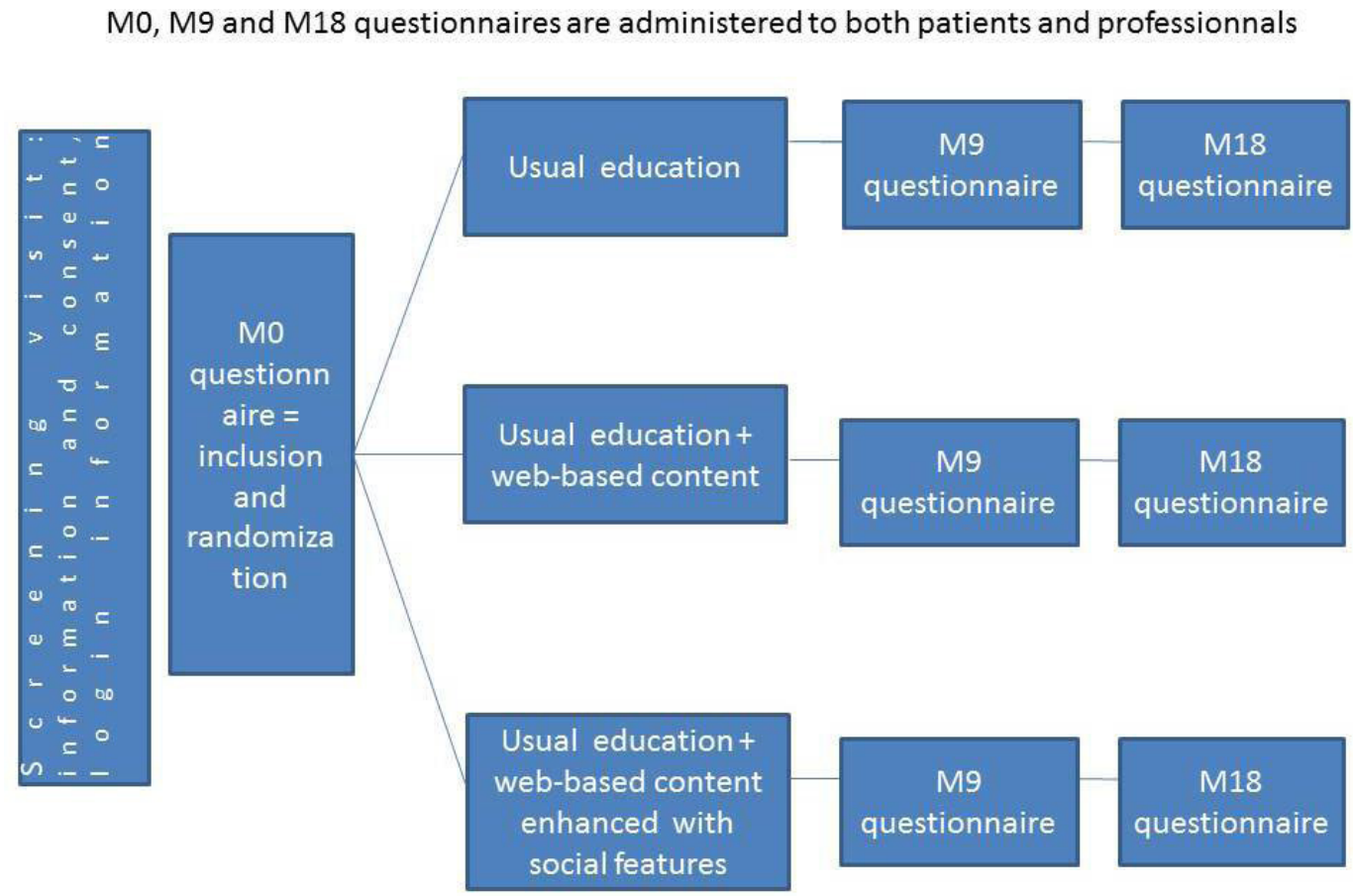

Figure 1 Flow chart of the study.

the platform is highly adaptable and can be incremented by each participating centre according to the specific requirements of its patient population. Additional information on new treatments, guidelines or timely advice on COVID-19 preventive measures can also be entered by the medical teams.

Outcome measures

The primary endpoint is the incremental cost utility ratios (ICURs); health-related quality of life will be calculated based on the EQ-5D-5L (Euro Quality Of Life 5 Dimensions 5 Levels) utility scores and capability quality of life calculated based on the Investigating Choice Experiments Capability Measure for Adults (ICECAP-A).[20–27] Secondary endpoints are the investment and operating costs of the education platform; overall survival measured by the percentage of patients alive at 18 months; compliance and persistence measured by the percentage of patients and professionals using the app at 18 months; disease knowledge measured by the initial answers to a questionnaire and change in the number of correct answers; lifestyle changes measured by the reported risk factors; app utilisation by professionals and patients measured by the number of connections, shares, likes; health-related quality of life measured by the EQ5D5L questionnaire complemented by the ICECAP questionnaire; changes in care organisation measured by number of interactions (chats) between healthcare professionals and patients, admissions for adverse events (AEs), emergency room visits and healthcare costs.

Participant timelines

During the baseline visit, patients will have demographic details recorded including age, educational status, residential postcode, phone number, disease status. Consent is requested by the attending nephrologist.

During the baseline visit, patients who have given consent are requested to fill in the Month 0 (M0) questionnaires; after filling initial (M0) questionnaire, they are included and randomised to one of the three trial arms. They will be requested to fill out subsequent questionnaires at M9 and M18 (end of the study). Patients who do not fill out the M9 and M18 online questionnaire are called by an independent survey company. The following table summarises the data collection procedures. Items in italics are self-reported by the patient in a dedicated elctronic case report form (e-CRF) (possibly with the help of the survey company), items underlined by the investigators, and other items are from external sources. Self-reporting by patients at M9 and M18 is aided by a personal leaflet where to record relevant events and care episodes when they are occurring in a view to ease the completion of the e-CRF and to enhance the quality of information by supporting recollection;

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Table 2 Data collection procedures

	Sélection/inclusion	M0 (0–30 days)	M9	M18 (end of study)
Information and consent	✓			
Questionnaire on socio demographic characteristics and income (sex, date of birth, phone no, disease stage, literacy and knowledge of the renal disease)		✓		
Questionnaire on computer literacy		✓		
Questionnaire on personality traits (tenacity, extraversion, risk aversion)		✓		
Disease specific medical questionnaires		✓	✓	✓
Questionnaires on disease knowledge, lifestyle, experience of disease		✓	✓	✓
Quality of life EQ-5D5L		✓	✓	✓
Well-being (ICECAP-A)		✓	✓	✓
Medical events			✓	✓
Questionnaire on user's experience of the platform			✓	✓
Patients' use of the platform (type and duration of connections, use of each function)			✓ (automated weekly)	✓ (automated weekly)
Hospital admissions (hospital discharge database)			✓ (automated)	✓ (automated)

EQ-5D5L, Euro Quality Of Life 5 Dimensions 5 Levels; ICECAP-A, Investigating Choice Experiments Capability Measure for Adults.

this personal leaflet is given at the baseline visit and remains patient's property. Patients who do not fill out the M9 and M18 online questionnaire are called by an independent survey company. Table 2 presents to data collection procedures.

Assignment of interventions

Participants will be randomly assigned to either control or experimental group with a 1:1:1 allocation as per a computer-generated randomisation schedule stratified by site and renal disease stage using permuted blocks of random sizes (10×3 blocks). We use the online central randomisation service provided by the eCRF Cleanweb (2019 Telemedicine Technologies). Allocation concealment will be ensured up to the time the patient has completed the M0 questionnaire. All patients who give consent for participation and who fulfil the inclusion criteria are eligible and their identifiers entered into the study eCRF Cleanweb. Patients receive an email with a link to M0 questionnaire at the time of the screening visit and a reminder sent 15 days later. Randomisation is delayed until patients have completed the M0 questionnaire; they are automatically allocated to their randomisation group on completion. Due to the nature of the intervention neither participants nor staff can be blinded to allocation. In order to reduce the bias on the part of the investigators, questionnaires are filled by the patients online, with the help of an independent survey company if needed.

Sample size justification

The sample size was calculated to allow the detection of a minimally clinically significant difference of 20% of the SD of the ICURs assuming a 15% drop-out with α=5% and ß=20%. We also explored the effect of a 30% drop-out rate. Table 3 presents the power calculations.

Analysis of outcome measure

The primary comparison groups will be composed of those randomised to usual PTE (control group) versus those randomised to usual PTE supplemented with the platform without and with social features (experimental groups). All analyses will be based on the intention to treat principle, complemented by per protocol analyses excluding patients non-compliant with the allocated arm. No interim or subgroup analyses are planned.

Adherence with the PIC-R intervention will be measured by the percentage of participants who complete the M9 and M18 questionnaires as scheduled and number of visits to the platform.

Quantitative variables will be described by size, mean, SD and 95% CIs. Groups will be compared by Student or Wilcoxon tests. Qualitative variables will be described by size, percentages and 95% CI and compared by χ^2 or Fisher's exact test. Analysis of variance procedures will be used to test the differences between the two interventional arms and the control arm. Multivariate analyses will be undertaken to test associations between patients' characteristics and outcomes.

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Table 3 Power calculations

	n	Share of treated patients	Minimum effect detected
(A) With a 15% drop-out rate			
Platform vs control	1200	0.67	0.19
Platform enhanced with social functions versus Platform without enhanced social functions	800	0.50	0.21
(B) With a 30% drop-out rate			
Platform versus control	1200	0.67	0.21
Platform enhanced with social functions versus platform without enhanced social functions	800	0.50	0.24

The table displays sample size, share of treated patients and standardised minimum detectable effects. (A) assumes a 15% drop-out rate, (B) assumes a 30% drop-out rate. We consider two comparisons: combined experimental groups with access to the platform versus control patients; experimental group with access to the platform enhanced with social functions versus experimental group with access to the platform without enhanced social functions. Reading: when comparing the combined experimental groups to control patients, the targeted sample has 1200 patients; 67% (=800) of them are treated; given 15% drop-out, the minimum detectable effect (with α=5% and ß=20%) is 0.19 of an SD.

The primary analysis for the trial will occur once all participants have completed the M18 questionnaire, data on hospital resource utilisation has been retrieved and patients' satisfaction collected and the database locked. The analysis will include data up to the M18 assessment.

Missing data

The web-based questionnaires will allow collecting follow-up data on all study participants. An independent contractor has been commissioned to ensure that patients have the necessary support for completing the M9 and M18 questionnaire thereby reducing the risk of missing data. Missing data will be examined, and if necessary a sensitivity analysis will be performed using multiple imputation equations.[28 29]

Health economics

In this study, we will capture the costs and outcomes (EQ5D-5L and ICECAP-A) to inform an economic evaluation. The economic evaluation will compare resource use related to the kidney disease and its complications across the three arms of the study. The perspective adopted will be the French healthcare system restricted to the hospital and we will use the national hospital discharge database to collect information on in-patient hospitalisation. Resource use will be valued using the most recent version of the French national cost study. Healthcare/Severity adjusted diagnosis related group specific costs will be used. Unit costs for the intervention and healthcare resources are presented in table 4.

The mean costs will be calculated for the three trial arms

We will use the self-administered EQ5D- at baseline, M9 and M18. Scores are converted into utilities using the French tables.[30] A value of zero is attributed to deceased patient from the time of death. We will calculate QALYs over 18 months for each study participant using utilities and the area under the curve approach. Both costs and outcomes will be discounted at a yearly 2.5% rate according to the French guidelines for economic evaluation.[31] ICURs will be calculated based on the mean cost difference divided by the mean effectiveness differences of the platform either without or with enhanced interactive

Table 4 Unit costs for the intervention and healthcare resources

Item description	Unit cost (€)	Source
PIC R platform licence for 12 centres and 2 years	240 000	Manufacturer
Specialist's (nephrologist) consultation	42–60	Social health insurance schedule https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000035542928?r=et1OEWl5x2
Accident and emergency	80–227	https://www.senat.fr/rap/r16-685/r16-6857.html https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000041663256
Admission for post transplant monitoring	1206–10 984	Depending on severity and length of stay National cost study, DRG 11M171-4 https://www.scansante.fr/applications/enc-mco
Haemodialysis (per session)	319	National cost study, DRG 28Z04Z https://www.scansante.fr/applications/enc-mco

DRG, diagnosis related group; PIC-R, Plateforme Interactive Communautaire—dialyse et transplantation Rénale.

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educational content compared with the recommended PTE. ICURs will be presented where any one option has both higher costs and increased effects compared with another. ICURs calculations controlling for baseline will be also estimated.[30 32] One-way sensitivity analyses will be conducted by varying resource consumption and unit cost parameters by plus or minus 20% and illustrated graphically in a Tornado diagram. The incremental cost–utility ratio, defined as the difference in cost between the two strategies divided by the difference in utility, is expressed in cost per QALY gained. The uncertainty of the results will be analysed using a nonparametric bootstrap, which provides multiple estimates of the ICURs by randomly resampling the patient population 1000 times. All the 95% CI will be estimated with this bootstrap technique. A $p<0.05$ will be considered significant. Confidence regions will be represented by ellipses at the 50% and 95% level. To additionally increase robustness, uncertainty around the ICURs will be taken into account by calculating the probability that belonged to each of the quadrants of the cost-effectiveness plane. Cost effectiveness acceptability curves will be generated. Difference in QALYs will be compared with Student's test or Mann-Whitney U test depending on the distribution. The difference in costs will be compared with a permutation test. ICECAP-A will be used in the same way as the EQ-5D-5L to calculate a capability difference between the three trial arms.[21 22] As there is not French tariffs yet, the UK tariffs will be used.[24 33] We also plan to generate years of full capability (YFC) and cost per YFC Years using an area under the curve analysis, which is in theory possible.[34] ICECAP-A measures can be combined with time to generate YFC. However, there are important conceptual differences with the QALY measure commonly used in health economics. These differences raise the question of how to use capability to inform decision makers.[35] Last developments, for example, years of sufficient capability, will be explored.[26 36–38] The ICECAP-A will be used to estimate the cost per YFC.[34] This other method will compensate for the risk of the QALY approach to undervalue patients' utility where the intervention is targeting patient autonomy and lifestyles, as well as broader (family or care) environment.

All analyses will be done with R V.4.0.1 and a health economics analysis plan which will be completed before the analysis begins.[39]

Recruitment

Centres were selected for participation in the PIC-R study based on their ability to include 150–200 patients over a 12-month period (assessed by individual questionnaires and queries of the national hospital discharge database) as well as their expertise in therapeutic education. Patients are recruited by nephrologists at the time of a systematic monitoring clinic visit. No financial incentives are provided to either investigators or participants. This recruitment goal proved ambitious and an extension of the study duration was granted by the ethics committee.

Monitoring and data management

The trial steering committee will monitor all aspects of the conduct and progress of the trial, ensure that the protocol is followed and take corrective action if necessary. The risk associated with the trial was considered minimal. The trial's research assistants will check consent forms, data consistency, inform on the completion of the M18 questionnaire and missing data. The presence of signed copies of the consent forms in the patients' charts is systematically checked. The steering committee undertakes monthly monitoring and auditing of data entry procedures.

All data will be entered electronically. The data entry screens have been designed for easy use by patients. Data security is primarily addressed by the use of the Cleanweb (2019 Telemedicine Technologies) an online application for case report forms that provides for secure data entry, storage and transfer. All data will be securely managed and stored at Assistance Publique Hopitaux de Paris which retains data ownership. Following the completion of the study analyses, a deidentified data set will be made available on reasonable request. Participant files will be maintained in storage for a period of 15 years after completion of the study.

Adverse events

The collection and reporting of AEs will be in accordance with the French Policy: PIC-R is a biomedical research with a risk level considered negligible, therefore AEs are not recorded; a serious AEs formulary is nevertheless provided to investigators.

Ethical and dissemination

The study protocol was approved by the Ile de France ethics committee (CPP IDF IV) on 9 December 2016, and by the national medicines agency (ANSM) on 14 October 2016. Authorisation for the consolidated patient database was obtained from the French data protection committee (CNIL) and registered as DR 2017–272. The trial was registered on clinical trials.gov NCT03090828. Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with General Data Protection Regulation (GDPR) regulation.

The owner of the DOCMADI platform had no role in the trial design, data collection and statistical analysis plan.

To disseminate findings, papers will be published in peer-reviewed journals and abstracts submitted to relevant conferences.[40] Practitioners' forums have been held in nephrology meetings to inform on the progress of the study. Study participants will be provided with a summary of study findings on request.

Trial management

To date, 10 amendments required to the study have been agreed on by the trial steering committee, and approved by the Ile de France ethics committee prior to being

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implemented. The amendments concerned: removal of the request to link the patients database to the national claims database (the use of the unique identifier is no longer possible for multicentre studies), addition of an information leaflet for patients, addition of Moritsky questionnaire, a 30-day limit for patients to fill out the inclusion questionnaire, addition of COVID-19-related questions, use of teleconsulation to include patients during the COVID-19 lockdown, two subsequent extensions of the inclusion period, inclusion of new centres and replacement of centres that did not include patients. All consecutive versions of the protocol were distributed to all investigators. The informed consent statement was complemented by an addendum in April 2019 after the GDPR regulation became effective.

Patient and public involvement

An advisory board was established at the onset of the platform development, with representatives of healthcare professionals and patients' advocates (Renaloo association) The content of the information provided on the platform to patients was developed by healthcare professionals and each development was discussed and tested with patients' advocates of the Renaloo association. The platform was tested by patients from St Louis hospital (dialyzed, transplant or post-transplant patients) with an online questionnaire 1 year after the initiation of the pilot testing.

Before the trial initiation, patients from Saint Louis hospital were asked, on a voluntary basis, to test the questionnaires and provide feedback on the questions and the time burden. Their contribution allowed to streamline the three questionnaires and provide information on the approximate time required, which varied between 45 and 60 mn. The information on time required for the questionnaires is provided in the informed consent form.

Trial status

Recruitment started in May 2018 and was completed in January 2021 with final follow-up occurring in September 2022. Final health data linkage will be undertaken in the 6 months after final follow-up. Health economic analyses will then be completed.

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Contributors EP, LR, LB and LP conceived the protocol and critically revised the manuscript for important intellectual content; ID-Z: designed the protocol and drafted the manuscript; JCKD and CdC: designed the protocol and provided critical revision of the manuscript for important intellectual content; LF provided critical revision of the manuscript for important intellectual content.

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Competing interests ID-Z has received honoraria for research, lecturing and acting as an advisor to a number of companies although has no conflict of interest related directly to this work. LF is president and CEO of Docmadi, owner of the PIC R platform. The platform is investor-owned and its use is billed to hospitals. The other authors declare no conflict of interest related directly to this work.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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