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Patient mobile application for peritoneal dialysis patients: a pilot study

Submission date	Recruitment status	[X] Prospectively registered
26/04/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/01/2023	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Peritoneal dialysis (PD) is a type of dialysis which uses the peritoneum in a person's abdomen as the membrane through which fluid and dissolved substances are exchanged with the blood. It is used to remove excess fluid, correct electrolyte problems, and remove toxins in those with kidney failure.
In peritoneal dialysis supported by remote monitoring programs, there are no tools for mobile applications, properly evaluated and validated, so a project that undertakes these tasks is very relevant.
The primary objective of this trial is to assess the impact on patient treatment engagement of a remote monitoring program based on a patient mobile application (PMA) compared to standard health care without the mobile application.

Who can participate?
Peritoneal dialysis (PD) patients aged between 18 and 84 years.

What does the study involve?
Participants will be randomly allocated to use the Patient Mobile Application (PMA) or receive standard care.

What are the possible benefits and risks of participating?
The expected benefits come from the fact that having more data on what is happening with the treatment at the patient's home could improve their health outcomes.
The intervention in this study, which is the use of the application for mobile devices, does not imply any risk for the patient.

Where is the study run from?
Baxter Healthcare Corporation (Colombia)

When is the study starting and how long is it expected to run for?
November 2021 to August 2023

Who is funding the study?
Baxter Healthcare Corporation (USA)

Who is the main contact?
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Additional identifiers

Protocol serial number
RCS2021-003

Study information

Scientific Title

Multicenter, open-label, randomized controlled clinical trial of prevalent peritoneal dialysis (PD) patients using the Patient Mobile Application (PMA) versus a standard care group: A pilot study.

Acronym
My PD

Study objectives
There is a difference in the degree of patient engagement in treatment with a remote monitoring program based on an application for mobile devices, compared to patients with standard care without the application for mobile devices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/02/2022, Ethics research committee Fundación Cardioinfantil-La Cardio (Bogotá DC, Colombia; Calle 163A numero 13B 60; +57 6672727; eticainvestigacion@cardioinfantil.org), ref: CEIC-0028-2022

Primary study design
Interventional

Study design
Multicenter open-label randomized controlled pilot study

Study type(s)
Other

Health condition(s) or problem(s) studied
Remote monitoring programm based on mobile application for patients on peritoneal dialysis.

Interventions
The trial contemplates a 24-week follow-up. Patients will be randomly assigned to the program with remote monitoring based on an application for mobile devices (PMA) or to standard health care (without PMA).

Patients belonging to the renal clinics selected for the study who meet the inclusion criteria and do not meet the exclusion criteria will be invited to participate in the experiment, under a rigorous informed consent process. Once the patient accepts the invitation to participate, compliance with the participation criteria will be evaluated in detail, and he/she will then be randomly assigned to one of the two arms of the study. Patients assigned to the intervention arm (remote monitoring program based on a mobile device application) will be trained in the use of the application, and in the adjustments to the care plan that will be made within the remote monitoring program. Baseline assessments will be performed in both groups and follow-up will be initiated for up to 24 weeks.

Randomization is performed using an online tool based on REDCap (Research Electronic Data Capture).

Intervention Type

Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
My PD Remote Monitoring APP

Primary outcome(s)
Patient/renal clinical interaction, assessed by:
1. Number of changes in dialysis prescription per patient on follow-up from the start of follow-up for up to 24 weeks.
2. Documented frequency of patient-clinic and clinic-patient communications from start of follow-up for up to 24 weeks; and
3. Number of preventive visits to the renal clinic at six (6) months follow-up. These visits are defined as those that are not the regular monthly scheduled visits, that are cited by the clinical staff, and that are intended to proactively intervene in any condition detected in the patient, will be recorded from the start of follow-up for up to 24 weeks.

Key secondary outcome(s)
Impact on clinical interventions, measured as:
1. Changes in the number of antihypertensives prescribed per patient at 24-week follow-up.
2. Number of emergency department visits per patient at six-month follow-up.
3. Number of hospitalizations per patient at six-month follow-up.
4. Health-related quality of life measured at baseline and at six months (week 24), measured with the KDQoL-36 and PROMIS-29 profile v2.1 instruments.
5. Evaluation of the usability of the cell phone application assessed with the mHealth App Interactive Usability Questionnaire (MAUQ) instrument for patients and health professionals. This evaluation will be performed in week 4 of use and only for the arm randomized to the cell phone application.

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Patient ≥18 and ≤85 years of age.
2. Being diagnosed with chronic kidney disease with renal failure.
3. Being a prevalent PD patient (having reached day 90 in a chronic PD program)
4. Having a smart phone (patient or caregiver) that meets the conditions for installing the application (App).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. A patient who does not provide informed consent to participate in the study.
2. If the patient is female, pregnancy status.
3. Patients with a prescription for peritoneal dialysis due to a non-renal cause (e.g., cardiorenal).
4. Patients with cirrhosis or hepatic cancer.
5. A patient who is currently participating or has participated in a clinical trial within the last 30 days.
6. Patients with a sensory or cognitive compromise that prevents adequate interaction with the mobile device app.

Date of first enrolment
15/09/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Colombia

Study participating centre
RTS Instituto Nacional del Riñon
Calle 43 No. 25-61
Bogota DC
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111311

Study participating centre
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Carrera 14a No. 163a-98
Bogota DC
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Study participating centre

RTS Agencia Universidad Nacional
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Bogota DC
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Study participating centre
RTS Agencia la Calleja
Calle 127 bis No. 19-25
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Study participating centre
RTS Sucursal Bucaramanga
Transversal 93 No. 34-99
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RTS Servicios de Terapia Renal del Valle
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Study participating centre
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Sponsor information

Organisation
Baxter Healthcare Corporation

Funder(s)

Funder type
Industry

Funder Name
Baxter Healthcare Corporation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the patients give inform consent only for investigators of our study.

IPD sharing plan summary
Not expected to be made available