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Continuous Ambulatory Peritoneal Dialysis (CAPD) retraining

Submission date
31/10/2017

Recruitment status
No longer recruiting

Registration date
07/11/2017

Overall study status
Completed

Last Edited
16/06/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic renal disease has become an important challenging global health issue in the past decade. Hong Kong (HK) ranked the 11th in the prevalence of end stage renal disease (ESRD) by regions in 2012 (USRDS, 2014). The main treatment for chronic renal disease is called continuous ambulatory peritoneal dialysis (CAPD) in HK. CAPD is a procedure that removes waste, chemicals and extra fluid within the body, involving pumping a dialysis fluid into the space inside the abdomen (tummy) to draw out waste and then passing them from the vessels lining. Peritonitis is the most common and serious complication among the CAPD patients. Peritonitis is an inflammation of the thin tissue that lines the abdomen. Severe, relapsed or prolonged peritonitis leads to peritoneal membrane failure, which patients are required to convert to long-term hemodialysis (HD). HD is procedure that involves diverting blood into an external machine, where it's filtered and then returned to the body. CAPD is a home-based therapy, it is important for patients and care-givers to execute all steps of exchange procedure, recognize infection and contamination, and able to take appropriate action to the potential problem. The aim of the study is to examine the effectiveness of an evidence-based CAPD retraining program to reduce peritonitis incidents and exit site infection in CPAD patients age 55 or over.

Who can participate?
Adult patients aged 55 or older who are new CAPD patients.

What does the study involve?
Participants are asked to join this study while they have completed their initial training of CAPD therapy in the hospital. Participants must pass their initial CAPD training and perform CAPD exchange independently or assisted by a family member. Participants are randomly allocated to one of two groups. Those in the first group are asked to continue with usual care and regular follow-up provided by the nephrology (kidney specialist) team. Those in the second group are then asked to attend a two hour retraining session at 12th week after they have started on CAPD home therapy. During the retraining, participants are evaluated on their knowledge, exchange skill, compliance on hand washing and exit site care. Additional discussion and demonstration focuses on identifying and closing the gaps between participant’s current

practice and required competency. Participants medical record are reviewed through hospital computer systems every month during the one year study period to obtain information on incidents of exit-site infection, peritonitis, emergency room visits, hospitalised and death.

What are the possible benefits and risks of participating?
Participants may benefit from receiving an additional training session. There are no risks of physical injury or harm associated with participating.

Where is the study run from?
Tun Mum Hospital (Hong Kong)

When is the study starting and how long is it expected to run for?
October 2017 to December 2021

Who is funding the study?
Association of Hong Kong Nursing Staff (Hong Kong)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
The effectiveness of an evidence-based continuous ambulatory peritoneal dialysis (CAPD) retraining program to reduce peritonitis among incident CAPD patients

Acronym
CAPD retraining program

Study objectives
Compared with ESRD patients undergoing CAPD who receive usual care, those who enroll into a retraining program will have a low incidence rate of peritonitis and exit site infection, lesser number of healthcare services utilization and lower overall costs of utilization of healthcare service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee approval, 18/08/2017, ref: CREC Ref. No: 2017.308
2. New Territories West Cluster Clinical & Research Ethics Committee approval, 29/09/2017, ref: CREC Ref No. NTWC/CREC/17050

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Continuous Ambulatory Peritoneal Dialysis (CAPD)

Interventions
Providing retraining at 3 months after CAPD patients started their home regimen

A sample of 392 participants is recruited from two public hospitals located at New territory West area. This study includes two phases:
Phase 1 is a pilot study of 10 patients, and it will be done to assess the feasibility of the study.
Phase 2 study is a prospective randomized controlled trial to assess the effectiveness of the retraining program. All participants are randomized in equal proportions to one of two groups: the intervention or the control group. They are followed for 1 year after the retraining program.

Intervention Group
The adult learning theory is used to guide the design and implementation of CAPD retraining program. There are four assumptions of adult learning theory include self-concept and motivation to learn, experience, readiness to learn, and orientation to learning. Adult learning theory has several implications in the design and implementation of the CAPD retraining program. Assessment tools are used for the participants to self-diagnose their learning needs and identify the gaps between current practice and required competency. Through discussing, reasoning, skill evaluation and demonstration, the retraining helps them build on their learned PD-related knowledge and strengthen their skills.

Patients in the intervention groups are contacted in the 10th week of the training to schedule a 2-hour retraining session during the 13th to 14th weeks after they have started on CAPD home regimen. Retraining is based on their knowledge gap and learning needs. Each participant at the intervention group are evaluated by their pre- and post-knowledge score, exchange skill score. Their compliance on hand washing and exit-site care is documented after the retraining. For those who fail to answer 80% of knowledge assessment questions correctly or fail to perform all steps of the practical tests, including exchange technique, hand washing and exit-site care, correctly after the retraining, further training is arranged until the goal of learning is achieved.

Control Group
Patients allocated in the control group continue to receive the usual care provided by the nephrology team. They have regular follow-up at the renal clinic and they can contact the renal unit if they encounter any problem or have questions related to their CAPD regimen or care.

Patients in both groups are followed for 12-month period after they started home CAPD regimen. The investigator checks each patient's medical record monthly and record any incidence of peritonitis and exit-site infection through hospital medical record computer system. Also, any emergency room visits, hospitalization and days of hospitalization related to CAPD complications are recorded. All the data is summarized and reported at the intervals of three months.

Compared with ESRD patients undergoing CAPD who receive usual care, those who enroll into a retraining program will have a
1. Low incidence rate of peritonitis and exit site infection
2. Lesser number of healthcare services utilization
3. Lower overall costs of utilization of healthcare service

Intervention Type
Behavioural

Primary outcome(s)
Peritonitis rate is measured using the number of patients who developed peritonitis within 12 months after they had started on CAPD divided by the total number of patients in each group. Related information of peritonitis are obtained by reviewing patient medical records every month through hospital computer system.

Key secondary outcome(s)
1. Exit site infection is measured using the number of patients who developed exit--site infection within 12 months after they had started on CAPD divided by the total number of patients in each group. Related information of exit--site infection are obtained by reviewing patient medical records every month through hospital computer system.
2. Healthcare services utilization is measured using numbers of emergency room visits and hospitalization related to CAPD related infection divided by total number of patients in each group. Related information of healthcare services utilization are obtained by reviewing patient medical records every month through hospital computer system.
3. Costs of utilization of healthcare service is measured using non--subsidy charge at the current hospital authority financial year for daily hospitalisation and emergency room visit multiplied by the length of hospital stay and numbers of emergency room visit in each group. Total expenses for the retraining session, including the nurse salary and costs of training tools are included as part of costs of utilization of healthcare service in the retraining group. The analysis are performed at the end of the trial.

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged 55 or over
2. Those who can perform CAPD exchange independently, assisted by family member or performed by family member
3. CAPD patients or family member who have passed their initial CAPD training
4. Started home CAPD regimen for at least 3 months
5. Use “Ultrabag” CAPD exchange system
6. Cognitive competent to provide informed consent for the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Nursing home residents
2. Those CAPD exchange is performed by non-regular domestic helper

Date of first enrolment
31/10/2017

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Hong Kong

Study participating centre
NTW hospitals (Tuen Mun Hospital and Pok Oi Hospital)
Hong Kong
Hong Kong

Sponsor information

Organisation
Association of Hong Kong Nursing Staff

Funder(s)

Funder type
Research organisation

Funder Name
Association of Hong Kong Nursing Staff

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Wai Yin Leung at waiyin.leung@link.cuhk.edu.hk

IPD sharing plan summary
Available on request