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The effectiveness of a self-efficacy psychoeducational programme to enhance outcomes of patients with end-stage renal disease

Submission date
20/11/2015

Recruitment status
No longer recruiting

Registration date
25/11/2015

Overall study status
Completed

Last Edited
24/11/2015

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
End-stage renal disease (ESRD) is the last stage of chronic kidney disease, when the kidneys are no longer able to work at a level needed for day-to-day life. Treatment for ESRD may involve dialysis or kidney transplant. Patients with ESRD suffer from physical illness and psychological distress due to the complex treatment plans, which often affect the patients' social and psychological functioning. As a result, the patients may fail to perform daily self-care and self-management, and consequently experience worsening conditions. Self-efficacy is a person's belief in their ability to achieve a goal or outcome. This study aims to examine the effectiveness of a self-efficacy psychoeducational programme on self-efficacy, psychological wellbeing, treatment adherence, and quality of life in patients with ESRD undergoing dialysis in Singapore.

Who can participate?
Patients aged 21 and over with ESRD who are undergoing dialysis.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the control group receive routine treatment. Participants in the intervention group attend a self-efficacy psychoeducational programme in addition to the routine treatment. The programme involves a booklet, two sessions of face-to-face individual education, and an abdominal breathing exercise.

What are the possible benefits and risks of participating?
Patients in the intervention group may benefit from the educational intervention. There is no risk or any discomforts for the patients in this study. The only inconvenience will be the time spent filling out questionnaires.

Where is the study run from?
National University Hospital (Singapore)

When is the study starting and how long is it expected to run for?
July 2011 to July 2016

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NKFRC/2013/01/07

Study information

Scientific Title
The effectiveness of a self-efficacy psychoeducational programme to enhance outcomes of patients with end-stage renal disease: a randomised controlled trial

Study objectives
When compared to the control group, patients in the intervention group receiving self-efficacy psychoeducational intervention will:
1. Report higher level of self-efficacy in self-care behaviour

2. Report lower level of anxiety and depression
3. Demonstrate better treatment adherence
4. Report better quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Healthcare Group Domain Specific Review Boards, 16/06/2014, NHG DSRB Ref: 2013 /00702

Study design
Randomised controlled two-group pre-test and repeated post-tests design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
End-stage renal disease (ESRD)

Interventions
In Singapore, patients have to attend a one-hour face-to-face haemodialysis education provided by the physicians before their first haemodialysis. In this one hour routine care, the physician will inform them how to eat (less fluid intake and less salt intake), how often they need to visit dialysis centre/renal centre, how many and what medications they need to take, recommended graft that will be used for dialysis, and schedule time for their graft surgery. After that, patients will have a regular appointment with their physician every 3 to 6 months to follow-up the effect of haemodialysis and receive their medications for the next 3 or 6 months. Each follow-up appointment usually lasts for about 10 minutes. In this study, the participants in the control group will receive a routine care one-hour face-to-face haemodialysis education. The participants in the intervention group will receive the self-efficacy psychoeducational programme (SEPP) in addition to routine care.

The SEPP intervention aims to enhance the patients' self-efficacy in self-care behaviour, which will help to improve their psychological wellbeing, treatment adherence and quality of life. To establish treatment fidelity, the five strategies proposed by Bellg et al. (2004) are used:
1. The study interventions are theoretical framework based (Bandura's self-efficacy theory) (Bandura, 1997) and the protocol for interventions are prepared

2. The research team will be trained by the PI. The research team will conduct all the intervention with a checklist to ensure the intervention will be delivered consistently for all participants and avoid any intervention bias
3. The PI will regularly assess the intervention conducted by the research team to ensure that the intervention is conducted as planned by observing the intervention on site
4. The educational booklet will further standardize the intervention to ensure consistency
5. Patients will be asked to record the frequency and duration when they perform breathing exercises at home for four weeks.

The theoretical framework of this self-efficacy psychoeducational programme (SEPP) is built on Bandura's self-efficacy theory (Bandura, 1997; Crothers, Hughes, & Morine, 2008). Self-efficacy is an optimistic self-belief that a person is capable of performing the behaviours necessary to achieve a particular outcome. There are four specific sources for enhancing self-efficacy in positive self-care behaviour including enactive attainments, vicarious experiences, verbal persuasion, and physiological arousal (Bandura, 1997; Crothers et al., 2008). For example, renal patients' health outcomes are influenced by self-willingness (self-efficacy and self-care) to perform a behaviour (psychological and physical well-being, and treatment adherence). There are several strategies for increasing self-efficacy according to Bandura's self-efficacy theory:
1. Enactive attainments: discuss personal past successful experience
2. Vicarious experiences: learn from other similar successes
3. Verbal persuasion: assure the participants of their abilities
4. Physiological arousal: work with participants to manage their psychological and physical arousal that might impede goals (Bandura, 1997; Crothers et al., 2008).

The proposed intervention aims to enhance patients' self-efficacy through promoting self-awareness, knowledge and planning action and positive emotional status consequently changing their health behaviour (improving self-care behaviour). Patients with better self-efficacy in self-care behaviour will have better treatment adherence and psychological wellbeing, which will eventually improve their quality of life.

The SEPP involves two sessions of educational intervention in a week. The participants will attend a one and half hour face-to-face educational session provided by research team weekly. The intervention includes three components:
1. SEPP booklet
2. Two consecutive sessions of face-to-face individual education (90 minutes per session)
3. Abdominal breathing exercise with an audio track for participants to practice during these education sessions and at home (Riemsma et al., 2003).

A SEPP booklet will be provided to the participants as a participant guidebook. The booklet will cover all contents of the education (Appendix II). The participants will be able to read the booklet on their own time at home. The contents of the booklet will be developed based on the theoretical framework of the study, Bandura's self-efficacy theory, previous literature, and the findings from the preliminary studies (Chow et al., 2013; Lee et al., 2013). An expert panel of five health care professionals (one nursing professor who is experienced in psychoeducation, one Professor in psychology, one Senior Consultant and two registered nurses from NUH Renal Centre), and two patients undergoing haemodialysis will review the booklet before the commencement of the study.

In addition to the SEPP booklet, face-to-face individual education sessions are designed based on self-efficacy theory (Bandura, 1997). The intervention protocol is shown in Appendix II. Discussion, case study, role play with scenario, action plan, and breathing exercise will be used during the face-to-face education sessions. Active discussion will be encouraged throughout the

session and there will be ample time for clarification of doubts. Researcher will assist patients to better understand and recognise their weaknesses and strengths in order to assist them to set a goal step by step to change their attitude and behaviour through case study and role play with scenario. They will have an opportunity to know what personal factors are and how these factors influence their self-efficacy. Through these four sessions, the participants will learn about personal awareness, positive thinking, information of fluid and diet restriction, importance of BP monitoring, and action planning.

The intervention will be conducted one hour after the beginning of haemodialysis or in ward 55 in NUH. Reasons for selecting this timing slot are:
1. Patients have enough time to rest after travelling from home
2. Patients are more stable for receiving the intervention without much interruption by other healthcare providers.

Normally each haemodialysis takes four hours; therefore each intervention session can be completed centre or NUH dialysis centre. During the intervention and interview, participants will have their own cubicle with curtain to maintain privacy. All participants are allowed to refuse to participate or withdraw from the study any time. If participants are feeling unwell during the intervention, the research team will stop the intervention and refer the participants to their nurses and doctors in ward 55, NUH renal centre or NUH dialysis centre immediately for further assistance and treatment and make another appointment for the intervention should the patient wants to continue with the study. Moreover, feedbacks for SEPP will be identified and corrected immediately. To avoid any intervention bias, the research team will follow the checklist for each session to ensure the quality of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Dialysis Specific Self-efficacy Scale (DSSS) (Appendix VI) will be used to measure ESRD patients' self-efficacy in relation to their self-management of dialysis including fluid and diet management (Griva et al., 2011). The DSSS is an 8-item questionnaire using a 10-point Likert scale ranging from 1 to 10 (with 1 representing "not all confident" and 10 representing "totally confident"). The higher scores indicate higher self-efficacy. Outcomes will be measured at baseline, 1- and 3- and 6-month follow-up.

Secondary outcome measures
Outcomes will be measured at baseline, 1- and 3- and 6-month follow-up:
1. Patients' demographic data (e.g. age, gender, ethnicity, education) and clinical data (e.g. type, period and frequency of haemodialysis, blood pressure etc) will be collected at baseline.
2. Kidney Disease Quality of Life 36 (KDQoL-36) (Appendix VII) will be used to measure the quality of life of patients with ESRD and haemodialysis. The KDQoL-36 is a self-report measure developed for individuals with kidney disease and those on dialysis, which includes contents of symptoms, effects of kidney disease on daily life, burden of kidney disease, cognitive function, work status, sexual function, quality of social interaction, and sleep. KDQOL-36 have been validated with a Cronbach's alpha ranging from 0.72 to 0.95 in numerous studies conducted in Asia and Overseas on patients with chronic kidney disease, end-stage renal disease and dialysis (Joshi et al., 2010).
3. Hospital Anxiety and Depression Scale (HADS) (Appendix VIII) will be used to measure the psychological wellbeing of the participants. This instrument has been widely used in different contexts for different age groups of patients. HADS has been found to perform well in assessing

the symptom severity and cases of anxiety disorders and depression in both the general population and the somatic, psychiatric and primary care patients (Bjelland, Dahl, Haug, & Neckelmann, 2002). A review study by Bjelland et al. (2002) reported that Cronbach's alpha for HADS-A varied from .68 to .93 (mean .83) and for HADS-D from .67 to .90 (mean .82). The sensitivity and specificity for both HADS-A and HADS-D were approximately 0.80.
4. Renal Adherence Attitudes Questionnaire (RAAQ) (Appendix IX) will be used to assess patients' treatment adherence attitude (Griva et al., 2011). RAAQ is a 26-item questionnaire to measure general attitudes toward compliance including patients' attitudes toward social restrictions, well-being, self-care/support, and acceptance. Fincham et al. (2008) reported the items from 4 subscales: (a) attitude towards social restrictions (6 items, =0.88); (b) attitudes towards wellbeing (7 items, =0.77); (c) attitudes towards self-care/ support (4 items, =0.68); and (d) acceptance (9 items, = 0.86).
5. Renal Adherence Behaviour Questionnaire (RABQ) (Appendix X) will be used to assess patients' treatment adherence behaviour. RABQ is a 25-item self-reported questionnaire measuring patients' diet, fluid, and medication taking adherence. In a Likert-type scoring system with a five-point scale from 1 to 5 (with 1 representing "Never" and 10 representing "Always"), higher scores indicate greater adherence (Rushe & McGee, 1998). Fincham et al. (2008) reported the items from 5 subscales: (a) adherence to fluid restrictions (11items, =0.80); (b) adherence to potassium/ phosphate medication (5 items, =0.70); (c) self-care (2 items, =0.78); (d) adherence in times of particular difficulty (5 items, = 0.56); (e) adherence to sodium restrictions (2 items, =0. 68).
6. Process evaluation: An interview guide (Appendix XI) will be developed for the individual semi-structured face-to-face interview (about 30 minutes) to identify the strengths and limitations of the interventions from the perspectives of participants and the opinion on the routine care. Participants will also be asked to comment on the content, activities, and delivery methods of the intervention as well as the effectiveness of the intervention. The interview will be conducted at the post-test 2. All interviews will be recorded using a digital voice recorder.

Overall study start date
10/07/2011

Completion date
10/07/2016

Eligibility

Key inclusion criteria
1. Diagnosed with ESRD and undergoing haemodialysis
2. Age 21 years old and above
3. Able to speak, read and write either English or Mandarin

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

154

Key exclusion criteria
1. Cognitive impairment and/or mental disorder identified from their medical records
2. Vision and hearing impairment

Date of first enrolment
01/01/2015

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
Singapore

Study participating centre
National University Hospital
5 Lower Kent Ridge Road
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Sponsor information

Organisation
National Kidney Foundation of Singapore

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Sponsor type
Government

Website
http://www.nkfs.org/

ROR
https://ror.org/01jz2hz84

Funder(s)

Funder type
Government

Funder Name
National Kidney Foundation of Singapore

Results and Publications

Publication and dissemination plan
The study protocol and the study results will be published. The study protocol will be submitted in December 2015 and the main results will be submitted in June 2016.

Intention to publish date
10/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository