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The effectiveness of a psychological intervention to improve treatment adherence and quality of life in dialysis patients

Submission date	Recruitment status	[_] Prospectively registered
30/07/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2019	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Konstadina Griva

Contact details
Department of Psychology
Faculty of Arts and Social Sciences
National University of Singapore
Block AS4 #02-28
9 arts link
Singapore
Singapore
117570

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NKFRC2008/07/24

Study information

Scientific Title
The effectiveness of a self-management intervention to improve outcomes in prevalent haemodialysis patients: a randomised controlled trial

Study objectives
This study will use self management principles to improve clinical and psychological outcomes through enabling patients to better follow their treatment regimes.
The overall aim of this randomised controlled trial is to evaluate the effectiveness of a self management intervention delivered in group to established haemodialysis patients (i.e. at least 6 months on haemodialysis). Effectiveness of the group based self management intervention will be established by assessing clinical outcomes, biological markers of adherence and psychosocial functioning in established haemodialysis patients compared to a control group receiving standard care.
The primary hypothesis is that participation in the self management program will lead to better psychosocial wellbeing, greater adherence to treatment recommendations and improved clinical markers in established haemodialysis patients compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National University of Singapore Institutional Review Board, 19/12/2008, ref: NUS IRB 08-151

Study design
Single-blind cluster randomised controlled trial with randomisation at dialysis shift level

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Chronic kidney disease; end stage renal disease; haemodialysis

Interventions

The study will recruit prevalent haemodialysis patients and will randomise them to one of two groups:
1. Standard Care Care currently received by patients as defined by National Kidney Foundation Clinical Practice Guidelines. All healthcare resources used and advice given to prevalent patients relating to their kidney failure and its treatment will be standardised.
2. Intervention Group based self management intervention will take place over a 6 week period with one 120 minute session every two weeks, facilitated by a psychologist, dietician and nurse. Patients are required to implement the coping-strategies taught from each session between sessions. Each session will be broadly structured to consist of a brief introduction to the theme to be covered in the session, elicitation of patients views on the topic, addressing of misconceptions, group discussion of possible coping strategies, identification of barriers to change, training in specific management strategies, drawing up of individual goals to be achieved, formulating actions plans to achieve these goals and reviewing previously set goals. Healthcare professionals working in National Kidney Foundation, Singapore will be trained in self management techniques to facilitate the sessions and provide participants with the knowledge and skills to improve their management.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
These will be obtained by reviewing participants medical records during the study period.
1. Adherence to medication and dietary restrictions, as indicated by attendance for dialysis, blood phosphate, calcium x phosphate and potassium levels and gain between dialysis sessions. Data will be obtained from patients medical records throughout the study window. Baseline values will be compared to follow-up values immediately post- intervention and at 3 and 9 months post- intervention.
2. Blood pressure control
3. Baseline values will be compared to follow up values immediately post- intervention and at 3 and 9 months post- intervention
4. Hospitalisation rates
5. Dialysis attendance (skipping and shortening behaviours)
6. The Charlson Comorbidity Index and The End Stage Renal Disease Severity Index (ESRD-SI) will be used to measure co-morbid illnesses and other complications of end stage renal disease
7. Medical notes will be also reviewed and relevant information regarding dialysis history and dialysis related events (e.g. access complications) during the study period

Secondary outcome measures
1. Quality of Life measured using the Kidney Disease Quality of Life Short Form (KDQoL-SF) and the World Health Organisation Quality of Life Assessment-Bref (WHOQOL-Bref)
2. Mood as measured by the Hospital Anxiety and Depression Scale (HADS) Self efficacy Scores using the Self Efficacy for Managing Chronic Disease Scale
3. Treatment and medication beliefs as measured by The Renal Adherence Attitudes Questionnaire and the Beliefs about medication questionnaire
4. Health Education measured using the Health Education Impact Questionnaire (HEIQ)
5. Self-reported adherence to dietary and fluid restrictions using the Renal Adherence

Questionnaire and a 12 item self report adherence scale developed for the purposes of the study All questionnaire measures will be taken at patients enrolment into the study (baseline), 1 week after completion of self management program and at 3 and 9 months post- intervention.

Overall study start date
20/08/2010

Completion date
30/12/2012

Eligibility

Key inclusion criteria
1. Chronic Kidney Disease patients (either sex) who have been receiving haemodialysis for at least 6 months
2. Aged 21 and over
3. Patients willing to attend all sessions of the self management programme

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A target sample of 152 haemodialysis patients [n = 76 intervention group; n = 76 standard care control group].

Key exclusion criteria
1 Newly established on haemodialysis (< 6 months)
2. Unable to give informed consent
3. Unable to understand spoken English and/or Mandarin, Malay, Tamil dialects to allow effective communication with the intervention facilitator(s)
4. A diagnosis of functional psychosis or organic brain disorder
5. Impaired cognition
6. Major visual or hearing impairments, or other sensory or motor impairments that may prohibit completion of the scheduled assessments
7. Unable to participate in a group program (e.g. housebound)
8. Limited life expectancy due to comorbid illness such as malignancy

Date of first enrolment
20/08/2010

Date of final enrolment
30/12/2012

Locations

Countries of recruitment
Singapore

Study participating centre
National University of Singapore
Singapore
Singapore
117570

Sponsor information

Organisation
National Kidney Foundation (Singapore)

Sponsor details
NKF Research Committee
c/o Clinical Affairs, Level 3
81 Kim Keat Road
Singapore
Singapore
328836

Sponsor type
Charity

ROR
https://ror.org/01jz2hz84

Funder(s)

Funder type
Research organisation

Funder Name
National Kidney Foundation (Singapore) - Venerable Yen Pei - National Kidney Foundation Research Fund (ref: NKFRC2008/07/24)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/01/2011		Yes	No
Results article	results	01/03/2018		Yes	No
Results article	results	01/10/2018	11/10/2019	Yes	No