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Improving outcomes in patients with diabetes and on dialysis – A brief intervention to support self-care and adjustment

Submission date
12/09/2016

Recruitment status
No longer recruiting

Registration date
14/09/2016

Overall study status
Completed

Last Edited
17/02/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a life-long condition where a person is unable to control their blood sugar levels. There are type main types of diabetes. In type 1 diabetes the body is unable to produce a hormone called insulin, which is responsible for breaking down glucose and turning it into energy. In type 2 diabetes the body either does not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Diabetes is one of the main causes of kidney failure, as the fluxuations in blood sugar that characterise diabetes can cause damage to the kidneys (nephropathy), which can lead to kidney failure. When the kidneys fail, they stop cleaning the blood, leading to the build-up of harmful waste products. Haemodialysis is one of the most common treatments for kidney failure. It involves diverting the blood into an external machine so that it can be cleaned, before being returned to the body. Having to manage treatment for diabetes and kidney failure can be very difficult to patients. The aim of this study is to evaluate a new nurse-led self-management program designed to empower diabetes patients on dialysis, to help them better manage their condition.

Who can participate?
Patients aged 21 and over with diabetes and kidney failure, who have been receiving haemodialysis treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard treatment for the duration of the study. Those in the second group take part in the nurse-led self-management program. This involves attending three 30 minute sessions with NKF diabetes link nurses during normal dialysis sessions at the dialysis centre. In these sessions, the nurse support patients in setting healthy goals and provide education around diet, medication, exercise, foot care or blood sugar monitoring. The content is tailored to patients' needs and preferences for support. At the start of the study and then again 2-4 weeks after the end of the self-management program, participants in both groups complete a number of questionnaires about how they deal with their illness, treatment recommendations, and emotional wellbeing.

Information about how well participants are controlling their diabetes and their kidney health is taken from medical records at the same times. At the end of the study, participants are also interviewed about their experiences of the program.

What are the possible benefits and risks of participating?
Participants may benefit from learning how to better manage their condition, which could improve their mental and physical health. There are no notable risks involved with participating in this study.

Where is the study run from?
Five dialysis centres in Singapore (Singapore)

When is the study starting and how long is it expected to run for?
January 2016 to December 2016

Who is funding the study?
National Kidney Foundation Singapore (Singapore)

Who is the main contact?
Professor Konstadina Griva
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Improving outcomes in patients with coexisting multi-morbid conditions – the development and evaluation of the combined diabetes and renal control feasibility trial (C-DIRECT)

Acronym
C-DIRECT

Study objectives
Overall study aim:
The aim of this study is to assess the feasibility and acceptability of a nurse-led intervention based on motivational interviewing (MI) and self management and its potential efficacy to improve glycaemic control, as well as psychosocial and self-care outcomes of patients with coexisting End stage renal disease and diabetes mellitus (DM-ESRD) compared with usual care.

Study aims:
1. To explore rates of recruitment and retention into the trial
2. To examine willingness to be randomised to either the intervention arm standard care
3. To explore the potential efficacy of C-DIRECT intervention when compared to usual care in improve glycaemic control and other clinical markers (interdialytic weight gains, blood pressure, serum potassium and phosphate levels and nutritional markers)
4. To compare quality of life, psychosocial and self-care outcomes between the intervention arm and control arm
5. To qualitatively explore patient and facilitators' experience of the program, and identify areas of improvement for (any) further refinements

Ethics approval required
Old ethics approval format

Ethics approval(s)
National University of Singapore Institutional Review Board, 01/04/2016, ref: 13-394

Primary study design
Interventional

Study design
Feasibility parallel arm blinded randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coexisting Diabetes Mellitus and End Stage Renal Disease

Interventions
Participants are randomised to one of two groups in a 1:1 allocation ratio.

Intervention group: Participants will take part in a brief nurse led program designed to support adjustments to the lifestyle changes required by diabetes patients on hemodialysis. This will involve 3 visits by the NKF diabetes link nurses during one of their regular dialysis sessions at the dialysis center. During these sessions, the nurses will support patients in setting goals and will provide education around diet, medication, exercise, foot care or blood sugar monitoring, if they so require (based on Elicit-Provide-Elicit framework in Motivational Interviewing). The contents of the sessions will be tailored to their needs and preferences for support. Participants will decide the direction and content of these empowering conversations. A self-management

record sheet will be used as part of the consultation. DM Link renal nurses and patients work together to complete the sheet in each session. Focus of each session, goal setting and confidence will be recorded. These visits will take approximately 30 minutes and will be scheduled over 3 consecutive weeks.

Control group: Participants will receive standard care for the duration of the study.

Assessment procedures are identical for control and intervention participants . These include a baseline assessment (self report questionnaires listed) and follow up assessment (12 weeks post baseline) - this is approximately 2-4 weeks post completion of the C-DIRECT intervention. Follow up assessments include same set of questionnaires (C-DRECT participants will also be invited to participate in a brief interview on their experience of the program).

Intervention Type
Behavioural

Primary outcome(s)
1. HbA1c and home glucose monitoring records
2. Biochemical markers (phosphate & potassium levels)
3. Protein catabolic rate, albumin, hemoglobin
4. Interdialytic weight gains v) blood pressure readings

Key secondary outcome(s)
1. Generic and diabetes specific distress is measured using the Hospital Anxiety and Depression Scale and Problem Areas in Diabetes Scale at baseline and 4 weeks post intervention
2. Health related Quality of Life is measured using the Kidney Disease Quality of Life Short Form at baseline and 2/4 weeks post intervention
3. Self-reported adherence/self-care is measured using the Dialysis Diet and Fluid Non-Adherence Questionnaire, Summary of 2/4. Diabetes Self-Care Activities and self-report adherence items developed for study at baseline and 2-4 weeks post intervention
4. Self-Management Skills are measured using the Self Efficacy Scale and Health Education Impact Questionnaire at baseline and 2/4 weeks post intervention
5. Experiences of the intervention are measured through qualitative interviews with intervention participants 4 weeks post intervention

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged 21 years or over
2. Diagnosed with type 1 or type 2 diabetes and End Stage Renal Disease
3. Receive hospital haemodialysis three times for a minimum of 3 months
4. Hb1Ac = >8%.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Suffering from severe mental illness e.g. psychosis
2. Insufficient communication skills in the English, Malay or Chinese language to participate in the intervention
3. Any other severe communication difficulties that would prevent them following study procedures

Date of first enrolment
01/05/2016

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
Singapore

Study participating centre
National Kidney Foundation Ang Moh Kio Dialysis Centre 1
17 Ang Mo Kio Ave 9 #03-01 Ang Mo Kio
Thye Hua Kwan Hospital
Singapore
Singapore
569766

Study participating centre
National Kidney Foundation Ang Moh Kio Dialysis Centre 2
Blk 565 Ang Mo Kio Ave 3 #01-3401
Singapore
Singapore
560565

Study participating centre

National Kidney Foundation Bukit Merah Dialysis Centre
Blk 128 Bukit Merah View #01-22
Singapore
Singapore
150128

Study participating centre
National Kidney Foundation Hougang Dialysis Centre
Blk 628 Hougang Ave 8 #01-108
Singapore
Singapore
530628

Study participating centre
National Kidney Foundation Yishun Dialysis Centre
Blk 203 Yishun Street 21 #01-239
Singapore
Singapore
760203

Sponsor information

Organisation
National University of Singapore

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
Charity

Funder Name
National Kidney Foundation Singapore

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/01/2019		Yes	No