Peer support for late presenters

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/04/2023		Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/04/2023	Completed	Results		
Last Edited	Condition category Urological and Genital Diseases	Individual participant data		
02/05/2023		Record updated in last year		

Plain English summary of protocol

Background and study aims

People with kidney disease find it reassuring and useful to talk to other patients with kidney disease. This is known as peer support. Research has shown that peer support can be particularly helpful when people are making decisions about kidney treatments. Unfortunately, some patients get very little time to be involved with these decisions because they are not known to kidney specialists until they urgently need treatment. This can make a carefully planned start on kidney dialysis difficult. As a result, these 'late presenters' often find it more difficult to adjust to life with kidney disease, have reduced or delayed access to a transplant and home dialysis, and have more medical problems. They might particularly benefit from peer support, but this has never been formally tried or tested. A full-scale test of the idea will be risky to set up because of the things that are not known. For example, it is not known whether it's possible to recruit enough peer supporters or exactly when and how late-presenting patients are able to or interested in receiving peer support. This study aims to answer these questions.

Who can participate?

Adult patients with established kidney disease

What does the study involve?

This study will answer the research questions by doing a 'test run' on a small number of late-presenting patients who will be offered regular contact with a peer supporter for four weeks. It will also explore how easy it is to measure the effects of peer support by asking the patients to complete questionnaires about their care and quality of life. We will compare their answers to those we get from patients who presented late but did not receive peer support. We also want patients to tell us in their own words how peer support has affected them and so will interview them.

What are the possible benefits and risks of participating?

Participation will help the development of peer support for kidney patients and inform how larger trials should look to investigate its benefits. Peer support is a social intervention so can't harm participants in any physical way. There is a small chance that instead of finding peer support reassuring and helpful participants find it upsetting or makes them more anxious. Previous studies suggest that this is very unlikely.

Where is the study run from? Kings College London (UK)

When is the study starting and how long is it expected to run for? June 2015 to February 2018

Who is funding the study? British Renal Society (UK)

Who is the main contact? Eleri Wood, eleri.wood@nhs.net (UK)

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

204510

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 204510, CPMS 32564

Study information

Scientific Title

A pilot study on the impact of peer support for people with advanced kidney failure presenting late to renal services

Acronym

PS for LP

Study objectives

Peer support is a feasible treatment for people who start dialysis after presenting late to renal services

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/07/2016, London - Chelsea Research Ethics Committee (Royal Brompton Hospital, Sydney Street, London, SW3 6NP, UK; +44 (0)207 1048029; chelsea.rec@hra.nhs.uk), ref: 16/LO/1209

Study design

Non-randomized pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital, Internet/virtual, Telephone

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Established kidney disease

Interventions

Peer support (once weekly for four weeks) with standard care versus standard care alone.

Standard Care:

Standard care after starting dialysis without preparation includes a nephrologist review within 1 week, support from a dialysis nurse 1-5 times weekly, a dietitian review, and the optional offer of counselling with a renal counsellor.

The intervention:

Standard care plus Peer support ie emotional or informational support delivered by experienced peer support workers (PSWs).

PSWs are patients of the renal unit who themselves live with kidney disease; who have had 5 hours of in-house training to help them have the necessary understanding of the expectations and barriers of the role and basic communication skills; and who are registered King's College Hospital volunteers.

Delivered one-to-one.

The initial peer support session is face-to-face at King's College Hospital Renal Unit within two weeks of RRT start. A minimum of three further contacts (either face-to-face at the renal unit, by phone, or by email, at the preference of the participant) over the following three weeks.

Allocation: Non-randomised. All eligible patients who consented in months 1-6 received standard care; those who consented in months 7-12 received the intervention.

Intervention Type

Behavioural

Primary outcome measure

Acceptability measured using semi-structured interviews, with thematic analysis, at the 3 months follow up

Secondary outcome measures

- 1. Biochemical/biological variables [blood pressure, Haemoglobin, potassium, phosphate, and calcium] measured using data recorded in the unit's database at baseline and 3-month follow-up
- 2. Treatment outcomes [dialysis modality, access, attendance/service use] measured using data recorded in the unit's database at 3-month follow-up
- 3. Patient-reported health-related quality of life outcomes measured using the EQ5D at baseline and 3 months
- 4. Patient activation measured using the Patient Activation Measure at baseline and 3 months

Overall study start date

30/06/2015

Completion date

15/02/2018

Eligibility

Key inclusion criteria

- 1. Aged over 18 years old
- 2. Commencing dialysis without preparation
- 3. Mental capacity to consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Total final enrolment

23

Key exclusion criteria

- 1. Lack of mental capacity
- 2. Acute kidney injury

Date of first enrolment

16/10/2016

Date of final enrolment

15/10/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Kings College Hospital Renal Dialysis Unit

Kings College Hospital Denmark Hill London United Kingdom SE5 9RS

Sponsor information

Organisation

King's College Hospital NHS Foundation Trust

Sponsor details

Denmark Hill London England United Kingdom SE5 9RS None available kch-tr.renal@nhs.net

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01n0k5m85

Funder(s)

Funder type

Research organisation

Funder Name

British Renal Society

Alternative Name(s)

BRS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Publications planned of feasibility report and of analysis of qualitative data/patient experience

Intention to publish date

01/06/2023

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the study are available upon request from Eleri Wood (eleri.wood@nhs.net). Spreadsheets showing anonymized secondary data will be shared and will be available immediately. Eligible patients were approached and issued with study information while an inpatient or attending dialysis. Written informed consent was obtained at least 24 hours later. All data was anonymized.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No