ISRCTN18080970 https://doi.org/10.1186/ISRCTN18080970

Piloting an intervention for improving treatment adherence

Submission date
03/10/2014

Recruitment status
No longer recruiting

Registration date
03/10/2014

Overall study status
Completed

Last Edited
22/05/2017

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Patients who live with long-term illnesses have to make many changes to the way they live. These include changes to what they can eat and drink, and the need to take a number of medicines, often many times a day. Many find this difficult. It is particularly difficult for patients with severe kidney disease who, as well having to avoid many foods, cut down the amount they drink and take a large number of tablets daily, also have to have dialysis. This usually means attending the hospital three times a week for treatment lasting around four hours at a time. It is perhaps not surprising that almost half of patients are not able to do what their doctor advises. It is very important that we learn how we can help patients to make the best choices for their health. We know that it will not be easy. For example, simply telling patients why their treatment is important and what will happen if they do not do it, does not help some patients who dont fully recognise the risk. We need to do more to help these patients. We need to understand why some patients cannot manage their treatment and we need to improve the way we give them information, so they are able to hear it, understand it and hopefully act on it, to change their behaviour. The idea we want to test is to make patients feel better about themselves before we talk to them about their treatment. This has the effect of making people more open to hearing things about their illness and its treatment that they might otherwise feel uncomfortable about. The method is called self-affirmation. The method has already been shown to help people change the way they live such as stopping smoking or drinking less alcohol. We want to test the method in patients on dialysis for kidney disease. If we can show it also works for these patients, this could open the way for doctors and nurses to use it with their patients with other long-term illnesses. It is easy to use and the benefits for patients and the NHS could be great.

Who can participate?
Adult patients requiring haemodialysis.

What does the study involve?
Patients will be randomly allocated to one of two groups: the self-affirmation group (includes self-affirmation message) or the control group (does not include self-affirmation message). Patients will be asked to complete a short questionnaire pack at the start of the study. Included in the questionnaire pack is a health risk message about the consequences of poor treatment

control. Patients will then be asked to respond to specific questions about the health risk message and their future treatment control. The questionnaire pack is repeated at 1, 3 and 6 months. Clinical data is collected for analysis during the study but is already routinely obtained in usual care and therefore no additional clinical assessments are required.

What are the possible benefits and risks of participating?
The benefit in taking part is that the patient is reminded of the importance of managing their treatment to minimise future health risks. Patients will be asked to consider their previous treatment control and whether they might be putting their health at risk if they have not been able to control it. If patients have not managed their treatment adequately in the past, this might be uncomfortable for them. Members of the clinical team with expertise in patient treatment were available for consultation at any time if the patient wished to discuss their personal treatment plan.

Where is the study run from?
Six haemodialysis centres across the UK will take part in the study, one based at Southend University Hospital NHS Trust, three centres managed under the East and North Herts NHS Trust (Stevenage, Luton and St Albans)and two centres managed by the Royal Free NHS Trust, (Edgware and St Pancras, London).

When is the study starting and how long is it expected to run for?
The study started in November 2012 and ended in August 2013.

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

Who is the main contact?
Dr Vari Wileman
v.a.wileman@herts.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Vari Wileman

Contact details
Clinical Trials Co-ordinating Centre
Health Research Building
College Lane
Hatfield
United Kingdom
AL10 9AB
-
v.a.wileman@herts.ac.uk

Additional identifiers

Protocol serial number

14238

Study information

Scientific Title
Piloting a novel behaviour change intervention for improving treatment adherence in haemodialysis patients

Study objectives
The study aims to determine whether a behavioural intervention informed by self-affirmation theory alters patients perceptions of health risk information about the importance of fluid treatment control. It is predicted that, compared with a control group, patients receiving a brief self-affirmation activity would:
1. Have a more positive evaluation of the fluid health risk information
2. Report greater intention and self-efficacy to improve fluid control
3. Have lower Interdialytic Weight Gain levels at follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/WS/0191; First MREC approval date 02/08/2012

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
Self-affirmation: The self-affirmation intervention used in this study consists of ten questions with Yes or No responses which require the respondent to consider times when they have been kind to others ((Reed & Aspinwall, 1998).

Control patients completed ten matched control questions with no self-affirming properties (Reed & Aspinwall, 1998).

The treatment was delivered at baseline and repeated at 1, 3 and 6 months

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Psychological responses; Timepoint(s): Self-reported responses to the health risk information, intention and self-efficacy, assessed immediately after the first presentation of the health risk information.

Key secondary outcome(s)
Interdialytic weight gain; Timepoint(s): Reduction in interdialytic weight gain assessed at 1, 3, 6, 9 and 12 months

Completion date
27/08/2013

Eligibility

Key inclusion criteria
1. Adult (over 18 years) haemodialysis patients
2. Fluency in spoken and written English
3. 3 months from initiation of dialysis
4. Three month Interdialytic Weight Gain (IDWG) > 2.0 kg
5. Residual renal urea clearance (KRU) <1 ml/min or reported urine output<200 ml per day

Patients recruited to the observational study will not need to meet inclusion criteria points 4 and 5
Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Hospitalised at the time of study or during the two months prior for reasons other than dialysis
2. Being treated for another condition assessed as compromising treatment or participation in study (e.g., mental health)
3. In preparation for live donor transplant

Date of first enrolment
01/11/2012

Date of final enrolment
27/08/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Trials Co-ordinating Centre
Hatfield
United Kingdom
AL10 9AB

Sponsor information

Organisation
Southend University Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/05fa42p74

Funder(s)

Funder type
Charity

Funder Name
The British Renal Society (UK)

Results and Publications

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?
Results article	results	01/01/2016		Yes	No