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The effects of expressive writing on haemodialysis patients

Submission date
10/12/2012

Recruitment status
No longer recruiting

Registration date
16/01/2013

Overall study status
Completed

Last Edited
13/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
We are carrying out a study to examine the effects of a technique known as expressive writing, when used with patients who are undergoing dialysis treatment. This technique has been used with lots of other groups of patients before, such as those with arthritis, and it has been shown to have positive effects on their physical health and psychological well-being. The studys findings should help us to know whether this technique can be applied to patients with kidney failure and whether it has the same benefits for them.

Who can participate?
The study aims to screen approximately 200 dialysis patients, with the aim of recruiting 50 patients into the expressive writing part of the study. The participants will all be age > 18 years, under the care of Guy's and St Thomas's renal team and undergoing dialysis treatment in three pre-selected hospital clinics.

What does the study involve?
Participants will initially be required to complete a series of questionnaires concerning a number of factors linked to psychological well-being (e.g., mood, fatigue, distress and illness beliefs). If they are found to meet the inclusion criteria, they will be asked to take part in an expressive writing exercise and be placed randomly into one of two groups (one is an expressive writing group and one a control group). Both groups will write about aspects of their kidney problem and dialysis treatment for 15 to 20 minutes, whilst dialysing, on three consecutive dialysis days. Participants will be asked to complete the same series of questionnaires following the expressive writing exercise (at one week), after 3 months and finally after 6 months. We will also collect some basic data on certain markers of physical health from the participants medical notes. The main aim of the study is to see whether the writing procedure is feasible to use with the dialysis population (i.e., whether people agree to take part, whether they drop out, whether are able to complete the task correctly and whether there are any difficulties). The second aim is to see whether there are any benefits of using an expressive writing procedure over a neutral control procedure. At the end of the study, we will compare the measures of wellbeing and health markers before and after the intervention to see whether there is improvement over time and also between groups to see whether the expressive procedure is more beneficial than the non-expressive procedure.

What are the possible benefits and risks of participating?
It is possible the expressive writing sessions will improve physical health and some aspects of psychological well-being of those taking part. However, this cannot be guaranteed. If it is found to be beneficial, this study may help researchers to develop this procedure so that it can be used with future patients undergoing dialysis treatment, therefore improving their overall quality of life.
Although unlikely, there is a small risk of distress caused by the writing sessions as participants may become aware of an issue that they had not previously thought of. The usual risk management procedure will take place if increased distress is identified by researchers and psychologists attached to the renal unit will be on hand to provide support if required.

Where is the study run from?
This study is being conducted by academic staff and students at the Institute of Psychiatry (IoP), part of Kings College London, alongside a consultant nephrologist who has given permission to recruit patients at three UK dialysis units run by Guys & St Thomas NHS Trust. These are Bostock unit and Astley Cooper unit, which are based at Guys and St Thomas Hospital and one satellite dialysis unit, which are based in Camberwell, London.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start early 2013. Participants will be enrolled on the study for a period of six months.

Who is funding the study?
Funding has been provided by the Institute of Psychiatry (IoP), part of King's College London.

Who is the main contact?
1. Jennifer Hunt (Jennifer.hunt@kcl.ac.uk)
2. Project Supervisor: Joe Chilcot (joseph.chilcot@kcl.ac.uk)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number: 6.0. Sponsorship reference: CSA/12/029

Study information

Scientific Title
A randomised controlled trial to assess the feasibility and efficacy of using an expressive writing intervention with patients on haemodialysis

Study objectives
Research questions have been designed to address both the feasibility of this approach and clinical efficacy of the intervention. These are outlined as follows:

Feasibility
1. What percentage of patients undergoing dialysis treatment in the targeted clinics will be eligible for screening (i.e., those that do not meet exclusion criteria)?
2. Among those patients found to be eligible, what percentage of patients will be willing to consent to screening and randomisation? Are there differences in the characteristics of patients who are willing and those not willing to consent?
3. Among those patients screened, what percentage will be eligible to be randomised [i.e., score above 3 on the General Health Questionnaire (GHQ-12)]? Are there differences in the characteristics of patients who are significantly distressed and those who are not?
4. What percentage of patients drop out of the study? Are there differences in the characteristics of patients who do and do not drop out?
5. What percentage of patients adhere to the task instructions and complete all three writing tasks? Are there differences in the characteristics of those who are able and those not able to adhere to the task instructions?
6. Is this procedure safe for widespread use in clinics? Do patients report that they were comfortably able to write whilst on dialysis? Are there reports of distress or other problems as a result of taking part in the writing task?

Efficacy
Is the intervention effective in producing health benefits? In particular, we hypothesise change in patient-reported levels of distress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London Camden and Islington,19/12/ 2012, REC Number: 12/LO/1858

Study design
Single-centre two-armed randomised controlled trial

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
Depression associated with kidney disease

Interventions
Expressive Writing (EW) intervention vs. control.

Participants and research team will be blind to condition assignment, apart from Chief Investigator (CI).

Expressive Writing (EW) or emotional expression is a therapeutic technique, developed by Pennebaker and Buell (1986), typically involves participants writing about their deepest thoughts and feelings regarding a stressful or traumatic event for 15-20 minutes over several brief writing sessions. In this study, the expressive writing group will be instructed to write about their deepest thoughts and feelings about the experience of undergoing dialysis treatment.

The control group will write about unemotional neutral topics, related to the patients day-to-day management of the disease, as suggested by Pennebaker (1989).

Intervention Type
Behavioural

Primary outcome measure
Feasibility measured by:
1. Recording the number of patients who are eligible in the targeted clinics
2. The number willing to consent to screening and randomisation
3. The number eligible for randomisation
4. The number of drop-outs
5. The number who adhere to task instructions

Secondary outcome measures
Data from a series of psychosocial questionnaire:
1. General Health Questionnaire (GHQ-12)
2. Brief Illness Perception Questionnaire (BIPQ)
3. Patient Health Questionnaire (PHQ-2)
4. Pain Visual Analogue Scale (VAS)
5. Chalder Fatigue Scale]

At one week, after 3 months and finally after 6 months.

Overall study start date
03/01/2013

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. To be included in the study, patients (>18 years of age, either sex) will need to be a renal patient currently undergoing haemodialysis treatment within one of the dialysis units of Guy's and St Thomas's NHS Trust.
2. To be included in the writing intervention patients will have met a cut-off score of 3 or more on the General Health Questionnaire (GHQ-12) as part of the screening phase, indicating some level of distress.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
We aim to recruit 50 patients (20-25 patients per group) who are undergoing HD treatment based in three UK dialysis units managed by Guys & St Thomas NHS Foundation Trust.

Key exclusion criteria
Exclusion criteria (for both the screening and RCT phases) will include:
1. Patients under the age of 18
2. Those with significant visual or physical impairment preventing completion of the questionnaires
3. Inability to speak or write in English
4. Known cognitive impairment
5. Documented history of psychiatric illness including severe depression (identified as being under the care of a psychiatrist), and
6. Length of time on dialysis as <90 days

Following screening, patients with a General Health Questionnaire score of less than 3 will not be eligible for the writing task.

Date of first enrolment
03/01/2013

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's & St Thomas' Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London ref: CSA/12/029

Alternative Name(s)
Collegium Regale Londiniense, King's, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Thesis results	results		13/08/2020	No	No
HRA research summary			28/06/2023	No	No