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Kidney-specific psychosocial assessment and support

Submission date
06/05/2021

Recruitment status
No longer recruiting

Registration date
07/06/2021

Overall study status
Completed

Last Edited
17/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
One in three people on kidney replacement therapy experience depression. This is important because depression is linked with poor physical health. Worryingly, this includes a 50% increase in mortality (death rate). Despite this, kidney services do not look for mental health problems routinely. Researchers have developed an intervention aimed at proactive detection and prevention of common mental health difficulties for people with kidney disease. The aim of this study is to assess whether the study design is appropriate prior to a full trial.

Who can participate?
Adults under the care of a kidney specialist will be approached to undergo self-report screening for depression and anxiety using validated measures. If they have some evidence of common mental health difficulty and do not meet the self-report exclusion criteria, they will be offered participation.

What does the study involve?
In addition to 6 months of standard care, participants will be randomly allocated to immediate or delayed intervention (lasting 6 months). At the start of the study, participants will be asked to fill in a survey. They will be asked to repeat the same survey three more times over the course of a year. For those in the immediate group, this will be at 3, 6 and 12 months. For those in the delayed group, this will be at 6, 9 and 12 months. After the survey, participants will be randomly allocated and informed of the outcome by their site research nurse. During the intervention, participants will have an initial appointment scheduled with the Assistant Psychological Practitioner (APP). Intervention components and the frequency of subsequent contact will be guided by this initial meeting and participant preference, with a planned fortnightly interaction with options including in-person, or by telephone, email and video call. Participants will be offered participation in monthly peer groups organised and facilitated by the APP. After 6 months, participants will be offered an interview regarding their experiences and will return to standard care.

What are the possible benefits and risks of participating?
Whilst the researchers cannot guarantee any benefits, the kidney PASSPORT intervention is designed to detect early problems and equip people and their informal carers with the right

skills to live well with kidney disease. It is hoped that kidney PASSPORT will facilitate greater access to treatment for people, where required. There is no physical risk to participants from this study. This study will not affect any medical care they receive.

Where is the study run from?
Royal Devon and Exeter NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2021 to April 2023

Who is funding the study?
The Kidney Patient Research Partnership (British Renal Society and Kidney Care UK)

Who is the main contact?
Dr Alexander Hamilton
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Study website
https://twitter.com/KidneyPassport

Contact information

Type(s)
Scientific

Contact name
Dr Alexander Hamilton

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
296551

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1, IRAS 296551

Study information

Scientific Title
A single-centre prospective single-blind wait-list randomised controlled feasibility trial of the kidney-specific psychosocial assessment and support intervention

Acronym
Kidney PASSPORT

Study objectives
This feasibility trial of the kidney-specific Psychosocial ASSessment and supPORT (Kidney PASSPORT) will establish the suitability of the research methods, acceptability to patients and implementation within the National Health Service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2021, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8388; sheffield.rec@hra.nhs.uk), ref: 21/YH/0124

Study design
Single-centre prospective single-blind wait-list individually randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Common mental health difficulties for people with kidney disease

Interventions
Participants will receive 6 months of the intervention and 6 months of standard care, and will be individually randomised into immediate and delayed intervention groups.

The multi-component intervention is named Kidney PASSPORT and is coordinated by an Assistant Psychological Practitioner (APP). Adapted from an approved Institute of Apprenticeship role, the APP will be fully embedded into the kidney collaborative care team, to support evidence-based psychological practice specific to kidney patients. Whilst the APP role is centred on the prevention of subthreshold common mental health difficulties, where indicated by patient need, they will be able to support referral for treatment. A Band 3 healthcare assistant already in renal services (hence having practical knowledge of kidney replacement therapies and the challenges facing patients) will be appointed and through generic and specific competency-based training, will carry out the APP role with weekly supervision of their caseload. In light of the COVID-19 pandemic, they can operate virtually by telephone, email or videoconference where required. APP competencies include:

1. The identification and monitoring of common mental health difficulties and wider psychosocial needs, by administering and interpreting psychometrically sound short form screening
2. Supporting self-management and kidney education as part of the collaborative care team
3. Signposting to community/charitable services of support
4. Collaboration with appropriate health and social care organisations and professionals
5. The organisation and facilitation of patient user groups
6. Education of colleagues/staff to enhance their core role with a greater psychosocial appreciation
7. Supporting evidence-informed prevention approaches based on Low-Intensity Cognitive Behavioural Therapy, relevant to COVID-19 and adapted for kidney patients for mild-moderate anxiety/depression
8. Supporting referral to Improving Access to Psychological Therapies for the treatment of moderate-severe anxiety/depression
9. Provide psychoeducation (where physical symptoms are identified) using the CBT 'here and now' principle, to educate patients to appreciate the links between the psychological and physical. APPs will also liaise with the CCT and signpost to primary care where relevant

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment rate: % of those eligible and approached who have consented to study participation at 3 months
2. Retention rate: % that remain in the study until the end of follow up at 12 months

Secondary outcome measures
1. Consent to screen rate: % of those approached who consent to the screening survey at 3 months
2. Screening positivity rate: % of those screened who score 3 or more on the PHQ-2/GAD-2 at 3 months
3. Randomisation acceptability assessed through qualitative interviews. Interviews will take place at 6 months for the immediate group and 12 months for the delayed group.
4. Adherence to intervention and fidelity of intervention delivery, assessed using Assistant Psychological Practitioner self-report against a quantitative checklist and qualitative interviews with participants. Checklists and Interviews will be undertaken at 6 months for the immediate

group and 12 months for the delayed group.
5. Completion of outcome measures: proportion of missing data at 0, 3, 6 and 12 months (immediate group) and 0, 6, 9 and 12 months (delayed intervention group)

Overall study start date
16/02/2021

Completion date
26/04/2023

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Under the active care of a Nephrologist
3. Patient Health Questionnaire (PHQ)-2 score OR Generalized Anxiety Disorder (GAD-2) score ≥3
4. Capable of giving informed consent, completing self-report measures, and using written self-help materials in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36

Total final enrolment
24

Key exclusion criteria
1. Currently receiving formal psychotherapy
2. A previous diagnosis of a severe or enduring mental health problem
3. Change in antidepressant medication in the last month
4. Current substance or alcohol addiction

Date of first enrolment
18/11/2021

Date of final enrolment
26/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Royal Devon and Exeter Hospital

Sponsor details
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joanne.lowe3@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://rderesearch.co.uk/

ROR
https://ror.org/03jrh3t05

Funder(s)

Funder type
Charity

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

Funder Name
Kidney Care UK

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and conference presentation.

Intention to publish date
26/04/2024

Individual participant data (IPD) sharing plan
The dataset will not be made available due to the small numbers and single centre and high risk of re-identification. The data will be held on secure institutional servers.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Basic results			17/04/2024	No	No