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Physical activity, depression and illness perceptions in CKD

Submission date 18/08/2016	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/09/2016	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 31/10/2017	**Condition category** Urological and Genital Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Background and study aims
The purpose of this study is to investigate the relationships between depression, patients' feelings about having kidney disease, the symptoms they experience, and how active they are. This study will help researchers to understand how kidney disease makes people feel in themselves and how it affects their quality of life. It is hoped that this will lead to new ways of helping patients cope better with living with kidney disease.

Who can participate?
Adults (aged at least 18) with chronic kidney disease.

What does the study involve?
Each participant is asked to complete a survey made up of 8 sections. Each section is a separate, simple questionnaire. The participants are given the survey to take home so that they can complete it in their own time. They are all given a stamped addressed envelope to post it back. The survey asks questions about how a person with kidney disease feels about their condition and how it impacts on their quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?
August 2016 to March 2019

Who is funding the study?
1. University of Leicester (Doctorate in Clinical Psychology grant)
2. Loughborough University (Commonwealth PhD studentship)

Who is the main contact?
Dr Alice Smith

Contact information

Type(s)
Scientific

Contact name
Dr Alice Smith

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1 1st February 2016

Study information

Scientific Title
Physical activity, depression and illness perceptions in CKD: a cross-sectional survey study

Acronym
ADAPT

Study objectives
There is a paucity of research on the illness perception of individuals living with chronic kidney diseases (CKD) and its association with health behaviour; research in this field will assist to understand if illness perception is predictive of the levels of physical activity in individuals with CKD.

The purpose of this study is to investigate the relationships between depression, patients' feelings about having CKD, the symptoms they experience, and how active they are. This study will help researchers to understand how kidney disease makes people feel in themselves and how it affects their quality of life. It is hoped that this will lead to new ways of helping patients cope better with living with kidney disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Queen Square Research Ethics Committee, 06/06/2016, ref: 16/LO/0980

Study design
Cross-sectional survey design

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
People with CKD are invited to complete a survey consisting of 8 sections, each of which is a separate simple questionnaire. The survey will be given to participants to fill in at home, and they will then return it to the researchers in a stamped addressed envelope. They are also asked for their permission for a researcher to extract some information from their medical records (recent blood and urine test results, medications, past medical history including any other health conditions).

The survey consists of the following sections:
Section 1: Some questions about you
Section 2: A questionnaire about how you feel about Chronic Kidney Disease
Section 3: A questionnaire about your mood over the last 2 weeks
Section 4: A questionnaire about your physical activity over the last 7 days
Section 5: A questionnaire about your ability to carry out day-to-day activities
Section 6: A questionnaire about the symptoms you experience
Section 7 : A questionnaire about how tired you have felt over the last week
Section 8: A questionnaire about your quality of life

There will be no further follow up of the participants. A descriptive analysis of the results will be carried out, and associations and relationships between the questionnaire responses and clinical parameters using correlation and regression explored.

Intervention Type
Other

Primary outcome measure
Association between self-reported physical activity measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF) and perception of chronic kidney disease measured using the Illness Perception Questionnaire (IPQ-R) at a single time point.

Secondary outcome measures
1. Depression measured using the Beck Depression Inventory (BDI-II)
2. Physical capacity measured using the Duke Activity Status Index (DASI)
3. Experience of symptoms measured using the Kidney Symptom Questionnaire (KSQ)
4. Fatigue levels measured using the Leicester Kidney Fatigue Scale
5. Quality of Life measured using the EuroQOL 5 Dimension scale (EQ5D)
6. Associations between the above questionnaires and:
6.1. Clinical markers of disease severity (routine blood and urine test results; prescribed medications; comorbidities)
6.2. Demographic indicators measured by questionnaire (age, sex, ethnicity, educational level, smoking status)

Overall study start date
01/08/2016

Completion date
15/03/2019

Eligibility

Key inclusion criteria
1. The participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. With chronic kidney diseases (including diabetic kidney disease) attending outpatient clinics

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size is 44 (n = 44)

Key exclusion criteria
1. Individuals who are unable to understand, read and write English
2. Unable to consent for any other reason

Date of first enrolment
01/08/2016

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Leicester Kidney Exercise Team
Academic Unit
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Sponsor information

Organisation
University Hospitals of Leicester NHS Trust

Sponsor details
Research and Innovation Office
Leicester General Hospital
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+44 1162584109
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Sponsor type
Research council

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
University/education

Funder Name
University of Leicester

Alternative Name(s)
UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Loughborough University

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
15/03/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		25/08/2016	26/09/2016	No	Yes
HRA research summary			28/06/2023	No	No