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Evaluation of the BRIGHT intervention in primary care

Submission date
11/09/2012

Recruitment status
No longer recruiting

Registration date
05/10/2012

Overall study status
Completed

Last Edited
14/07/2015

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims:
Improving the quality of care for people with vascular conditions is a global priority. For example, primary care has an important role in identifying and managing people with chronic kidney disease (CKD). CKD is common but often unrecognised as there are no symptoms in the early stages of the disease. It is usually associated with other conditions, such as hypertension (high blood pressure), diabetes and cardiovascular disease. Early recognition and treatment of CKD, aimed at reducing blood pressure can prevent or delay the progression of CKD and reduce the risk of cardiovascular disease. However, patients report a lack of awareness of the condition and there are concerns by GPs and nurses over the lack of appropriate information. This results in missed opportunities to support people diagnosed with CKD. To prevent or delay future health problems, there are actions people with kidney problems can take. The BRIGHT study aims to improve understanding and support for people with kidney problems by providing self-help information and improve access to local support services.

Who can participate?
Adult patients registered in general practices in Greater Manchester who have a diagnosis of stage 3 chronic kidney disease.

What does the study involve?
Participants will be randomly split into two groups:
Group 1: will be given a kidney information guidebook followed by a telephone call from a support worker who will talk to participants about local support services for people with health problems. Details of a website linking participants to these services will also be provided
Group 2: will be given a kidney information guidebook six months after this face-to-face meeting.
At the start of the study and then six months later, we will ask participants to complete a questionnaire. We will also ask participants' GPs to send us details of participants' blood pressure readings, taken at the start of the study and at six months.

What are the possible benefits and risks of participating?
There is potential that information about chronic kidney disease may cause distress for participants. However, both the intervention and the study trial have been designed to address this issue. Although we cannot promise any direct benefit for participants, we believe that

involvement in the study might help improve benefit for the way services are provided to NHS patients in the future.

Where is the study run from?
The Health Sciences Research Group at The University of Manchester.

When is study starting and how long is it expected to run for?
We are recruiting participants between April and November 2012. A written report of the study is likely to be available by December 2013. This will be provided to participants' general practices and will be also be available on the CLAHRC for Greater Manchester website at http://clahrc-gm.nihr.ac.uk/.

Who is funding the study?
NIHR CLAHRC for Greater Manchester (http://clahrc-gm.nihr.ac.uk/)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of the BRIGHT (Bringing Information & Guided Help Together) intervention in primary care: improving outcomes for people with chronic kidney disease through effective self-management support

Acronym
BRIGHT

Study objectives
In participants with stage 3 chronic kidney disease, does a complex self-management intervention to improve knowledge of CKD management and promote links with local community resources improve blood pressure control, self-management capacity and health-related quality of life compared to care as usual?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Greater Manchester Central, 12/01/2012, ref: 11/NW/0855

Study design
Two-arm patient 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 above to request a patient information sheet

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

Interventions
The BRIGHT trial will evaluate an intervention aimed at addressing current gaps in care delivery for people with stage 3 CKD.

The research is being carried in general practices across Greater Manchester.

The BRIGHT intervention comprises:
1. A kidney information guidebook

2. A short self-assessment questionnaire to tailor access to types of community-based resources which is linked to:
2.1. Telephone support with a support coordinator
2.2. A website detailing available community resources

The BRIGHT intervention aims to build on existing care delivery and is to be delivered after a recent clinical appointment with a GP or practice nurse.

500 patients identified by their GP as having stage 3 chronic kidney disease will be randomly allocated to receive the BRIGHT intervention or to continue to receive usual care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All outcomes are at the level of the patient.

The trial has three primary outcomes including:
One clinical outcome of blood pressure control collected from the patients' general practice medical record, readings taken at time of baseline and 6 month review appointments.

Two patient-reported outcomes of:
1. Self-management capacity (health education impact questionnaire (heiq)
2. Health-related quality of life (EQ5D)

Each participant will complete a baseline questionnaire, and a follow-up questionnaire will be sent at 6 months.

Secondary outcome measures
1. Anxiety: Hospital Anxiety and Depression scale (HADS)
2. CKD specific anxiety: Adaptation of an item from The Brief Illness Perceptions Questionnaire.
3. Loneliness: The UCLA Loneliness Scale
4. Medication Adherence: Adapted version of the Self-reported Measure of Medication-taking Scale
5. Social Capital: Health Survey for England
6. Social Networks
7. Service utilisation: modification of the service utilisation questionnaire from the national evaluation of the Expert Patients Programme.
8. Glycaemic control: (for patients with diabetes only, collected from patient's general practice medical records)

Overall study start date
06/03/2012

Completion date
30/04/2013

Eligibility

Key inclusion criteria
Stage 3 chronic kidney disease (both stages 3a and 3b)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Mental incapacity to provide informed consent
2. Unable to communicate in English
3. Receiving palliative care
4. Only one person per household will be eligible for the study to avoid contamination between control and intervention patients

Date of first enrolment
01/04/2012

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

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Sponsor type
Government

Website
http://www.manchester.ac.uk

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - CLAHRC for Greater Manchester (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?

Protocol article	protocol	28/01/2013	Yes	No
Results article	results	16/10/2014	Yes	No