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The Online Parent Information and Support project

Submission date
25/07/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
17/12/2014

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
Children and young people with chronic kidney disease (CKD) are happier at home, so when possible medical professionals teach and support parents to deliver home-based clinical care. In previous research, parents of children with CKD gave skilled care at home such as administering complex medications and injections, monitoring diet/fluids, and communicating clinical changes to medical professionals. Parents identified a need for reliable, continuously available, online materials to supplement (not replace) existing professional support and to empower them, particularly when professionals are less accessible, e.g. night-time. The aim of our study is to evaluate the impact of On-line Parent Information and Support (OPIS) use over 20 weeks on the extent to which parents perceive themselves empowered to care for their childs CKD, and test procedures for a later national trial.

Who can participate?
Parents of children and young people up to 19 years of age with CKD whose care is managed by the multidisciplinary team (MDT) in the kidney unit in one childrens hospital in the North of England.

What does the study involve?
Participants were randomly allocated into two groups. One group (the control group) received standard support and information to support home-based clinical care-giving from the MDT. The other group (the OPIS group) received usual support plus password-protected access to OPIS for 20 weeks. Both groups completed questionnaires at the start and end of the trial to compare family condition management, whether parents felt empowered to deliver care, and the amount and helpfulness of fathers involvement between groups.

What are the possible benefits and risks of participating?
We anticipate that parents using OPIS will report improved empowerment. Whilst creating online resources for and with parents of children with CKD the study may also inform care /research in other conditions. By taking part in the study there are no risks of physical injury or harm. Increased levels of anxiety could result from talking about home-based care-giving but a

Clinical Psychologist was available to provide support if needed. However, in previous studies parents have often described a positive therapeutic benefit of taking part in research that could improve the experience of other parents.

Where is the study run from?
The University of Manchester (UK).

When is the study starting and how long is it expected to run for?
The study started in September 2012 and ran for 12 months.

Who is funding the study?
The National Institute for Health Research, Research for Patient Benefit Programme (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
11186

Study information

Scientific Title
The OPIS (On-line Parent Information and Support) project: meeting mothers' and fathers' information and support needs for home-based management of childhood chronic kidney disease stages 3-5

Acronym
OPIS

Study objectives
That access to OPIS plus standard support from health care professionals will improve parents' ability to manage their child's chronic kidney disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/N/W/0268; First MREC approval date 06/02/2012

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Online parent information and web-based resource. The intervention group received password-protected access to OPIS as well as standard support from the MDT; the control group received standard support only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Family management levels (FaMM) measured at pre- and post-20 weeks accessing the intervention

Secondary outcome measures
1. Amount and helpfulness of fathers' involvement in home-based clinical care giving (DADS)
2. Family empowerment (FES)
3. Rapid Estimate of Adult Literacy (REALM)
4. OPIS usage, acceptability and accessibility (USE)

Overall study start date
08/12/2011

Completion date
27/03/2013

Eligibility

Key inclusion criteria
Phase 1:
1. Children aged (0-19 years)
2. Commenced management for CKD in the preceding 5 years and require home-based care
3. (10 South Asian and 30 English)

Parents: of the above
1. New or experienced caregivers
2. Willing to participate
3. Child (if old enough) also willing to participate
4. Have existing home computer and internet access

Professionals (MDT):
1. Currently caring for one of the selected children (hospital or community)
2. Willing to participate

Phase 2:
We will establish a virtual development group comprising four children and four young people with CKD (English and South Asian)

Parents of the above:
1. Two/three representatives of Trust-based and community health professionals
2. Two/three representatives from voluntary sector (e.g., ContactAFamily, NW Region Kidney Patients Association, HealthTalkGroup, Fatherhood Institute, Manchester South Asian Organisation)

Phase 3:
Up to 40 'new' and 'experienced' parental (biological, step or adoptive) caregivers of up to eight South Asian and 32 white children from clinical (up to 20 per group, to allow for a 25% attrition rate)

Inclusion criteria:
1. Child commenced management for CKD

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
Phase 1:
1. Do not wish to participate
2. Commenced CKD management more than 5 years ago and require home-based care

Parents of the above:
1. No home computer or internet access
2. Child not participating in study
3. Do not wish to participate

Professionals (MDT):
1. Not currently caring for one of the selected children
2. Not willing to participate

Phase 3:
1. Child no longer requires home-based care
2. Do not have home computer and internet access

Date of first enrolment
08/12/2011

Date of final enrolment
27/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Road
Manchester

United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB) (UK); Grant Codes: PB-PG-0110-21305

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?
Results article	results	03/12/2014		Yes	No