

Comparing intervention to lower systolic blood pressure in chronic kidney disease (CKD): a cluster randomised trial (CRT)

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Registration date 12/06/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/07/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
7395/4843 (HF)

Study information

Scientific Title

Acronym

QI CKD

Study objectives

This cluster randomised trial (CRT) will compare two well-established quality improvement interventions with usual practice. The two intervention arms are:

1. Provision of clinical practice guidelines with prompts
2. Audit-based education

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Oxford Research Ethics Committee (Committee C) on the 31st October 2006 (ref: 07/H0606/141).

Primary study design

Interventional

Study design

A two-year three-armed cluster randomised trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Chronic kidney disease

Interventions

The three interventions are:

1. Usual practice: a minimum of contacts will be made of these practices other than for data collection (n = 35 practices)
2. Distribution of clinical practice guidelines with prompts: this is an established, low cost method. It will provide a benchmark with which the effectiveness of other quality improvement interventions can be compared. We will develop a consensus between the study team, our expert advisory group and external peer reviewers', and produce appropriate guidance for the management of CKD in primary care. We will use the "Appraisal of Guidelines Research and Evaluation" (AGREE) instrument do to this. AGREE is a validated guideline development tool. This guidance will be distributed to practices with quarterly updates/reminders (n = 35 practices). In addition practices will have access to a supportive website with information about CKD, frequently asked questions (FAQs) and tools to improve CKD management.
3. Audit-based education: in addition to clinical practice guidelines, practices will receive six-monthly detailed comparative feedback about their quality of CKD management (n = 35 practices)

The total duration of the intervention is two years.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The reduction of systolic blood pressure in hypertensive people with stage 3 to 5 chronic kidney disease according to the agreed target.

The measure of primary and secondary outcome measures will take place at t = 0 (baseline), t = 1 year and t = 2 years.

Key secondary outcome(s)

Clinical and laboratory markers:

1. Recording and management of key co-morbidities:

1.1. Diabetes and its complications

1.2. Ischaemic heart disease

1.3. Heart failure

1.4. Obstruction/lower urinary tract symptoms

2. Recording and management of other cardiovascular risk factors:

2.1. Smoking status

2.2. Lipid management

2.3. Proteinuria

2.4. Anaemia

2.5. Glycated haemoglobin and microalbuminuria in people with diabetes mellitus

3. Serial measures of serum creatinine concentration and estimated glomerular filtration rate (GFR)

4. Avoiding harm. We wish to collect data to monitor whether blood pressure reduction is associated with an increased number of falls particularly in older people. Most people with CKD are elderly and at potential risk of falls. Notwithstanding the results of recent systematic reviews which failed to show an association between falls and anti-hypertensive medication, this possibility remains a genuine concern to some practitioners, and one that we propose to examine. A falls dataset will be devised and integrated into the renal dataset. We will investigate the relationship with use of angiotensin converting enzymes (ACE) inhibitors and angiotensin II receptor blockers and systolic blood pressure below 120 in CKD.

5. Practitioner confidence to be measured at t = 0, t = 1 year, and at end of project

6. Medicines management:

6.1. Use of drugs/therapy which affect renal function (for example non-steroidal anti-inflammatory drugs)

6.2. Use of angiotensin converting enzyme inhibitors and angiotensin II receptor blockers to control hypertension

6.3. Recording of medicines possession ratio based on days prescribed therapy as an index of concordance with anti-hypertensive therapy

The measure of primary and secondary outcome measures will take place at t = 0 (baseline), t = 1 year and t = 2 years.

Completion date

01/04/2010

Eligibility

Key inclusion criteria

The primary research participants are general practitioners involved in the study who will receive the various quality improvement interventions listed below. The interventions will be implemented at the practice (cluster) rather than the individual level. The study subjects (who may be regarded as secondary participants) will be all individuals with chronic kidney disease within the study practices.

Inclusion criteria:

1. Practices who provide written consent to participate
2. Locality specialist who will support the participation of the practice and the implementation of standard guidelines across the participating practices (appropriate to the arm of the study they are involved in)
3. Primary Care Trust (PCT) commissioners' engagement with the project and willingness to consider learning from its findings
4. Practice has had the same computer system for the last five years and has no plans to change it, or will allow access to check data quality
5. Practice has electronic laboratory links for the last three years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Practices in whom the computing system has changed over the last five years
2. Practices lacking an appropriate computer system from which data can be extracted
3. Practices in which referral data (from primary care to secondary care) is not available

Date of first enrolment

01/04/2007

Date of final enrolment

01/04/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department in Health Care
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation

St George's University of London (UK)

ROR

<https://ror.org/040f08y74>

Funder(s)

Funder type

Charity

Funder Name

The Health Foundation (UK) (ref: 7395/4843 (HF))

Funder Name

Kidney Research (UK) (ref: CDK/2007)

Results and Publications

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	25/01/2013		Yes	No
Results article	results	10/09/2013		Yes	No
Other publications	cross-sectional analysis	25/02/2013		Yes	No