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Self Testing Own Kidneys (STOK) Study

Submission date
08/01/2019

Recruitment status
No longer recruiting

Registration date
14/01/2019

Overall study status
Completed

Last Edited
08/06/2023

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
Patients are often required to attend NHS clinics for routine monitoring of their kidney function - when they themselves are well and do not otherwise need to see a healthcare professional. Although such tests are necessary, having to attend clinics often impacts negatively upon patient experience by interrupting employment or social commitments and incurring travel costs. Unnecessary clinic visits also consume NHS resources which are commonly working at full capacity to manage patients who are unwell. Enabling selected patients to self-test their own kidney function at home could thus hugely benefit both patients and the NHS. This study will assess whether it is feasible for selected kidney transplant recipients to be trained to safely use hand-held medical devices to self-test their own kidney function at home, with results that agree with standard NHS kidney function tests.

Who can participate?
Patients aged 18 or over with who have previously received a kidney transplant and are clinically well with stable kidney function

What does the study involve?
Each participant uses two handheld devices to self-test their own kidney function at home. The Abbott i-STAT Alinity device is used by participants to self-test their blood tests (https://www.pointofcare.abbott/int/en/offerings/istat-alinity/details) and the Dip.io device to self-test their urine (https://healthy.io/). Each participant self-tests their kidney function one day per week for a total of four weeks. On the same day that they self-test their kidney function at home, participants attend the hospital for NHS standard kidney tests by study nurses. Participants keep a diary during the study and are interviewed to evaluate their experience of self-testing. The study team assesses how the results of participant self-testing compares with NHS standard test results and evaluate if self-testing of kidney function with these devices is safe and acceptable to the study participants.

What are the possible benefits and risks of participating?
It will be explained to study participants that their participation in the study will be of no direct benefit to themselves at the time of this study. It will be explained, however, that this study may provide potential benefit to other patients in the future, by limiting unnecessary clinic visits for routine testing of kidney function. The main (pre-perceived) risks to participants are related to needle-stick injuries and use of study devices (minimised by developing participant training

resources, which will be used alongside participant competency based training and assessment by study nurses – participants will not begin home self-testing until they have demonstrated devices competency through study nurses' assessment) and the finding of unexpected test results for tests that would not have otherwise been taken at the time of the study (this will be explained during recruitment and the consent process, and participants will have prompt access to study medical staff to fully support them should such circumstances arise).

Where is the study run from?
The James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2016 to October 2020

Who is funding the study?
Northern Counties Kidney Research Fund, AHSN NENC and Healthy.io (Commercial Funding)

Who is the main contact?
Dr Jonathan Murray
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Study website
http://www.nckrf.org.uk/pages/awarded_grants_236991.cfm

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40094

Study information

Scientific Title
A study to evaluate feasibility, safety and impact of patients self-testing their own kidney function at home

Acronym
STOK

Study objectives
The self-testing of kidney function using the I STAT Alinity device and Dip.io device is safe and acceptable to participants and produces results that agree with NHS standard testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee, Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, Tel: 02071048033/53, Email: nrescommittee.london-cityandeast@nhs.net, 24/10/2018, REC ref: 18/LO/1837

Study design
Non-randomised; Both; Design type: Process of Care, Device, Management of Care, Active Monitoring, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Specialty: Renal Disorders, Primary sub-specialty: Renal Disorders; Health Category: Renal and Urogenital; Disease/Condition: Other disorders of kidney and ureter

Interventions

The study design and methodology has been influenced and chosen following input by members of the Research Design Service. The trialists have also incorporated health economist and statistician review by staff from the Newcastle NIHR MedTech and In Vitro Diagnostics Co-operative, at Newcastle University. Their expertise has aided formulation of research questions and methodology, such as sample size and statistical analyses, as explained below.

The study is a single-centre mixed methods exploratory study. Following participant recruitment, valid consent and competency based training to use the study medical devices, the study will comprise of the following components:

1. Participant (n=15) self-testing blood and urine at home and then NHS standard tests of blood and urine at a hospital clinic, one day per week for four weeks
2. Statistical analysis to explore agreement between participant self-testing and standard NHS testing of kidney blood results
3. Exploration of whether clinical interpretation and utilisation of participant urinalysis self-test results alongside self-test blood results agrees with clinical interpretation of standard NHS urinalysis and blood test results (i.e. clinical interpretation of participant self-test kidney results yields conclusions that replicate standard clinical practice)
4. Participant questionnaires to evaluate competency-based training resources to enable safe and competent utilisation of POCT devices to self-test kidney function
5. Interview and diary review with study participants (n=15) to understand experience and acceptance of self-testing their own kidney blood and urine tests
6. Questionnaires to evaluate renal healthcare staff to explore how patient self-testing may impact upon renal patient care
7. Interview with non-renal health professionals (n=10) and wider care pathway analyses to identify the optimal clinical scenarios where patient self-testing of kidney function may enable greatest patient and NHS benefits

Study Settings

Self-testing of blood and urine will be undertaken by participants within their own homes. Participants will also visit the Renal Unit, James Cook University Hospital, Middlesbrough to have their blood and urine tested by healthcare professionals. Participant interviews will take place either at James Cook University Hospital, or at the participants' homes, depending on participant preference. Health professional interviews will take place at their place of work, or by telephone, as dictated by the health professional.

Blood and urine testing

On a Thursday morning, once a week for four weeks, the participant at home will:

1. Prick their finger to obtain a capillary blood sample and analyse this themselves using a hand-held medical device (the Abbott i-STAT Alinity device)
2. Use a second medical device (the Dip.io) to self-test their urine at home

On the same Thursday in the afternoon, once a week for four weeks, the participant will attend the Renal Unit and:

1. Have a capillary sample taken by a health professional that will be analyzed by the health professional using the i-STAT device
2. Have a venous sample taken by a health professional that will be sent for standard laboratory testing
3. (When able to produce a second urine sample) Have a urine sample analyzed in clinic by a health professional, using a standard NHS urinalysis device (Siemens Clinitek Status® Urinalysis Machine)

Blood test results analysis
Self test and NHS standard blood test results will be collected to establish if there are agreement or variables between results obtained by:
1. A participant self-testing their own blood (a capillary sample obtained by pricking their finger) using a hand-held medical device (i-STAT) at home and a healthcare professional testing a participant's blood (a capillary sample) using an i-STAT device in the Renal Unit, at James Cook University Hospital
2. A health professional in the Renal Unit testing a participant's blood (a capillary sample) and analyzing it with the i-STAT and a venous sample (a blood sample from a vein in the arm) sent for standard laboratory testing

Previous studies observed strong agreement between the i-STAT creatinine and potassium levels with laboratory reference standards when used by healthcare professionals (Society for Academic Primary Care, 2015 and Lasserson, D 2016). In this study, the i-STAT measurements will also be performed by patients. The primary analysis will use Bland Altman plots to allow formal identification of any systematic differences between measurements of potassium and creatinine obtain through capillary blood and venous blood. This analysis will be repeated to assess:
1. Agreement between i-STAT capillary potassium and creatinine blood measurements taken by healthcare professionals, with venous potassium and creatinine blood measurements taken by health professionals
2. Agreement between i-STAT capillary potassium and creatinine blood measurements taken by healthcare professionals, with Abbott i-STAT capillary potassium and creatinine blood measurements taken by participants
3. Agreement between i-STAT capillary potassium and creatinine blood measurements taken by participants, with venous potassium and creatinine blood measurements taken by health professionals

There is no formal sample size calculation for an exploratory Bland Altman analysis, therefore we have chosen our sample size based on the primary outcome of feasibility and safety of self-testing at home. We expect that choosing 15 participants will allow us to explore the feasibility, acceptability and importantly the safety of self-testing at home within the study. Each of these participants will provide 4 measurements and 60 datasets in total. Allowing a 5% error rate (including missing data) results in 57 analysable data points, which will allow identification of any differences between the data, providing sufficient information to plan follow on comparative evaluations.

Urine test results analysis
Self-test and study nurse test urinalysis results will be recorded within study participant Case Report Forms (CRFs). These results will be reviewed by study renal clinicians to enable clinical interpretation of blood and urine results in tandem; this replicates standard assessment of kidney function in NHS clinics, where urinalysis results enrich and support clinical interpretation of kidney blood results.

Dip.io urinalysis tests enable detection and semi-quantitative measurement of proteinuria (neg, 1+, 2+, 3+, 4+) and haematuria (neg, 1+, 2+, 3+, 4+), which enrich clinical interpretation of kidney blood test results. Good analytical agreement has been demonstrated between urinalysis results obtained with this device and standard laboratory based urinalysis analysers (https://healthy.io /product/).

Should study clinician interpretation of urinalysis results obtained through participant self-testing using Dip.io devices differ from interpretation of urinalysis results obtained when repeat urine samples are tested by study nurses, then this will be recorded within CRFs.

Qualitative Data Collection

Participant experience of i-STAT Training: Participants will be asked to complete a questionnaire to evaluate their training experience and confidence, when they return to clinic to have their safety and competency using the iSTAT assessed. Information from this questionnaire will be analysed after each cohort and used to inform training sessions for future cohorts of participants.

Participant experience undertaking blood tests with the i-STAT: Participants will be asked to complete a simple diary to record their weekly experiences whilst undertaking blood tests with the i-STAT.

Participant experience using Dip.io home urine test: Participants will be asked to complete a short questionnaire to assess their use of the Dip.io, at the end of the four weeks self-testing period.

Estimating the cost of attending hospital for kidney function monitoring: Participants will be asked to complete a short questionnaire at the start of the study to capture the cost of attending hospital appointments. Questions will cover their employment status, their journey time, mode and cost of getting to hospital appointments and if they are accompanied to appointments.

Overall participant experience of self-testing kidney function at home: At the end of four weeks self-testing, all 15 participants will be invited to meet with a qualitative researcher on a one to one basis to share their study experience. Interviews will semi-structured and audio recorded. All data will be transcribed verbatim, and then coded by the study qualitative researchers. The data collection will be carried out by experienced qualitative researchers, facilitated with a topic guide, with prompts for discussion, rather than a prescriptive set of questions. This will allow participants to speak freely on issues which are important to them, which can be explored further by the researcher, to fully capture the participants' experiences of the hand-held medical devices in this study.

The topic guide will include, but will not be limited to, the following prompts:

1. Participants' feelings about their increased involvement in their care
2. Participants' use of the POCT
3. What participants felt worked well in the POCT experience
4. What participants felt could be improved in the POCT experience
5. Participants' reflections on how they felt after using POCT devices
6. What issues did the study raise for participants
7. What would participants tell other patients/healthcare professionals

Other prompts may be added/amended during data collection as a result of participant feedback and data analysis. This semi-structured approach will allow the participants to influence the data collection process so researcher bias and assumptions are minimised, ensuring that the relationship between the study participants and researchers is be one of mutual reciprocity

Health Professional Insight: Potential utilities for self-testing of kidney function

The study team will utilise professional links with colleagues across South Tees Hospitals NHS Foundation Trust, to identify 10 experts including nephrologists, cardiologists, point of care managers, and nurses who regularly undertake monitoring of kidney function within a UK NHS hospital. Researchers will explore opinions on where patient self-testing kidney function at home could fit within existing care pathways and the evidence that would be required for the monitoring of kidney function to be changed from in clinic or hospital to home. Semi-structured interviews with these staff will be carried out by experienced qualitative researchers, facilitated with a topic guide, with prompts for discussion, rather than a prescriptive set of questions. This

will allow health professionals to speak freely on issues that are important to them, which can be explored further by the researcher, to fully capture their views. The topic guide will be updated iteratively allowing incorporation of findings from earlier interviews. The topic guide will include, but will not be limited to, the following prompts:
1. Interviewees' understanding of current pathways that patients follow to have their kidney function monitored
2. What works well and what doesn't in the current pathway
3. What are the clinical scenarios where the availability of the i-STAT and Dip.io devices could alter such pathways for patients.
4. What, if any are the potential barriers and facilitators that might impact upon adoption and spread of such technologies?
5. How could any barriers be overcome?
6. What evidence requirements would the clinicians want to see to feel confident in replacing clinics with patient self-testing and reporting of results?

Renal healthcare staff: Feasibility of self-testing
Renal healthcare staff at James Cook Hospital will be asked to complete a questionnaire to explore how patient self-testing may impact upon renal patient care. Questions will include extent to which staff felt trained and supported for their role in this exploratory new care pathway, perceived benefits of self testing to patients and renal care, barriers to adoption and feasibility of implementation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
The feasibility, safety and accuracy of patients self-testing their kidney function from capillary blood samples using ISTAT Alinity devices at home, when compared to blood samples obtained and tested by study nurses using both i-STAT Alinity devices and NHS laboratory analysis. This will be measured from baseline to the end of study at week 4.

Secondary outcome measures
1. Patient experience, acceptability and usability, assessed through diary, questionnaires and interview analysis from baseline until the end of study interviews
2. Economic viability of patient self-testing kidney function at home, assessed through analysis of questionnaires, interviews and care pathway analysis from baseline until the end of study interviews
3. Complications and adverse events: the nature and frequency of device-specific and non-device events collected by direct questioning of the patient on a weekly basis when they attend clinic and note review where necessary. This is from the baseline visit until week 4

Overall study start date
23/11/2016

Completion date

15/10/2020

Eligibility

Key inclusion criteria
1. Participant criteria - adequate cognitive and functional ability to enable competency-based training to use hand-held medical devices
2. Clinical criteria - adults who have previously received a kidney transplant and are clinically well with stable kidney transplant function, based upon assessment by their consultant nephrologist
3. Aged 18 years or older
4. Capacity to consent to take part in study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 15; UK Sample Size: 15

Total final enrolment
15

Key exclusion criteria
1. Patients not meeting inclusion criteria
2. Pregnancy
3. Clinical instability or drug changes within previous 4 weeks
4. Participants currently taking part in another research study

Date of first enrolment
28/11/2018

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Tees Hospitals NHS Foundation Trust
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Charity

Funder Name
Northern Counties Kidney Research Fund

Alternative Name(s)
NCKRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Academic Health Science Network: North East and North Cumbria

Funder Name
Healthy.io Ltd

Results and Publications

Publication and dissemination plan
Documentation currently not available online. These may become available after study publication.

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/03/2023	08/06/2023	Yes	No
HRA research summary			28/06/2023	No	No