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Video information versus approved leaflets - which is better to provide informed consent for flexible cystoscopy?

Submission date
09/06/2015

Recruitment status
No longer recruiting

Registration date
16/09/2015

Overall study status
Completed

Last Edited
13/04/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and Aims
This study is about whether it is better to teach patients about flexible cystoscopy (a camera test to look inside the bladder) with a leaflet or a video animation. Video information is used widely for consumer information outside healthcare, but has been slow to catch on in hospitals. Adult literacy in the population served by Guy's and St Thomas' Trust is poor. Having compared reading ability with the readability of existing leaflets, there is a concern that a large portion of our patients currently cannot access the information they need. We have chosen our most common invasive test to look at whether video information is better than leaflets at getting important information across to patients.

Who can participate?
Adult patients who are attending the Urology Centre at Guy's Hospital for their first flexible cystoscopy test. Patients will be free to withdraw from the study at any time and without giving a reason – this will not affect the standard of care they receive.

What does the study involve?
We will divide the patients in this study into two groups: one group will read a leaflet before their procedure, and one will watch an animation. Any patient giving informed consent to take part will first be placed by chance into either a leaflet group or an animation group before the procedure. This process is called randomisation. The aim is to try and ensure that the groups are as similar as possible. There will be a 50% chance of being placed in either group. Then the patients will read the leaflet or watch the video, complete a short set of questions and have the cystoscopy procedure. The whole process, including your procedure, should not take longer than one hour.

What are the possible benefits and risks of participation?
The information we collect will help us to provide information more clearly to our patients who need this test in future. Communicating information by video could be more effective than by leaflet, especially for patients who struggle to read, or need an interpreter, for children, and for those with a learning disability.

Some patients may find the video makes them nervous. However, it was first shown to expert doctors and patients, who made sure that this would not be beyond the normal anxiety felt by a patient having this test.

Where is the study run from?
The study has been set up by a research team at Guy's and St Thomas' NHS Foundation Trust and will be conducted at the Urology Centre, Guy's Hospital, with assistance from Angus Fitchie, medical student at King's College London and under supervision of Mr Ben Challacombe, consultant urological surgeon and Dr John Withington, urology research fellow. Guy's and St Thomas' NHS Foundation Trust will act as sponsor for this study and assumes responsibility for governance of the study.

When is the study starting and how long is it expected to run for?
December 2014 to October 2015. It is anticipated that the recruitment period will begin in July 2015 and end in October 2015.

Who is funding the study?
It is not expected that this trial will generate any significant financial costs. Any minimal costs incurred will be covered by the Urology Centre at Guy's.

Who is the main contact?
Mr Ben Challacombe, ben.challacombe@gstt.nhs.uk
Angus Fitchie, angus.fitchie@kcl.ac.uk

Study website
N/A

Contact information

Type(s)
Public

Contact name
Mr Ben Challacombe

Contact details
Urology Centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Type(s)
Public

Contact name
Mr Angus Fitchie

Contact details

Urology Centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of outpatients attending urology clinic at Guy's Hospital, comparing information provision to patients in leaflet versus video animation format with a view to informed consent to flexible cystoscopy procedure

Study objectives
Information provision for informed consent to flexible cystoscopy by video animation is superior to that by trust-approved leaflet with regard to: 1) accessibility of information and 2) patient satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge East Research Ethics Committee, 17/02/2016, ref: 16/EE/0036

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Other

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
Patient information provision by video animation for flexible cystoscopy

Interventions
All patients attending Guy's Urology Centre for their first flexible cystoscopy procedure will be approached upon arrival by a researcher in the clinical care team for recruitment into the trial, provided they meet the trial's inclusion criteria. As this trial will evaluate how patients engage with information about a procedure, it is crucial that the patients recruited have no prior experience of flexible cystoscopy. Patients who express interest to participate after a short verbal explanation of the trial will be offered a Patient Information Sheet (PIS) and consent form, which they will read and complete (available on request). The researcher will be present to answer any questions at this point. The date that the PIS is given to the patient must documented in the patient's notes.

On offering informed consent to take part in the trial, patients will be randomised to either the leaflet or video animation arm of the trial (by a quick phone call to research nurse for access to the next number in a randomised sequence). Patients in the leaflet arm will be given a trust-approved information leaflet to read, and those allocated to the video animation arm will be shown the video by the researcher. Following viewing of either supplementary information source, the patients will be asked to complete a basic cystoscopy questionnaire, testing their knowledge about the procedure gained from the leaflet or video animation. Thereafter, the leaflet patients will be requested to fill out a leaflet satisfaction questionnaire, and the video animation patients will be requested to fill out a video animation satisfaction questionnaire. The final question in both of these questionnaires asks the patients to choose whether they would prefer a video animation or leaflet for information on the procedure in future. Finally the patients from both arms will have a chance to ask any questions they may have about the procedure to either the researcher or the clinician performing the cystoscopy, before undergoing the flexible cystoscopy itself.

It is not expected that any patient involved will spend greater than one hour in the study in total. After reading the patient information and consent forms and discussing any questions with a member of the research team, it is felt that any potential participants would need no longer than the duration of that day's cystoscopy list (up to three hours) to consider participation. This is due to the simple and unobjectionable nature of what is required of a patient in this study (reading a leaflet or watching a short video and answering a small number of questions). Verbal and written consent will be obtained on the patient consent form in the presence of a member of the research team. The participant's right to withdraw from the study at any time and for any reason will be emphasised.

Intervention Type
Other

Primary outcome measure

The final score on a questionnaire testing patient knowledge about flexible cystoscopy (after having viewed the information source) – this will assess accessibility of supplementary information.

Secondary outcome measures
Thefinal score on a questionnaire about patient satisfaction with regard to information source – this will determine patient preference for information in leaflet or animation format.

Overall study start date
02/12/2014

Completion date
01/10/2015

Eligibility

Key inclusion criteria
1. Adult patients between the ages of 18 and 100 years old
2. Male or female (inclusive of patients of child-bearing age, contraception irrelevant)
3. Patients attending for a first flexible cystoscopy at Guy's Urology Centre
4. Patients able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients less than 18 years old or greater than 100 years old
2. Patients with prior experience of flexible cystoscopy
3. Patients with severe visual impairment who could not watch the video animation
4. Patients unable to offer informed consent due to limited ability to communicate
5. Patients who cannot understand the information presented without an interpreter (including British Sign Language) when an appropriate interpreter is not present

Date of first enrolment
01/07/2015

Date of final enrolment

01/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Urology Centre, Guy's and St Thomas' Foundation NHS Trust
Guy’s Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
R&D Department, 16th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor type
Research organisation

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Research organisation

Funder Name

Guy's and St Thomas' NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is the intended that the results of the study are published in peer-reviewed scientific journals and also disseminated by internal report and conference presentation.

Intention to publish date
01/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

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