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The effectiveness of hand-held digital multimedia presentation of trial information on recruitment and retention of patients to a trial in primary care: an embedded methodology trial protocol

Submission date
14/08/2017

Recruitment status
Stopped

Registration date
11/10/2017

Overall study status
Stopped

Last Edited
01/07/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Recruiting patients to studies is a major challenge. Failure to meet recruitment targets can result in delays and underpowered studies. The aim of this study is to assess the effectiveness of a hand-held digital multimedia presentation of study information to potential participants on recruitment and retention to the SATIN study (http://www.isrctn.com/ISRCTN88111427).

Who can participate?
Healthy non-pregnant women visiting participating general practices for a suspected urinary tract infection

What does the study involve?
Participants are randomly allocated to receive either a written participant information leaflet or a multimedia digital information resource, delivered through a handheld tablet device, plus a written participant information leaflet. Participants are invited to ask questions related to participation in the SATIN study. Either the GP or practice nurse completes the SATIN study screening questionnaire. Willing patients are asked to sign an informed consent form and are enrolled into the SATIN study, while patients unwilling to participate are referred back to the GP and receive treatment as per usual clinical practice.

What are the possible benefits and risks of participating?
The results will provide evidence to design effective and comprehensive patient recruitment information. These approaches may be adopted by similar studies in the future. There is no direct benefit to participants. The risks could include spending more time viewing recruitment material.

Where is the study run from?
National University of Ireland Galway (Ireland)

When is the study starting and how long is it expected to run for?
February 2016 to December 2018

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Prof. Declan Devane

Contact information

Type(s)
Public

Contact name
Prof Declan Devane

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SWAT

Study information

Scientific Title
The effect of a handheld digital multimedia information resource on recruitment and retention of patients to a trial in primary care

Study objectives

Studies within trials (SWATs) present an opportunity to examine information on the different design factors that impact the outcome of trials. One area in need of research is trial recruitment. Recruiting patients to trials is a major challenge facing trialists. Failure to meet recruitment targets can result in delays and underpowered studies. This SWAT aims to evaluate the effectiveness of a hand-held digital multimedia presentation of trial information to potential patient participants on recruitment and retention to the host trial (SATIN: http://www.isrctn.com/ISRCTN88111427).

Ethics approval required
Old ethics approval format

Ethics approval(s)
ICGP Ethics Committee, 01/12/2016, ref: ICGP_DEC 2016

Study design
Two-group parallel randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Uncomplicated urinary tract infection

Interventions
Eligible patients will be identified by the General Practitioner (GP) within participating practices based on the inclusion and exclusion criteria outlined by SATIN. GPs will invite eligible patients to consider participating in the SATIN trial. Women who have agreed to participate in the SATIN host trial will be randomly allocated by block randomisation to:
1. Comparator: Written participant information leaflet (n=230). This will be written in adherence to good research ethics practice and will invite participation of the women to SATIN.
2. Intervention: Access to multimedia digital information through a handheld tablet device and written participant information leaflet within the general practice (n=230). A handheld, tablet device containing a hard-installed, digital multimedia presentation of the trial information will be given to potential participants. The multimedia presentation of trial information will contain generic information on trial participation and SATIN trial specific content.

Following consideration of either the comparator or intervention, women are invited to ask questions related to participation in the SATIN trial. Either the GP or practice nurse completes the SATIN trial screening questionnaire. Willing women are asked to sign an informed consent form and are enrolled into the SATIN trial, patients unwilling to participate are referred back to the GP and receive treatment as per usual clinical practice. The period of follow up is up to 14 days after the participant has viewed the study material.

Intervention Type
Other

Primary outcome measure
The proportion of potentially eligible participants willing to participate in the SATIN trial, calculated as the number of participants who sign the SATIN informed consent form, Measured at 1 year or when trial recruitment has closed

Secondary outcome measures
1. The proportion of participants recruited to the SATIN trial (in case this differs from the number of participants willing to participate, due to e.g. exclusion criteria), recorded in the SATIN electronic case report form (eCRF), measured at 1 year or when trial recruitment has closed
2. The proportion of recruited participants who are retained to the end of the SATIN trial. Retention will be measured as the number of participants who complete the UTI Symptom Score (see SATIN protocol) on days 0-7 and until day 14 or until recovery is achieved, whichever occurs first. Measured at 1 year or when trial recruitment has closed
3. The quality of decision-making, measured through the completion of a decisional scale 2 days after viewing the recruitment material. The scale is adapted from one used within the REFORM trial and drawing conceptually on the SURE and DelibeRATE scales

Overall study start date
01/02/2016

Completion date
01/12/2018

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
This SWAT will include healthy, non-pregnant, adult women presenting for consultation for a suspected uncomplicated UTI. The study population are individuals who are being screened for and/or who are eligible to take part in the host SATIN trial.

To participate in SWAT-15 individuals must:
1. Be attending a general practice that is taking part in the SATIN trial
2. Have a GP-diagnosed UTI, and at least one of the symptoms dysuria, urinary frequency, or urgency with/without low abdominal pain

3. Be a woman (non-pregnant) aged 18 years or above
4. Be able and willing to give written informed consent
5. Own a smartphone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
N = 460

Key exclusion criteria
Key exclusion criteria are as per the SATIN host trial:
1. Any signs of complicated infection or any condition that may lead to complications
2. Current or recent antibiotic use
3. Recent UTI
4. Current intake of NSAIDs
5. Pregnancy or breastfeeding
6. Non-use of highly effective contraception
7. Previous adverse reaction to any of the study drugs
8. Current intake of drugs potentially interacting with the trial drugs
9. Diabetes mellitus, chronic kidney disease or any other previous illness related to kidney or urinary tract
10. History of gastro-intestinal ulcers, Glucose 6 phosphate Dehydrogenase deficiency or any other medical condition that may put the participant at risk or influence the study results in the investigators' opinion

Date of first enrolment
11/09/2017

Date of final enrolment
10/09/2018

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland Galway
Galway

Ireland
-

Sponsor information

Organisation
HRB Primary Care Clinical Trials Network

Sponsor details
Discipline of General Practice
School of Medicine
NUI Galway
Galway
Ireland
Galway

Sponsor type
University/education

Website
http://primarycaretrials.ie/

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
The trialists plan to publish the study protocol as soon as the study is registered and publish the results in an open access journal around one year after the overall trial end date.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sinead Duane (sinead.duane@nuigalway.ie).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/03/2020	01/07/2020	Yes	No