

A primary care trial of a tailored interactive website for the self-management of respiratory infections.

Submission date 31/08/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/05/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Many people with respiratory illnesses such as coughs, colds, influenza, sore throats or sinusitis go to see their general practitioner (GP), taking up large amounts of time and NHS resources. The majority of these illnesses do not require treatment and will get better on their own. However, people go to their doctor because they do not have good information about how long these illnesses normally last or how severe the symptoms can be. The study aims to improve the information made available to patients about how they can manage these illnesses without visiting their doctor and also when they should seek medical advice.

Who can participate?

Participants need to be over the age of 18, have no serious mental health problems, have access to the internet and be the only person from their household taking part in the study.

What does the study involve?

Recruitment will be through letters sent out by GPs inviting people to take part in the study. Participants will be placed randomly into one of two groups (treatment and control). Both groups will be asked to complete monthly online questionnaires about any respiratory illnesses they have. The treatment group will have immediate access to an interactive website which will give them advice about how to manage their illness based on the answers they give to questions asked by the website. The control group will be allowed to use the website when the study has ended. A small number of people from the treatment group will be interviewed to find out what they think about the website. A review of the relevant parts of the patient's notes will be carried out six months after the end of the study for both groups.

What are the possible benefits and risks of participating?

Participants may find that they are more able to cope with respiratory illnesses without consulting their GP and be more aware of symptoms that indicate when they should seek medical advice. There is a very slight risk that patients may not seek medical advice for a serious illness; however, the questions on the website have been developed by experts to ensure patients are given clear instructions about when they should consult a health professional.

Where is the study run from?

The study is being run by Primary Medical Care, University of Southampton (UK)

When is the study starting and how long will it run for?

The study is hoping to recruit about 2300 people from October 2011 through to Spring 2012. Recruits will be in the study for six months but the review of their notes will take place 12 months after they are recruited.

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Mrs Susan Broomfield (Study Manager)

seb4@soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

Mrs Susan Broomfield

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10049

Study information

Scientific Title

A primary care trial of a tailored interactive website for the self-management of respiratory infections.: a randomised controlled trial

Acronym

Internet Doctor

Study objectives

This study will be trialling a theoretically-based website providing interactive and personalised advice on:

1. Whether and why the patient needs/does not need to consult the general practitioner (GP)
2. How to self-care for respiratory tract infections (RTIs) and manage concerns. The study will recruit a minimum of 2266 patients to the website through their primary care network. During the trial patients information on RTIs and influenza like illnesses (ILIs) will be collected, along with doctors notes for visits and treatment. The study will provide evidence on the cost-effectiveness of using a web-intervention to alleviate the drain on primary care resources.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and South West Hampshire Research Ethics Committee A, 11/03/2011, 11/H0502/10

Study design

Randomised; Interventional; Design type: Diagnosis

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

1. Baseline: Participants complete online questionnaires prior to randomisation
2. End of Study: Participants complete online questionnaires
3. Monthly questionnaires: Patients asked to report RTIs in previous month (both groups)
4. Use of website: Treatment arm log on if they have an RTI to report symptoms and access Internet Doctor

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

25% reduction in GP visits for RTIs; Timepoint(s): 12 months

Secondary outcome measures

1. Whether the use of the website alters antibiotic expectations and use
2. The cost effectiveness of the website

Overall study start date

01/10/2011

Completion date

31/03/2012

Eligibility

Key inclusion criteria

1. Aged 18 or over
2. Access to the internet

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 2266; UK Sample Size: 2266

Key exclusion criteria

1. Serious mental health problem
2. Terminal illness
3. Someone from the household is already enrolled on the study

Date of first enrolment

01/10/2011

Date of final enrolment

31/03/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Aldermoor Health Centre

Southampton

United Kingdom

SO16 5ST

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

Primary Medical Care

Aldermoor Health Centre

Aldermoor Close

Southampton

England

United Kingdom

SO16 5ST

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notprovided@email.com

Sponsor type

University/education

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (Grant Codes: RP-PG-0407-10098)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	20/04/2016		Yes	No