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A PRimary care trial of a website based Infection control intervention to Modify Influenza-like illness and respiratory infection Transmission

Submission date	Recruitment status	[_] Prospectively registered
02/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/01/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/09/2021	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.virusdefence.org.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/800/22

Study information

Scientific Title
A primary care trial of a website based infection control intervention to modify influenza-like illness and respiratory infection transmission: a randomised controlled trial with a nested viral study

Acronym
PRIMIT

Study objectives
We hypothesise that:
1. The intervention will reduce the number of episodes of influenza-like illness and respiratory tract infections (by reducing transmission) and hence the number of days with symptoms
2. The intervention will reduce the number of health service contacts by reducing the number of episodes
3. The intervention will change attitudes, beliefs, intentions, and behaviour

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Southampton and West Hampshire REC (A), 10/04/2008, ref: 08/H0502/14

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Respiratory tract infections, influenza

Interventions

Infection control website:
Our key intervention will be access with a personal password to a website providing advice on infection control behaviours, with reinforcement by email reminders to use the site. A website is likely to be the most efficient and cost-effective mode of delivery in a pandemic as the majority of homes now have access to the web and the figure rises each year (National Statistics; August 2006). Currently more than 60% of households have access to the web and the figure goes up year on year by 5% each year in a linear fashion - which suggests that even by the end of this trial 80 - 90% of families could have home access to the web. The website will be tailored to provide targeted advice based on the factors that have been shown to be important influences on behaviour in the qualitative study and survey carried out in the development phase. The randomised individual (the index person) will be the main target for behaviour change which should limit spread from that person to members of the household and vice versa. Through the website and the individual passwords we will be able to monitor whether patients have used the website, and how often. Patients who have not used the website will be prompted by email to use the site. Following accessing of the website we will generate regular automated emails at monthly intervals as a reminder to use the website; these reminders will enable us to monitor compliance in the intervention group and give targeted advice.

Control group:
As in the intervention group, the control group will have access to the GP/practice in the normal way for respiratory illnesses and ILI (where low levels of antivirals are normally prescribed). They will have access to the intervention website at the end of the study.

All groups questionnaire follow up at month 1, 2, 3 and 4. Notes reviewed at 1 year.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Index patients will be prompted by email to log onto the website monthly to complete questionnaires about illnesses during the last month since the duration of symptoms can be remembered reliably over a period of a few weeks. For each episode the index person will document:
1. The nature of the infection
2. The duration of symptoms rated moderately bad (which we have shown is the most likely to be sensitive to change for individuals with cough and fever and can be remembered reliably over a period of a few weeks)
3. The number of days where work/normal activities were impaired
4. Whether other family members either had a similar infection before or after the index case, and what the time interval was
5. Whether contact with the health service was needed
6. How well the index patient and other family members complied with the target behaviours (for the intervention group only)

The monthly illness information will be supplemented by a questionnaire at the end of the winter documenting the summary information, and which can be validated against the monthly information. We will base our definition of RTI on consensus definitions developed in previous

studies - which have defined a respiratory tract infection as 2 symptoms of an RTI for at least 1 day or 1 symptom for 2 consecutive days. Evidence of transmission will be defined as a respiratory illness developing within a week of another family member.

Secondary outcome measures
At the end of the study all patients' GP notes will be reviewed to document admission to hospital for respiratory or cardiovascular complications, whether patients attended the GP for their ILI or other respiratory tract infections68, whether antibiotics or antivirals were prescribed, and/or any subsequent referrals. Assessment of the notes will be made blind to group, and has been shown to be reliable and unbiased. We will assess attitudes, beliefs, intentions, and self-reported adherence for each behaviour on 7 point Likert scales both in the pilot study (after 1 month and 3 months), and in the main trial at the end of the winter (we will randomly choose 1: 20 patients for this outcome). These outcomes will be measured in both groups in the main trial only at the end of the winter, to minimise any effect on behaviour change of administering questionnaires in the control group. These outcomes will allow us to check whether the intervention is successful in effecting change and whether outcomes of the intervention are mediated by changes in these variables.To accompany the winter illness questionnaire we will use an adherence questionnaire (the 'Problematic Experiences of Therapy Scale'; PETS) that we have used in previous studies, including the MRC ATEAM trial, and two vertigo trials To reduce social desirability effects on reporting of adherence, the PETS asks patients to what extent they have been prevented from carrying out the intervention by socially acceptable reasons (e.g. symptoms too severe or aggravated by the intervention; doubts about efficacy; uncertainty about how to carry out the intervention; practical problems such as lack of time or opportunity, forgetting). They are only then asked how often and over how many weeks/months they adhered to each aspect of the intervention. To compare the effects of the intervention as a whole with the effects of the website and the target behaviours, in addition to the main intention-to-treat analysis we will carry out per protocol analyses to determine the effectiveness of the intervention in a) those who logged on to the website and b) those who reported adhering to each of the different target behaviours.

Overall study start date
01/11/2007

Completion date
01/06/2012

Eligibility

Key inclusion criteria
Adult patients (aged 18+ years, either sex) living with at least one other person

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
15,000

Total final enrolment
20066

Key exclusion criteria
1. GP notes show a skin problem that may affect handwashing ability
2. Live in households where no one else is willing to provide illness feedback
3. Terminal illness/severe mental health problems
4. Unable to complete online questionnaires

Date of first enrolment
01/11/2007

Date of final enrolment
01/06/2012

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)

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Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC)/National Institutes of Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme (ref: EME 09/800/22)

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	09/12/2011		Yes	No
Results article	results	24/10/2015		Yes	No
Results article	process evaluation	30/05/2021	21/09/2021	Yes	No