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# Does sending a group of patients an advice leaflet advising them on the benefits of taking probiotics reduce the number of respiratory infections they get over the winter?

**Submission date**
08/10/2013

**Recruitment status**
No longer recruiting

**Registration date**
21/10/2013

**Overall study status**
Completed

**Last Edited**
08/02/2017

**Condition category**
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
This study aims to find out whether writing to a whole group of patients and advising them to take probiotics (microbes that may have health benefits) throughout the colder half of the year might be an effective measure in reducing the need for antibiotics and visits to the doctor for respiratory infections.

Who can participate?
All people on the asthmatic register for the participating clinic are eligible to take part in the study.

What does the study involve?
Participants will automatically be sent the advice leaflets at the same time as they are sent their annual influenza vaccination invite. Half of the participants will receive the standard advice leaflet which gives advice on getting annual influenza vaccinations, good hygiene measures, and making sure their asthma control/inhaler technique is checked. The other half will receive a leaflet containing all of this advice plus some additional advice about taking probiotics. This additional advice group will receive vouchers enabling them to receive the probiotic for free, through the company that makes it, Cultech.

What are the possible benefits and risks of participating?
Probiotics have an excellent safety record and are widely available over the counter. Risks to participants are therefore minimal.

Where is the study run from?
Ashfields Primary Care Centre, Sandbach (UK).

When is the study starting and how long is it expected to run for?
The study will take place from October 2013 to March 2014.

Who is funding the study?
The vouchers and free probiotics are funded by Cultech (UK). All other costs are self-funded by the investigators.

Who is the main contact?
Dr Tim Smith
timothy.d.smith11@imperial.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Robert Boyle

### Contact details
Paediatric Research Unit
Wright Fleming Building
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
123564

# Study information

### Scientific Title
Reducing respiratory infections in asthmatics: a randomised controlled trial of two different advice leaflets

### Study objectives
Null hypothesis:
There will be no differences in the rates of antibiotic prescriptions or consultations for patients with respiratory infections amongst those who have received written advice that infection rates could be reduced by taking probiotics each day.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
NRES Committee London - Bloomsbury, 03/06/2013, ref: 13/LO/0783

## Study design
Parallel-group single-blind randomised controlled study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## 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
Asthma

## Interventions
Both groups receive an advice leaflet aimed at reducing the rate of respiratory infections for the 6-month period of October to March. This will be sent out to participants at the time of their letters which invite them to attend their annual influenza vaccination. The standard advice leaflet contains the following headings: Flu jabs, Catch it, bin it, kill it, Hand hygiene and Inhaler technique and asthma control and the additional advice leaflet has everything similar to a standard leaflet but with an additional section headed Probiotics.
1. Standard advice group: This group will receive advice about receiving their influenza vaccination, decontaminating hands that have may carry their own or have come into contact with other people's germs and attending asthma clinics to ensure good asthma control and inhaler technique.
2. Additional advice group: In addition to all the advice received by the standard advice group, this group will also receive written advice that probiotic consumption can reduce respiratory infections. As well as the advice leaflet, this group will also receive three vouchers, each covering a different 2-month period for October 2013 to March 2014, enabling them to receive free Lab4 probiotic capsules from Cultech via their website or mail order.
Following the 6-month period, unless participants have opted out of us doing so, one of the trial doctors who is also a GP at the participants' surgery will look at their primary care medical records to see whether they have received antibiotics or consulted regarding a respiratory infection during the 6-month period from October 2013 to March 2014. Data will also be provided by Cultech as to who opted to receive probiotic from them during this time. A range of contact methods are available for patients to opt out of inclusion in the data analysis for which their medical records will be looked at by one of their doctors.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
Percentage of group prescribed at least one of the following antibiotics in primary care during the 6-month period for which probiotic consumption is recommended: Amoxicillin, Azithromycin, Cefaclor, Cefalexin, Ciprofloxacin, Clarithromycin, Co-amoxiclav, Doxycycline, Erythromycin, Phenoxymethylpenicillin

## Secondary outcome measures
Current secondary outcome measures as of 09/05/2014:
1. Total number of antibiotic prescriptions for the above antibiotics in each group provided by the GP surgery. This is another way of measuring effects on antibiotic prescribing
2. Total number of the above listed antibiotic prescriptions issued by the GP surgery for per group during the 6 month study period
3. Total cost of the above listed antibiotic prescriptions during the 6 month study period per group. This will be based on the NHS drug tariff for England and Wales at the time the prescription was issued
4. Percentage of group prescribed at least one course of any type of oral antibiotics by the GP surgery
5. Total number of any type of oral antibiotic prescriptions issued by the GP surgery per group during the 6 months
6. Total cost of any type of oral antibiotic prescriptions per group. This will be based on the NHS drug tariff for England and Wales at the time the prescription was issued
7. Total number of URTI episodes for which antibiotics were issued
8. Percentage of group having at least 1 URTI episode for which antibiotics were prescribed
9. Total number of all respiratory episodes for which antibiotics were issued
10. Percentage of group having at least 1 respiratory episode for which antibiotics were prescribed
11. Percentage of patients consulting at least once for an URTI during this 6 month period
12. Total number of URTI episodes per group during the 6 month period for which Lab4 is to be recommended
13. Percentage of patients consulting at least once for an LRTI during this 6 month period
14. Total number of LRTI episodes per group during the 6 month period for which Lab4 is to be recommended
15. Percentage of patients consulting at least once for an acute exacerbation of asthma during the 6 months
16. Total number of acute asthma exacerbation episodes per group during the 6 months
17. Percentage of patients consulting at least once with acute respiratory symptoms during this time. This might be due to URTI, LRTI, influenza, flu-like illness or an exacerbation of asthma
18. Total number of acute respiratory episodes for each group as a whole
19. Percentage of participants obtaining Lab4 at any time in the 6 month period for which it was suggested
20. Percentage of participants obtaining deliveries of Lab4 2 or 3 times during this time

Previous secondary outcome measures:
1.Total number of antibiotic prescriptions prescribed in primary care for any of the above antibiotics during the 6 months for the whole group
2. Percentage of group prescribed any type of oral antibiotics in primary care at least once during the 6-month period
3. Total number of oral antibiotic prescriptions issued in primary care during the 6 months for

the whole group
4. Total cost (based on current BNF prices) of antibiotic prescriptions per group
5. Percentage of patients consulting at least once for symptoms of URTI during this time
6. Total number of consultations with symptoms of URTI for the group within the 6-month period
7. Percentage of patients consulting at least once with acute respiratory symptoms (suggestive of URTI, LRTI, influenza, flu-like illness or exacerbation of asthma) during this time
8. Total number of consultations with acute respiratory symptoms for the group within the 6-month period
9. Percentage of people taking Lab4 at any point during the 6-month period for which it was suggested
10. Percentage of people taking Lab4 on more than half of the days during this time

### Overall study start date
01/10/2013

### Completion date
31/03/2014

## Eligibility

### Key inclusion criteria
1. Patients registered at Ashfields Primary Care Centre (UK)
2. Aged 5 years or more

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
1340

### Key exclusion criteria
Only one participant per household is eligible who will be selected at random with the others excluded

### Date of first enrolment
01/10/2013

### Date of final enrolment
31/03/2014

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Paediatric Research Unit**
London
United Kingdom
W2 1PG

# Sponsor information

**Organisation**
Imperial College London and Imperial College Healthcare NHS Trust (UK)

**Sponsor details**
Joint Research Compliance Office
Room 5L10D
5th Floor
Lab Block
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF

**Sponsor type**
Hospital/treatment centre

**Website**
http://www3.imperial.ac.uk/

**ROR**
https://ror.org/041kmwe10

# Funder(s)

**Funder type**
Industry

**Funder Name**
Vouchers/Lab4 probiotic provided by Cultech (UK)

**Funder Name**
Other expenses incurred by doctors of Ashfields Primary Care Centre, Sandbach (UK)

# 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 | 01/09/2016 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |