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Evaluating nasal sprays and physical activity /stress management in reducing respiratory infections in primary care

Submission date
29/09/2020

Recruitment status
No longer recruiting

Registration date
30/10/2020

Overall study status
Completed

Last Edited
11/09/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
A range of viruses circulate each winter and cause respiratory infections (RTIs) (the viruses that cause colds, sore throats, sinus, chest or ear infections, flu). These can lead to people being off work, seeking help from the NHS, and being admitted to hospital in the winter months. The combined effect of both the normal winter viruses (and also the COVID-19 virus in the current pandemic) are likely to cause a major problem for the NHS not only during the coming 2020-21 winter season but in subsequent years. There is promising evidence that using nasal sprays, or alternatively reducing stress and increasing exercise, could help people's immune defences, reduce the number of people getting infections, and reduce how severe illnesses are and how long they last. The NIHR has funded the RECUR Programme to develop and test interventions to find out if they reduce the incidence of infections. The researchers have developed a website called Immune Defence which will help us to see if using nasal sprays or getting more physically active and reducing stress can help people get fewer and less severe infections.

Who can participate?
This study will involve approximately 200 GP practices and up to 15,000 patients who are at risk from respiratory infections.

What does the study involve?
Participants will be invited to take part in the study through invitation letters from their GP surgery. Those who are interested in taking part will be asked to register online and to answer some questions to ensure the study is right for them. Eligible patients will be randomly allocated to one of the following treatments for 12 months: a microgel nasal spray, a saline nasal spray, support for getting active and reducing stress, or usual care for infections. Participants will be asked to complete monthly questionnaires for 12 months and more detailed questionnaires at 3, 6 and 12 months about any infections and about their general health. Patients happy to do so will complete a daily diary of symptoms if they do become unwell to give a more detailed understanding of the course of each illness. A sample of patients and healthcare practitioners will be asked to take part in a telephone interview about their experiences of taking part in the study.

What are the possible benefits and risks of participating?
Using nasal sprays or being more active and reducing stress may help participants get fewer infections. Participation in the study will help researchers find out if any of the treatments make a difference during the time of the COVID-19 pandemic. It will also help researchers plan more studies in the future to find out which treatment is best to reduce the number of cold and flu infections that people get during 'normal' winters. The main disadvantage is that it will take time to complete the questionnaires. Very rarely the microgel nasal spray can cause dryness in the nose resulting in a nosebleed.

Where is the study run from?
University of Southampton (UK)

When is the study starting and when is it expected to run from?
September 2019 to March 2025

Who is funding the study?
NIHR-Programme Grants for Applied Research (PGfAR) (NIHR) (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
288431

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UoS 56474, CPMS 47080

Study information

Scientific Title
Reducing respiratory infections in primary care: the Immune Defence Study

Acronym
Immune Defence

Study objectives
This study will estimate the effectiveness and cost-effectiveness of commonly available nasal sprays and a brief physical activity and stress management intervention in preventing and reducing the incidence, severity and duration of RTIs among patient at risk of serious infection in the COVID-19 pandemic

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/10/2020, South East Scotland REC 01 (South East Scotland Research Ethics Committee 1, 2nd Floor, Waverley Gate, Edinburgh, EH1 3EG, UK; +44 (0)7814 764 241; Sandra.Wyllie@nhslothian.scot.nhs.uk), REC ref: 20/SS/0102

Study design
Multicentre open randomized controlled four-arm trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory tract infections

Interventions
Participants will be invited to take part in the study through invitation letters from their GP surgery. Those who are interested in taking part will be asked to register online and to answer some questions to ensure the study is right for them. Participants will be randomized to one of four interventions for 12 months:
1. Microgel nasal spray (medical device)
2. Saline nasal spray (medical device)
3. Support for physical activity and stress management (behavioural intervention)
4. Usual care for infections

Participants will be asked to complete monthly questionnaires for 12 months, and more detailed questionnaires at 3, 6 and 12 months about any infections and about their general health. Patients happy to do so will complete a daily diary of symptoms if they do become unwell to give a more detailed understanding of the course of each illness. A sample of patients and healthcare practitioners will be asked to take part in a telephone interview about their experiences of taking part in the trial.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Microgel nasal spray, saline nasal spray

Primary outcome(s)
Duration of illness due to respiratory tract infections (RTIs) measured using patient report of total days with symptoms over 6 months (data collected monthly, at 3, 6 and 12 months)

Key secondary outcome(s))
1. The incidence of respiratory tract infections measured using patient report of the total number of infections over 6 months (data collected monthly, at 3, 6 and 12 months)
2. Number of health service contacts measured using patient report over 6 months (data collected monthly, at 3, 6 and 12 months)
3. Number of admissions to hospital in total and for respiratory tract infections using patient report and GP report (data collected monthly, at 3, 6 and 12 months) and medical notes review (12 months)
4. Use of health service resource (to estimate the cost-effectiveness of each intervention) measured by patient report (data collected monthly, at 3, 6 and 12 months) and medical notes review (12 months)
5. Use of antibiotics for respiratory tract infections measured by patient report (data collected monthly, at 3, 6 and 12 months) and medical notes review (12 months)

6. The incidence of COVID-like infections (during winters when COVID is circulating) measured using patient report of the total number of infections over 6 months (data collected monthly and at 6 months)
7. The incidence of confirmed COVID infections measured through patient report as part of normal management (data collected monthly, at 3, 6 and 12 months) and medical notes review (12 months)

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Patients aged ≥18 years with a risk factor:
1.1. Known weakened immune system due to a serious illness or medication (e.g. chemotherapy)
1.2. Known heart disease
1.3. Known asthma or lung disease
1.4. Known diabetes
1.5. Known mild hepatic impairment
1.6. Known stroke or neurological problem
1.7. Obesity (BMI >30)
1.8. Patients with ≥3 episodes of an RTI in the last year
2. Patients aged ≥65
3. Have access to the internet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
13799

Key exclusion criteria
1. Terminal illness/palliative care
2. Living with dementia
3. Living in residential care
4. Pregnancy or breastfeeding
5. Regular use of nasal sprays for respiratory infection control in the last 6 months
6. Allergy to nasal sprays

7. Living in the same household as another participant
8. Previously involved in RECUR programme development work

Date of first enrolment
01/11/2020

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Wessex CRN
Unit 7, Berrywood Business Village
Tollbar Way
Hedge End
Southamton
United Kingdom
SO30 2UN

Study participating centre
NIHR West of England
Whitefriars
Lewins Mead
Bristol
United Kingdom
BS1 2NT

Study participating centre
NIHR Thames Valley and South Midlands
John Radcliffe Hospital
Headley Way
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OX3 9DU

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (PGfAR ref RP-PG-0218-20005)

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

Individual participant data (IPD) sharing plan
At the end of the study anonymous questionnaire data will be deposited in a secure data archive which will be made available to researchers at University of Southampton for secondary data analysis.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/07/2024	16/07/2024	Yes	No
Protocol article		14/07/2023	17/07/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative process evaluation	29/04/2025	01/05/2025	Yes	No

Other publications	Qualitative process evaluation	09/09/2025	11/09/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 8.2	18/09/2023	06/10/2023	No	No
Statistical Analysis Plan	version 2	19/10/2023	14/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes