

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

<b>Submission date</b> 29/09/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/10/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/05/2025	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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?

Dr Jane Vennik

j.vennik@soton.ac.uk

### **Study website**

<https://www.southampton.ac.uk/IDStudy>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

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Scientific

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

288431

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Treatment

### **Participant information sheet**

The participant information sheet is available from the study website (<https://www.southampton.ac.uk/IDStudy>) or by contacting the study team on [IDstudy@soton.ac.uk](mailto:IDstudy@soton.ac.uk)

### **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 measure**

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)

## Secondary outcome measures

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)

## Overall study start date

01/09/2019

## Completion date

31/03/2025

# Eligibility

## Key inclusion criteria

1. Patients aged  $\geq 18$  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  $\geq 3$  episodes of an RTI in the last year
2. Patients aged  $\geq 65$
3. Have access to the internet

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

**Target number of participants**

15,000

**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**

England

United Kingdom

**Study participating centre**

**NIHR Wessex CRN**

Unit 7, Berrywood Business Village  
Tollbar Way  
Hedge End  
Southampton  
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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## **Sponsor information**

**Organisation**  
University of Southampton

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**Sponsor type**  
University/education

**Website**  
<http://www.southampton.ac.uk/>

**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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. The researchers will make the REC-approved protocol available on their trial website.

**Intention to publish date**

01/10/2025

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		14/07/2023	17/07/2023	Yes	No
<a href="#">Protocol file</a>	version 8.2	18/09/2023	06/10/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 2	19/10/2023	14/06/2024	No	No
<a href="#">Results article</a>		11/07/2024	16/07/2024	Yes	No
<a href="#">Other publications</a>	Qualitative process evaluation	29/04/2025	01/05/2025	Yes	No