

COVID-19 Germ Defence: a website to improve infection control during the COVID-19 pandemic

Submission date 12/08/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/12/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Recent research into coronavirus has shown that members of the public can play a crucial role in controlling infection outbreaks in their homes by adopting simple behaviours such as handwashing, cleaning surfaces, wearing of face coverings and social distancing. Despite public health advice, evidence shows most people need to change their behaviour to help prevent infection.

Germ Defence is an interactive website (<https://www.germdefence.org>) which uses behaviour change techniques to supplement public health advice. It was developed during the swine 'flu pandemic using theory, evidence and extensive feedback from members of the public. It was then trialled in over 20,000 patients and shown to reduce the number and severity of infections of users and members of their household. Germ Defence has recently been updated for use in the COVID-19 pandemic. The website helps users with pre-planning about effective isolation of an infected household member; personalised goal setting for increasing a range of infection control behaviours; changing the home environment to support new habits and problem-solving to overcome barriers.

This study will examine the effects of randomising dissemination of the Germ Defence website via GP practices on rates of respiratory infection including COVID-19 and seasonal 'flu.

Who can participate?

The researchers are not looking to recruit individual participants for this study. Instead, they will work with GP practices in England and ask them to promote the Germ Defence intervention to all their patients aged 18 and over.

What does the study involve?

The researchers will contact every GP practice in England and ask them to support this study. This will involve each practice sharing a weblink to Germ Defence website with their adult patients. Half of the practices will be randomly chosen and asked to send out the Germ Defence link to their patients in the Autumn of 2020. These practices will be known as the immediate implementation group or intervention arm. The other half of the practices will be contacted to send out Germ Defence in March 2021. These practices will be known as the delayed implementation group or usual care arm. The researchers will assess usage of the Germ Defence weblink from anonymous data produced by the website. They will then use anonymised NHS

data collected as part of routine care to compare whether infection rates are lower in practices that sent Germ Defence information to their patients immediately compared with rates in those that didn't send the information until later.

What are the possible benefits and risks of participating?

Germ Defence has been designed so that anyone can use and benefit from its information and ideas on how to lower their risk of catching COVID-19. This includes specific techniques for handwashing (when, where and how to wash hands effectively), keeping a safe distance, and not touching the face, as well as information to help people decide if they need to wear face coverings and how to minimise the amount of virus that they are exposed to. The website also provides advice on how people might look after family and friends who are ill whilst still protecting themselves. The researchers are not aware of any risks that might arise from taking part in the study.

Where is the study run from?

The study will be run by the University of Bristol with support from colleagues at the University of Southampton, University of Bath, NIHR Applied Research Collaboration West, NIHR Clinical Research Network West of England and NHS Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group (UK)

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

October 2020 to March 2021

Who is funding the study?

1. UK Research and Innovation (UKRI) (UK)
2. National Institute of Health Research (NIHR) Applied Research Collaboration (ARC West) (UK)
3. NIHR Health Protection Research Unit (HPRU) in Behavioural Science and Evaluation (UK)

Who is the main contact?

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Study website

<https://www.germdefence.org>

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

287978

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 46740, IRAS 287978, UKRI (MRC) MC_PC_19068, UoB 2020-3213

Study information

Scientific Title

Primary care implementation of Germ Defence: a digital behaviour change intervention to improve infection control during the COVID-19 pandemic

Acronym

COVID-19 GDI

Study objectives

Germ Defence implementation will decrease the number of respiratory tract infection diagnoses - including COVID-19 - recorded in primary care.

The Germ Defence digital behaviour change website has already proven effective at reducing the spread of viral infections such as colds and flu (Little et al, 2015). It is possible that Germ Defence could also protect people from other respiratory tract infections and so increase the capability and capacity of the health service to cope with the number of patients using it. However, although the Germ Defence intervention has been updated to be relevant to COVID-19, we have no evidence that it will be effective. By disseminating the intervention randomly via GP practices to patients, we can examine the effects of implementing Germ Defence across primary care for all respiratory tract infections including those with a COVID-19 diagnosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 2/9/2020, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8018; leedswest.rec@hra.nhs.uk), ref: 20/YH/0261

Study design

Single-centre two-arm cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Respiratory tract infections including COVID-19 (SARS-CoV-2 infection)

Interventions

Germ Defence is a digital behavioural change intervention to improve infection control.

The Germ Defence content was developed using theoretical modelling and qualitative research (Yardley et al. 2011), in line with the person-based approach (Yardley et al., 2015), drawing principally on the theory of planned behaviour (Ajzen, 1985), Leventhal's common-sense model of illness (Leventhal, 2016) and protection motivation theory (Rippetoe, 1987). Intervention content, design and structure were optimised iteratively using in-depth qualitative 'think-aloud' interviews with members of the general public in order to ensure the intervention was accessible, credible and motivating for as many people as possible (Yardley et al. 2015). Based on process evaluations of the original randomised controlled trial (Little et al., 2015) and previous public dissemination activities (Ainsworth et al., 2017), Germ Defence has been updated and

streamlined for use since the coronavirus pandemic, including translation into 20 languages (including Traditional and Simple Chinese), and broadening the infection control behaviours that were recommended. The intervention is a single session, designed to be easily accessible with no sign-up or password required, and the consent process placed within the website privacy policy. Data collection is unobtrusive and kept to a minimum to reduce dropout.

Germ Defence seeks to increase users' perceived risk by emphasising the personal and social health consequences of contracting RTIs including COVID-19. These are followed by messages to increase skills and confidence to reduce exposure to the virus. The Germ Defence content is tailored such that a user selects one of four streams that is relevant to the user's situation:

1. To protect themselves generally
2. To protect others if the user was showing symptoms
3. To protect themselves if household member(s) showed symptoms; or
4. To protect a household member who is at high risk

Content is tailored in this way to encourage users to adopt behaviours appropriate to the perceived level and pattern of risk in their household. Clear and detailed advice is then provided for self-isolating, social distancing, disinfecting and/or cleaning, wearing face-coverings, and putting items aside that may have viruses on them such as shopping/packages, to the extent that users feel is appropriate for the perceived risk. These pages also contain ideas and information on how to structure the home and engage in behaviours safely. The website can be accessed for free at <https://www.germdefence.org>.

All GP practices in England will be randomised on a 1:1 basis by the independent Bristol Randomised Trials Collaboration (BRTC) unit. CCGs in England will be divided into blocks according to region, and equal numbers in each block will be randomly allocated to intervention or usual care. The randomisation schedule will be generated in Stata statistical software by a statistician not otherwise involved in the enrolment of general practices into the study. The researchers will ask staff at GP practices randomised to the intervention arm to share the link to Germ Defence with all adult patients registered at their practice during the 4-month trial implementation period and care will otherwise follow current standard management. Patients at GP practices randomised to the usual care arm will receive current standard management for the trial period after which they will be given a link to the Germ Defence intervention by their practices. The outcome data from patients in practices promoting the Germ Defence intervention will be compared with the outcome data of patients in 'usual care' practices as part of this efficient, pragmatic trial.

Intervention Type

Behavioural

Primary outcome measure

Respiratory tract infection diagnoses measured using routine GPES [general practice extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months

Secondary outcome measures

1. Incidence of COVID-19 diagnoses measured using routine GPES [general practice extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months
2. Incidence of COVID-19 symptom presentation measured using routine GPES [general practice extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months
3. Incidence of gastrointestinal infections measured using routine GPES [general practice

extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months

4. Number of primary care consultations measured using routine GPES [general practice extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months

5. Antibiotic usage measured using routine GPES [general practice extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months

6. Hospital admissions measured using routine GPES [general practice extraction service] for pandemic planning and research (COVID-19) data at baseline and 4 months

7. Uptake of GP practices disseminating Germ Defence to their patients measured using website analytics at baseline and 4 months

8. Usage of Germ Defence by individuals granted access to the website by their GP practice measured using website analytics at baseline and 4 months

Overall study start date

30/03/2020

Completion date

10/03/2021

Eligibility

Key inclusion criteria

Current inclusion criteria as of 09/10/2020:

No individual patients will be recruited to this trial. However, all GP practices in England will be asked to support the study by promoting the use of the Germ Defence website to their adult patients either on 14/10/2020 (intervention arm) or on/after 31/01/2021 (usual care arm)

Previous inclusion criteria:

No individual patients will be recruited to this trial. However, all GP practices in England will be asked to support the study by promoting the use of the Germ Defence website to their adult patients either on 01/10/2020 (intervention arm) or after 31/01/2021 (usual care arm)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

All GP practices in England will be asked to support the trial (N = 6822) in some way. However, half will be randomised and allocated to the intervention arm of the trial (n=3292)

Total final enrolment

Key exclusion criteria

1. GP practices outside England
2. Patients under the age of 18 years

Date of first enrolment

01/10/2020

Date of final enrolment

09/03/2021

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

NIHR Clinical Research Network West of England

Whitefriars

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Study participating centre

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Sponsor type

University/education

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ROR

Funder(s)

Funder type

Government

Funder Name

UK Research and Innovation

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

National Institute for Health Research, Applied Research Collaboration West (NIHR ARC West)

Funder Name

NIHR Health Protection Research Unit (HPRU) in Behavioural Science and Evaluation

Results and Publications

Publication and dissemination plan

Findings will be presented at primary care and behaviour change conferences e.g. those of the Society of Academic Primary Care (SAPC), the Royal College of General Practitioners (RCGP) and the UK Society for Behavioural Medicine (UKSBM).

Peer-reviewed journal papers will be produced reporting the results and submitted to high impact journals (e.g. British Journal of Public Health, British Journal of General Practice).

In order to influence policy and inform healthcare practice, the researchers will collaborate with University of Bristol's Policy Bristol team and use their links with NHS England, the Royal College of General Practitioners (RCGP) and Public Health England (PHE) to disseminate their findings.

The researchers will also consider writing blog posts e.g. for GPOnline, Commissioning Elf and The Conversation.

A plain-language summary of the findings will be made available to study participants and members of the public via the Germ Defence website, GP practices and social media.

Intention to publish date

31/10/2022

Individual participant data (IPD) sharing plan

Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the Medical Research Council (MRC) Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. Data requests should be made to the Principal Investigator Dr Jeremy Horwood by emailing germdefence-study@bristol.ac.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/04/2021	12/04/2021	Yes	No
HRA research summary			26/07/2023	No	No
Results article		04/12/2023	05/12/2023	Yes	No