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

Submission date	Recruitment status	[X] Prospectively registered
12/08/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2023	Infections and Infestations	

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?
Dr Melanie Chalder
germdefence-study@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Horwood

ORCID ID
https://orcid.org/0000-0001-7092-4960

Contact details
NIHR ARC West
9th floor Whitefriars
Lewins Mead
Bristol
United Kingdom

BS1 2NT
-
germdefence-study@bristol.ac.uk

Type(s)
Public

Contact name
Dr Melanie Chalder

ORCID ID
https://orcid.org/0000-0003-1964-2815

Contact details
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PR
-
germdefence-study@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
287978

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
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

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)

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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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
459

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
United Kingdom

England

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

Study participating centre
NIHR Clinical Research Network North East and North Cumbria
Regent Point
Regent Farm Road
Gosforth
Newcastle-upon-Tyne
United Kingdom
NE3 3HD

Study participating centre
NIHR Clinical Research Network North West Coast
iC1 Liverpool Science Park
131 Mount Pleasant
Liverpool
United Kingdom
L3 5TF

Study participating centre
NIHR Clinical Research Network Yorkshire & Humber
Unit 1
Calder Close
Calder Park
Wakefield
United Kingdom
WF4 3BA

Study participating centre

NIHR Clinical Research Network Greater Manchester
Citylabs
1.0 Nelson Street
Manchester
United Kingdom
M13 9NQ

Study participating centre
NIHR Clinical Research Network East MIdlands
Knighton Street Outpatients
1st Floor
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
NIHR Clinical Research Network West MIdlands
Birmingham Research Park
Vincent Drive
Birmingham
United Kingdom
B15 2SQ

Study participating centre
NIHR Clinical Research Network Thames Valley and South Midlands
Block 8, Nuffield Orthopaedic Centre
Old Road
Headington
Oxford
United Kingdom
OX3 6HE

Study participating centre
NIHR Clinical Research Network Eastern
20 Rouen Road
Norwich
United Kingdom
NR1 1QQ

Study participating centre

NIHR Clinical Research Network Kent, Surrey and Sussex
Bevendean House
Room BE205
University of Brighton
Falmer
United Kingdom
BN1 9PH

Study participating centre
NIHR Clinical Research Network Wessex
Unit 7
Berrywood Business Village
Tollbar Way
Hedge End
Southampton
United Kingdom
SO30 2UN

Study participating centre
NIHR Clinical Research Network South West Peninsula
Plymouth Science Park
1 Davy Road
Derriford
Plymouth
United Kingdom
PL6 8BX.

Study participating centre
NIHR Clinical Research Network North Thames
170 Tottenham Court Road
London
United Kingdom
W1T 7HA

Study participating centre
NIHR Clinical Research Network South London
16th Floor
BRC Faculty
Guy's Tower
Guy's Hospital
Great Maze Pond

London
United Kingdom
SE1 9RT

Study participating centre
NIHR Clinical Research Network North West London
3rd Floor
Administrative Block South
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HT

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

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

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?
Results article		04/12/2023	05/12/2023	Yes	No
Protocol article		09/04/2021	12/04/2021	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes