ISRCTN17520749 https://doi.org/10.1186/ISRCTN17520749

4S Study - Scores and swabs to self-assess sore throat feasibility study

Submission date	Recruitment status	[_] Prospectively registered
06/01/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/09/2023	Respiratory	

Plain English summary of protocol

Background and study aims
Most sore throats are caused by viruses. Taking antibiotics does not help with viruses and can result in side effects and antibiotic resistance. General practitioners use symptom scores to decide if a sore throat is caused by bacteria. Since the onset of the coronavirus pandemic, people with problems like sore throat are often assessed through telephone or video consultations. However, we do not know how well people are able to assess their own or their child's sore throat. We don't know if it is possible for patients/parents to take swabs of their throats accurately to help establish when antibiotics should be used.
We want to find out if it's possible to run a study to see how well patients can assess features of sore throat and take throat swab/sample tests during a telephone or video consultation.
The results will help us understand whether it is possible for patients to use swab tests or symptom scores at home to help treat sore throats better. This is a small study to find out if a larger study is possible with the ultimate aim to reduce inappropriate antibiotic use.

Who can participate?
Healthy adults (stage 1), adults and children with a sore throat (stage 2).

What does the study involve?
We will firstly work with patients to develop information to help patients perform home throat swab/sampling tests and know what to look for when they have a sore throat. We will then conduct a small study with 40 - 60 adults and children with sore throat. We will collect information about their illness and ask them to collect one or two throat swabs. We will observe patients to see how well they are able to do these procedures and look at laboratory tests of the swabs to check that they picked up what is needed for an accurate test.

What are the possible benefits and risks of participating?
Benefits - By taking part, participants will help us determine if they can adequately assess sore throats at home. This is particularly important for us to know as more healthcare is being delivered remotely particularly during the COVID pandemic. This work could also importantly lead to further work which could potentially reduce unnecessary antibiotic use which is of great importance. The laboratory results that we will obtain from this work will not be used to guide treatment and are purely for research purposes. There will be no direct benefits to patients in

terms of changes to treatment or the clinical care provided.
Risks - Participants will be advised to access usual care. If there is thought to be a Serious Adverse Event as a result of the study, which is not expected, this will be reported to the study team for review. Participants can stop trial procedures at any point.
All participants are free to withdraw at any time from the study without giving reasons and without prejudicing further treatment. If participants do not want their data to be used, we will delete their database records and dispose of biological samples. If the research fellow deems that the participant is unsuitable for study following consent, for example because of ill health or on discovery that any of the exclusion criterias are met the participant will also be withdrawn. Participant consultations will be video-recorded during the study. The videos will also be looked at by researchers at the University of Southampton for analysis. All videos will be collected, managed and stored according to GDPR recommendations. The study team and other researchers at University of Southampton have experience of successfully collecting, storing and managing video-recorded research data for such purposes.

Where is the study run from?
NIHR CRN Wessex (UK)

When is the study starting and how long is it expected to run for?
July 2020 to October2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof Nick Francis, nick.francis@soton.ac.uk

Study website
https://www.southampton.ac.uk/medicine/academic_units/projects/4s.page

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288006

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47589, IRAS 288006

Study information

Scientific Title
4S throat feasibility study – Scores and Swabs to Self-assess Sore throat

Study objectives
It is feasible to conduct studies in participants with sore throat who are at home, to evaluate the diagnostic properties of home assessment of sore throat using clinical scores, and (self) -testing for pathogenic streptococci, and inflammatory markers and other pathogens including COVID-19 using throat swabs and saliva tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/12/2020, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 20/SW/0175

Study design
Observational qualitative

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Acute upper respiratory infections

Interventions
Stage 1:
We will firstly work with up to 30 healthy participants to develop information to help patients do a home assessment and throat swab/saliva tests and know what to look for when they have a sore throat. This part of the study will involve up to 10 adult patients aged > 16, up to 10 young children aged 3 to 5 years and 10 older children aged > 5. We will interview patients or parents of children to help refine the information.
The steps in this stage of the trial are:
• Participant contacts study team via study website or email
• Participant is consented (via Lifeguide)
• Research Fellow contacts to arrange time(s) for video consult. Swabs are sent to the participant by next day delivery once confirmed
• Participant accesses study tools / training material via website and is observed making an assessment by the study
research assistant via video. Participants will be interviewed during this procedure
• Participant is observed and rated taking self swab(s)/saliva sample and sends them back using pre-paid postage

Participants will be interviewed regarding the testing.

Stage 2:
We will then conduct a small study with 40-70 adults and children with sore throat. We will collect information about their illness and ask them to collect throat swabs/saliva sample. We will observe patients to see how well they are able to do these procedures and look at laboratory tests of the swabs to check that they picked up what is needed for an accurate test.

The steps in this part of the trial will be the same as in the first stage except that the patient will have a sore thro developing the materials as in stage 1.

Intervention Type
Other

Primary outcome measure
Feasibility outcome measures:
1. Recruitment rate (recruited participants/month) throughout the study (measured using the Lifeguide database)
2. Data completion rates throughout the study (Lifeguide database)
3. Number of participants able to assess each clinical feature and able to obtain an adequate throat swabs + saliva samples (measured during video call and using FeverPAIN and Centor score)
4. Description of participants, including the proportions with a positive throat swab culture for group A, C and G streptococcus, and demographics (age gender, ethnicity, etc.) (Lifeguide database and laboratory results)
5. Number of participants willing to provide a second throat swab +/- saliva samples for inflammatory marker testing (measured during video call)
6. The distribution of inflammatory marker concentrations by presence/absence of pathogenic streptococci, and by adequacy of swabbing achieved (Laboratory results)

7. The impact of sample storage/transport time on inflammatory marker concentrations (Laboratory results)
8. Views of participating participants/parents on acceptability, barriers and facilitators to assessing clinical features and obtaining home (self-)tests assessed by interview (analysis by noting and recording initial themes and then conducting systematic and detailed open coding using NVivo)
9. Assessment of the quality of participant assessment of features (such as lymph node enlargement and tenderness) and swabbing/saliva tests assessed by interview (analysis by noting and recording initial themes and then conducting systematic and detailed open coding using NVivo)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2020

Completion date
31/10/2021

Eligibility

Key inclusion criteria
1. Sore throat <2 weeks duration (for Stage 2 only; Stage 1 participants are healthy volunteers not required to have an acute sore throat)
2. Fully conversant in the English language
3. Able to communicate easily by video consultation
4. Able and willing (in the investigator's opinion) to comply with all study requirements
5. Informed consent to participate in the trial
6. Adults aged >16 years <= 65 years
7. Parents of children aged 3 - 16 years

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
56

Key exclusion criteria
1. Any significant disease, disorder, or finding which may significantly increase the risk to the volunteer because of participation in the study, affect the ability of the volunteer to participate

in the study or impair interpretation of the study data, for example recent surgery to the pharynx or acute illness which would contraindicate swabbing eg epiglottis
2. Current or recent (within 3 months) involvement in a clinical trial

Date of first enrolment
07/11/2020

Date of final enrolment
14/05/2021

Locations

Countries of recruitment
England

United Kingdom

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

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

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.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.1	11/12/2020	07/01/2021	No	Yes

Participant information sheet	version v4	30/11/2020	07/01/2021	No	Yes
Participant information sheet	version v2	11/12/2020	07/01/2021	No	Yes
Participant information sheet	version v3	09/12/2020	07/01/2021	No	Yes
Participant information sheet	version v3	30/11/2020	07/01/2021	No	Yes
Participant information sheet	version v3	09/12/2020	07/01/2021	No	Yes
Protocol file	version v4	30/11/2020	07/01/2021	No	No
Results article		06/10/2022	05/12/2022	Yes	No
HRA research summary			20/09/2023	No	No