ISRCTN62534664 https://doi.org/10.1186/ISRCTN62534664

RAPIER: Can a new hearing referral pathway reduce the time taken to diagnose and treat hearing problems in military personnel?

Submission date
03/02/2020

Recruitment status
No longer recruiting

Registration date
14/02/2020

Overall study status
Completed

Last Edited
12/12/2023

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is exploring the potential for a change in the way that hearing healthcare is provided for people who work in the military. Due to their jobs, Armed Forces personnel are at much higher risk of hearing injury than the general public and therefore have more frequent tests of their ears and hearing as part of their work. This research will compare how long it takes for patients who have a hearing problem picked up on their routine hearing test to be reviewed, diagnosed and treated through the current pathway or through a new pathway.

Who can participate?
Adults working in the Armed Forces

What does the study involve?
The new pathway will use pictures/video taken of the ears with an automated hearing test performed with a boothless headset, meaning that a soundproof booth is not needed, and complete a questionnaire on a tablet computer. In order to do this people who are due for their routine hearing test will be offered the chance to join the study, if they chose to join they will be randomly allocated to either have their routine test or their routine test plus the new tests as well. The results of the hearing test and pictures will be sent securely to the Queen Elizabeth Hospital Birmingham where they will be reviewed by a team of specialists. The results will be returned electronically to the patient and GP. If a problem is found the patient will be offered an appointment in an optimised clinic the following week with the aim of requiring only a single visit.

What are the possible benefits and risks of participating?
There are minimal risks as all tests are non-invasive and painless. There is also no immediate direct benefit to study participants. Patients in the new model arm may receive their diagnosis and management plan more quickly.

Where is the study run from?
Queen Elizabeth Hospital, Birmingham (UK)

When is the study starting and how long is it expected to run for?
April 2018 to June2024

Who is funding the study?
The Ministry of Defence (UK)

Who is the main contact?
Christopher Coulson, Christopher.coulson@uhb.nhs.uk

Contact information

Type(s)
Principal Investigator

Contact name
Mr Christopher Coulson

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272239

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43759, IRAS 272239

Study information

Scientific Title
Remote Audiometric Performance Innovation Evaluation and Review (RAPIER) study

Acronym

RAPIER

Study objectives
This study is exploring the potential for a change in the way that hearing healthcare is provided for people that work in the military. Due to their jobs Armed Forces personnel are at much higher risk of hearing injury than the general public and therefore have more frequent tests of their ears and hearing as part of their work. We will compare how long it takes for patients that have a hearing problem picked up on their routine hearing test to be reviewed, diagnosed and treated through the current pathway or through a new pathway. The new pathway will use pictures/video taken of the ears with an automated hearing test performed with a boothless headset, meaning that a soundproof booth is not needed, and complete a questionnaire on a tablet computer. In order to do this people that are due for their routine hearing test will be offered the chance to join the study, if they chose to join they will be randomly allocated to either have their routine test or their routine test plus the new tests as well. The results of the hearing test and pictures will be sent securely to the Queen Elizabeth Hospital Birmingham where they will be reviewed by a team of specialists. The results will be returned electronically to the patient and GP. If a problem is found the patient will be offered an appoint in an optimised clinic the following week with the aim of requiring only a single visit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2020, MOD Research Ethics Committee (MODREC Secretariat, Bldg 005, G02 Dstl Porton Down, Salisbury, Wiltshire, SP4 0JQ, UK; +44 (0)1980 956351; MODREC@dstl.gov.uk), ref: 996/MoDREC/2020

Study design
Randomized; Interventional; Design type: Screening, Diagnosis, Prevention, Device, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Hearing injury

Interventions
The population will solely include Defence personnel presenting to primary care for routine occupational hearing screening or due to self-reported problems with their hearing. The

population will be drawn from four fixed locations, one of which will be Reservists, and one special forces.

Intervention: New model of hearing assessment with automated hearing testing, tympanometry, pictures/video of ear drums and structured history questionnaire.

Comparison: Currently occupational hearing screening and secondary care referral system.

Outcomes: Time from presentation to diagnosis and management, proportion of referrals that can be managed remotely (for both routine screening and acute presentations). Measurement of time required to assess and manage referrals via this model to predict resource implications.

This observational study will be run concurrently in four military locations remote to University Hospitals Birmingham. The use of multiple physical locations will increase the number of potential participants in the study, allow qualitative feedback to be collected from a larger number of clinicians and provide a more generalised estimate of effect size than a single location which may have a non-standard population. Service personnel due for routine hearing screening as part of their occupational health programme or presenting complaining of problems with their hearing will be offered the opportunity to join the study. If they consent they will be randomised to either the current hearing referral model or to have their routine assessment plus screening through the RAPIER service. Results will be securely linked back to UHB for review at the military hearing MDT. Following the weekly MDT diagnosis and treatment plan information will be returned to the unit medical officer via the same system. Comparison will be made between pure tone audiometry obtained in their base and audiometric results captured by the RAPEIR service.

Test Measures

In addition to their routine screening protocol participants will receive:

Pure Tone Audiometry, tympanometry and endoscopic examination.
Unaided thresholds will be obtained via the Wireless Automated Hearing Test System (WAHTS) using pure tones up to 8kHz, tympanometry and i-endoscopic examination.

Participant's questionnaires
A standardised history proforma will be used covering details of: age, previous noise exposure, previous ear problems/surgery, otological symptoms such as pain, discharge, tinnitus or balance problems as well as any previous hearing investigations.

All of these tests are non-invasive and non-painful.

Completing the additional tests will take less than 30 minutes and each subject will only complete the test battery once within the study period. The test will be completed in the following order: a) history via structured proforma b) video examination of the ears c) automated hearing test d) tympanometery (pressure testing). This is the most practicable order as this allows a patient to compete the history proforma without the attention of the medical officer or medic prior to clinical examination. Of the clinical tests the ears need to be inspected first to ensure the canals are not blocked with wax (which would falsely alter the results of the other tests) and tympanometry is an objective measure which does not require a patient's active participation so should be performed after the subjective pure tone audiogram.

Data Analysis
Data will be collected on the time taken from screening abnormality to definitive diagnosis, the duration of time held on a temporary grading (if any) and the proportion of referrals that can be dealt with entirely remotely. The distributions of the times within each group will be assessed by visual inspection of Normal Q-Q plots and an independent samples t test will be used for the comparison of the two groups if the data for both groups appear to be approximately Normally distributed and a Mann-Whitney test will be used if they do not.Data will be compared to existing audit data on the Military Hearing Referral Pathway.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Time from presentation to diagnosis and management
2. Proportion of referrals that can be managed remotely (for both routine screening and acute presentations)
3. Time required to assess and manage referrals via this model to predict resource implications
The methods of measurement of these outcome measures cannot be disclosed at this time.

Secondary outcome measures
-

Overall study start date
01/04/2018

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Armed Forces personnel aged over 18 years
2. Written and spoken English of sufficient standard to complete hearing history on a tablet computer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1200; UK Sample Size: 1200

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2020

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
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B15 2TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

Sponsor details
HQ Joint Medical Group
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Royal Centre for Defence Medicine
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97 Vincent Drive
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Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.uk/

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

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
31/01/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study cannot be disclosed at this time.

IPD sharing plan summary
Data sharing statement to be made available at a later date