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Mobile application for the proper use of head and neck diagnostic imaging tests

Submission date	Recruitment status	[_] Prospectively registered
16/09/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/10/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/10/2020	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Although of enormous potential utility, Decision Support Tools (DSTs) connected with computerized medical history systems are still at a very early stage of development. No public system in Spain has these types of tools incorporated into their digital medical records. Mobile Health Applications (e-Health) can also be conceived as a DST, both of an active nature (that is, the professional resorting to them proactively to obtain information at the moment) and of a passive type, since they are capable of being integrated into Corporate Information Systems. Based on the data contained from the medical history, these DSTs would provide information directly and passively, without the need to request it.
On the other hand, despite the enormous amount of scientific information that is generated every day, available in real-time thanks to the internet, clinicians have many difficulties with efficiently accessing the best information filtered by quality and relevance. The need for continuous updating in an extraordinarily changing scientific reality makes mobile applications very useful tools to keep us updated, with quick access in real-time through a device that can accompany us at all times (smartphone, tablet).
The main aim of this study is to demonstrate that the appropriate use of head and neck imaging tests can be improved with an app as a DST.

Who can participate?
Requests made by the doctors of the Puerta del Mar Hospital for head and neck imaging tests in the field of emergencies, outpatient consultations and hospitalization, in a given period of time.

What does the study involve?
After a period of dissemination and learning, the mobile application will be offered to the hospital physicians involved in the study. The percentage of requests for inappropriate diagnostic imaging tests will be analyzed in a period before and another after the implementation of the app.

What are the possible benefits and risks of participating?
The expected benefits are better use of imaging tests, avoiding useless imaging tests and/or recommending the best.

Where is the study run from?
Puerta del Mar University Hospital (Spain)

When is the study starting and how long is it expected to run for?
January 2017 to March 2021

Who is funding the study?
Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (Spain)

Who is the main contact?
Javier Jaén-Olasolo, MD, PhD
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PIN-0365-2016

Study information

Scientific Title
Evaluation of the impact of a mobile application for the proper use of head and neck diagnostic imaging tests

Acronym
HANDIT (Head And Neck Diagnostic Imaging Tests)

Study objectives
A mobile application can improve the proper use of head and neck diagnostic imaging tests leading to decrease variability in medical practice, incorporate evidence-based diagnostic procedures and possibly at lower costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission pending, Research Ethics Committee of Cádiz (Comité de Ética de la Investigación de Cádiz, Office 817. 8ª Floor, Hospital Universitario Puerta del Mar, Ana de Viya, 21,Cádiz, Spain, 11009; +34 (0)956002005; ceic.hpm.sspa@juntadeandalucia.es), ref: N/A

Study design
Comparative study before-and-after the intervention

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Head and neck pathology

Interventions
Use of a mobile application as a decision-making aid tool for head and neck pathology imaging by physicians who request them.

After a period of dissemination and learning, the mobile application will be offered to the hospital physicians involved in the study. The degree of adequacy of requests for imaging tests to the best available scientific evidence will be analyzed in a period prior to and another after the implementation of the APP to compare.

For the analysis, the study consists of a period of 3 months prior to the intervention (use of the app) from June to August 2010 and a second phase after the intervention, from September to December 2020.

Intervention Type
Other

Primary outcome measure
Percentage of requests for inappropriate diagnostic imaging tests, evaluated by clinicians and /or radiologists belonging to the research group. First, a radiologist makes an initial evaluation and then another clinician or radiologist different from the previous one makes a second evaluation, without knowing the previous result. In case of discrepancy, a third party is called in. The degree of suitability of the application is established according to the criteria of the American College of Radiology: a) appropriate, b) may be appropriate or doubtful, c) not appropriate. The application recruitment period is 3 months before and 3 months after the intervention.

Secondary outcome measures
1. Evaluation of the economic impact: the researchers will perform a conservative analysis by minimizing costs, assuming that the effects on health and well-being are identical. They will calculate the economic benefit only in relation to the number of scans avoided or modified, without taking into account the time lost by patients or caregivers or the possible health consequences. Evaluated 3 months after the intervention.
2. Degree of satisfaction and usability by the professionals using the mobile application, measured by a survey and a Likert-type scale with five levels of response: 1) totally disagree, 2) disagree, 3) neither agree nor disagree, 4) agree, 5) totally agree. Measured 3 months after the intervention.

Overall study start date
01/01/2017

Completion date
31/03/2021

Eligibility

Key inclusion criteria
Requests made by the doctors of the Puerta del Mar Hospital for head and neck imaging tests, in the field of emergencies, outpatient consultations and hospitalization

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
364 requests for head and neck imaging tests

Key exclusion criteria

Pathology different to head and neck and/or outside to the field of emergencies, outpatient consultations and hospitalization

Date of first enrolment
01/06/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Spain

Study participating centre
Puerta del Mar University Hospital
Ana de Viya Avenue, 21
Cádiz
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Sponsor information

Organisation
Fundación para la Gestión de la Investigación Biomedica de Cádiz

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Sponsor type
Research organisation

Website
http://www.juntadeandalucia.es/index.html

Funder(s)

Funder type
Government

Funder Name
Council of Andalusian Health Services (Consejería de Salud, Junta de Andalucia) (Spain)

Results and Publications

Publication and dissemination plan
Dissemination of the research results within the clinical and scientific community, through papers published in clinical journals and presentations at conferences. The research team must provide the Andalusian government's Health Department with a final report before the end of 2021. The intention is to publish the results of the study before and, in any case, about 1 year after the overall trial end date.

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The data that will appear in the data collection sheet are the following: diagnostic suspicion, requested test, checklist of signs and symptoms, clinical unit or service requestor and care setting. Personal data will not be recorded. Each patient will be assigned a code, which only the researcher collecting the data will be able to connect with his/her name. Only the researcher will have access to the table where codes and names are linked. This table will be destroyed when the data collection is finished. For other types of data, available upon request, the contact person is the principal investigator of the study: Javier Jaén-Olasolo, MD, PhD (javier.jaen.sspa@juntadeandalucia.es).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			08/10/2020	No	No