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Remotely guided self-performed lung ultrasound for COVID

Submission date
05/09/2022

Recruitment status
No longer recruiting

Registration date
10/09/2022

Overall study status
Completed

Last Edited
09/09/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 pneumonia is disrupting life on the planet earth in an unprecedented fashion. While many if not most people have mild or asymptomatic disease, others, even young previously healthy people, may become rapidly sick with severe hypoxia despite exhibiting minimal symptoms, including shortness of breath (dyspnea). The burden on health care systems may be extraordinary, with even well-developed nations' health care systems being overwhelmed. Health care providers may be particularly susceptible if appropriate infection prevention and control measures are not in place. Thus, solutions need to be sought to provide excellent patient care, but also to protect provider health. COVID-19 is a paradox, as, despite the risk to providers, the majority contracting the virus will not develop COVID-19 pneumonia. Most will have none or minor symptoms and can safely self-isolate at home. However, those who develop severe disease, need to be identified early. Compared to chest x-rays (radiography) and the imaging procedure computed tomography (CT), lung ultrasound (LUS; a procedure that uses high-frequency sound waves to create an image) is a simpler, more portable, economical, and potentially home-based technology that might be used for at-risk patients to self-monitor their lungs for early signs of COVID-19 pneumonia. Findings from COVID-19 pneumonia are typically present in the lung periphery, an anatomic fact that permits LUS to be used to diagnose and manage all phases of care in COVID-19. LUS may detect early disease progression as the lungs worsen from normal to diseased. Through work onboard the International Space Station examining telementored lung ultrasonography (SPTMLUS) self-performed by inexperienced point-of-care users guided by remote experts, we have long known that accurate ultrasound images of the lungs can be self-obtained. What has never been examined, is whether willing but ultrasound-naïve adults can be remotely mentored to obtain meaningful lung ultrasound images upon themselves for lung diseases, such as COVID-19. The purpose of this study was to examine the feasibility and quality of SPTMLUS for novices when expertly guided. Furthermore, this paradigm may be considered a specific example of a broader concept that may contribute to many facets of patient-focused and individualized healthcare.

Who can participate?
Adults self-isolating due to COVID-19 infection

What does the study involve?
A lung ultrasound expert will guide the participants using teleconferencing software to measure their own blood pressure and conduct a standardized lung examination.

What are the possible benefits and risks of participating?
The potential benefits of the study were learning new knowledge including a better understanding of the volunteers' own physiology. The most pertinent risk of participating in anything during strict isolation protocols is being exposed to the agent people were isolated from; in this case the COVID virus. Thus, the ultrasound probe, cell phone, blood pressure cuff, and pulse oximeter were repeatedly sanitized and wrapped in sterile packing and there was no human-to-human contact at any point in the study.

Where is the study run from?
Foothills Medical Centre (Canada)

When is the study starting and how long is it expected to run for?
January 2020 to October 2020

Who is funding the study?
The University of Calgary, The Office of Surgical Research, Department of Surgery (Canada)

Who is the main contact?
Prof Andrew Kirkpatrick (Canada)
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
01

Study information

Scientific Title
Empowering the willing: The feasibility of tele-mentored self-performed pleural ultrasound assessment for the surveillance of lung health

Study objectives
Can ultrasound-naive members of the lay public be remotely guided to obtain interpretable and accurate ultrasound images of their own lungs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/04/2020, Certification of Institutional Ethics Approval, The Conjoint Health Research Ethics Board (CHREB), (University of Calgary, Research Services Office, 2500 University Drive NW, Calgary AB T2N 1N4, Canada; +1 (403) 220-2297; resethic@ucalgary.ca), ref: REB14-0634_MOD4

Study design
Single-centre uncontrolled interventional unmasked study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Early COVID 19 pneumonia

Interventions
After informed consent, participants will complete an electronic demographic survey and receive a package containing a disinfected hand-held high-frequency linear ultrasound probe (Philips Lumify, Philips, Amsterdam, NL), and a package of sterile ultrasound gel. Participants will be directed to watch a brief instructional video on how to hold the probe and where anatomically they would be guided to scan. A lung ultrasound expert will then remotely mentor and guide participants to measure their blood pressure and conduct a standardized lung examination with the hand-held ultrasound device based on the 14-zone method proposed by Soldati for International Standardization of the Use of Lung Ultrasound for Patients with COVID-19.

Images will be optimized through remote control of ultrasound “knobology” by the mentor using remote access software (Teamviwer). The pleural interface will be interrogated with 2D, M-mode, and color-Power Doppler (CPD) modes, and all image acquisition attempts will be video

recorded. The results will be scored in real-time by the mentor using the proposed Soldati method from 0 (normal) to 3 (very abnormal) and the number of B-lines present at each anatomic location will be counted.

Each participant will be asked to complete an online post-test evaluation that includes their perceptions of the difficulty in performing their self-examination including a 5-point Likert scale rating the examination at each location as being one of; 1—Very Hard, 2—Hard, 3—Neutral, 4—Easy, 5—Very Easy.
An a-priori planned independent review will be undertaken by three outside lung ultrasound experts, who will rate both the image quality (as adequate versus inadequate) and the degree of abnormality using the same Soldati scoring protocol.

Intervention Type
Other

Primary outcome(s)
Acquisition of good-quality interpretable images based on the 14-zone method proposed by Soldati for International Standardization of the Use of Lung Ultrasound for Patients with COVID-19 as assessed by the lung ultrasound expert during telementored self-performed lung ultrasound

Key secondary outcome(s))
1. The ability for volunteers to physically reach each anatomic location of a standard recommended COVID lung ultrasound examination as assessed by the lung ultrasound expert during telementored self-performed lung ultrasound
2. Calculated test performance characteristics of standard lung examination protocols recommending a variety of differing anatomic assessment locations measured using the Likert scale generated by the lung ultrasound experts reviewing the telementored self-performed lung ultrasound, and patient self-rated user difficulty scores of a different Likert scale following the examination

Completion date
20/10/2020

Eligibility

Key inclusion criteria
Adults self-isolating according to public health measures for the purpose of reducing person to person transmission of COVID 19

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Total final enrolment
27

Key exclusion criteria
1. Non-English speaking
2. Illiterate
3. Not willing to participate

Date of first enrolment
01/05/2020

Date of final enrolment
20/10/2020

Locations

Countries of recruitment
Canada

Study participating centre
Foothills Medical Centre
1403 29 ST NW
Calgary
Canada
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Sponsor information

Organisation
University of Calgary

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
University/education

Funder Name

University of Calgary, The Office of Surgical Research, Department of Surgery

Alternative Name(s)
UCalgary, University of Calgary in Alberta, The University of Calgary, Normal School, Calgary Normal School, Calgary Branch of the Faculty of Education of the University of Alberta, University of Alberta in Calgary, U of C

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
De-identified participant-level data may be obtained from the Investigators if permitted by Ethical Concerns

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/01/2022	06/09/2022	Yes	No
Participant information sheet	version 12	16/04/2020	09/09/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes