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The Safety And efficacy of digital telereView for the follow-up of patients with abdominal pain: a randomised-controlled trial (RCT) Evaluating the Doctorbell platform (SAVED trial)

Submission date
16/06/2019

Recruitment status
No longer recruiting

Registration date
21/06/2019

Overall study status
Completed

Last Edited
28/05/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Studies on telemedicine suggest that it safely enables cost savings and improves right-siting of patients with diverse illnesses. These reports have fueled a rise in the adoption of these applications in various clinical settings, allowing new models for de-centralized care to alleviate shortages in tertiary hospital resources. The use of telehealth modalities by patients directly for follow-up review of acute ailments has not been definitively examined for clinical effectiveness, particularly in patients with gastrointestinal diseases. The aim of this study is to evaluate the efficacy and safety of digital telereview as a “pull-from-patient” form of service delivery innovation in comparison with existing telephone-based telereview as a “push-to-patient” form of service delivery. This is the first head-to-head comparison of these alternative forms of service delivery for the follow-up of patients with acute abdominal pain.

Who can participate?
Patients with acute abdominal pain admitted to and discharged from the ED observation ward of a tertiary hospital in Singapore

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The control group receive scheduled telephone-based telereview with missed reviews actively coordinated and rescheduled by ED staff three times. Participants in the intervention group have access to an integrated platform for digital telereview, patient-led appointment rescheduling, and automated patient/provider notifications. Service utilisation is measured in terms of patient usage of the follow-up telereview service at 48-72 hours (whether telephone-based or digital telereview).

What are the possible benefits and risks of participating?
Possible benefits include early detection in the event of any persistent illness during follow-up assessment. It may help address anxiety so patients would be less likely to return to the ED for

advice regarding the same medical problem, since they will be able to consult the healthcare worker on-duty from the comfort of their home during telereview. Participants will contribute to medical knowledge about digital consultations. Possible risks include patients missing the follow-up telereview, which occurs in the context of existing practices in the emergency department. Existing practices for missed telereviews are that they are actively and manually rescheduled by ED staff on-duty by phone call for three attempts within the 48 to 72-hour telereview window following discharge. No further attempt is made to contact patients who are not contactable in 72 hours or who decline telereview. There is a potential breach of confidentiality during review of medical records. The study has the added precaution of medical record review only being conducted by staff in the institution who do not have any conflict of interest. No patient medical information is stored on the digital consultation platform, and is instead entered directly into hospital electronic medical record by the attending healthcare worker. There may be inconveniences in connecting to the internet to access the platform and survey, and risks that are currently unforeseeable.

Where is the study run from?
Singapore General Hospital (Singapore)

When is the study starting and how long is it expected to run for?
February 2017 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CIRB Ref no: 2017/2049

Study information

Scientific Title
Pilot prospective randomized controlled trial to assess feasibility of teleconsultation for the follow-up of patients with undifferentiated abdominal pain following discharge from Singapore General Hospital using the DoctorBell platform

Acronym
SAVED

Study objectives
The study hypotheses are that the use of a digital platform is safe and effective for follow-up of patients with abdominal pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/02/2017, centralized Institutional Review Board (CIRB) of the Singapore General Hospital (SGH), (31 Hospital Avenue, #0303, Boyer Block C, S168753, Singapore; Tel: +65 (0) 62250488; Email: irb@singhealth.com.sg), Singhealth CIRB protocol number: 2017/2049

Study design
Single-centre prospective parallel-group randomised-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Acute abdominal pain

Interventions
Study population were patients with acute abdominal pain admitted to the ED observation ward (EOW) of a tertiary hospital in Singapore. Patients were considered for recruitment in this study at the point of discharge from the EOW when study team members were on duty, after the patients had received routine management and disposition plans. This includes counselling for self-efficacy and monitoring at home, as well as advice regarding clinical features and red flags that warrant telereview and/or re-presentation to the ED.

After completion of informed consent, simple randomisation was conducted by a study team member drawing lots from a study box for allocation concealment. The lots in the study box were equal numbers of sheets of paper replenished after each draw, indicating either control (c) or intervention (i) study arm, that were maintained by a study team member SY not involved in clinical care and the implementation of the randomisation. Study team members recruiting patients provided participants with links to web-based surveys about symptoms at initial presentation and follow-up, to be reported by patients directly following recruitment and following telereview, respectively.

Follow-up telereview is routinely conducted in this population by the ED staff on-duty. This is done to facilitate early right siting of these patients through prompt identification of deteriorating patients as well as to encourage self-efficacy in anxious-well patients that do not require re-presentation. In this study, patients in the control arm received routine scheduled telephone-based telereview within 48-72 hours following discharge from the EOW. Telereview was then conducted by the ED staff on-shift at the time of the patient's booked appointment, with communication subsequently documented in the patient's electronic medical record. Any missed telereviews were actively and manually rescheduled by ED staff on-duty by phone call for three attempts within the 48 to 72-hour window following discharge. No further attempt was made to contact patients who were not contactable in 72 hours or declined telereview.

Patients in the intervention arm instead had access to the novel telehealth platform, DoctorBell. This web-based platform allowed patient-led booking of one digital telereview along with rescheduling or cancellation based on their individual availability, within a restricted 48 to 72-hour window following discharge from the ED. Digital telereviews through this platform were patient-led, and were not actively followed-up to be rescheduled by ED staff. Additionally, the ED staff on-duty was able to view the bookings rostered during their shift when they started work, and received automated real-time notifications of any changes made to appointment bookings by patients in the digital platform. Before the telereview appointment, patients first received an in-application form that allowed them to start reporting key history or symptoms

that they had. This information was then available to the ED staff on-duty before they began the web-based teleconsultation with the patient, giving staff an opportunity to clarify uncertainties with the ED consultant on-duty before beginning teleconsultation with the patient.

Initially service utilisation and safety were the only outcome measures studied. However, study team members observed that while they needed to instruct some patients to re-present during telereview, not all patients complied with these instructions. Therefore, efficacy in terms of patient compliance to final disposition plan was added as an outcome measure for analysis after trial initiation, using existing available data collected during the study and with no change to study procedures.

Intervention Type
Other

Primary outcome measure
Service utilisation measured in terms of patient usage of follow-up telereview service at 48-72 hours (whether telephone-based or digital telereview)

Secondary outcome measures
1. Safety measured in terms of re-presentation to the emergency department within 72 hours and within 2 weeks
2. Efficacy measured in terms of patient compliance to the final disposition plan. For patients who did not receive telereview, final disposition plan was that given at the point of discharge from the ED i.e. self-management and monitoring at home (that was accompanied by routine education regarding red flags that should prompt telereview and/or re-presentation). For patients who received telereview, final disposition plan was that given after telereview i.e. whether to continue self-management at home or re-present at the ED. Measured at 2 weeks.

Overall study start date
20/02/2017

Completion date
12/12/2018

Eligibility

Key inclusion criteria
1. Patients with acute abdominal pain admitted to the ED observation ward (EOW) of a tertiary hospital in Singapore
2. Ability to read in English and operate messaging telephone applications such as WhatsApp

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160

Total final enrolment
70

Key exclusion criteria
1. Below 21 years of age
2. Pregnant
3. Prisoners
4. Cognitively impaired

Date of first enrolment
01/08/2017

Date of final enrolment
28/05/2018

Locations

Countries of recruitment
Singapore

Study participating centre
Singapore General Hospital
1 Hospital Drive
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
https://www.sgh.com.sg/

ROR
https://ror.org/036j6sg82

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication in a peer-reviewed journal and dissemination through research presentations at scientific conferences.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
This data is not made available due to a lack of participant consent for data sharing and will be held by the Singapore General Hospital in accordance with Singapore law.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/06/2020	28/05/2020	Yes	No