PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Can a smartphone-delivered tool facilitate the assessment of surgical site infection and result in earlier treatment? Tracking Wound Infection with Smartphone Technology (TWIST): protocol for a randomized-controlled trial in emergency surgery patients.
AUTHORS	McLean, Kenneth; Mountain, Katie; Shaw, Catherine; Drake, Thomas; Ots, Riinu; Knight, Stephen; Fairfield, Cameron; Sgrò, Alessandro; Skipworth, Richard; Wigmore, Stephen; Potter, Mark; Harrison, Ewen

VERSION 1 – REVIEW

REVIEWER	Alberto Piaggesi Diabetic Foot Section Department of Medicine Azienda Ospedaliero-Universitaria Pisana
REVIEW RETURNED	20-Feb-2019

GENERAL COMMENTS	The study protocol presented here is on the possibility of using a smartphone-delivered tool to early diagnosing surgical site infections. The protocol is clear-written, concise and informative and the idea is original and useful, joining telemedicine and patient-empowerment in the prevention of a common complication of surgical interventions.

REVIEWER	Heather Evans Medical University of South Carolina, USA
REVIEW RETURNED	25-Feb-2019

GENERAL COMMENTS	I have some concern that all subjects will not have in-person followup. For this subgroup, Is the diagnosis of SSI dependent upon patient report without photographs in the control group? Are wound cultures to be included in the diagnostic strategy? Have you done any pilot work using the study app? Missing several key references - this is not the first RCT of a mobile health app to evaluate wounds after surgery: 1. Armstrong KA, Coyte PC, Bhatia RS, Semple JL. The effect of mobile app home monitoring on number of in-person visits following ambulatory surgery: protocol for a randomized controlled trial. JMIR Res Protoc. 2015;4(2):e65. doi:10.2196/resprot.4352. 2. Armstrong KA, Coyte PC, Brown M, Beber B, Semple JL. Effect of Home Monitoring via Mobile App on the Number of In-Person Visits Following Ambulatory Surgery: A Randomized

Clinical Trial. JAMA Surg. 2017;152(7):622-627. doi:10.1001/jamasurg.2017.0111.
3. Fernandes-Taylor S, Gunter RL, Bennett KM, et al. Feasibility of Implementing a Patient-Centered Postoperative Wound Monitoring Program Using Smartphone Images: A Pilot Protocol. JMIR Res Protoc. 2017;6(2):e26. doi:10.2196/resprot.6819.
4. Gunter RL, Chouinard S, Fernandes-Taylor S, et al. Current Use of Telemedicine for Post-Discharge Surgical Care: A Systematic Review. J Am Coll Surg. 2016;222(5):915-927. doi:10.1016/j.jamcollsurg.2016.01.062.
5. Broman KK, Gaskill CE, Faqih A, et al. Evaluation of Wound Photography for Remote Postoperative Assessment of Surgical Site Infections. JAMA Surg. October 2018. doi:10.1001/jamasurg.2018.3861.

REVIEWER	Sadanori Akita Fukuoka Univrersity
REVIEW RETURNED	07-Apr-2019

GENERAL COMMENTS	McLean KA, Mountain KE, Shaw CA, Drake TM, Ots R, Knight SR, Fairfield CJ, Sgrò A, Skipworth RJE, Wigmore SJ, Potter M and Harrison EM reported a manuscript entitled, “Can a smartphone-delivered tool facilitate the assessment of surgical site infection and result in earlier treatment? Tracking Wound Infection with Smartphone Technology (TWIST): a randomized-controlled trial in emergency surgery patients.” To British Medical Journal, BMJ, OPEN. The authors tried to set this clinical trial as a single-blinded (evaluator-blinded) randomized clinical trial if a smartphone-delivered questionnaires and pictures can affect the time-to-diagnosis, TTD, of surgical site infection, SSI or measurements of services by medical experts as secondary outcome. As this may be very intrigued attempts in patient-care post-operatively, however, current format contains few new information in methodology, future outcome and integrity by those. First, how would the authors hypothesize the actual SSI occur? Will it occur by more careful patient-or physician- intervention by observing, answering the questionnaires? The picture quality including angle, magnification and background lighting and contrast should be standardized and formatted in certain settings otherwise picture information may mask and deteriorate. Other than pictures, it may be replaced with telephone or face-to-face questionnaires and the authors are requested to prove why a smartphone is actually superior to a conventional method.

REVIEWER	Boonying Siribumrungwong Division of Vascular and Endovascular Surgery, Department of Surgery, Faculty of Medicine, Thammasat University Hospital, Thammasat University, Thailand
REVIEW RETURNED	13-Jun-2019

GENERAL COMMENTS	This is the randomised controlled trial with aim to determine the efficacy of smartphone delivered tool to detect SSI. The primary outcome was time to SSI diagnosis. Here is my concern and comments to improve the study. Abstract □ Usually all abbreviations should be specified before using them in the text (i.e. UK page 3 line 17, A&E and GP page 3 line 41). □ Page 3, Line 45-46 --- > analysis of time-to-diagnosis will be by comparison of means using a Mann-Whitney U-test o For continuous data with normal distribution, mean and standard deviation are used to summarise the data and be compared between groups by independent t test. o For continuous data with non-normal distribution, median and range or interquartile range are used to summarise the data and be compared between groups by Mann-Whitney U-test Methods and analysis Overview □ The author will include all patients who have undergone emergency abdominal surgery. This mean that all types of surgery will be included ranging from simple appendicitis to generalized peritonitis with feculent contamination. Degree of contamination and type of operation have different rate of postoperative SSI and may or may not affect to time of occurrence of SSI which is the primary outcome of interest and thus may be one of confounder if this is not balanced by randomisation process. The author should take this into account whether to use stratified randomisation or find some references that degree of contamination, and type of operation (e.g. appendectomy, colectomy, cholecystectomy,…) do not affect to the time of occurrence of SSI. Recruitment □ Recruitment process should be specified whether it will be done pre-operatively or post-operatively on what day. Pre-operative recruitment in the emergency setting when the patients are suffering from the disease is not necessary in this study. Information process and consent form after the operation is better. Randomisation and blinding □ The randomisation sequence generation will be done using computer-generated. The author should be more clearly specify whether stratification or block randomisation will be applied or not and why? □ The author did not clearly mention about how to deliver the sequence to the patient (allocation concealment process). Who will be responsible for open the randomisation code and when (immediately after recruitment or before discharge)? This process is important to ensure the quality of randomisation process and prevent selection bias. □ Page 11, Line 15-16 -- > the clinician undertaking follow-up will be blinded to the status? Is the blinding process be applied at every follow up or just at 30 day follow up. Intervention

	□ Page 11, Line 47 -- > The patient will have access to the tool on discharge o From different type of operation, the discharge date will be different ranging from postoperative day 2-3 after appendectomy to 1 to 2 weeks after operation especially after operation in peritonitis with sepsis case. □ What will the author do in case which SSI occur during hospitalization? Responses □ Page 12, Line 34-35 -- > an experienced clinician will review all participants' response; line 55-56 -- > The wound photographs will also be reviewed by the clinical researcher o Who is experienced clinician and who is clinical researcher? Are they the same person or not? If not, what is the different between them and the purpose of having two assessors? Please clarify. □ One of the objective of this study (page 8, line 8-9) is to investigate whether the tool can be used to diagnose wound infection or not. o In my understanding after reading the protocol, the gold standard diagnostic tool to compare is from blinded clinicians at 30 day follow up. However, the author did not mention the criteria to diagnosis wound infection (SSI) by the smartphone tool 1) criteria to classify the patient into no concern vs. medium vs. high risk and 2) when to consider wound infection diagnosed by the tool? (just only high risk or medium + high risk to be SSI diagnosed by smartphone tool) Algorithm □ The protocol will give more knowledge to the reader if the author provide more detail and explanation about the algorithm (what is it?, how to get?, what is the different between algorithm and clinician judging using criteria and …) Wound reviews □ The author should specify more clearly about how to obtain wound swab (do the practitioner need to open the wound before swab or just swab the discharge from the wound) □ In case that the patient does not go to seek medical attention according to the recommendation. What should the author do? Outcome measures □ Page 15, line 13-14; time to diagnosis will be compared using Cox proportional hazard regression analysis. In my understanding the primary outcome is time-to-diagnosis which should use t test or Mann-Whitney U-test as the author describe in the abstract. Cox-proportional hazard regression analysis is appropriated for comparison of time-to-event data and not be appropriated in this study. □ Page 15, line 39-40; for secondary outcome that include GP and A&E attendance. I recommend collecting data about unnecessary attendance between groups and compare between the groups (in introduction part that the author state that the tool may reduce work load of healthcare practitioner) o Like medium and high risk of SSI diagnosed by smartphone and go to seek medical attention but no SSI as diagnose at 30 day follow up = unnecessary attendance in the intervention group. o GP and A&E attendance with diagnose of SSI in control group = unnecessary attendance in the control group. □ Page 15, line 50-51; Can the author clearly specify the questionnaires to the protocol?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 (Alberto Piaggesi)

- The study protocol presented here is on the possibility of using a smartphone-delivered tool to early diagnosing surgical site infections.
- The protocol is clear-written, concise and informative and the idea is original and useful, joining telemedicine and patient-empowerment in the prevention of a common complication of surgical interventions.

- We would like to thank Professor Piaggesi for his review and his kind comments.

Reviewer 2 (Heather Evans)

- I have some concern that all subjects will not have in-person follow-up. For this subgroup, Is the diagnosis of SSI dependent upon patient report without photographs in the control group?

- Many thanks for this question. SSI in the control group is detected by 3 methods. 1. Each patient has a wound log which is completed by healthcare personnel during the 30 day follow up period. For instance, if the patient attends the GP with a question about their wound, the GP completes the wound log and it is sent to the trial team. 2. Hospital records. The electronic patient record is queried for any attendance in the 30 day period for wound review. 3. The patient is interviewed by telephone at 30 days post surgery by blinded individuals and answers questions relating to their wound in the post surgery period. We believe that the combination of these 3 measures is robust. Reviewing the patient in person at 30 days would not add anything unless the patient had an active wound infection at that time, which they had not reported symptoms of by telephone. We have clarified this in the text.

- Are wound cultures to be included in the diagnostic strategy?

- Wound swabs are part of standard post-operative care when there is a suspicion of an SSI. Wound swab results retrieved from the electronic patient record are incorporated into the gold standard diagnosis of SSI as per the CDC SSI diagnostic criteria. We have made this aspect more explicit within the protocol.

- Have you done any pilot work using the study app?

- An internal pilot study in the first 80 patients recruited was performed to ensure the trial design and app were practical and deliverable. This is described in the methods and analysis section. This was included to allow adaption of the trial design in response to the pilot study findings.

- Missing several key references - this is not the first RCT of a mobile health app to evaluate wounds after surgery:

1. Armstrong KA, Coyte PC, Bhatia RS, Semple JL. The effect of mobile app home monitoring on number of in-person visits following ambulatory surgery: protocol for a randomized controlled trial. JMIR Res Protoc. 2015;4(2):e65. doi:10.2196/resprot.4352.
2. Armstrong KA, Coyte PC, Brown M, Beber B, Semple JL. Effect of Home Monitoring via Mobile App on the Number of In-Person Visits Following Ambulatory Surgery: A Randomized Clinical Trial. JAMA Surg. 2017;152(7):622-627. doi:10.1001/jamasurg.2017.0111.
3. Fernandes-Taylor S, Gunter RL, Bennett KM, et al. Feasibility of Implementing a Patient-Centered Postoperative Wound Monitoring Program Using Smartphone Images: A Pilot Protocol. JMIR Res Protoc. 2017;6(2):e26. doi:10.2196/resprot.6819.
4. Gunter RL, Chouinard S, Fernandes-Taylor S, et al. Current Use of Telemedicine for Post-Discharge Surgical Care: A Systematic Review. J Am Coll Surg. 2016;222(5):915-927. doi:10.1016/j.jamcollsurg.2016.01.062.

5. Broman KK, Gaskill CE, Faqih A, et al. Evaluation of Wound Photography for Remote Postoperative Assessment of Surgical Site Infections. JAMA Surg. October 2018. doi:10.1001/jamasurg.2018.3861.

- Thank you for highlighting these studies, and we agree this study is certainly not the first RCT of a mobile health app to evaluate wounds after surgery.
- However, as we outline in our strengths and limitations section as far as we are aware this study does represent the first randomised controlled trial on the use of a smartphone-delivered wound assessment tool to facilitate the assessment of surgical site infection and the impact on time-to-diagnosis. The trial by Armstrong et al. focussed on in-person follow-up visits as the primary outcome, and we agree provides important evidence to support the use of telemedicine follow-up in postoperative care. We read the protocol by Fernandes-Taylor et al. with interest, and while this is directly relevant to the TWIST trial we note this is focussed on the feasibility of the method rather than on the utility in practice. We look forward to comparing the results of the trial to TWIST. Overall, we agree that these studies provide an important context to the TWIST trial, and so have included within the introduction of this protocol and look forward to discussing in more detail within the final paper.

Reviewer 3 (Sadanori Akita)

- The authors tried to set this clinical trial as a single-blinded (evaluator-blinded) randomized clinical trial if a smartphone-delivered questionnaires and pictures can affect the time-to-diagnosis, TTD, of surgical site infection, SSI or measurements of services by medical experts as secondary outcome.
- As this may be very intrigued attempts in patient-care post-operatively, however, current format contains few new information in methodology, future outcome and integrity by those.

- First, how would the authors hypothesize the actual SSI occur? Will it occur by more careful patient-or physician- intervention by observing, answering the questionnaires?
- Diagnosis of SSI will occur based on the CDC criteria during clinical assessment in primary or secondary care, however the smartphone tool will risk stratify patients by assessment of their responses and photographs by a senior clinician. A potential consequence could be that “overdiagnosis” of SSI could occur (in terms of increased identification of superficial SSI which would likely otherwise self-resolve). Nevertheless, we believe this would be an improvement over standard care (which could be viewed as “underdiagnosing” SSI rates), given this would allow follow-up and/or treatment of these SSI if appropriate. It is hypothesised this could reduce the rate of more severe SSI developing. We have mentioned this important point in the safety sub-section of Ethics and dissemination.

- The picture quality including angle, magnification and background lighting and contrast should be standardized and formatted in certain settings otherwise picture information may mask and deteriorate.
- We agree these are important factors to be considered, and as such all patients are provided with basic guidance at the time of recruitment. However, this is intended to be a pragmatic trial to determine utility of these smartphone tools in routine practice as it is unlikely that stringent photographic requirements could be maintained out with the context of research. If the photograph does not yield clinically assessable views the clinician response can be based on the patient questionnaire alone (both the photograph and questionnaire are assessed independently) or the patient could be contacted with specific advice to improve the clinical utility of the photograph.

- Other than pictures, it may be replaced with telephone or face-to-face questionnaires and the authors are requested to prove why a smartphone is actually superior to a conventional method.
- This is a superiority randomised-controlled trial, using a parallel two-arm design, of standard postoperative care vs the addition of smartphone follow-up. Telephone or face-to-face questionnaires

are more routine within research on the topic of SSI (with substantial literature available). However, this is a time and resource intensive process and so is generally thought to be unsuitable for implementation within routine clinical practice. A smartphone tool also empowers patients to identify when they have concerns with their wound, rather than limited to scheduled telephone or face-to-face questionnaires. Following the outcome of this trial, further work could compare more directly alternate methods of delivery of the questionnaire.

Reviewer 4 (Boonying Siribumrungwong)
This is the randomised controlled trial with aim to determine the efficacy of smartphone delivered tool to detect SSI. The primary outcome was time to SSI diagnosis. Here is my concern and comments to improve the study.

Abstract
• Usually all abbreviations should be specified before using them in the text (i.e. UK page 3 line 17, A&E and GP page 3 line 41).
- This is an oversight on our part and we agree in that these abbreviations may not be apparent, particularly outside of the UK. Therefore, we have specified these abbreviations within the abstract and have ensured this has been done in all cases the first time such abbreviations occur throughout the manuscript.

• Page 3, Line 45-46 --- > analysis of time-to-diagnosis will be by comparison of means using a Mann-Whitney U-test o For continuous data with normal distribution, mean and standard deviation are used to summarise the data and be compared between groups by independent t test. o For continuous data with non-normal distribution, median and range or interquartile range are used to summarise the data and be compared between groups by Mann-Whitney U-test Methods and analysis
- Thank you for highlighting - this now reads “Analysis of time-to-diagnosis will be by comparison of means using an independent 2 sample t-test”.

• The author will include all patients who have undergone emergency abdominal surgery. This mean that all types of surgery will be included ranging from simple appendicitis to generalized peritonitis with feculent contamination. Degree of contamination and type of operation have different rate of postoperative SSI and may or may not affect to time of occurrence of SSI which is the primary outcome of interest and thus may be one of confounder if this is not balanced by randomisation process. The author should take this into account whether to use stratified randomisation or find some references that degree of contamination, and type of operation (e.g. appendectomy, colectomy, cholecystectomy,…) do not affect to the time of occurrence of SSI.
- This is an important point and agree that the SSI rates will likely differ with degree of contamination and type of operation. Stratified randomisation could provide a solution to balance these variables, and this was discussed within the trial management group during the design stage. However, given the patients in TWIST are enrolled one at a time on a continuous basis (with the first routine smartphone follow-up starting at day 3), we did not feel this would be practical in this context. The differences between control and intervention groups were reviewed at the end of the pilot study and demonstrated no significant differences between these on those variables.

• Recruitment process should be specified whether it will be done pre-operatively or post-operatively on what day. Pre-operative recruitment in the emergency setting when the patients are suffering from the disease is not necessary in this study. Information process and consent form after the operation is better.
- Thank you for highlighting, we can confirm that patients are recruited following surgery. This is clarified.

• The randomisation sequence generation will be done using computer-generated. The author should be more clearly specify whether stratification or block randomisation will be applied or not and why?
- As highlighted above, we did not feel that stratified / block randomisation would be appropriate in the context of the TWIST trial and this has now been made explicit within the protocol.

• The author did not clearly ment o From different type of operation, the discharge date will be different ranging from postoperative day 2-3 after appendectomy to 1 to 2 weeks after operation especially after operation in peritonitis with sepsis case. □ What will the author do in case which SSI occur during hospitalization?
- We agree that particularly in the case of emergency surgery, patients may be an inpatient during the time that routine smartphone follow-up begins. For SSI that occur as an inpatient, patients are encouraged to highlight any wound concerns to their clinical team in the first instance but to also complete the questionnaire. SSI diagnosed as an inpatient from the time of surgery will be noted in the TWIST analysis.

• Responses □ Page 12, Line 34-35 -- > an experienced clinician will review all participants' response; line 55-56 -- > The wound photographs will also be reviewed by the clinical researcher o Who is experienced clinician and who is clinical researcher? Are they the same person or not? If not, what is the different between them and the purpose of having two assessors? Please clarify.
- Thank you for highlighting this point – we can confirm that the experienced clinician and clinical researcher referred to in the "Responses" section refer to the same assessor and we have now standardised the terminology within the protocol to remove ambiguity. An experienced clinician would be considered as a surgical registrar or consultant (all reviews to date have been conducted by Professor Harrison, a consultant surgeon). However, the clinical researcher conducting "30 Day Follow-up" is a separate clinician who is blinded to intervention status (has no involvement in recruitment or reviewing questionnaires submitted by patients in the intervention arm). These points have been made explicit within the protocol.

• One of the objective of this study (page 8, line 8-9) is to investigate whether the tool can be used to diagnose wound infection or not. In my understanding after reading the protocol, the gold standard diagnostic tool to compare is from blinded clinicians at 30 day follow up. However, the author did not mention the criteria to diagnosis wound infection (SSI) by the smartphone tool 1) criteria to classify the patient into no concern vs. medium vs. high risk and 2) when to consider wound infection diagnosed by the tool? (just only high risk or medium + high risk to be SSI diagnosed by smartphone tool)
- Apologies for the lack of clarity regarding this – to confirm the smartphone tool is intended to stratify risk of SSI and facilitate assessment (with the aim of reducing time-to-diagnosis of SSI). Therefore, at this stage it is not intended as a diagnostic tool (although the diagnostic accuracy will be compared to in person assessment conducted in primary and secondary care). As such we have amended the sentence to "This randomised-controlled trial will investigate whether a smartphone-delivered wound assessment tool can be used to in the diagnosis of SSI and result in earlier treatment" better reflect this and other statements of the aim within the protocol.

• Algorithm: The protocol will give more knowledge to the reader if the author provide more detail and explanation about the algorithm (what is it?, how to get?, what is the different between algorithm and clinician judging using criteria and …)
- While the algorithm will have no impact on patient care within the TWIST trial, this is a prespecified sub-study we will conduct to compare agreement between the algorithm and clinician responses to the smartphone questionnaires in TWIST. We agree this will be of interest and have now amended Table 1 to include the scoring system used in the algorithm.

• The author should specify more clearly about how to obtain wound swab (do the practitioner need to open the wound before swab or just swab the discharge from the wound).
- Wound swabs can be of any discharge or the wound bed (this would then include swabs taken in both hospital and community settings where wounds would not be routinely opened by general practitioners). We have made this explicit within the protocol.

• In case that the patient does not go to seek medical attention according to the recommendation. What should the author do?
- All patients will be made aware at recruitment of the risks of SSI and potential benefit of early diagnosis and treatment, and that the clinician response reflects advice from a senior surgeon based on the information they provided. All patients will be made aware the aim of the study is to investigate the utility of the smartphone tool in addition to standard postoperative care. Therefore, patients in the intervention arm can make an informed decision to not follow the advice provided. There is no specific follow-up of patients in the intervention arm within the study beyond on days 3, 7, 15, and 30.

• Outcome measures Page 15, line 13-14; time to diagnosis will be compared using Cox proportional hazard regression analysis. In my understanding the primary outcome is time-todiagnosis which should use t test or Mann-Whitney U-test as the author describe in the abstract. Cox-proportional hazard regression analysis is appropriated for comparison of time-to-event data and not be appropriated in this study.
- Apologies for the lack of clarity on this point (this has been made more explicit within the protocol) – while the primary outcome is mean time-to-diagnosis of SSI, we will also seek to do a time-to-diagnosis analysis between the two arms (with diagnosis of SSI as the event).

• Page 15, line 39-40; for secondary outcome that include GP and A&E attendance. I recommend collecting data about unnecessary attendance between groups and compare between the groups (in introduction part that the author state that the tool may reduce work load of healthcare practitioner) o Like medium and high risk of SSI diagnosed by smartphone and go to seek medical attention but no SSI as diagnose at 30 day follow up = unnecessary attendance in the intervention group. o GP and A&E attendance with diagnose of SSI in control group = unnecessary attendance in the control group.
- We agree this is an important aspect of data to collect and within the “Wound Reviews” section we outline that patients are provided with wound logs to record the results of any wound reviews conducted in the community. These will be reviewed alongside electronic records from hospital attendances to determine whether or not an SSI was diagnosed at these attendances – this has been made more explicit within this section.

• Page 15, line 50-51; Can the author clearly specify the questionnaires to the protocol?
- We have now included an additional table 2 with the 30-day patient experience questionnaire clearly outlined (in addition to Table 1 containing the wound assessment tool).

VERSION 2 – REVIEW

REVIEWER	Sadanori Akita Fukuoka University, Japan
REVIEW RETURNED	28-Jul-2019

GENERAL COMMENTS	McLean KA, Mountain KE, Shaw CA, Drake TM, Ots R, Knight SR, Fairfield CJ, Sgrò A, Skipworth RJE, Wigmore SJ, Potter M and Harrison EM reported a manuscript entitled, "Can a smartphone-delivered tool facilitate the assessment of surgical site infection and result in earlier treatment? Tracking Wound Infection with Smartphone Technology (TWIST): protocol for a randomized-controlled trial in emergency surgery patients." to British Medical Journal, BMJ, OPEN. Smartphone-delivered questionnaire and independent algorism scoring systems are highly concerned in this study. There are several patients' subjective responses such as "pain", "burning sensation" and "fever" last 24 hours and their symptoms are to be compared between smartphone-delivery and a face-to-face with a physician otherwise the whole system may be threatened and cannot be validated.

REVIEWER	Boonying Siribumrungwong Division of Vascular and Endovascular Surgery, Department of Surgery, Thammasat University Hospital, Thammasat University
REVIEW RETURNED	26-Jul-2019

GENERAL COMMENTS	The author had clearly addressed all of my comments. Wish the study will be success.

VERSION 2 – AUTHOR RESPONSE

Reviewer 4 (Boonying Siribumrungwong)

- The author had clearly addressed all of my comments. Wish the study will be success.
- We would like to thank Dr Siribumrungwong for his review and kind words. We are glad that we have been able to address his comments adequately, and certainly feel these allowed us to make important improvements to the manuscript.

Reviewer 3 (Sadanori Akita)

- Smartphone-delivered questionnaire and independent algorism scoring systems are highly concerned in this study. There are several patients' subjective responses such as "pain", "burning sensation" and "fever" last 24 hours and their symptoms are to be compared between smartphone-delivery and a face-to-face with a physician otherwise the whole system may be threatened and cannot be validated.
- Many thanks for highlighting this important point. To clarify, we are assessing the accuracy of patients' subjective responses in diagnosing surgical site infection. As highlighted the "Action from Response" subsection, patients who report such symptoms via the smartphone app will be

assessed in person by a physician (e.g. "symptoms consistent with wound infection will be directed for further assessment"). This will be either in the community or hospital context depending on the assessment by the responding clinician. Therefore, we do seek to validate the proposed smart-phone delivered patient-reported outcomes with physician assessment.

VERSION 3 – REVIEW

REVIEWER	Sadanori Akita Fukuoka University
REVIEW RETURNED	16-Aug-2019

GENERAL COMMENTS	McLean KA, Mountain KE, Shaw CA, Drake TM, Ots R, Knight SR, Fairfield CJ, Sgrò A, Skipworth RJE, Wigmore SJ, Potter M and Harrison EM reported a manuscript entitled, “Can a smartphone-delivered tool facilitate the assessment of surgical site infection and result in earlier treatment? Tracking Wound Infection with Smartphone Technology (TWIST): protocol for a randomized-controlled trial in emergency surgery patients.” to British Medical Journal, BMJ, OPEN. The authors and the responsible persons of the study are requested to clarify the ownership of the data and validation of the security of the data via Smartphone-delivered questionnaire and subsequent outcome.

VERSION 3 – AUTHOR RESPONSE

Reviewer 3 (Sadanori Akita)

- The authors and the responsible persons of the study are requested to clarify the ownership of the data and validation of the security of the data via Smartphone-delivered questionnaire and subsequent outcome.

Data security is an important point in this trial given participants are completing follow-up using their personal smartphone devices, and this was reviewed in full in the context of our ethical approval. The security of the REDCap platform is explained within our "Data Protection and Management" subsection of methods.

However, to outline in full for the purposes of review, REDCap is run by the Surgical and Perioperative Health Research (SPHeRe), University of Edinburgh under licence from Vanderbilt University. REDCap was developed specifically around HIPAA-Security guidelines. It is hosted within the University of Edinburgh Virtual Machine architecture which is physically secured. Linux web servers running apache2/php5host the application. Web browser communication to the server is SSL-encrypted by default. All other ports are firewall protected. Data is stored in MySQL databases on a separate server. This server is behind a firewall and can only be accessed from the IP address of the

web server. An SSL tunnel encrypts communication between the web and databases servers. File upload is secured between servers using the WebDAV protocol with SSL. "At rest" encryption is in place on the database server. Daily back-ups are made of both servers and stored for two weeks prior to being deleted. Operating security updates are installed automatically. Antivirus software runs to a scheduled protocol on the web server. User passwords are managed directly. Accounts are disabled after 5 failed login attempts. Users are auto logged out after 30 mins of no activity. Users are forced to change password after 90 days.

Regarding ownership of the data, the patients specifically consent to the use of their data for the purposes of the trial. They are consenting to send their responses to questions (and a photo) from their mobile devices. However, as also outlined in the "Ethical Approval and Dissemination Plan", participants will have the right to withdraw from the study at any point.

We hope this will address in full the point raised, and we have added further details within the "Data Protection and Management" subsection of methods regarding the data security of REDCap.