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.

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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 randomised controlled trial in emergency surgery patients

Kenneth A McLean ,[1] Katie E Mountain,[1] Catherine A Shaw,[1] Thomas M Drake,[1] Riinu Ots,[1] Stephen R Knight ,[1] Cameron J Fairfield,[1] Alessandro Sgrò,[1] Richard J E Skipworth,[1] Stephen J Wigmore,[1] Mark A Potter,[2] Ewen M Harrison[1]

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For numbered affiliations see end of article.

Correspondence to
Dr Kenneth A McLean; v1kmcle6@ed.ac.uk

ABSTRACT

Introduction National data suggest that surgical site infection (SSI) complicates 2%–10% of general surgery cases, although the patient-reported incidence is much higher. SSIs cause significant patient morbidity and represent a significant burden on acute healthcare services, in a cohort predominantly suitable for outpatient management. Over three-quarters of UK adults now own smartphones, which could be harnessed to improve access to care. We aim to investigate if a smartphone-delivered wound assessment tool results in earlier treatment.

Methods and analysis This is a randomised controlled trial aiming to recruit 500 patients across National Health Service (NHS) hospitals. All emergency abdominal surgery patients over the age of 16 who own smartphones will be considered eligible, with the exclusion of those with significant visual impairment. Participants will be randomised in a 1:1 ratio between standard postoperative care and the intervention – use of the smartphone tool in addition to standard postoperative care. The main outcome measure will be time-to-diagnosis of SSI with secondary outcome measures considering use of emergency department and general practitioner services and patient experience. Follow-up will be conducted by clinicians blinded to group allocation. Analysis of time-to-diagnosis will be by comparison of means using an independent two sample t-test.

Ethics and dissemination This is the first randomised controlled trial on the use of a smartphone-delivered wound assessment tool to facilitate the assessment of SSI and the impact on time-to-diagnosis. The intervention is being used in addition to standard postoperative care. The study design and protocol were reviewed and approved by Southeast Scotland Research and Ethics Committee (REC Ref: 16/SS/0072 24/05/2016). Study findings will be presented at academic conferences, published in peer-reviewed journals and are expected in 2020. A written lay summary will be available to study participants on request.

Strengths and limitations of this study

- This is 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.
- There are broad eligibility criteria, and so it is expected the results will be generalisable to a wide population of patients undergoing abdominal surgery.
- Due to the nature of the intervention, only clinicians undertaking follow-up can be blinded to randomisation status.
- All patients will receive 30-day telephone or face-to-face follow-up to determine the occurrence of surgical site infections; however, the gold-standard for diagnosis remains direct clinical assessment.
- Data on patient experience and acceptability of smartphone-delivered follow-up will be collected concurrently to guide future implementation of future telehealth interventions.

Trial registration number NCT02704897; Pre-results.

INTRODUCTION

Surgical site infection (SSI) complicates 2%–10% of general surgical cases, with the highest rates of infection seen after colorectal surgery.[1] Infection and re-admission rates have not significantly changed in the last 10 years. The most common causative group is *Enterobactericae* (25% of cases), with *Staphylococcus aureus* (10%) and *Methicillin-resistant Staphylococcus aureus* (MRSA) (3%) accounting for a small proportion of overall cases.[1] National surveillance data from Scotland indicate

that peak incidence of infection is between day 6 and 12 postoperatively.[2]

A recent study indicated that national reports may underestimate the true incidence of SSI, and suggested that patient reported SSI is a more sensitive measure.[3] Many patients will have already consulted their general practitioner (GP) or attended the emergency department (ED) prior to surgical assessment. In addition, many patients have concerns about their wounds (in the absence of infection) and may experience delays in accessing appropriate medical assessment. Thus, SSI represents a significant burden on healthcare services, in a patient group who are predominantly appropriate for outpatient management.

There is currently an increased research focus on digital health: the use of communications technology to enhance healthcare, public health and delivery of health education.[4] There are several advantages to this approach, in particular the potential to improve access to care, and help streamline usage of emergency services. Indeed, there is evidence that these technologies have been used to improve outcome,[5] as well as to reduce specialist workload[6] and ED attendances.[7] In addition, the increasing use of healthcare technology is likely to help improve automatic data collection and recording, which may be used to identify areas for future research and drive quality improvement.[4]

Over three-quarters (78%) of UK adults now own smartphones,[8] with at least a third using a smartphone as their primary device to access the Internet.[4] Therefore, there is vast potential for the use of smartphones in digital health, with a growing literature on the use in the context of postoperative community follow-up.[9 10] Given the frequency with which patients report postoperative wound complications and the high incidence of SSI, this has become a research focus in telemedicine for postoperative care.[11 12]

We aim to investigate if an online wound assessment tool can be used to help diagnose SSI and improve patient access to care and clinical assessment. In addition, we aim to investigate if this results in earlier intervention to treat SSI and a decreased attendance at ED and GPs. The widespread use of smartphones, the integrated nature of their technology and their portability mean smartphones represent the best platform to deliver this tool, with the aim of facilitating rapid access to clinical care.

Objectives

This randomised controlled trial (RCT) will investigate whether a smartphone-delivered wound assessment tool can be used in the diagnosis of SSI and result in earlier treatment. It will also assess for a reduction in ED and GP attendances as a result of using the intervention. Data on patient experience will be used to evaluate perceived utility of the tool.

METHODS AND ANALYSIS

Overview

This is a superiority RCT, using a parallel two-arm design (figure 1). Once consent is obtained, participants will be randomised in a 1:1 ratio to either the intervention arm (receiving standard postoperative care plus access to the smartphone-delivered wound assessment tool), or the control arm (standard postoperative care). Patients will be recruited from the emergency surgery inpatient service across National Health Service (NHS) Lothian. The trial period will be 30 days. An internal pilot study in the first 80 patients recruited will be conducted to ensure the trial design is practical and deliverable. Following assessment of pilot data, there will an opportunity to adapt the trial design in response to the pilot study findings. Participants will be followed up by a researcher blinded

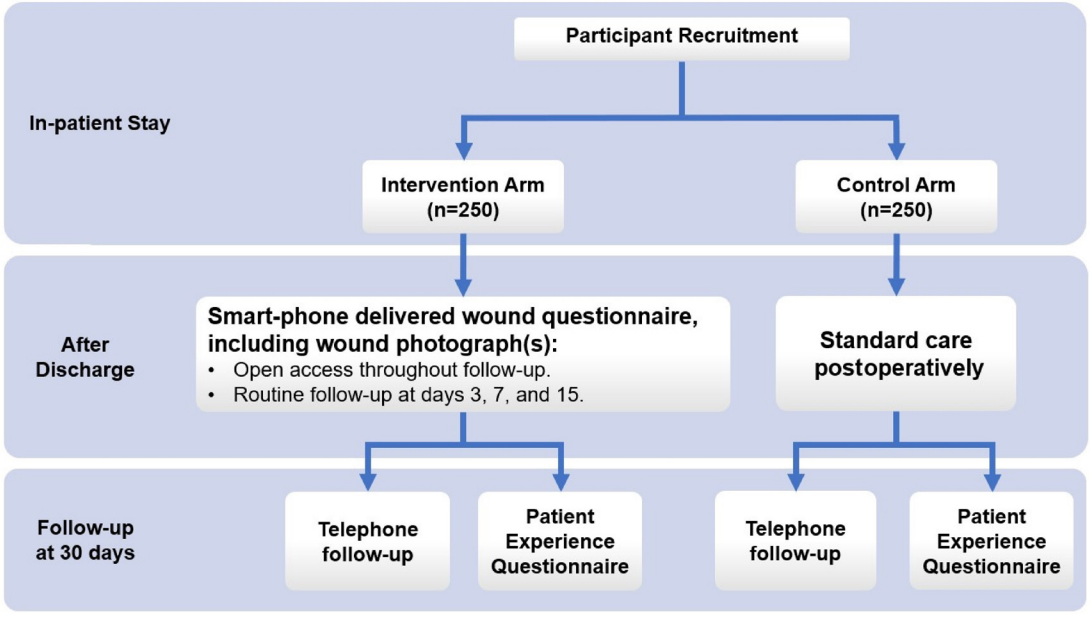

Figure 1 Schema of trial events for intervention and control arms.

to the intervention status. The primary outcome measure will be the number of days from surgery to diagnosis of SSI (time-to-diagnosis), with ED and GP service use as a secondary outcome measure. Additional data regarding patient experience will also be collected from patients in both arms of the trial via a smartphone-delivered questionnaire at 30 days.

Research setting

This research is being carried out in a large health board, serving a mixed urban and rural population of over 800 000. The emergency surgery service admits 300 patients per week between participating sites and performs 2500 procedures annually.

Participants

Emergency surgery inpatients who are adults (over age 16) and have undergone abdominal surgery (on the same admission as diagnosis) will be screened for eligibility. Potentially eligible patients will be screened and documented as (a) eligible and included, (b) eligible and missed, (c) eligible and declined, (iv) ineligible (visual impairment), (v) ineligible (no smartphone). Written consent will be obtained by the research team in line with good clinical practice guidance. Participation is voluntary and a patient's decision regarding participation will not affect any aspect of their care in the case of refusal. Participants will have the right to withdraw from the study at any point.

Inclusion criteria

Patients admitted to the emergency surgery inpatient service who meet the following criteria will be included in the study:

- Emergency surgery inpatients who have undergone abdominal surgery.
- Owners of a smartphone, with access to Internet.
- Adults over the age of 16.
- Able to give informed consent.

Exclusion criteria

Any patients with significant visual impairment preventing use of the online questionnaire will be excluded from the study (defined by self-reporting of the patient).

Study procedures

Recruitment

The clinical team will inform potentially eligible patients about the on-going trial, and offer them further information (written and verbal from the research team). Eligible patients will be recruited postoperatively as inpatients, with formal written consent taken by a member of the research team. Baseline information gathered will include: reason for admission, index procedure and date, significant co-morbidities—including history of diabetes or immunosuppression, as well as age and Body mass index (BMI). Participant contact details (mobile telephone number) will be entered into a secure, online data collection tool (Research Electronic Data Capture (REDCap) database).[13]

Randomisation and blinding

Participants will be assigned in a 1:1 ratio to the intervention or control arms and provided with the appropriate information packs prior to discharge. Simple randomisation will be carried out using REDCap,[13] utilising a computer-generated random number sequence. The emergency surgery nurses (who will provide care to patients as required during the trial) and those taking consent (which may include medical students and qualified clinicians) will not be blinded. The clinicians undertaking follow-up will be blinded to status. A trial entry will be made in the clinical notes, including contact details for the trial team should a member of the clinical team require more information or wish to discover their trial status.

Intervention

Smartphone-delivered wound assessment tool

A wound-based instrument to detect potential wound infection was developed. Our smartphone-delivered wound assessment model was based on the Center for Disease Control and Prevention (CDC) classification criteria, and the ASEPSIS model (Additional treatment, Serous discharge, Erythema, Purulent exudate, and Separation of the deep tissues, the Isolation of bacteria, and the duration of Inpatient Stay).[14 15] It detects symptoms of SSI and symptoms of systemic illness as a result of this, while being quick and simple to use (table 1).

Participants will have access to the smartphone-delivered wound assessment tool on discharge via a link sent by short-messaging system (SMS) to their smartphones. If at any time they have concerns about their wound, they can access the tool, and will be advised based on their responses. When a patient response is submitted, the research team will be automatically notified, and prompted to reply (figure 2).

In addition, a link to the smartphone-delivered wound assessment tool will be sent on days 3, 7, and 15 postoperatively. These time points have been selected to include peak incidence of infection and cover the time course of wound healing. This will ensure the collection of negative data in those without symptoms and will therefore assist in determining the specificity of the tool. If participants do not respond they will be sent a single reminder at these time points.

Wound photographs

Participants will be asked to upload at least one photograph of their wound each time they use the smartphone-delivered wound assessment tool. These will be reviewed by a clinical researcher and assigned into one of three categories: no concerns, medium-risk, high-risk. Further machine learning-based assessment of wound photographs will be investigated.

Table 1 Questions included in smartphone-delivered questionnaire and independent algorithm scoring system

Smartphone-delivered wound assessment		Algorithm scoring system		
Question	**Response (score)**	**Low-risk**	**Medium-risk**	**High-risk**
Is the pain worse than immediately after the operation?	No (0), yes (1)	Inflammation score 0	Inflammation score ≤2	Inflammation score ≥3
Is there new redness around your wound site excluding the wound itself?	No (0), yes (1)			
Is there more swelling around your wound site than at the time of surgery?	No (0), yes (1)			
Are you experiencing a new burning sensation or heat at the wound site?	No (0), yes (1)			
		AND	**AND**	**OR**
Is there liquid coming from the wound site? If so, please select which option best describes the liquid.	No (0), Yes—clear (1), Yes—bloody (1), Yes—yellowish (1), Yes—thick/yellow (2), Yes—green/brown (2)	Discharge score 0	Discharge score ≤1	Discharge score 2
Is your wound opening or gaping?	No, yes	Not scored in algorithm		
Have you experienced fevers in the last 24 hours?	No, yes			
Please upload a photograph of your wound.	Photograph	Not scored in algorithm		

Responses

An experienced clinician (surgical registrar or consultant) will review all participant responses and photographs in real time. Based on the response and the wound photographs, they will contact the patient by SMS with advice regarding the need for further assessment. The clinician will classify participants into three groups: no concern, medium-risk, high-risk. These three groups

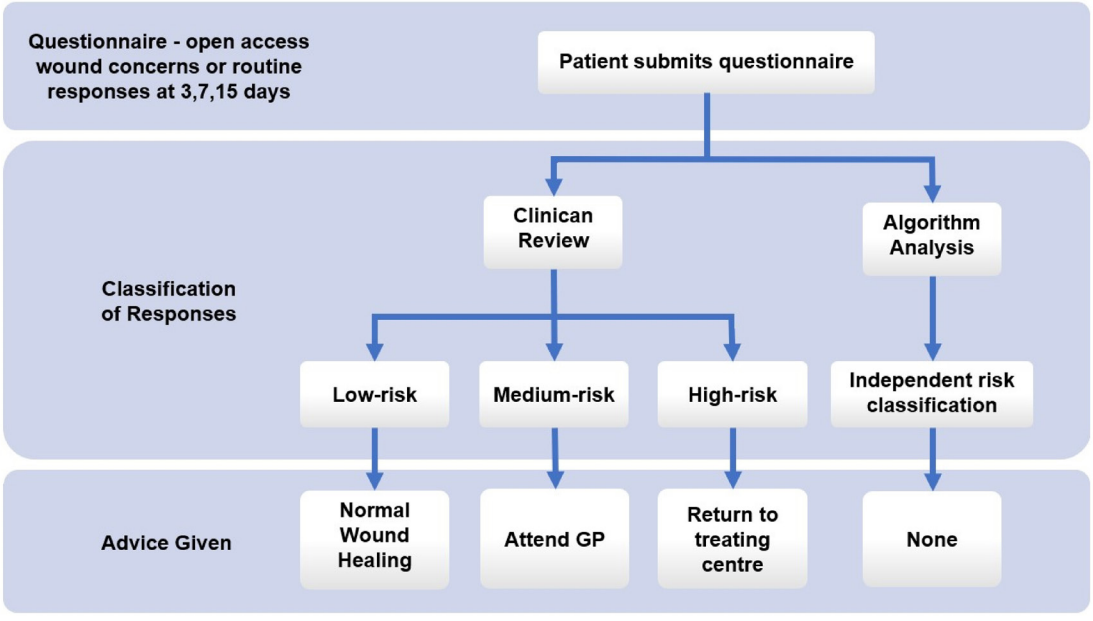

Figure 2 Handling of wound questionnaire submissions.

were agreed collectively by the researchers in collaboration with the emergency surgical team. Three potential outcomes were identified: (i) the patient does not require further assessment (no concern), (ii) the patient requires further assessment, but the symptoms identified suggest a mild infection (medium-risk), (iii) the symptoms suggest a potentially severe infection requiring urgent assessment (high-risk). The wound photographs will also be reviewed by the experienced clinician where available and classified into the same three groups. This may be used by the researcher to refine their response to the tool, if they consider this necessary.

Algorithm

An algorithm has been designed to classify participant responses into the same three categories listed earlier (table 1). This will be run on all participant responses (but will not impact on care), and will be compared with clinician rating, as a secondary sub-study. The correlation between clinician response, algorithm response and photo response will be used to determine if the algorithm can be used to assess for SSI independent of the responsible doctor.

Action from response

Participants whose responses raise no concerns will be advised of this. Participants who report symptoms consistent with wound infection will be directed for further assessment. Those in the medium-risk group will be directed to community care while those in the high-risk group will be advised to return for assessment at the centre where they had their procedure. This advice aligns to the degree of concern identified previously.

Wound reviews

For those in the intervention group who are identified as high-risk, the emergency surgery nurses will collect a wound swab from the patient to test for causative organisms (and aid in confirming infection). If a wound infection is diagnosed clinically, the patient will be started with antibiotics in line with local guidelines. This will be logged in the patient's trial record. If any patients in the control group attend the emergency surgery service for a review the same procedures will apply.

GPs will be informed about their patient's participation in the trial. We will request that if a participant enrolled in the trial visits their GP a wound swab is taken, and that they are treated in line with the GP's normal practice. This will also apply to those in the medium-risk group who will be directed to their GP.

All participants will be given a log to take to any wound reviews, and wound swabs may be taken of wound discharge or the wound bed as appropriate. If an infection is diagnosed the date treatment is commenced will be noted, alongside any intervention performed. This will then be returned to the trial team, and used in follow-up.

30-day follow-up

Both arms will receive a follow-up face-to-face or telephone consultation 30 days postoperatively (alternatively, written follow-up is also available for those with significant hearing impairment). This consultation will follow a standardised format and will be conducted with an independent clinical researcher blinded to the intervention status. The clinical researcher will gather data on postoperative course, any symptoms related to the wound and any treatment offered. They will also have access to electronic patient record (including all microbiology results from swabs taken in the community or hospital) and any wound logs returned. On the basis of these three sources of information, two independent, blinded clinical researchers will determine if an infection has been present (trained using the CDC criteria to diagnose infection).[14] Data on patient experience and service usage—ED and GP attendances, as well as contact with emergency surgery nurses—will also be collected via a separate questionnaire delivered alongside the 30-day follow-up (table 2).

Data analysis plan

All analysis will be carried out on an intention-to-treat basis. We do not anticipate missing data in patient demographics. However, any missing data values will be handled using multiple imputation. The volume of missing outcome data will be recorded for the control and intervention arms, and any differences in drop-out rate noted. Thereafter patients with missing outcome data will be excluded from analysis.

Outcome measures

This is a superiority RCT, and the primary outcome will be mean time from operation to diagnosis (time-to-diagnosis) of SSI. This outcome has been chosen (rather than time from symptom onset), as it can be more accurately recorded and is a measure of improved access to care. We assume an equal incidence of SSI in both groups and will ensure this using ORs. Time-to-diagnosis will also be compared using Cox proportional hazard regression analysis; a p value of<0.05 will be considered statistically significant.

For the intervention, we will calculate the sensitivity and specificity of the researcher response, the algorithm response and photograph response in the diagnosis of SSI. We will compare the correlation of the algorithm, which is based on questionnaire responses, with clinician advice and eventual diagnosis. Correlation analysis will be performed using Kendall tau rank test. This will assess the accuracy of the algorithm in stratifying risk, as compared with a clinician, and will indicate what additional benefit may be gained from photographic analysis.

The secondary outcome measure will be use of services: GP and ED attendances, as well as contact with emergency surgery nurses. This data will be gathered at 30 days. Differences in number of attendees to GP and ED will be compared using a χ^2 test. Differences in the number of attendances will be assessed using the Mann-Whitney U test.

Table 2 Questions included in smartphone-delivered 30-day patient experience questionnaire

Smartphone-delivered 30-day patient experience questionnaire	
Question	**Available responses**
1. Did you have access to the smartphone tool?	Yes, no
2. If you had access to the tool, how many times did you use the tool (not including the reminder questions sent)?	(integer)
3. If you had access to the tool, please rate the extent to which you agree/disagree with the statements below:	
a. The tool was easy to use	Strongly disagree, disagree, neutral/no opinion, agree, strongly agree.
b. I understood the questions in the tool	Strongly disagree, disagree, neutral/no opinion, agree,strongly agree.
c. It was easy to upload my wound photo	Strongly disagree, disagree, neutral/no opinion, agree,strongly agree.
d. The response from the tool was helpful	Strongly disagree, disagree, neutral/no opinion, agree,strongly agree.
4. Please rate the extent to which you agree/disagree with the statements below:	
a. It was easy to get hold of advice about my wound when needed	Strongly disagree, disagree, neutral/no opinion, agree, strongly agree.
b. I had to wait more than 1 day for advice about my wound	Strongly disagree, disagree, neutral/no opinion, agree,strongly agree.
c. The advice I received about my wound was useful	Strongly disagree, disagree, neutral/no opinion, agree,strongly agree.

Data on patient experience will also be gathered via a follow-up questionnaire and analysed separately (table 2). This will help determine if an online questionnaire delivered via a smartphone has a positive impact on patient experience of care, and if it helped facilitate their access to care.

Sample size and power analysis

Our primary outcome measure is time-to-diagnosis and we aim to detect a 1 day difference with a power of 90% (alpha 0.05). Assuming a SD of 1 day in time-to-diagnosis, 22 wound infections per group will be required. Estimating a 10% rate of wound infection (in line with national data)[2] and a drop-out rate of 10%, a sample size of 490 will be required (recruitment target 500 patients). Analyses will be intention-to-treat.

Assuming that 50 operations are performed per week and two thirds of these patients are likely to own smartphones, we estimate there will be 30 potentially eligible patients per week. Aiming for recruitment of 25% of eligible patients, we estimate a continuous recruitment time of 16 months. This rate of recruitment will also enable the researcher to respond to all patient concerns in a timely manner.

ETHICS AND DISSEMINATION

Safety

All participants will receive the normal standard of care. The smartphone-based intervention is in addition to the normal standard of care. If at any point participants have any concerns. they will be advised to contact the emergency surgery nurses regarding their care (in line with normal standard of care). Out-of-hours they will be advised to contact NHS out-of-hours services. Participants will be advised to contact the emergency surgery nurses if they have any concerns while they are awaiting a response to the tool. The research team will be notified automatically that a participant is awaiting a response, ensuring that in normal working hours patients receive a rapid reply. They will also be advised that if they access the tool at night, that it will not be reviewed until the following day. They will be advised to contact out-of-hours services if they require an overnight assessment. These actions will prevent any harm to patients resulting from a delayed response to the wound assessment tool. A potential consequence of closer follow-up of these postoperative patients could be increased identification of superficial SSI which would likely otherwise self-resolve; however, this would require closer surveillance or treatment if appropriate (this decision is made by an independent clinician at the time of review). Due to the low-risk nature of the trial, a formal data-monitoring committee has not been nominated.

Data protection and management

All participant data will be stored securely in a REDCap[13] database that has controlled access and designed as compliant with Health Insurance Portability and Accountability (HIPAA) security guidelines. This data will be anonymised, and only available to researchers listed on the protocol. Participant responses to the questionnaire will be reported directly to the REDCap database and will

not be stored on patient phones. However, patients will be advised to review the security setting on their phone if they intend to store their wound photographs. Patient details will be recorded in a trial log should any safety concerns arise necessitating they be contacted.

Ethical approval and dissemination plan

Any protocol amendments will be resubmitted for review. The study is sponsored by ACCORD, a collaboration between the University of Edinburgh and NHS Lothian Research and Development. In line with good clinical practice guidance, written consent will be obtained by appropriately trained medical students or clinicians. Participation is voluntary and a patient's decision regarding participation will not affect any aspect of their care in the case of refusal. Participants will have the right to withdraw from the study at any point.

Authorship on any papers derived from the study will be all authors involved in study design and protocol development, and any additional researchers involved in the writing group. Furthermore, patient recruiters who have recruited more than the prespecified 15 patients to the study will be listed as a 'collaborator'. All other persons involved in the study will be listed in the acknowledgements.

There are no financial and other competing interests for principal investigators for the overall trial or either study site. Study findings will be reported in line with Consolidated Standards of Reporting Trials (CONSORT) guidelines, and disseminated in the printed media, and learnt forums, and are expected by 2020. A written lay summary will be available to study participants on request.

Patient and public involvement

Patients were not directly involved in the design or delivery of this trial; however data on patient experience in using the smartphone tool will be evaluated via a follow-up questionnaire. This will inform future development and dissemination of this intervention. A summary of results will be provided to all patients involved once the trial has been completed and analysed.

Author affiliations
[1]Department of Clinical Surgery, University of Edinburgh, 51 Little France Crescent, Edinburgh, UK
[2]Department of Colorectal Surgery, Western General Hospital, Edinburgh, UK

Contributors Conception and design: KEM, CAS, TMD, KAM, RO, AS, RJES, MAP, SJW and EMH. Drafting the manuscript: KAM, KEM, CAS, TMD, RO, SRK, CJF and AS. Critical revision of the manuscript for scientific and factual content: KAM, KEM, CAS, TMD, RO, SRK, CJF, AS, RJES, MAP, SJW and EMH. Supervision: RJES, MAP, SJW and EMH. All authors read and approved the final manuscript.

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ORCID iDs
Kenneth A McLean http://orcid.org/0000-0001-6482-9086
Stephen R Knight http://orcid.org/0000-0003-0448-3719

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