Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

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SPONSOR

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FUNDER

The CI is funded through a Clinical Research Fellowship at Imperial College London and is not receiving any monetary compensation for the work.

This protocol describes a pre-post mixed methods pilot study assessing the impact of a mobile learning resource on the ability of clinicians to break bad news.

Every care was taken in its drafting, but corrections or amendments may be necessary. This protocol will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the CI.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

STUDY SUMMARY

Title	Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study.
Design	All participants granted access to a breaking bad news mobile learning resource (VitalTips). Baseline and post-intervention questionnaires, pre- and post-intervention simulated patient encounters, and post-intervention semi-structured interviews.
Objective	To assess if a breaking bad news mobile learning resource can improve the ability of clinicians to break bad news.
Population/Eligibility	15-20 junior doctors and nurses working within two NHS hospitals trusts and one private hospital in England.
Duration	January 2019 to August 2019.

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1. INTRODUCTION

1.1 BACKGROUND

Open and honest communication is paramount when aiming to provide safe, high quality care (1–4). Some conversations can be difficult, such as when breaking bad news (BBN) (5–7). Clinicians cite a number of fears when BBN (6), such as causing harm to the patient and or their relatives (8,9), but avoiding these difficult conversations may cause undue harm (1,10–13).

Effective communication is a complex two-way process (11,14), and is a teachable core skill (1,6). Communication skills training (CST) has been incorporated into health and social care professionals' training curriculums (15,16), reflecting its growing importance. However, as less than 2% of time in medical school is devoted to CST (17), there is a need and opportunity to provide adequate and appropriate training. Most CST courses are delivered face-to-face, which can be expensive, time-consuming to facilitate, and difficult to attend (17–20). As such, alternative methods of training need to be developed that are flexible, readily accessible and cost-effective (21).

The integration and use of digital technologies in education has increased rapidly in the last decade (22) and altered the way we learn and think (23). Digital learning is increasingly used in workplaces, classrooms and for continued professional development (22,24–28). Digital learning facilitates learning at your own pace and in your own time (18), and removes the constraints of the traditional classroom-based learning model (22). Having immediate access to the world wide web, social media, blogs and e-mail suits our current culture of learning (27).

A recent study reported that within a London hospital 98.9% of doctors and 95.1% of nurses owned a smartphone, and 73.5% and 64.7% owned a tablet device, respectively (29). Medical applications were owned by 78.3% doctors and 34.8% nurses, with the majority used for reference and training (29). With mobile devices becoming increasingly commonplace in healthcare (29–31), and evidence to support the use of digital learning for clinical skills acquisition (28,32,33), this medium of learning affords an avenue for CST and BBN training. However, the evidence-base is limited (4), especially when considering mobile learning as sub-set of digital learning (34,35).

1.2 RATIONALE

Digital and mobile learning is at the forefront of healthcare education, but there is little evidence of its use for breaking bad news training. This study aims to address this gap in knowledge by assessing how mobile learning resources may impact the ability of clinicians to break bad news.

1.3 HYPOTHESIS

The addition of a breaking bad news mobile learning resource to clinical practice improves the ability of junior doctors and nurses to break bad news.

2. STUDY OBJECTIVE

To assess if a breaking bad news mobile learning resource can improve the ability of clinicians to break bad news.

3. STUDY DESIGN

3.1 METHODOLOGY & DESIGN

The study objective will be investigated through a pre-post mixed methods pilot study (see figure 1).

Potential participants will be sent invitation e-mails (appendix 1A and 1B). Once potential participants have read the participant information sheet (PIS) (appendix 2) and given consent (appendix 3), they will be asked to complete a baseline questionnaire (appendix 4) to understand their demographics, their previous exposure to breaking bad news (through formal or informal training) and their engagement with digital resources.

Following consent, participants will be asked to complete a baseline simulated patient encounter (SPE) with a simulated patient (SP) (role-played by a professional actor/patient) to assess their baseline ability to break bad news. Participants will be given a task sheet (appendix 6A) with a brief history of the SP and what news they need to deliver. The details and history of the SP will be documented on a character sheet (appendix 7A) for the professional actor/patient to refer to. The SPE will last 15 minutes and it will be video-recorded. The SPEs will be evaluated against a validated mark sheet (36) (appendix 8) completed by the SP, the CI (immediately following the SPE) and an independent assessor (by watching the video footage).

Following the pre-intervention SPE, access to the mobile learning resource will be granted. The mobile learning resource is the freely available VitalTips mobile application, provided by VitalTalk. The participants will be expected to spend at least three hours using the VitalTips app, without this time impacting on their clinical and academic commitments. As the in-application metrics will not be available to the researchers, participants will be asked to self-report their engagement with the resource in the post-intervention questionnaire (appendix 5).

Four to six weeks later, all participants will be asked to complete a second videoed SPE, which will be marked as described above. The participants will also be asked to complete a post-intervention questionnaire to gauge the impact on their clinical practice and their engagement with the mobile resources. Each participant will act as their own control when comparing the baseline and post-intervention SPE scores and questionnaire responses.

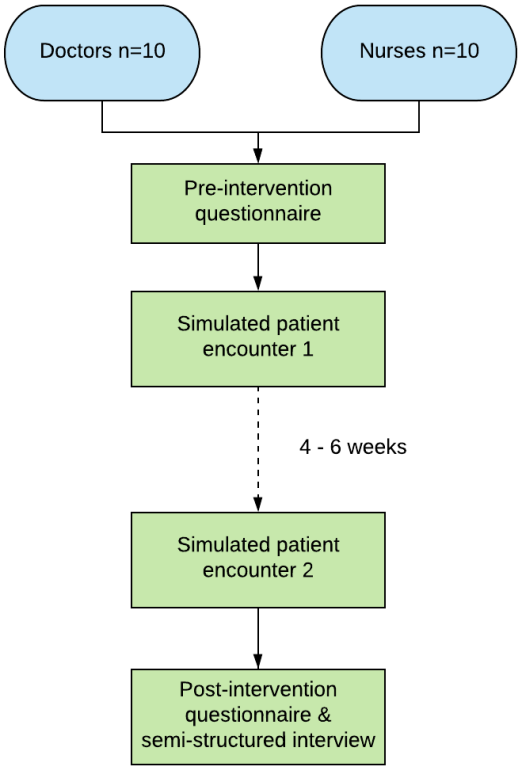
Soon after the completion of the questionnaire, the participant will be asked to participate in a 15-30 minutes semi-structured interview with the researcher. The participant will be asked about their general impressions of the mobile learning resource, their use of the resource in and outside of the clinical environment, their perception of their ability to break bad news before and after the intervention, their perception of their performance in the SPE and any impact on their practice.

3.2 STUDY SETTING

Participants will be recruited from hospitals within two NHS trusts - Imperial College Healthcare NHS Trust and Barts Health NHS Trust, and one private health care site - Bupa Cromwell Hospital. The intention is to recruit those working across a range of specialities, where staff frequently break bad news (e.g. oncology).

The study is intended to commence in January 2019 (dependant on HRA ethical approval) with final recruitment to be at the end of June 2019, to complete the study by August 2019.

Figure 1: ~~Outline of quasi-randomised controlled trial~~



3.3 PARTICIPANTS

Participants will be junior doctors (of any specialty, pre-certificate of completion of training) and junior nurses (of any specialty, band 5 to 6), currently working and training within the NHS or a private healthcare hospital in England. All participants must be able to communicate and write in English. They must be willing to engage with a mobile learning resource as an additional task to their clinical role, ensuring their learning does not take time out of their clinical commitments. Potential participants will be excluded if they are undergraduates, completed their training or retired.

There will be no coercion or pressure to participate. There will be no monetary reward for participation. Participants may use the SPE as a work-based assessment to be completed by the CI upon request.

3.4 SAMPLE SELECTION, PERMISSION & INVITATION

Recruitment of potential participants will utilise a number of methods. As the sample population will be those currently training and working within the hospital setting, the CI has the opportunity to present the study to doctors and nurses in training in their grand-rounds, trainee teaching sessions and department meetings. Having established contacts with the medical and nursing postgraduate training leads, the CI aims to disseminate e-mail invitations (see appendix 1A) to potential participants through the training leads. Once potential participants have been identified, a snowball approach will be used to identify further potential participants through peer word-of-mouth and recommendation. Finally, e-mail invitations will be disseminated through the CI and co-investigator's personal contacts, and through contacts of those working within the Department of Surgery and Cancer. Potential participants will be given up to two weeks to decide if they want to participate, with a reminder sent after one week (appendix 1B).

Potential participants will be sent a participant information sheet (PIS) (appendix 2) attached to the invitation e-mail. The number of potential participants who have been e-mailed will be tallied by the CI on an Excel spreadsheet to compare the number of those who have been approached as potential participants to those who become study participants. Each potential participant will be referenced by a participant ID number for confidentiality purposes.

3.4 CONSENT

Respondents to the invitation will be given the opportunity to read a paper-copy of the PIS and provide written consent (appendix 3) to join the study. Consent will be gained by the CI at a time that is convenient to the potential participant. Participants will be randomised once consent is signed and the baseline questionnaire is completed.

3.5 MEASURES

Questionnaires

Once consent is gained, the participants will complete a baseline (pre-intervention) questionnaire (appendix 4) reporting their demographics, previous exposure to breaking bad news training and their engagement with mobile learning resources. The questionnaires will be printed and available for completion following consent. If participants would rather have more time to complete the questionnaire, an electronic version will be sent via e-mail for them to complete and return within two weeks.

The post-intervention questionnaire (appendix 5) will be offered at the time of the second SPE (four to six weeks following randomisation). If any participants wish to not attend the SPE, the post-intervention questionnaire will still be offered to them. Participants will be given two weeks to complete and return the questionnaire.

The questionnaires utilise a five-point Likert scale (37,38) ranking of the user's confidence and agreeability with statements. Some statements have a white space to write comments. The questionnaires are novel to this study and were developed using principles of Kirkpatrick's Model of Learning Evaluation (39), the Theory of Planned Behaviour (40) and the Technology Acceptance Model (41), whilst also drawing on the most important curricula competencies derived from the content analysis of a sample of medical and nursing curricula followed by an expert consensus (unpublished work by CI).

Simulated patient encounters

SPEs allow assessments of skills in a safe and controlled environment, without impacting patient care (42). Participants will be asked to complete two SPEs – the first at baseline, and the second four to six weeks post-intervention. The CI will send dates for the candidates to choose the best time for the SPE. The participants will have to ensure the time taken for the assessments are outside their clinical commitments or they have adequate clinical cover if they are participating during work hours. Those working within the same department will be encouraged to participate on the same day to avoid discussion within the group of participants who have and have not completed the SPE. The SPEs will be arranged within the hospital premises where the participants work or within the premises of the Academic Surgical Unit at Imperial College London.

Prior to the start of the SPE, the participant will be given a participant task sheet to read, which summarises the task (appendix 6A and an example in appendix 6B). They will be reminded that their personal performance scores will remain confidential (not distributed beyond the CI and his co-investigators). They will be offered the opportunity to have the consultation documented as a work-based assessment for their portfolio.

The participant will be given 15 minutes to conduct a consultation with a SP where they have to break bad news. The SP will be role-played by a professional actor/patient known to Clinical Skills team within the Department of Surgery and Cancer, from a bank of professional actors/patients who have experience in communication skills training and have previously been trained to participate in SPEs. The actor/patient will be compensated for their time according to their agreement with the department. A short introduction to their character and how they may respond to questions and ques will be provided (appendix 7A and an example in appendix 7B). Task and character sheets are adapted from templates provided by MockOSCE (43). Separate scenarios will be used at baseline and post-intervention. The previously validated Breaking bad news Assessment Schedule (BAS) (36) will be used as the mark sheet (appendix 8) to quantify participant interaction with the SP. The BAS has been shown to have high internal consistency (Cronbach's alpha score of 0.93) and the inter-rater reliability was within the moderate to good range (weighted kappa values 0.4510, 0.6817 and 0.6114) (36). The mark-sheet will be completed by the SP and the CI at the time of the SPE. The encounter will be video-recorded so that it can be viewed by the independent assessor at a later date to complete the mark sheet. Therefore, three separate assessor scores will be used when calculating the overall performance score of each participant.

Following the completion of the SPE, the participant will be reminded not to discuss the scenario with other members of their department who have not yet completed the consultation. Following the completion of the second SPE and the post-intervention questionnaire, the participants will have no further commitments to the study.

Semi-structured interviews

To greater understand the participant's ability to break bad news following their use of the learning resource, they will be asked to participate in semi-structured interviews soon after the completion of the post-intervention questionnaire. During the interview, they will be asked about their ability to break bad news, how the learning may have impacted their clinical practice, their perception of their performance in the SPEs, and how they interacted with the learning resource in practice.

Participants will be read a short introduction prior to the start of the interview (see appendix 9). They will be reminded that what they disclose in their interview will remain anonymous. They will be informed that the interview will be audio recorded, transcribed and anonymised. A list of topics will guide the semi-structured interviews (see appendix 9). The interviews are expected to last 15- 30 minutes. An audio recording will be made of the interview and the researcher may take field notes documenting non-verbal responses and any reflections to be used to adapt the topic guide or study direction.

3.6 DATA HANDLING & CONFIDENTIALITY

Following consent, participants will be referenced by their participant ID number (e.g. MLR001). Their e-mail address will be recorded next to their participant ID number, gender, role (i.e. doctor or nurse) and training grade, on an Excel spreadsheet for the purpose of contacting participants as the study progresses. The participant's hospital of work will not be recorded. Once their commitment to the study has been ended, the e-mail address will be deleted. The Excel spreadsheet will be kept on a password protected laptop computer. Non-identifiable data will be backed up with secure storage for a period of 10 years for purpose of reference to data requested regarding any research published.

Video recordings from the SPEs will be transferred from the recording device to a password protected USB stick referenced by the participant ID followed by SPE1 (baseline) or SPE2 (post-intervention), e.g. MLR001_SPE1. Once the independent reviewer has viewed the video and marked

the participant, the video file will be destroyed. Audio recordings from the interviews will be transcribed by the CI and PageSix Transcription Services (we have a confidentiality agreement in place with PageSix). Transcripts will be identified by the participant study number and saved to the password protected computer. Once transcripts have been checked for accuracy, the original audio files will be destroyed.

Physical files (i.e. consent forms) will be kept in a security locked office in Academic Surgical Unit, 10th Floor, QEQM, St Mary's Hospital, London, W2 1NY.

3.7 RISKS

There are no foreseeable physical harms associated with this research. Some participants and the professional actors/patients may become emotional during the SPEs. They will be treated with dignity, respect and dealt with sensitively. If participants or professional actors/patients become overly distressed during the SPEs, it will be abandoned, and support offered, initially by the CI and if required the Occupational Health service for their institution. Alternatively, they will be asked to seek support from their General Practitioner.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATION

None.

4.2 INCLUSION CRITERIA

- Working and training within NHS England and Bupa Cromwell Hospital.
- Junior doctor, pre-certificate of completion of training (of any specialty).
- Junior nurse band 5 to 6 (any specialty).
- Over the age of 18.
- Able to communicate and write in English.
- Willing to engage with mobile learning resources as an additional task to their clinical role, ensuring their learning does not take time out of their clinical commitments.

4.3 EXCLUSION CRITERIA

- Medical and nursing students.
- Clinicians who have completed their training programmes i.e. medical or nursing consultants, matrons.
- Retired clinicians.

4.4 WITHDRAWAL CRITERIA

Participants can choose to stop participating in the study before or during the study, without giving a reason, by informing the CI. The SPEs can be stopped at any time by informing the assessors. Following completion of the study, the participant can decide to withdraw from the study up to two weeks after without giving a reason by informing the CI.

5. ADVERSE EFFECTS

5.1 DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- Results in death.
- Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
- Requires hospitalisation, or prolongation of existing inpatient's hospitalisation.
- Results in persistent or significant disability or incapacity.
- Is a congenital anomaly or birth defect.

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

5.2 REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the CI in the first instance.

Given the nature of this study, it is not anticipated that any AEs or SAEs will occur.

However, any SAEs should be reported to the Imperial College Research Ethics Committee where in the opinion of the CI, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and
- 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence.

Reports of related and unexpected SAEs should be submitted within 15 days of the CI becoming aware of the event, using the NRES SAE form for non-IMP studies. The CI must also notify the Sponsor of all SAEs.

6. ASSESSMENT & FOLLOW-UP

Following the completion of their semi-structured interview, the participant will have no further commitments to the study. The study is intended to commence in January 2019 with final recruitment to be at the end of June 2019, to complete the study by August 2019. Following this, there will be no follow-up of the participants unless they have chosen to receive a summary of the results, in which case this will be e-mailed to them.

7. STATISTICS & DATA ANALYSIS

7.1 SAMPLE SIZE

Due to the exploratory nature of this educational pilot study, the sample size will be relatively small, especially as all participants will be given the intervention and there are no comparator groups. Considering that there are two professional groups involved (doctors and nurses) a sample of ten participants from each (20 in total) should be sufficient to answer the research question and allow for thematic analysis of the post-intervention interview transcripts.

Schildmann et al. and similar studies either did not formally report on or had low attrition rates as their interventions were part of the participant's training (44). This makes it difficult to estimate the level of attrition in our study, especially as the intervention is not mandatory for training. However, it is estimated that attrition levels will be low as evidenced by similar studies.

7.2 DATA ANALYSIS

Data will be analysed at Imperial College London.

The SPE will be marked by three assessors: the CI, the SP and an independent assessor. The marks are in the form of a numerical scale (appendix 8) for quantitative analysis. The scores will be recorded on an Excel spreadsheet against the participant ID. Each participant will act as their own control, with their baseline and post-intervention scores being compared. Using IBM® SPSS Statistics Software, a paired sample t-test will be used to statistically analyse the results (with $p < 0.05$ considered a statistically significant change).

The baseline and post-intervention questionnaires will be analysed by the CI using a combination of a spreadsheet for the quantitative elements (converting the Likert scale into a numerical scale), and qualitative data management software (i.e. NVivo from QRS International) for the white space answers.

The user's confidence in breaking bad news at baseline and post-intervention will be self-assessed on a Likert scale which will be converted to a numerical scale:

- Confidence five-point scale: Not very confident at all (= 0); not very confident (= 1); somewhat confident (= 2); very confident (= 3); extremely confident (= 4).
- Agreeability five-point scale: Strongly disagree (= 0); disagree (= 1); neutral (= 2); agree (= 3); strongly agree (= 4).

Each participant will act as their own control, with comparisons drawn from their own Likert scale ratings from baseline and post-intervention. A paired sample t-test will be used to statistically analyse the results as above.

The answers to open ended questions will be transcribed into a Word file and then uploaded onto NVivo for thematic analysis. This will be performed by the CI becoming familiar with the content of the transcriptions and then thematically coded and analysed. To counter analysis bias, a selection will be reviewed and coded by a second researcher, with any disagreement resolved through discussion. The second researcher will not have access to personal data and will only view anonymised transcripts.

The semi-structured interviews will be transcribed verbatim either by the CI or PageSix Transcription Services and analysed by the CI using NVivo (qualitative data management software). Thematic analysis will be performed by the CI by becoming familiar with the content of the transcriptions

followed by thematic coding and analysis. To counter analysis bias, a selection will be reviewed and coded by a second researcher, with any disagreement resolved through discussion. The second researcher will not have access to personal data and will only view anonymised files.

7.3 DATA PROTECTION

Participants will have their identifiable data recorded in an Excel spreadsheet on a password protected computer and backed up regularly. Each participant will be referenced by their study ID number, recorded in this database. Any physical files (i.e. consent forms) will be kept in a security locked office in the Academic Surgical Unit, 10th Floor, QEQM, St Mary's Hospital, London.

Data will also be archived as per Imperial College standard operating procedures. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, a PIS offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw without giving reasons.

8.3 CONFIDENTIALITY

The CI will preserve the confidentiality of participants taking part in the study to fulfil transparency requirements under the General Data Protection Regulation for health and care research.

8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5 SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to any NHS trusts taking part in this study.

8.6 FUNDING

The research described in this protocol is primarily conducted by the CI who is funded through a Clinical Research Fellowship at Imperial College London.

8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as Sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through the CI (Dr Gehan Soosaipillai).

10. PUBLICATION POLICY

The results of this research may be submitted for conferences and published in journals. The data will also be used for the purposes of a doctoral thesis.

A summary of results will be made available to participants who wish to be informed.

11. REFERENCES

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APPENDICES

Appendix 1A Invitation email

Invitation Email (18/03/2019)

Dear [insert name of potential participant],

Invitation to study: Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study.

Open and honest communication is important when aiming to provide safe, high quality care. Some conversations can be difficult, such as when breaking bad news. Communication skills training are usually delivered face-to-face, which can be expensive, time-consuming, and difficult to attend. As such, alternative methods of training are needed. Digital learning is at the forefront of healthcare education, but there is little evidence of the use of digital learning for breaking bad news training. This study aims to address this gap in knowledge by assessing how mobile learning resources may impact the ability of clinicians to breaking bad news.

You have been invited to participate in this study as you are a junior doctor/nurse working [delete as appropriate] with experience in breaking bad news conversations.

You will be asked to complete baseline and post-intervention (four to six weeks later) questionnaires and video recorded simulated patient encounters. You will be given access to the mobile learning resource. Following the post-intervention questionnaire, a semi-structured interview will be conducted to understand your views on the learning resource and your ability to break bad news.

If you choose to participate, your details will be kept confidential. There is no obligation to participate and you can withdraw at any point during or up to two weeks after your participation in the study. The results of this study will be used for academic outputs, including a PhD research thesis and academic publications.

Please find attached a Participant Information Sheet with more details on the study. You can let me know if you would like to participate by replying to this e-mail and we can arrange a time to meet and begin the consent process.

Kind regards,

Dr Gehan Soosaipillai
Clinical Fellow, Department of Surgery and Cancer, Imperial College London

Appendix 1B Reminder invitation email

Reminder invitation Email (18/03/2019)

Dear [insert name of potential participant],

Invitation to study: Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study.

Following on from my email last week, I wanted to remind you about the opportunity to participant in this study.

Please find attached a Participant Information Sheet with more details on the study. You can let me know if you would like to participate by replying to this e-mail and we can arrange a time to meet and begin the consent process.

Kind regards,

Dr Gehan Soosaipillai

Appendix 2 Participant information sheet

Participant Information Sheet v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

(IRAS ID 258886)

Researcher: Dr Gehan Soosaipillai
Supervisor: Dr Stephanie Archer

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Please ask the researcher if there is anything that is not clear or if you would like more information.

What is the purpose the Study?
Open and honest communication is important when aiming to provide safe, high quality care. Some conversations can be difficult, such as when breaking bad news (BBN). Communication skills training (CST) has been incorporated into most health and social care professionals' training curriculums, reflecting its growing importance. Most CST courses are delivered face-to-face, which can be expensive, time-consuming to facilitate, and difficult to attend. As such, alternative methods of training need to be developed that are flexible, readily accessible and cost-effective. Digital learning is at the forefront of healthcare education, but there is little evidence of the use of digital learning for BBN training. This study aims to address this gap in knowledge by assessing how mobile learning resources may impact the ability of clinicians to BBN.

Why have I been invited to take part?
You have been invited to participate in this study as you are a junior doctor or nurse working in England with experience in breaking bad news conversations.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Participant Information Sheet (PIS) to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw before or during the study without giving a reason.

What will happen if I take part?
We will arrange a time and place that suits you to complete the consent form. Once consent is gained, you will be asked to complete a questionnaire on your background and experience in BBN. Following this, you will be asked to participate in a simulated patient encounter (SPE) with a simulated patient (SP). The SPE will be video recorded. Apart from the SP and the researcher, there will be no others in the room. Your performance of BBN will be marked by the researcher, the SP and an independent accessor (after watching the video). Your scores are kept confidential within the research team and your participation has no impact on your training.

Following the SPE you will be granted access to the mobile learning resource. You are expected to spend at least three hours using the resource over a four to six week period. After this, you will be asked to complete a second questionnaire with addition questions on your experiences of using the

mobile resource. Then you will be asked to complete a second video recorded SPE. Your performance of BBN will be marked by the researcher, the SP and an independent accessor.

Shortly after the second SPE, you will be asked to participate in a semi-structured interview to gauge your perception of your ability to break bad news and how you found using the learning resource. The interview will be audio recorded. Following this, your commitments to the study will end.

Is taking part anonymous and confidential?
Yes. All information which is collected from you during this study will be kept strictly confidential. Identifiable participant information will be stored on a password protected computer. All data will be anonymised and saved to this computer system. Once the video recordings are viewed by the independent assessor, they will be destroyed. Once the audio recordings of the interviews are transcribed, and the transcriptions checked for accuracy, the audio files will be destroyed.

Data will be backed up with secure storage for a period of 10 years after the completion of the study for purpose of reference to data requested regarding any research published.

What are the possible benefits of taking part in this study?
The aim of the study is to see if a mobile learning resource can enhance your ability to break bad news. If you are in a training role and require work-based assessments to be completed, you can ask the researcher to complete a relevant assessment for you following the SPE.

What are the possible risks of taking part in this study?
There is no foreseen physical harm associated with this study. You may find the SPE upsetting or difficult. If you become upset, then the SPE can be abandoned if you wish and support will be offered. It is important to remember that this is not an assessment that has any impact on your training.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Gehan Soosaipillai). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office.

What will happen after this study?
This study forms part of a PhD research project being undertaken by Dr Gehan Soosaipillai at Imperial College London. The research may be presented in academic conferences and/or published in academic journals. If you wish, we can send you a summary of the results of the study when they are ready.

Can I stop taking part?
You can decide that you do not want to participate without giving a reason by informing the researcher at any time before or during the study. Following completion of the study, you can decide to withdraw from the study up to two weeks after without giving a reason.

What if there is a problem?
We do not expect that this study will cause harm to anyone taking part. However, if you have concerns please inform the researcher.

Who has reviewed the study?
The study has been reviewed and approved by the Health Research Authority (HRA).

Who can answer my questions about this study?
You can talk to the researcher about any questions or concerns you have about this study:
Dr Gehan Soosaipillai (e-mail: gsoosaip@ic.ac.uk)

Thank you for taking time to read about this study. A copy of this Participant Information Sheet and signed consent form will be given to you to keep.

TRANSPARENCY NOTICE
Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you for:

- Ten years after the study has finished in relation to data subject consent forms.
- Ten years after the study has completed in relation to primary research data.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting the CI.

Legal basis
As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

International transfers
There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into

a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Contact us
If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via e-mail at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.
If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Imperial College Healthcare NHS Trust/ Barts Health NHS Trust/ Bupa Cromwell Hospital [delete as appropriate] will collect information from you for this research study in accordance with our instructions.

Imperial College Healthcare NHS Trust/ Barts Health NHS Trust/ Bupa Cromwell Hospital [delete as appropriate] will keep your name and contact details [e-mail address] confidential and will not pass this information to Imperial College London. Imperial College Healthcare NHS Trust/ Barts Health NHS Trust/ Bupa Cromwell Hospital [delete as appropriate] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Imperial College London and regulatory organisations may look at your research records to check the accuracy of the research study. Imperial College London will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Imperial College Healthcare NHS Trust/ Barts Health NHS Trust/ Bupa Cromwell Hospital [delete as appropriate] will keep identifiable information about you from this study for ten years after the study has finished.

Appendix 3 Consent form

Consent Form v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

(IRAS ID 258886)

Researcher: Dr Gehan Soosaipillai
Supervisors: Dr Stephanie Archer

Participant ID:

Instructions for the participant:
Please read each of the sections below. In the box next to each section, please write your initials to show that you agree with what the section says.

		Initials
1	I have read and understand the Participant Information Sheet for the above study (version 2.1 dated 18/03/2019).	
2	I have had the opportunity to think about the information and to ask questions about it if I want to. If I have asked questions, I am happy with the way my questions have been answered.	
3	I understand what will happen in the study.	
4	I understand that my answers to the questionnaires and interview questions, and the simulated patient encounter marks will be recorded and saved on the researcher's computer.	
5	I understand that the video recordings from the simulated patient encounter will be transferred from the recording device to a USB drive, and once it has been viewed by the independent assessor, the file will be destroyed.	
6	I understand that what I say in the interview will be recorded using a digital voice recorder, transcribed and saved on the researcher's computer, and once the transcriptions are checked for accuracy, the file will be destroyed.	
7	I have been informed that anything I write in the questionnaires or say during the simulated patient encounters will remain completely anonymous; no identifiable information will be used.	
8	I agree that my simulated patient encounter marks and parts of what I say in the questionnaires may be used anonymously in the results of this study.	
9	I agree that my simulated patient encounter marks and parts of what I say in the questionnaires may be used anonymously in academic conferences or publications, and the researcher's academic thesis.	
10	I understand that I can withdraw my consent to participate at any point before or during the interview or within two weeks of the date of participation without having to give a reason and without my legal rights being affected.	
11	I agree to take part in this study.	

If you agree to the above, print your name, your signature and today's date below.

_____	_____	_____
Name of participant	Signature	Date

_____

E-mail address

_____	_____	_____
Name of researcher	Signature	Date

If you would like to receive a summary of the results, please tick here: ☐

1 copy for participant; 1 copy for researcher.

Appendix 4 Baseline questionnaire

Baseline Questionnaire 2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

(IRAS ID 258886)

Participant ID:

Thank you for taking part in this study. Please could you complete this questionnaire? It is likely to take 15 minutes to complete. Your answers will be kept confidential.

PART A

Demographics
1. What is your gender?

Male / Female / Other / Rather not say

2. Which age bracket applies to you?

18-24 years old
25-34 years old
35-44 years old
45-54 years old
55-64 years old
65+

3A. What is your role?

Doctor / Nurse

3B. How long have you worked in this role?

_____ years

Breaking bad news
4. In your role, are you involved in breaking bad news?

Yes / No

4B. If 'Yes', in what capacity?

Comment:

4C. If ‘Yes’, how often are you involved in breaking bad news in a week?

Comment:

Training

5A. Have you received training on breaking bad news at either the undergraduate or postgraduate level?

Yes / No

5B. If ‘Yes’, what training did you receive?

Comment:

Mobile devices & learning

6A. Do you own or have access to a smartphone or tablet which you use whilst at work?

Yes / No

6B. If ‘Yes’, do you use the smartphone or tablet at work for learning?

Yes / No

6C. If ‘Yes’, what features or applications on your device(s) do you use for work?

Comment:

7. Have you ever used digital learning resources for breaking bad news training?

Yes / No

Comment:

PART B

Breaking bad news competencies

Please rate your level of confidence regarding the following statements related to breaking bad news:

1. Your ability to break bad news well.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

2. Your ability to recognise when to break bad news.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

3. Your ability to break bad news in planned and unexpected settings.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

4. Your ability to be empathetic, honest and sensitive when breaking bad news.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

5. Your ability to prepare for breaking bad news (i.e. setting the environment, having sufficient information).

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

6. Your ability to establish the person's understanding.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

7. Your ability to pick up and respond to verbal and visual cues.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

8. Your ability to recognise the impact of bad news on the person/people you are speaking to.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

9. You know that different people may respond to bad news in different ways.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

10. You know how to provide support for the person you have given the bad news to.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

11. You know when to ask for help when breaking bad news.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

12. You can recognise the impact of breaking bad news on yourself.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

13. You can recognise the impact of breaking bad news on your colleagues.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

Appendix 5 Post-intervention questionnaire

Post-intervention Questionnaire v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

(IRAS ID 258886)

Participant ID:

Please could you complete this questionnaire? It is likely to take 15 minutes to complete. Your answers will be kept confidential.

Since participating in this study, have you had any communication skills or breaking bad news training (other than the mobile app if you were in the intervention group)?

Yes / No

If yes, please provide details:

PART A

Breaking bad news competencies
You may recognise the following questions from the baseline questionnaire you completed. Please rate your level of confidence regarding the following statements related to breaking bad news:

1. Your ability to break bad news well.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

2. Your ability to recognise when to break bad news.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

3. Your ability to break bad news in planned and unexpected settings.

Not very confident at all
Not very confident

Somewhat confident
Very confident
Extremely confident

4. Your ability to be empathetic, honest and sensitive when breaking bad news.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

5. Your ability to prepare for breaking bad news (i.e. setting the environment, having sufficient information).

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

6. Your ability to establish the person's understanding.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

7. Your ability to pick up and respond to verbal and visual cues.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

8. Your ability to recognise the impact of bad news on the person/people you are speaking to.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

9. You know that different people may respond to bad news in different ways.

Not very confident at all
Not very confident
Somewhat confident
Very confident

Extremely confident

10. You know how to provide support for the person you have given the bad news to.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

11. You know when to ask for help when breaking bad news.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

12. You can recognise the impact of breaking bad news on yourself.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

13. You can recognise the impact of breaking bad news on your colleagues.

Not very confident at all
Not very confident
Somewhat confident
Very confident
Extremely confident

PART B

Please rate how you feel regarding the following statements:

1. I am more confident in breaking bad news.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

2. I feel more confident in leading breaking bad news conversations.

Strongly disagree
Disagree

Neutral
Agree
Strongly agree

3. I am more confident in identifying when I need to break bad news.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

4. I am able to break bad news in my practice earlier than I would have before.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

5. I am better prepared for breaking bad news conversations.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

6. When I break bad news, I feel that I am doing something positive for the person/people I am speaking with.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

PART C (for those in the interventional group)

1. How long did you spend using the mobile learning resource in total?

<1 hour
1-2 hours
2-3 hours
3-4 hours
>4 hours

2. How often did you use the mobile resource at work?

Never

Once only
Once a week
Once a day
Multiple times a day

3. How often did you use the mobile resource outside of work?

Never
Once only
Once a week
Once a day
Multiple times a day

4A. Did you use any other mobile learning resources during the last few weeks?

Yes / No

4B. If 'Yes', could you specify which one(s) and why?

Comment:

PART D (for those in the interventional group)

Having used the mobile learning resource, please rate how you feel regarding the following statements:

1. The mobile learning resource was useful for my clinical practice.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

2. It was easy to learn about breaking bad news using the mobile learning resource.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

3. Using the mobile learning resource was time consuming, impacting negatively on the time I spend on clinical work.

Strongly disagree
Disagree

Neutral
Agree
Strongly agree

4. The mobile learning resource did not teach me anything new.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

5. The learning from the mobile resource has not had an influence on the way I work.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

6. A mobile learning resource was a good choice of learning-tool for breaking bad news training.

Strongly disagree
Disagree
Neutral
Agree
Strongly agree

7. Would you recommend the mobile learning resource to your colleagues?
Yes / No

8. Do you have any further comments about the mobile learning resource and/or how the knowledge you gained has influenced your clinical practice?

Yes / No

Comments:

Appendix 6A Simulated patient encounter: Participant task sheet template

Participant Task Sheet Template v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

This is a breaking bad news simulated encounter. Please read the following before you start. If at any point, you would like to stop the encounter, please inform the researcher.

Title: Breaking bad news to [insert brief title]

Time allowed: 15 minutes

Location: [Insert location]

You are: [Insert role i.e. Senior house officer, Staff nurse]

Person's name: [Insert name]

Person's age: [Insert age]

Person's gender: Female / Male

Further information:

TASK	• Inform the person of the diagnosis of [insert brief scenario] or Inform the person of the results from [insert brief scenario] • Counsel the person regarding the next steps to be taken

Please note that you are not expected to take a medical history. If you need clarification of anything, ask the researcher.

Appendix 6B Simulated patient encounter: Participant task sheet example

Participant Task Sheet Example (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

This is breaking bad news simulated encounter. Please read the following before you start. If at any point, you would like to stop the encounter, please inform the researcher.

Title: Breaking bad news to a patient who has an incidental finding on a chest x-ray

Time allowed: 15 minutes

Location: Orthopaedic ward

You are: Senior house officer / Staff nurse on the Orthopaedic ward

Person's name: Mrs Ivy Bakewell

Person's age: 75 years old

Person's gender: Female

Further information: Mrs Bakewell has been electively admitted the night prior to her right hip replacement to control her blood glucose levels. The admitting doctor requested a chest x-ray due to Mrs Bakewell having a cough for over a month. The chest x-ray has shown a right upper lobe mass, which looks suspicious of a cancer. Mrs Bakewell is curious to know the results of the x-ray and has asked to speak to you. You have just started your shift and have not met Mrs Bakewell before.

TASK	• Inform Mrs Bakewell of the results from her chest x-ray including the suspicion of a cancer.

Please note that you are not expected to take a medical history. If you need clarification of anything, ask the researcher.

Appendix 7A Simulated patient encounter: Character sheet template

Character Sheet Template v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

This is breaking bad news simulated encounter. Please read the following before you start.

Title: Breaking bad news to [insert brief title]

Time allowed: 15 minutes

Location of consultation: [Insert location]

Your name: [Insert name]

Your age: [Insert age]

Your gender: Female / Male

Your occupation: [Insert occupation]

Clinician's details: [i.e. Senior house officer / Staff nurse]

Role Player Key Information	
Key information	insert details here (if relevant)
Past medical history	insert details here (if relevant)
Drug history (including allergies)	insert details here (if relevant)
Family history	insert details here (if relevant)
Social history	insert details here (if relevant)
PFICE: Prior knowledge, feelings, ideas, concerns and expectations	
P - Prior knowledge	insert details here
F - Feelings	insert details here
I - Ideas	insert details here
C - Concerns	insert details here
E - Expectations	insert details here

Appendix 7B Simulated patient encounter: Character sheet example

Character Sheet Example (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

This is breaking bad news simulated encounter. Please read the following before you start.

Title: Breaking bad news to a patient who has an incidental finding on a chest x-ray

Time allowed: 15 minutes

Location of consultation: Orthopaedic ward, NHS hospital

Your name: Mrs Ivy Bakewell

Your age: 75 years old

Your gender: Female

Your occupation: Retired veterinarian

Clinician's details: Senior house officer / Staff nurse on the Orthopaedic ward

Role Player Key Information	
Key information	You have been electively admitted the night prior to your right hip replacement to control your blood sugar levels. The admitting doctor requested a chest x-ray as you told her that you have had a cough for five weeks. The doctor told you she would come back and tell you the results of the x-ray, and you have waited most of the day but not seen the doctor again. You are curious as to the results of the x-ray and want to talk to someone on the team looking after you.
Past medical history	Insulin dependent diabetes, which recently has been difficult to control. Osteoarthritis affecting your hips and knees. You have been waiting for this hip operation for over a year as your mobility has been poor. You have never smoked, but your husband did.
Drug history (including allergies)	Novorapid insulin 10 units three times a day (with meals) and Lantus Glargine insulin 20 units at night, subcutaneous. Ramipril 1.25 mg once a day. No known drug allergies.
Family history	Diabetes on the maternal side. Mother possibly had breast cancer, but you know little about it.
Social history	You live alone in a one-bedroom first floor flat. Your husband died five years ago. You have a lot of friends and family members who visit frequently. You enjoy the company of others, reading journals and playing golf.
PFICE: Prior knowledge, feelings, ideas, concerns and expectations	

P - Prior knowledge	You decided not to see your GP, even though you were concerned about the cough, as you did not want to bother him, and you knew you would be coming for surgery soon. You have been more tired and breathless over the last month, but you just felt it was age rather than anything else. You do not have any prior knowledge that your symptoms could be due to a cancer.
F - Feelings	Your husband died of lung cancer. He was a heavy smoker. He had surgery followed by radiotherapy and chemotherapy. You cared for him during his illness and found it difficult to see him so unwell. You are shocked by the news of a possible cancer in the lung. Due to the reduced mobility from the osteoarthritis, and as you haven't played golf in months, you have been feeling low in mood. You are optimistic that the hip surgery will help you return to your prior level of fitness and would be very upset if this was cancelled.
I - Ideas	You thought only smokers could get lung cancer and you feel relatively well, so initially you feel the chest x-ray must be wrong.
C - Concerns	You are concerned about what this means for your surgery tomorrow – you are keen to have the surgery as you want to be well enough to play golf again. In the long term, you cared for your husband as he became increasingly ill with the cancer and the treatment, and you do not want to go through the same.
E - Expectations	You think there must be some mix up with the x-rays. You understand the need for further investigations, but you are not keen to go through all the treatments your husband did as you do not feel unwell at the moment. You are still expecting to have the surgery tomorrow.

Appendix 8 Simulated patient encounter: BAS Mark Sheet

BAS Mark Sheet v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

(IRAS ID 258886)

Participant ID:

Title: Breaking bad news to [insert brief title]

Time allowed: 15 minutes

Assessor (select one): Researcher / Simulated patient / Independent marker

Breaking bad news Assessment Schedule (BAS)

When marking please place a circle round the number which reflects the score you wish to give. The points adjacent to each question are for guidance only.

A. Setting the scene This section looks at whether the participant facilitated an initial rapport before breaking the bad news. This can be done by providing an environment which allows private and comfortable communication, by the participant introducing him/herself, and by the participant showing an interest in the patient as an individual.		
1.	**Did the participant arrange the environment?** very well 5 _ 4 _ 3 _ 2 _ 1 poorly	The participant may have • placed the chairs at an angle which allowed eye contact? • ensured that the desk was not in-between him/her and the patient? • prepared for the patient becoming upset, for example by placing the tissues so the patient could reach them? • taken measures to prevent interruptions?
2.	**Did the participant use an appropriate greeting and introduction?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	The participant may have • stood up to greet the patient? • established the patient's name? • introduced him/herself using his/her own name? • given a brief description of his/her occupation? • shown the patient where to sit?
3.	**Did the participant show interest in the patient's current state of well-being and personal circumstances at the beginning of the interview?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	The participant may have • used open questions? • established recent events for the patient? • established the patient's physical state? • asked how the patient felt emotionally? • enquired into the patient's social circumstances? • given the patient time to finish their statements?
B. Breaking the news This section specifically focuses on whether the participant was sensitive to this patient's perspective when he/she delivered the news (the establishment of rapport is scored in the above section). The amount of information to give each individual patient may vary depending on what		

the patient already knows. Individual patients may vary in the amount of information they wish to receive during this interview, and in the rate at which they assimilate the news.		
4.	**Before breaking the news, did the participant check what this patient knew already?** carefully 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • ask the patient what he/she believed was the nature of their problem? • enquire into what the patient thought the purpose of this meeting was? • check if the patient had thoughts about the possible outcomes from this consultation? • ensure that he/she understood the patient's perspective at this stage of the interview?
5.	**Before breaking the news, did the participant introduce it with sensitivity?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • gently alert the patient to the fact that what followed was going to be important, before using any specific terms? • take the lead from the patient as to whether to speak or listen after introducing the news?
6.	**When delivering the news did the participant allow the patient to decide the detail and language used?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • begin by using non-specific lay terminology? • respond to the patient's cues, or ask the patient if he/she wanted more detail, before becoming more specific? • check that the patient was satisfied with his/her own understanding of the terms used?
7.	**Did the participant allow the patient to set the pace for the delivery of the news?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • deliver appropriate information when it was asked for? • give the news at a rate which gave the patient time to think and respond? • check that the patient had understood and assimilated what had been said before giving more information?
8.	**Did the participant use an appropriate pause after giving the news?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • allow the news about the diagnosis and its implications to sink in? • give the patient time to respond? • appropriately break the silence if the pause was too long?
C. Eliciting concerns This section focuses on whether the participant actively attempted to gain a clear idea of the personal implications and meaning of the news to this patient, and the concerns that it generated.		
9.	**Did the participant specifically invite questions?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	The participant may need to invite questions repeatedly.
10.	**Did the participant explicitly attempt to obtain a complete list of the patient's concerns?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant explore • the patient's feelings and emotions about the news just given? • the patient's concerns about treatment? • the patient's concerns about prognosis? • the concerns arising from family and relationship issues? • the patient's concerns about the effect on their social setting, for example their employment?

11.	**Did the participant explicitly check which areas were most important to the patient?** carefully 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • ask the patient which issues were important to talk about during this meeting? • ask in which order the patient wanted to talk about these issues?
D. Information giving This section looks at aspects other than giving the news itself.		
12.	**Did the participant give information tailored to the patient's expressed concerns?** entirely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • give information in a manner which related to the patient's expressed concerns? • answer the patient's questions?
13.	**Did the participant clearly explain any information given so that the patient understood?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • give information in an ordered and logical manner? • use terms appropriate to this patient using plain English and avoiding jargon? • check that the patient understood, and offer clarification? • summarise points for the patient?
14.	**Did the participant manage to focus on any positive aspects?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • frame treatment options in a positive way? • achieve a good balance between explaining benefits and side-effects? • manage to give correct information about the prognosis without extinguishing hope?
15.	**Was the content of the interview factually accurate?** always 5 _ 4 _ 3 _ 2 _ 1 frequently inaccurate	• If all the information given was factually correct this should gain full marks. • If the participant admitted to uncertainty or lack of knowledge this should still allow full marks. • Marks should be deducted for incorrect statements, undue optimism, premature reassurance, or unjustified negativity.
E. General considerations The following points relate to the interview as a whole.		
16.	**How many of the patient's concerns from the character sheet were aired?** All concerns 5 _ 4 _ 3 _ 2 _ 1 none at all	• Depends on number of concerns elicited.
17.	**How many of the key areas of the patient's concerns were touched upon?** all of them 5 _ 4 _ 3 _ 2 _ 1 none at all	Each of the following five key areas should be touched upon to obtain full marks • treatment • prognosis • feelings and emotions • family and relationship issues • effect on social circumstances
18.	**Were the psychosocial issues which the patient flagged up during the interview explored?**	Did the participant • acknowledge: the patient's feelings and emotions; and the effects on family and relationships, and social circumstances? • allow the patient to talk about these issues?

	fully 5 _ 4 _ 3 _ 2 _ 1 not at all	• ask questions about them? • enter into a dialogue?
19.	**Did the participant manage to appear supportive during the interview?** always 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • show warmth? • show emotional supportiveness? • convey a sense that this really mattered to the participant? • convey a personal sense of strength and resourcefulness that was available to help the patient?
20.	**Did the participant use appropriate body language during the interview?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • maintain an appropriate level of eye contact? • look interested and alert to the patient's needs? • show a competent and caring professional manner?
21.	**Did the participant avoid appearing clumsy during the interview?** never clumsy 5 _ 4 _ 3 _ 2 _ 1 often clumsy	Did the participant • introduce difficult topics gently? • deal with painful issues sensitively? • show flexibility and sensitivity to the patient's needs? • avoid inappropriately changing the subject? • avoid using phrases that were inappropriate?
22.	**Did the participant tailor the pace of the interview to suit the patient?** definitely 5 _ 4 _ 3 _ 2 _ 1 not at all	Did the participant • let the patient speak without interruption? • respond to the patient's cues regarding timing and delivery? • deliver appropriate information when it was asked for? • use pauses where appropriate to give the patient time to think and respond? • check that the patient had finished with a topic before moving on to another?
23.	**Did the participant manage the time available?** very well 5 _ 4 _ 3 _ 2 _ 1 poorly	Did the participant • sensitively make the patient aware of how much time was available for discussion? • mention the opportunity of further interviews to the patient? • cover the important issues in this session? • make a plan for future action? • bring the interview to a conclusion?

Notes:

Appendix 9 Semi-structured interview: Topic guide

Topic Guide v2.1 (18/03/2019)

Mobile learning resources as a tool for improving clinician's ability to break bad news: A pre-post mixed methods pilot study

(IRAS ID 258886)

Introduction

Researcher:
"Thank you for participating in this study exploring mobile learning resources as a learning tool for breaking bad news.

"You have already completed a baseline questionnaire and simulated patient encounter. Following this, you have had access to a mobile learning resource on breaking bad news. Having completed the post-intervention questionnaire and simulated patient encounter, the purpose of this interview is to delve deeper into your experiences of using the learning resource and breaking bad news.

"Please remember that the interview will be audio recorded, transcribed and anonymised. What you disclose in this interview will remain anonymous. During the interview, I will take field notes documenting any non-verbal responses and any reflections. If you need to stop the interview at any time, let me know.

"Do you have any questions? Are you happy to proceed with the interview?"

Topic guide

- How would you compare your ability to BBN now to before joining having the learning resource?
    - What do you think your ability to BBN was before having the learning resource?
    - What do you think your ability to BBN is like following the learning resource?
- Do you think you learned something new from participating in the study?
- Do you think the learning has had an impact on your clinical practice?

- Do you think the mobile learning resource was a useful tool for BBN?
    - Do you think digital learning resources and/or mobile applications are a valuable platform for BBN training?
    - Would you recommend the mobile learning resource or other digital learning resources for BBN to your colleagues?

- How did you find using the mobile learning resource?
    - What were you first impressions?
    - Was it easy to use?
    - Is there something that you would have liked to have seen within the resource that was not available?
- Did you experience any technical difficulties when using the resource?
    - Did these technical difficulties impact your learning?

- When did you use the resource?

    - How often did you use the resource when at work?
    - Did you find the resource helpful in your day to day activities?
    - Did you use the resource before BBN in your practice?
    - How often did you use the resource outside of work?

- How do you feel the simulated patient encounters (SPEs) went?
    - How did it make you feel participating in the SPEs?
    - How did you find the two case scenarios?
    - Were they useful to your training?

- Is there anything else you would like to add?