

Second Ears Protocol

Consultation Audio-recording App

**Title:** Development of an app for audio-recording hospital consultations for oncology patients.

**Ethics no.:** 16/07L

**Version 5**

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# 1.0 Project Summary

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| **Long title** | Development of an app for audio-recording hospital consultations for oncology patients. |
| **Short title** | Second Ears: Consultation audio-recording app |
| **Funding** | The Victorian Managed Insurance Authority (VMIA) Funding of $15,000 over six months |
| **Chief investigator** | Amelia Hyatt |
| **Aims and Objectives** | The aim of this project is to develop a hospital consultation audio-recording app for integration into service delivery at Peter MacCallum Cancer Centre. This will be achieved by meeting the following objectives:  *Part #1: Development Phase*  1. To design a prototype of the app over three months, and run a co-design workshop including the research team, the design/development team, and potential users (cancer consumers and peter mac clinical staff).  2. To create and finalise a prototype app utilising results from the workshop.  *Part #2: Testing Phase*  To pilot test the prototype app in a clinical setting (Clinical Testing) over 2 months. This will involve trialling of the audio-recording app with consenting patients, family members, and clinicians. Assessment of facilitators and barriers to implementation and users’ satisfaction and willingness to use again in the future will be assessed through clinician and patient surveys.  Part #3 Implementation/Dissemination Interview  To discuss with key hospital stakeholders the best method for implementation and dissemination of the app in Peter Mac. |
| **Study design** | *Development Phase*  Co-design methodology will be used to guide the development of the audio-recording app. This will involve cancer consumers (i.e. cancer patients) working in conjunction with researchers and design experts to develop the app.  A workshop will be conducted during the three month development period to .review and provide feedback of the app prototype.  Testing phase  The app will be pilot tested within a clinical setting to identify barriers and facilitators to routine implementation within the hospital.  Patients and treating clinicians will be recruited from the following services:   * Nutrition Service Clinic * Skin & Melanoma * Urology (Prostate) * Physiotherapy * Lung   Recruitment will be held over approximately 1-2 days per clinic during December 2017 - February 2018 (additional days will be considered if recruitment is poor). Patients and their treating clinicians will be invited to take part.  Participation for oncology patients will involve trialing the app through audio-recording their consultation, and a follow-up telephone survey 1 week post their audio-recorded consultation.  Participating clinicians will also be invited to complete a short pen and paper survey post clinic.  *Family members* |
| **Participants** | *Development phase*  10 Consumers (cancer patients), will be invited to take part in a co-design workshop. Participants for this workshop will be recruited through Peter Mac Consumer networks.  *Testing phase*  A convenience sample of approximately 30-45 outpatients at Peter MacCallum Cancer Centre will be invited to trial the app, and to complete a survey regarding the use of the app. Participants will be recruited on pre-arranged dates in December 2017 – February 2018(e.g. 1-2 days per clinic) through Peter MacCallum Cancer Centre clinic lists and Nutrition Clinic Lists.  Clinicians will be notified about the study via MDM’s prior to recruitment. Clinicians in participating clinics will be invited to take part in the trial. Only patients of consenting clinicians will be invited to attend. Clinicians will be notified of the trial prior to the designated clinic recruitment dates, and invited to provide written informed consent. Clinicians will also be notified on the day which of their patients are participating and which consultations will be audio-recorded.  Family members attending appointments with participating patients will also be invited to take part. Only those patients whose family members consent to be audio-recorded will be able to participate.  *Implementation Interviews*  Key hospital stakeholders will be approached to take part in qualitative interviews to discuss future implementation of the app into standard practice of care, and effective dissemination of the app to clinical staff and patients. Discussion of risks and risk management will be included in the interview. All interviews will be audio-recorded and then transcribed for analysis. |
| **Setting & Data collection** | Development Phase  The co-design workshop will run as follows:  Workshop at Peter MacCallum Cancer Centre   * review and feedback of prototype * participants spend time using app and making notes for discussion * semi-structured focus group questions to guide discussion * audio-recorded for qualitative analysis * participants will be invited to complete a short 10 minute demographic questionnaire at the start of the workshop   Testing Phase  Data will be collected from piloting the app in outpatient clinics (listed above). Short paper and pencil surveys regarding the app will be given to clinicians to complete at the end of clinic. Patients will be invited to complete a follow-up telephone survey 1 week after the audio-recorded consultation. Clinician and patient surveys will investigate barriers, facilitators, and satisfaction regarding app usage, and extent of audio-recording use.  Implementation Interviews  Data will be collected via qualitative interviews. Key stakeholders will be interviewed face-to-face by the research team, and audio-recorded for analysis. |
| **Time period** | The following timeline is anticipated:  Expected trial commencement: April 2017  Workshop will occur on or close to 201715th May 2017.  Prototype and product completion:  Prototype – 30th 15th May 2017 – for review at workshop  Final Product – 10 November –  Clinical testing, analysis and reporting:  December 2017 – March 2018  Project completion: March 2018 |

# 2.0 Study Schema: Development Phase



# 3.0 Study Schema: Testing Phase

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# 4.0 Background and rationale

Level 1 evidence demonstrates that audio-recordings of key oncology consultations improve recall and understanding. Authors of the recent Cochrane review concluded that the most empirically robust outcome of the provision of consultation audiotapes is improved information recall from consultations, with 5 out of 9 randomized-controlled trials (RCTs) demonstrating this effect [1]. The studies that did not demonstrate a significant effect were all underpowered [2-5]. Hack, Butow and others have found that consultation recordings allow for learning of new information not recalled from the initial consultation, a clearer understanding of one’s cancer treatment, greater confidence that critical aspects of the disease and treatment have been discussed, and greater information recall in comparison to controls [1].

Consultation audio-recordings also allow patients to assume a significantly more active role in subsequent consultations and in treatment decision making [1] and provide patients with a means to initiate treatment discussions with family members [6]. Consultation recordings are particularly beneficial in reducing anxiety in cancer patients with low socioeconomic status [7]. A recent review concluded that consultation audio-recordings significantly enhance recall in comparison to standard, orally delivered information, and that these benefits in recall are not realised using general, standardised audio-recordings or consultation summary letters [10]. Research has shown that patients also prefer consultation recordings over standardised, pre-recorded consultations and general summary letters [11, 12]. Consultation audio-recordings are well received by the majority of cancer patients; patient satisfaction with this intervention is high [1].

The second ears smartphone app will therefore be designed to facilitate the audio-recording of hospital consultations, with a focus on convenience, and feasibility. As a native smartphone app, it aims to incorporate existing and available technology in an economically affordable and sustainable way. It will be designed to improve service delivery and informational resources for underserved populations such as culturally and linguistically diverse consumer groups.

The project outlined here will focus on creating and developing an audio-recording app which is sensitive to the recommendations, design input and needs of consumers. A co-design workshop will allow the app to be designed and reviewed by the end user. Clinical testing will also allow the app to be piloted and reviewed within the hospital setting, and will allow barriers and facilitators to routine service delivery to be identified. Findings from this study will then be available to assist the integration of the technology into standard practice of care within Peter MacCallum Cancer Centre.

# 5.0 Research aims

The aim of this project is to develop a hospital consultation audio-recording app for integration into service delivery at Peter MacCallum Cancer Centre. This will be completed in three parts, the development phase, the testing phase, and the implementation interview stage. Objectives and methods used within each phase are detailed in the relevant sections below.

Co-design methodology will be used to develop the consultation audio-recording app. Co-design refers to “collective creativity as it is applied across the whole span of a design process”[13]. Specifically, this entails experts (researchers, designers or developers) and potential users (consumers) working together from concept creation, prototype review, to final product [14].

Proposed testing in the clinics and services has been approved by the appropriate heads of department. Assessment of facilitators and barriers to implementation and users’ satisfaction and willingness to use again in the future will be assessed through clinician surveys, patient interviews, and interviews with key stake holders at Peter MacCallum Cancer Centre.

# 6.0 Study Setting

The study will be conducted from Peter MacCallum Cancer Centre at Parkville. The workshop will be run onsite at Peter MacCallum Cancer Centre. Testing of the app in a clinical setting will be completed at Peter MacCallum Cancer Centre outpatient clinics. Interviews will be conducted on-site or via telephone.

# 7.0 PART #1: Development Phase

## 7.1 Objectives: Development phase

1. To run a co-design workshop, including the research team, the design/development team, and potential users (cancer consumers).

2. To create and finalise a prototype app utilising results from the workshop.

## 7.2 Participants: Development phase

Participants will comprise cancer consumers and clinicians, as detailed below, to take part in the co-design workshop.

Consumers will be recruited through Peter MacCallum Cancer Centre (e.g. consumers who regularly take part in consumer/research work through the hospital and the department of Cancer Experiences Research). Working with consumers will allow the project to gain feedback and input from people who are familiar with being on the receiving end of cancer care and can provide the perspective of what they would have liked, or what they would recommend for others.

Eligibility Criteria

* Cancer Consumer on the Peter Mac Consumer Registry
* Able to read write and speak English

The study will aim to recruit a total of 10 cancer consumers to attend the workshop.

Clinicians will be recruited by the research team. Working with clinicians will ensure the app and workflow around design and functionality is appropriate for a clinical setting.

Eligibility criteria:

* Working at Peter Mac in one of the following roles: oncologist, nurse, allied health, volunteer, health information management or IT

This study will aim to recruit a representative from one of the above roles listed.

## 7.3 Recruitment and consent process: Development phase

*Users/Consumers*

The project manager will contact the consumer engagement manager at Peter MacCallum Cancer Centre regarding the project to collect contact information for consumers registered as part of the consumer engagement registry. Consumers identified by the consumer engagement manager will be sent a Participant Information and Consent Form (PICF) which details the study requirements and processes (i.e. workshop attendance). The project team will also contact invited consumers by telephone to go through the PICF and provide additional information regarding the project and answer any questions.

The PICF will clearly detail what participation will involve, and that the study is seeking consent to audio-record feedback for qualitative analysis for the consultation recording app development. Participants will be advised that audio-recordings will be converted into transcripts which will remove all identifying information. Audio-recordings of the workshop will be destroyed 5 years after the conclusion of the study. Consumers who would like to participate will be instructed to fill out the consent form and demographic questionnaire and bring them along to the workshop. Patients will be reminded at consent and before each workshop that they can withdraw at any time. If patients withdraw from the study before the last workshop is completed, additional participants using the methods above will be recruited to replace withdrawn participants.

*Design team*

The team hired for the designing the consultation audio-recording app will be notified at the time of hire regarding the proposed design process and whether they were comfortable with workshop sessions being run and audio-recorded. The design team will sign a consent form and be advised that the audio-recording will be converted into transcripts for analysis which will then be anonymised. Audio-files of the workshop will be destroyed 5 years post study completion.

Clinical Staff

A range of clinical staff working at Peter Mac will be contacted to attend the user workshop, with a representative of an oncologist, a nurse, allied health, volunteers, IT and health information management invited to attend. Clinicians will be briefed on the study by the research team, and give a clinician PICF to read and sign prior to the workshop. This PICF will include information regarding the workshop, audio-recording of feedback, and planned use and analysis of the workshop data. Clinicians are advised that they can withdraw from the study at any time.

## 7.4 Study Design/Methodology: Development phase

A co-design workshop will be run across Peter MacCallum Cancer Centre to develop the consultation audio-recording app. The planned session will run as follows:

*Workshop*

The workshop will focus on the review and feedback of the consultation audio-recording app prototype. The workshop will be run at Peter MacCallum Cancer Centre, and participants and the research team will be able to use and explore the prototype, and take notes for discussion. The researcher will facilitate discussion. The workshop will be audio-recorded for qualitative content analysis. Results of the content analysis will be fed back to the design team. The design team will then incorporate these results into finalising the app for clinical testing.

Once Part #1 (Development Phase) is complete, the app prototype will be finalised for pilot testing in Part #2 (Testing Phase).

# 8.0 PART #2: Testing Phase

## 8.1 Objective: Testing phase

1. To pilot test the prototype app in a clinical setting (Clinical Testing) over 2 months.

This will involve trialling of the audio-recording app in key clinical and allied health areas with consenting patients, family members, and clinicians. Assessment of facilitators and barriers to implementation and users’ satisfaction and willingness to use again in the future will be assessed through clinician and patient surveys.

## 8.2 Participants: Testing Phase

*Clinicians*

Clinicians from Peter MacCallum Cancer Centre working in Nutrition, Physiotherapy, Skin & Melanoma, Urology, and Lung clinics will be invited to take part in the testing phase of the project at multi-disciplinary team meetings prior to commencement of recruitment. No inclusion criteria aside from consent is required for clinicians.

*Oncology Patients*

Participants for the testing phase will comprise a convenience sample of approximately 30-45 oncology outpatients. Participants will be recruited on pre-arranged dates in May and June 2017 through Peter MacCallum Cancer Centre Clinic Lists. Recruitment will run across 1-2 days per clinic. Patients attending clinic on the anticipated date of recruitment whose treating clinician has consented to take part in the trial will be identified by clinic lists and invited to take part in the study.

Inclusion criteria

* Aged ≥18 years
* Attending clinic on day of recruitment
* Able to read, write, and speak English
* Have access to an iphone

Exclusion criteria

* Patient’s clinician has declined participation

*Family members/friends*

All family members and friends attending the appointment with the participant will also be asked to provide consent to having the consultation audio-recorded. If they do not provide consent and the participant wishes them to attend the consultation, the participant will be withdrawn from the trial and the appointment will not be audio-recorded. No inclusion criteria aside from consent is required for family members.

## 8.3 Sample size: Testing phase

Approximately 30-45 oncology outpatients will be recruited to the study. The target sample is pragmatic, based on funds available and study time frames. The sample size of clinicians recruited will be pragmatic, with an estimate of approximately 10 clinicians being recruited.

## 8.4 Recruitment and consent process: Testing phase

Patients and clinicians will be recruited from the specialist clinics at Peter MacCallum Cancer Centre to pilot test the app, and to provide feedback regarding the barriers and facilitators of implementing the app as part of routine service.

*Clinicians*

Clinicians will be notified about the study via MDM’s prior to recruitment. Prior to the day/s of recruitment clinicians will be asked to sign consent forms for consultation audio-recording. On the day of recruitment, clinicians will be notified which patients are participating and which consultations will be audio-recorded. Only patients attending appointments with consenting clinician will be invited to take part in the study.

*Oncology patients*

Recruitment will run across participating specialist tumour stream and allied health clinics, for approximately of 1-2 days per clinic (additional days will be considered if recruitment is poor). Patients will be identified and screened for eligibility using clinic lists prior to the appointment. A study invitation letter and participant information and consent form will be mailed or emailed to eligible participants. If the timeframe between screening and patient’s clinical attendance is short, a study invitation letter and participant information and consent form will be emailed to eligible participants. The research team will follow up with a telephone call (maximum 2 attempts) to talk through the PICF, answer any questions about the trial, or using the app. Interested participants will be emailed instructions on how to download the app. The project team will also organise to meet interested participants 10mins before their scheduled clinic appointment time to collect the signed PICF and some demographic information, and run through using the app before their clinic appointment. A suitable date and time to contact patients for the post-consultation telephone survey will be arranged with participants. If the patient is unable to be reached via telephone before their appointment, they will still be met by the research team in clinic before their appointment and invited to take part. Patients who decline to participate (either when speaking to the researcher over the phone or when met in clinic), or who are ineligible to participate because they do not have access to an iPhone, will be asked four demographic questions to assess recruitment bias. The recruitment bias questions will be identical to the demographic questions given to participating patients.

## 8.5 Study Design/Methodology: Testing phase

The app will be tested by patients and clinical staff at Peter MacCallum Cancer Centre. Testing will involve patients downloading and using the app for audio-recording consultations. Testing will focus on identifying facilitators and barriers of app usage within a busy clinical setting. Downloading and usage instructions and ease will be assessed, along with implementation as part of standard service delivery. Testing and implementation will be assessed using a pen and paper survey to be completed by clinical staff and a telephone survey completed with oncology patients approximately 7-10 days post consultation audio-recording.

Participants will have the app downloaded and will be briefed on how to use it before their consultation (either over the phone or in the waiting room). They will then be invited to use it to audio-record the consultation. The research team will be on hand to answer any questions or assist with this process.

## 8.6 Measures: Testing phase

*Field notes*

Feasibility feedback given by participants over the phone or in person will be collected by the research team.

*App Use Survey - Clinicians*

Participating clinicians will be invited to complete a short pen and paper survey post clinic regarding the app. This survey will assess functional aspects of the app, along with clinician identified barriers and facilitators around clinical implementation.

*Survey: Telephone follow-up 1 week post audio-recorded consultation*

Participants will be contacted by the a member of the research team 1 week after their audio-recorded consultation to complete a telephone survey regarding their use and feedback of the consultation audio-recording. Participants will be sent a reminder email prior to their interview. The email will include 3 sub-scales from the Mobile Application Rating Scale (MARS).Participants will be asked to complete the MARS before their telephone interview and will report their answers to the interviewer during the telephone survey. The telephone survey will take no longer than 30 minutes to complete. This survey will assess patient’s experiences with regard to the usability and functionality of the consultation audio-recording; particularly file receipt, downloading, sharing, and listening quality.

# 9.0 Part #3 Implementation interview phase

## 9.1 Objective: Implementation interview Phase

To discuss with key hospital stakeholders the best methods and barriers and facilitators for implementation Second Ears in Peter Mac.

## 9.2 Participants: Implementation interview Phase

Individuals working in key roles outlined below will be invited to participate.

* Health Information Management,
* Deputy Chief Executive Officer,
* Chief Operations Officer,
* Chief Medical Officer,
* Outpatient clinics coordinator,
* Head Allied Health,
* Program lead Electronic Medical Record and
* Legal Counsel.

## 9.3 Sample size: Implementation interview phase

Purposive sampling will be used. Roles which were listed above were identified by the project steering committee as key staff likely to be involved or impacted if the app is to be implemented into usual care at Peter Mac. Most of these staff members are already aware of the app and have a basic understanding of the project.

## 9.4 Recruitment and consent process: Implementation interview phase

All staff listed will be formally approached by the project PI by email. The email will contain information regarding the purpose and content of the interview, how long it will take, and how the data will be used. Participants will specifically be asked if they are happy for information and/or quotes to be attributed to their role when the results are disseminated. Participants can elect for this not to occur.

## 9.5 Measures: Implementation interview phase

A custom built semi-structured interview has been developed to elicit information pertinent to implementing the Second Ears app into usual care at Peter Mac.

This interview has been designed to follow a really great theoretical framework…!

# 9.0 Data collection and processing

## 9.1 Co-design workshop data collection

As noted above, the co-design workshop will be audio-recorded. Participant responses will be transcribed and collated using summarising content analysis. Participant feedback will directly inform the creation of the consultation audio-recording app, its review and its finalisation for pilot testing. Transcripts will be altered to remove identifying information. Audio-recordings will be permanently destroyed 5 years post study completion.

*Consumer/User demographic data collection*

We will also be collecting demographic information from participants at the start of the workshop. This data will be collected for accurate reporting of participant demographic details at publication and for making inferences with regard to generalizability etc. This short demographic questionnaire will take no more than 5 minutes for participants to complete.

## 9.3 Testing phase data collection

Data will be collected via surveys, interviews and backend user data from the app itself. The first (written survey) will collect information from clinical staff. The second (telephone surveys) will collect audio-recording use and quality information from patients. Telephone surveys will be audio-recorded and then transcribed prior to content analysis. User data will also be collected via the app regarding app use using build-in app analytics, including the following:

* How many recordings each person made?
* What proportion of files were uploaded
* Did they make more audio-recordings than just in the testing clinic during the two weeks?
* Sound quality

# 10.0 Data analysis

## 10.1 Co-design workshop

Data will be generated during the co-design workshop and will be collected using audio-recordings. These will then be transcribed, with identifying information removed. Qualitative content analysis will be used to analyse transcribed data. Content analysis involves a manual systematic, replicable technique for compressing many words of text into fewer content categories based on explicit rules of coding16. Coding will be based on categories (question/topic discussed under) and frequencies (how many times raised/agreed with). All discussion points raised will be included in a report. Feedback in the reports will be collapsed by frequency (most often raised to least often raised) and organised by category (question/topic). This will allow the design team to review all feedback generated by the workshop, and to consider the consensus and salience of the feedback when incorporating it into the consultation audio-recording app development/review/finalisation.

## 10.2 Demographic survey

Data will be generated from the clinician and oncology patient structured surveys. Descriptive statistics (counts/percentages, means/standard deviations or medians/inter-quartile ranges, as appropriate) will be used to summarise patient demographic and clinical characteristics and survey responses (this will include a summary of missing items and forms).Clinician demographic characteristics and survey responses will be summarised in the same manner.

## 10.3 Qualitative survey data (patient and stakeholder)

Qualitative survey questions which elicit qualitative responses will be analysed using interpretive description. Transcribed data will be sorted into codes, then categories and themes, according to clinical utility. Analysis will be conducted using NVIVO.

## 10.4 Quantitative survey data

Quantitative Survey items (MARS) for the first two sub-scales (aesthetics and functionality) will be summed to generate mean scores for each participant, with these aggregated and reported using descriptive statistics. The final scale (subjective app use) items will be described independently (again using descriptive statistics stated above), as per recommendations by the MARS developers (16). Data will be analysed using appropriate statistical software.

## 10.4 App analytics

Anonymised user data will be collected by the app regarding user actions. This will be aggregated and exported as numerical counts and percentages. Data will be further aggregated and described descriptively where required.

# 11.0 Ethical considerations

## 11.1 Data storage and privacy issues

All electronic data collected from this study will be stored on a computer that will be password secured. The research team who have been granted permission will have access to this data. The interviews will be stored as electronic files and archived once the data has been processed. ID codes will be used for all survey and interview data and no identifying information will be made available during the study report or publications.

## 11.2 Publication policy

There are no limitations or restrictions on the publication of results by researchers.

## 11.3 Project governance

This study will be coordinated centrally by the research team based at Peter MacCallum Cancer Centre at East Melbourne. PI Hyatt will ensure that the study is running smoothly and adherence to the research protocol will be monitored throughout the study.

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