**Identifying and responding to anxiety and depression in adult cancer patients: Pilot testing of an on-line communication skills education program for oncology health professionals**

PICO format: Identifying and responding to anxiety and depression in adult cancer patients: Pilot testing of an on-line communication skills education program for oncology health professionals

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| Co-ordinating Centre: | Psycho-Oncology Co-operative Group (PoCoG)Level 6 – North, Chris O’Brien Lifehouse119-143 Missenden Rd (C39Z)The University of SydneyNSW 2006 |

**Principal Investigator:**

|  |  |
| --- | --- |
| Name: | Dr Joanne Shaw |
| Institution: | The University of Sydney |
| Address: | Level 6 – North, Chris O’Brien Lifehouse119-143 Missenden Rd (C39Z)The University of SydneyNSW 2006 |
| Contact details: | (ph) | (02) 9351 3761   | (f) | (02) 9036 5292 |
| Email: | joanne.shaw@sydney.edu.au |

**Chief investigators**:

Colette Dolan

Susan Stapleton

Prof Phyllis Butow

Dr Melanie Price

Dr Heather Shepherd

Karen Allison

Lindy Masya

**Protocol ID: 2015-PoCoG-101**

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# List of Abbreviations

|  |  |
| --- | --- |
| PoCoG | Psycho-Oncology Co-operative Group |
| CINSW | Cancer Institute NSW |
| HP | Health Professional |
| GCP | Good Clinical Practice |
| HREC | Human Research Ethics Committee |
| AE | Adverse Event |
| CRF | Case Report Form |
| ICH-GCP | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice |
| QoL | Quality of Life |
| PI | Principal Investigator |
| CI | Chief Investigator |
| SAC | Scientific Advisory Committee |
| ICMJE | International Committee of Medical Journal Editors |

# Study synopsis

|  |  |
| --- | --- |
| Title:  | Identifying and responding to anxiety and depression in adult cancer patients: Pilot testing of an on-line communication skills education program for oncology health professionals |
| Sponsor: | CINSW 14/TPG/1-02 |
| Study number: | PoCoG-2015-101 |
| Primary objective: | To test acceptability of an online training program for identifying and responding to anxiety and depression in adult cancer patients. |
| Rationale: | Health professional education forms a resource for wider implementation of the clinical pathway for the management of anxiety and depression in cancer care. The online training modules provide an overview of the Australian clinical pathway for management of anxiety and depression in cancer and the communication skills associated with screening and referral. Pilot testing of the online training will confirm the acceptability and the effectiveness of the training to improve HP communication. |
| Study design: | Pre-post simulation study design  |
| Sample size (by treatment group): | 12 health professional participants who would typically have the role of explaining screening processes to patients. |
| Study arms (interventions and controls): | No controls – pre and post exposure only |
| Study endpoints (primary and secondary): | Primary outcome is acceptability of the online training. Secondary outcome is effectiveness of the training to improve communication related to screening and referral. |

# Study objectives

## Primary objective

To evaluate whether the specifically developed online education resource for health professionals working with patients with cancer is acceptable to health professionals in understanding the process of screening and the use of a clinical pathway to assess and manage anxiety and/or depression.

## Secondary objective

To determine effectiveness of the training to improve health professional’s communication related to conducting conversations about screening for anxiety and depression, conducting conversations recommending referral to psychological support services and how to manage patients who refuse a recommended referral.

# Introduction and rationale

## Background

Anxiety and depression are common in cancer, and can cause great suffering, yet are poorly detected and not always well treated in the midst of cancer care (Mitchell et al., 2011). There is good evidence that a number of treatments can effectively treat anxiety and depression, but they are not consistently applied and despite international recognition for the need for screening and publication of the Clinical practice guidelines for the psychosocial care of adults with cancer in Australia (2003), there is variability across Australian centres with respect to screening for anxiety and depression. As a result, symptoms often go undetected and their severity is under-estimated (Newell, Sanson‐Fisher, Girgis, & Bonaventura, 1998). There is little evidence, however, on how well guidelines are implemented for the treatment of anxiety and depression in conjunction with cancer treatment (Faller et al., 2013; Walker et al., 2014).

Clinical pathways in health care are standardised, evidence-based multidisciplinary management plans which identify an appropriate sequence of clinical interventions, timeframes, milestones and expected outcomes for a homogenous patient. The Psycho-Oncology Co-operative Research Group (PoCoG) has recently completed the development of a Clinical Pathway for the management of anxiety and depression in adults with cancer (Butow et al., 2015). The pathway incorporates iterative screening, five steps of care (from universal care and self-management to specialist care for those with severe anxiety and/or depression), with review and change in step of care where necessary. However, implementation of the pathway is contingent on oncology health professionals’ competence in identifying anxiety and depression and referring those patients with symptoms to the appropriate level of care. A recent systematic review identified lack of training and low personal skills or confidence about undertaking screening as key barriers to routine screening (Mitchell, 2013). In centres where screening is conducted, the responsibility typically falls to nurses (Mitchell, Kaar, Coggan, & Herdman, 2008). This is challenging, firstly because less than 10% of nurses report using a formal screening tool with most preferring to rely on their own clinical skills (Mitchell, 2013), and secondly because research suggests that nurses are reluctant to ask patients about their problems and use blocking tactics to discourage patients from raising concerns (Wilkinson, 1991), most likely due to a lack of training and fears about the consequences of delving into sensitive issues (Booth, Maguire, & Hillier, 1999).

This study will evaluate whether the education modules are acceptable to health professionals working in oncology and improve health professional’s communication related to conducting conversations about screening for anxiety and depression, referral to psychological support services and how to manage patients who refuse a recommended referral. The online training consists of 5 modules and is hosted on the Cancer Institute of NSW clinical education website, eviQ.

This study will be conducted in compliance with the protocol, Good Clinical Practice (GCP) and relevant human research ethics committees.

## Justification/ Significance

This pilot study will use a quasi-experimental design to ascertain the acceptability of using on-line training to improve communication related to anxiety and depression management. The results of this study will inform further iterations of the training prior to the training being incorporated as a resource for the ADAPT Program evaluating implementation of the Australian Clinical Pathway for the Identification and Management of Anxiety and Depression in Adult Cancer Patients into routine care.

### Risks

Testing of acceptability of the online training modules will involve participants completing self-report assessments of confidence and knowledge related to anxiety and depression discussions pre and post exposure to the online education. Participants will also participate in simulated interactions with a patient (actor) which will be videotaped. Individual participant results will be confidential and will not be available to their employer. Participation in this pilot study has negligible to low risk to participants.

## Lay summary

The purpose of this study is to assess the acceptability of the online training modules to oncology health professionals. The training involves explanations about talking to patients about screening for anxiety and depression and discussing referrals to support services with patients. The online training consists of 5 modules and is hosted by eviQ, the Cancer Institute NSW’s clinical education website. Health professionals will be asked to complete a questionnaire and participate in three patient simulated consultations (where patients are played by actors) before receiving online training. The participants will be asked to participate in another three patient simulated consultations (played by actors) and complete another questionnaire after completing the online training.

# Study design

## Research aim(s)

## To evaluate whether the specifically developed online education resource for health professionals working with patients with cancer is acceptable to health professionals in understanding the process of screening and the use of a clinical pathway to assess and manage anxiety and/or depression

## To determine the effectiveness of the training to improve health professional’s communication related to conducting conversations about screening for anxiety and depression, conducting conversations recommending referral to psychological support services and how to manage patients who refuse a recommended referral

## . Hypotheses

1. The training module content will be acceptable to health professionals
2. The online training format will be acceptable to health professionals
3. Perceived confidence in discussing screening and referral, and dealing with declining referral will be increased post-training compared to pre-training
4. Health professionals will demonstrate improved communication related to screening and referral, and dealing with declining referral post-training compared to pre-training
5. Appropriateness of referrals for psychological support will improve post-training compared to pre-training

## Study design

We have developed an online education training program for health professionals that provides education on the recommendations within the *Australian Clinical Pathway for the Identification and Management of Anxiety and Depression in Adult Cancer Patients*.

This study will pilot test the online training modules with 12 health professionals working in cancer care. After providing written informed consent, study participants will complete a self-report questionnaire and participate in 3 standardised simulated patient consultations. The pre-simulation questionnaire will collect general demographic and work experience information and assess the participant’s confidence talking to patients about screening and referral for anxiety and depression. Participants will then participate in 3 standardised medical simulations with an actor/patient to (1) introduce screening to a patient; (2) make a recommendation to a patient for referral to psychological support; and (3) manage a patient who refuses referral to psychological support. All simulated consultations will be videotaped. Communication will be assessed using a study specific analysis framework. The appropriateness of the referral based on the Clinical Pathway will be determined by comparing the referral made during the simulation to the evidence-based recommendations outlined in the stepped care model of the clinical pathway.

All study participants will then be invited to complete the online training. Three weeks after training the participants will participate in a second series of 3 standardised medical simulations with an actor/patient. The simulated patient consultations will cover: (1) introducing screening to a patient (2) making a recommendation to a patient for referral to psychological support; and (3) managing a patient who refuses referral to psychological support. Participants will also complete a short post-study questionnaire to assess post-training acceptability of the training and their perceived confidence discussing screening and referral for anxiety and depression. Communication will be assessed again using a study specific analysis framework pre- and post-training across scenarios. The appropriateness of the referral based on the Clinical Pathway will be determined by comparing the referral made during the simulation to the evidence-based recommendations outlined in the stepped care model of the clinical pathway.

The following documents have been created as part of this study:

* Consent form
* Participant information sheet
* Participant pre-training questionnaire
* Participant post-training questionnaire
* Analysis framework for assessment of the videotaped scenarios

# Study population

## Inclusion criteria

Eligible participants:

* Health professionals working in oncology where discussing anxiety and depression is part of their current role
* Ability to complete the study questionnaires and participate in the medical simulations
* Aged 18 years or over
* Provision of informed consent

## Exclusion criteria

* Health professionals not working in oncology
* Health professionals unable to complete both pre and post training simulation assessments

## Withdrawal criteria

Participation in the study requires completion of 2 questionnaires and participation in 3 pre- and 3 post-training standardised simulated patient consultations. Completion of the questionnaires and participation of the simulated consultations will be done at two time points spaced 2 – 4 weeks apart. Given the short term nature of the study, it is not expected that participants will withdraw throughout the study. However, participants can withdraw at any time and opt to have their data removed from the identifiable data.

# Study Procedures

## Enrolment procedure

Two methods of recruitment will be used for this study:

1. The research team including the local PI will present at team meetings of eligible staff to explain the study and invite staff to participate. Potential participants will indicate their willingness to participate by providing their contact details to the research team.
2. Participants who meet the eligibility criteria will be identified by the local site investigator and will be invited to provide their contact details to the research team if interested in participating. The researchers will then contact eligible and interested potential participants to explain the study in greater detail and obtain written consent.

The study research officer will provide potential participants with an information sheet, consent form and reply paid envelope, and will provide an opportunity to discuss the study with the research officer prior to participation.

## Allocation method

All participating health professionals will complete the online training after completion of the pre-training assessments.

## Duration of study

The study will commence in August 2016 and conclude in October 2017.

Table 1 Study Timeline

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Aug-Sept 2016** | **Sept-Oct 2016** | **Nov-Dec 2016** | **Jan-Oct 2017** |
| Applying for ethics |  |  |  |  |
| Recruitment |  |  |  |  |
| Conduct data collection |  |  |  |  |
| Adjustments to online education based on feedback |  |  |  |  |
| Data analysis finalised and papers drafted |  |  |  |  |

## Assessment schedule and follow up

Participants will complete two questionnaires and participate in 6 simulated patient consultations over a one month period. There will be no additional follow up.

Table 2 Study Assessment Schedule

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time point:** | **Screening/ recruitment** | **Baseline Assessment (T0)** | **Exposure to Intervention (T1)** | **Endpoint Assessment (T2)** |
| **Week:** | 0 | 0 | 1 | 4 |
| **Informed Consent** | x |  |  |  |
| **Pre-exposure Questionnaire Completed** |  | x |  |  |
| **Participation in 3 Simulated (Pre-exposure) Consultations** |  | x |  |  |
| **Completion of the Online Training** |  |  | x |  |
| **Participation in 3 Simulated (Post-exposure) Consultations** |  |  |  | x |
| **Post-exposure Questionnaire Completed** |  |  |  | x |

# Intervention

## Intervention

The intervention is an online training program designed for cancer health professionals and provides education on a clinical pathway into the screening and management of anxiety and depression in adult cancer patients. The online training modules provide health professionals with communication skills training and practical tips for having conversations with patients about screening and talking to patients about referrals for anxiety and depression. The training modules include videos of example scenarios (played by actors) to teach these skills. The online education also includes videos from current health professionals talking about their experiences of screening and management of patients with anxiety and depression. The online training is made up of five modules and takes 4 hours to complete:

* Module 1: Anxiety and Depression in Cancer
* Module 2: A Stepped Care Model for Anxiety and Depression in Cancer
* Module 3: Initiating a Conversation about Routine Screening for Anxiety and Depression in Cancer
* Module 4: Initiating a Conversation about Referral to Psycho-oncology Services
* Module 5: Managing Declining Referral in at Risk Patients and other Challenging Conversations

The online training will be hosted by eviQ, the Cancer Institute NSW’s clinical education website.

# Safety reporting

It is not envisaged that health professionals will experience any adverse events. Any unexpected adverse events that arise as a result of this study, will be recorded on an AE Case Report Form (CRF) and AEs will reported to the HREC according to reporting guidelines

# Outcomes/ Measures

## Primary outcome

The primary outcome is acceptability of the online training to oncology health professionals.

## Secondary outcomes

The secondary outcome of the study is (1) effectiveness of the online training to improve health professional’s communication in relation to conducting conversations about screening for anxiety and depression, recommending referral to psychological support services and how to manage patients who refuse a recommended referral; and (2) improved ability to make appropriate referrals based on the evidence-based referral pathway outlined in the stepped care model of the clinical pathway.

## Primary outcome data will be collected through a study specific self-report questionnaire completed pre and post training and an analysis. Secondary outcome data will be assessed using a study specific analysis framework pre- and post-training across scenarios to code communication behaviour based on videos of the interactions. The communication skills described in the training are based on the Comskil Model (Brown & Bylund, 2008). This Comskil Model provides a framework for physician-patient communication across five components: goals, strategies, skills, process tasks, and cognitive appraisals (Brown & Bylund, 2008). Therefore the analysis framework (specifically designed for this study) will analyse participant’s communication skills based on this communication model. The appropriateness of the referral based on the Clinical Pathway will be determined as a single item by comparing the referral made during the simulation to the evidence-based recommendations outlined in the stepped care model of the clinical pathway.

## Potential confounders and biases

Some of the health professionals participating in the study may have experience in screening and management of anxiety and depression. However, formal programs for the screening and management of anxiety and depression are not currently routine practice at the cancer centre. None of the participants will have used the clinical pathway as part of their practice. We aim to recruit a participant sample with a range of experience, determined by their years of work experience.

# Statistical methods

## Sample size and justification

Twelve oncology health professionals will be recruited to participate in this study. As this is a pilot study to assess acceptability, no formal sample size calculations have been conducted. A sample of 12 health professionals (36 interactions) is sufficient to provide preliminary data on the ability of the training to improve health professional communication.

## Feasibility

This study is part of the larger ADAPT Program, a 5 year Translational Program grant funded by the Cancer Institute NSW led by the Psycho-Oncology Co-operative Group (PoCoG). St Vincents Hospital has agreed to act as a pilot site for the resources developed to support the overall program of work. The cancer service has sufficient health professionals for the pilot study.

## Analyses plan

Data will be collected from participants in two ways: (1) via questionnaire data collected pre and post training; and (2) assessment of communication pre-post training through analysis of the video recorded simulated consultations. Assessment of communication will be independently coded by two trained researchers and inter-rater reliability calculated to confirm coding reliability.

A repeated measures ANOVA will be used to assess changes in confidence and communication. Acceptability will be assessed qualitatively.

## Deviations from original statistical plan

As a general rule, there should be no deviations from the original statistical plan. Any deviation from the plan will require approval from the Chief Investigator. The version of this document will be updated with each change/deviation, and each change noted.

# Study administration and data management

## Protocol deviations

As a general rule, there should be no deviations from the protocol. Any deviation from the protocol will require approval from the Chief Investigator. All protocol deviations will be documented as part of the study and retained as part of the trial master file.

## Case Report Forms

Case report forms (CRFs) for this study take the form of study specific questionnaires.

All required data will be clearly recorded on the appropriate CRFs. Every effort will be made to ensure that the dates recorded on CRFs are accurate. The study will be conducted using paper CRFs. Data will be recorded using black/blue ballpoint pen and any errors requiring correction must be clearly crossed out (no white-out is permitted), initialed and dated.

CRFs will be completed for each participant who is invited to participate in the study. Adverse Events will be recorded on a study specific adverse event log.

All data on CRFs will be available for review by PoCoG and other regulatory bodies.

## Data handling

Data will be collected from participants via two methods:

1. Consent forms and questionnaires which participants will complete on paper copies and will be either returned in a reply-paid envelope or will be collected in person prior to the simulated consultations by the research officer at University of Sydney; and
2. Simulated patient consultations with actors which will be video recorded and analysed according to the study’s coding framework.

All consent forms and questionnaires will be stored in a locked filing cabinet at the University of Sydney and all electronic data will be password protected and also kept at the University of Sydney, accessible to members of the research team only. Study questionnaires and consent forms will be stored separately.

Consent forms and questionnaires will be collected from participants prior to the simulated consultations by the research officer at the University of Sydney. Video recordings of simulated consultations between participants and patients (played by actors) will be collected at the time of the simulated consultation. Directly following the simulated consultations, these recordings will be password protected and saved on a secure server within the University of Sydney.

Analysis documentation of video-recorded simulated patient consultations will not include any identifying information about the participant.

## Record keeping

### Participant records

While the study is ongoing, paper-based participant data will be stored in locked filing cabinets in a locked office at The University of Sydney. Electronic data will be password protected and also kept at The University of Sydney on a secure server, which is backed up daily. Access to the database and passwords will be restricted to the Principal Investigator, Program Manager, Study Research Officers, PoCoG Executive Director, and PoCoG Research Manager.

Study-related records for all participants will be retained in a secure storage facility for at least seven years after the completion of the research, according to the National Health and Medical Research Council. These include: participant files, study protocol, signed consent forms, CRFs, questionnaires, ethics correspondence and approvals, other regulatory documentation, and other documents pertaining to the conduct of the study.

The records will be accessible for inspection and copying by authorised persons of relevant health authorities, and PoCoG representatives or their subcontractors. Should the Investigator wish to assign the study documentation to another party or move to another location, PoCoG will be notified.

### Investigator/site records

All site specific study documentation will be stored by the Chief Investigator and the research team at the University of Sydney. These documents will be stored on the secure server of the University of Sydney in a folder that is accessible only by direct project staff (Principal Investigator, Program Manager and Research Officers).

## Training, monitoring and auditing

The principal investigator, or delegate, will meet with the study site investigator to provide the study materials and to clearly describe and rehearse the role of the site investigator and the study procedure. The principal investigator will answer any questions the site investigator may have and assure them of continued support from the research team.

The principal investigator, or delegate, will conduct the research at the recruitment site or in a location convenient to the participants. This study requires two visits for the participants after which there is no ongoing input required from the clinicians on site.

As a PoCoG administered trial, this study will adhere to PoCoG’s quality assurance processes, including adherence to standard operating procedures and regularly reporting of study progress to the organisation.

## Cost assessment

This study will be conducted with approved funding from the Cancer Institute NSW. A cost assessment for the anticipated cost of this study is below. There will be no costs incurred by the study site.

Project staff salaries $28,000

Simulated consultations writing/preparation $6,000

Actors $8,500

Audio visual $1,000

Total $43,500

These costs are necessary to conduct the study, which will provide the following benefits:

* Publications on training outcomes for health professionals
* Enhanced communication skills for health professionals discussing anxiety and depression with patients
* Feedback from participants on the online training so that improvements to the training can be made.

# Regulatory considerations

## Participant consent

The nature of the study, known side effects and risks will be explained to the participants in a written document (Participant Information Sheet) and verbally if required. This document will address the participant’s right to informed consent and the obligations of the researchers under privacy legislation in concordance with individual institutional ethics committees.

The Investigator will obtain written informed consent from each participant **prior** to participation in the study, in accordance with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, Declaration of Helsinki 2000, and any local regulatory requirements. Consent will be documented in a password protected database and the form will be stored securely in a locked filing cabinet in a locked office where it will be available for future reference.

## Compliance with regulatory guidelines

This study will be conducted in compliance with the:

* International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (ICH-GCP),
* the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research,
* The Australian Code for the Responsible Conduct of Research, and
* Declaration of Helsinki.

## Ethical review

Prior to the commencement of the study, the protocol and any amendment(s), Informed Consent form, information sheet, and CRFs will be submitted to the lead Human Research Ethics Committee (HREC) and a copy of the written approval will be provided to PoCoG and the site investigators. The approval will refer to the study by title, protocol number and version date and will provide details of the documents reviewed by the HREC. The sites will comply with HREC regulations throughout the study.

During the course of the study, the investigator will submit to the HREC the following:

* amendments to the protocol,
* serious and unexpected adverse events and the outcome,
* specific site updates as agreed to by the investigator and respective HREC, and
* any additional information (e.g., unexpected serious adverse events reported by other sites, and administrative changes to the protocol).

At the end of the study, the Investigator will inform the HREC in writing that the study has ended and no further activities regarding this protocol will be conducted at the site.

## Sponsor

PoCoG will act as a sponsor for the study. In the role of sponsor, PoCoG will conduct quality assurance of the study.

# Publication and use of study findings

## Ownership, access and use of data

The Principal Investigator (PI) at PoCoG will have ownership of all data collected from this study and will be responsible for its security and long term storage. The PI will also be responsible for analysing the data.

No analysis, presentation or publication of results can precede using the data without consent of the study CIs. The PoCoG Executive Director and Research Manager will have access to the data.

While the data is owned by the Principal Investigator, any use of the data in analyses, presentation or publication of results cannot proceed without consent of all the Chief Investigators.

## Authorship requirements

In accordance with accepted standards, the manuscript will be circulated to all those who have made a contribution to the study. Final authorship on the manuscript will be determined by evidence of intellectual contribution, in terms of formulation of the protocol, comment on the results, and preparation of the final manuscripts.

Refer to the International Committee of Medical Journal Editors (ICMJE) for further guidance on what constitutes authorship: <http://www.icmje.org/ethical_1author.html>.

All investigators on the study have been provided with **ADAPT Program Authorship Guidelines** as part of the ADAPT Program.

## Presentation of findings

Presentation of results of the study will be decided by the Principal Investigator. PoCoG requirements as to presentation of findings are to be met.

## Acknowledgment of funding

The Cancer Institute NSW via the Translational Program Grant is the only source of funding for this study. All publications, resources and any other materials produced will acknowledge the Cancer Institute NSW as the source of funding. Wording of all materials will be agreed between PoCoG and the Cancer Institute NSW.

## Publication disputes

Any disputes concerning authorship, contents and timing of any publication and presentation will first be dealt with by the ADAPT Program Steering Committee. If disputes concerning authorship, contents and timing of any publication and presentation cannot be resolved at this level it will be dealt with by the PoCoG SAC Chair.

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# Appendices

The following documents are attached in the appendix:

1. Pre-training questionnaire, Version 1, 19 August 2016
2. Post-training questionnaire, Version 1, 19 August 2016
3. Analysis framework, Version 1, 24 August 2016
4. Consent form, Version 1, 24 August 2016
5. Withdrawal form, Version 1, 24 July 2016
6. Participant information sheet, Version 1, 24 August 2016