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**Preconsultation compassion intervention to reduce anxiety among patients referred to a cancer center: protocol for a randomised control trial**

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**ABSTRACT**

**Introduction** Patients diagnosed with cancer commonly have a high degree of anxiety during an initial oncology consultation, which may interfere with a patient’s ability to retain information required to make informed treatment decisions. A previous study randomised breast cancer survivors (volunteers) to view either (a) a brief video depicting a standard initial consultation from an oncologist or (b) an identical consultation with the addition of compassionate statements from the oncologist, and found the compassionate statements reduced anxiety among the volunteers. However, while compassionate statements reduced anxiety during simulation, it is currently unknown whether watching a video containing compassionate statements from an oncologist prior to an initial oncology consultation will reduce anxiety among patients referred to a cancer centre. The aim of this randomised control trial is to test whether watching a brief video containing compassionate statements from an oncologist, compared with watching a standard introduction video, prior to an initial oncology consultation will reduce the degree of anxiety among patients referred to a cancer centre.

**Methods and analysis** This is a prospective, randomised controlled clinical trial at an academic cancer centre. We will enrol adult patients scheduled for an initial oncology consultation. Subjects will be randomly assigned to receive a standard introduction video or enhanced compassion video for viewing prior to the initial oncology consultation. On arrival to the cancer centre, we will measure anxiety severity using the Hospital Anxiety and Depression Scale (HADS). The HADS has two 7-item subscales (HADS anxiety and HADS depression) and is well-validated among oncology patients. We will use Wilcoxon rank-sum test to test for a difference in the HADS subscales between the two video groups.

**Ethics and dissemination** The Cooper University Hospital Institutional Review Board approved this study. The results from this randomised control trial will be submitted for publication to a peer-reviewed journal.

**Trial registration number** NCT04503681.

**INTRODUCTION**

During an initial oncology consultation, when clinicians are discussing cancer diagnosis and treatment options, it is common for patients to have a high degree of anxiety.¹² Not only is anxiety psychologically distressing, but also anxiety is a common reason for patients not attending (ie, ‘no show’) urgent referral appointments for suspected cancer,³ with approximately 5%–7% of referred patients not attending their scheduled appointment.⁴ In addition, a high degree of anxiety has been shown to compete with task-relevant processes and restrict the capacity of working memory.⁵ Therefore, anxiety may interfere with a patient’s ability to retain information and attenuate a patient’s ability to make informed treatment decisions. Perhaps more concerning, anxiety among patients with cancer is associated with increased mortality; while alternatively anxiety treatment is associated with reduced mortality risk.⁶ Interventions aimed at reducing anxiety among patients with suspected cancer may allow for enhanced patient involvement in care, improved quality of life and improved outcomes.

Compassion is commonly defined as the emotional response to another’s pain or suffering involving an authentic desire to...
help. Clinician compassion can be conveyed to patients through patient-centred communication, which has been shown to be associated with better patient emotional health. During consultation, clinician assessment of the patient’s feelings and concerns, in addition to the physical aspects of the patient’s ailment, is positively associated with patient emotional health and symptom resolution. In addition, compassionate communication is viewed by patients as an vital component of the clinician–patient relationship. Previous studies have found when volunteers watch video-vignettes of clinician–patient interactions, videos containing compassionate statements increase volunteer trust in the physician and overall satisfaction, as well as decrease volunteer uncertainty and anxiety. A study by Fogarty et al randomised breast cancer survivors (volunteers) to watch one of two different videos. The standard video was a dramatised oncologist–breast cancer patient consultation in which a physician described two treatment options for metastatic breast cancer. The second ‘enhanced compassion’ video was identical to the standard video, but also included two additional segments, during which the oncologist acknowledged the psychological concerns of the patient, validated the patient’s emotional state and expressed emotional support. They found that the breast cancer survivor volunteers who watched the enhanced compassion video had a significantly lower degree of anxiety compared with the group who watched the standard video. Although compassionate statements significantly reduced anxiety among the volunteers who watched the simulated video, it is currently unknown whether the same intervention would reduce anxiety among active cancer patients undergoing an initial consultation.

The primary aim of this randomised control trial is to test whether watching a video containing compassionate statements from an oncologist, compared with watching a standard introduction video (sent as part of an ongoing clinical quality initiative at our institution), prior to an initial oncology consultation will reduce the degree of anxiety among patients referred to a cancer centre. In addition, we will test whether the enhanced compassion video reduces the patient no-show rate for the initial oncology consultation. We hypothesise that among patients referred to a cancer centre for suspected cancer, watching a video containing compassionate statements from an oncologist prior to the initial cancer consultation will reduce patient anxiety and no-show rate compared with watching a standard introduction video.

**METHODS AND ANALYSIS**

**Protocol and registration**

This randomised control trial protocol was prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement. The final results will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement. This randomised control trial has been registered on the US National Library of Medicine ClinicalTrials.gov.

**Study design**

This study is a prospective, randomised, controlled, parallel-group clinical trial at a single university-based cancer centre (MD Anderson Cancer Center at Cooper, Cooper University Health Care, Camden, NJ, USA). Enrolment is anticipated to occur between 1 May 2021 and 31 July 2021. Potential subjects will be enrolled at the time of scheduling an initial cancer consultation. Our institutional review board allowed alteration of the requirements of obtaining informed consent under 45 CFR 46.116(d) given the intervention was deemed no greater than minimal risk. All new adult patients scheduled for an initial cancer consultation at MD Anderson Cancer Center at Cooper will be randomised to receive an email containing a link for either the ‘standard introduction video’ or the ‘enhanced compassion video.’ Emails will be sent to patients prior to obtaining informed consent to allow for viewing of the video prior to the initial oncology consultation. The study will not be discussed with patients prior to their scheduled appointment to keep the patients masked to the study hypotheses prior to the consultation and to prevent any influence knowledge of the videos’ purpose may have on the outcome measures. When the patients arrive to the cancer centre waiting room for his/her initial cancer consultation they will be approached by research staff to obtain written informed consent (online supplemental file) to complete the research questionnaire and for use of data. All appointments will take place in the office (ie, no telemedicine appointments).

**Participants**

We will enrol adult patients scheduled for an initial cancer consultation at MD Anderson Cancer Center at Cooper. Inclusion criteria include the following: (1) age ≥18 years and (2) scheduled for an initial cancer consultation. We will exclude patients who do not have an active email address or are medically unable to complete the research questionnaire at the time of the initial cancer consultation.

**Randomisation and masking**

Patients will be randomly assigned to one of two groups, standard introduction video or enhanced compassion video. An independent statistician will generate the group assignment sequence using a parallel design, 1:1 randomisation schedule. Standard measures will be used to ensure appropriate concealment of group assignment. The randomisation assignments will be kept in a sequential list and maintained in the scheduling operator office. At the time of scheduling an initial consultation, appointment operators will identify the next assignment in the series, which will be labelled either ‘video A’ or ‘video B.’ The operators will then send the appropriate email containing a link to a website for the matching video. The independent statistician will maintain the code link for the videos. Thus, the operators, investigators and research
**Interventions**
As part of a currently ongoing clinical quality initiative at our institution, when a new patient schedules an appointment for an initial cancer consultation the scheduling operator sends an email to the patient containing a link for a standard introduction video (see script below). For the purposes of this study, a second enhanced compassion video was developed, which added five additional sentences to the standard introduction video. Those five sentences were compassion-focused statements. Both videos feature the same oncologist (ie, Medical Director of MD Anderson Cancer Center at Cooper) and are identical aside from the additional compassionate statements. The compassionate statements added to the enhanced compassion video were based on the statements used in the Fogarty et al study,15 and further modified based on the results of a recent systematic review of clinician compassionate behaviours, which found incorporating statements of support, acknowledgement, patient’s perspective, emotion naming and validation increased patient perception of compassion.19

**Script for the standard introduction video**
Hello, I’m Dr. X, Medical Director of MD Anderson Cancer Center at Cooper.
Thank you for choosing MD Anderson at Cooper. We value your confidence in our team.
We believe that exceptional treatment requires a team of experts who specialize in a specific type of cancer. We call this multidisciplinary care. This means that cancer specialists work together to develop and deliver a personalized care plan just for you.
Our nurse navigators are important members of our team. Your nurse navigator will educate you about your diagnosis and treatment, and help guide you throughout your journey—answering your questions and putting you in touch with the services you need.
We encourage you to be an active participant in your care. Ask questions, take notes during your visits, and take advantage of the many different supportive care services we have available to you—like our complementary medicine therapies, nutrition counseling, and social work services.
**We know a cancer diagnosis is a tough experience to go through, and I want you to know that we are here with you. Some of the things said during your upcoming visit may be difficult to understand, and we want you to feel comfortable with asking questions if something is confusing or doesn’t make sense. We will be with you, and we will go through this together.**
We believe that exceptional treatment requires a team of experts who specialize in a specific type of cancer. We call this multidisciplinary care. This means that cancer specialists work together to develop and deliver a personalized care plan just for you.
Our nurse navigators are important members of our team. Your nurse navigator will educate you about your diagnosis and treatment, and help guide you throughout your journey—answering your questions and putting you in touch with the services you need.
We encourage you to be an active participant in your care. Ask questions, take notes during your visits, and take advantage of the many different supportive care services we have available to you—like our complementary medicine therapies, nutrition counseling, and social work services.
**I know this is a tough time for you, and I want to emphasize again that we are in this together. We will be with you each step along the way.**
Once again, thank you for choosing MD Anderson at Cooper for your care.

**Measurements and data collection**
After obtaining written informed consent, we will administer a research questionnaire to patients at the cancer centre prior to the initial cancer consultation. The questionnaire will assess the patients’ perception of the video oncologist’s compassion using the 5-item compassion measure, a previously validated patient-assessed measure of perceived compassion during patient care.20 21 We will abstract patient demographics, as well as clinical information pertaining to cancer diagnosis from the medical record.

**Outcome measures**
The primary outcome measure will be anxiety severity on arrival to the cancer centre for the initial consultation. As part of the research questionnaire, patients will be asked to complete the Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-item self-reported instrument that assesses anxiety and depressive symptoms in populations with medical conditions (both in-patients and out-patients).22 23 It has two 7-item subscales: HADS anxiety and HADS depression. Each item is scored on a 4-point scale (0=not at all to 3=nearly all the time); thus, each subscale can range from 0 to 21. The HADS has been extensively validated in oncology populations, and is a commonly used measure of anxiety and depression in oncology studies.24-27 The HADS depression score will be analysed as a secondary outcome. As an additional secondary outcome measure, we will determine the no-show rate for the initial consultation among each group. We will enter all data into Research Electronic Data Capture, a secure, web-based application designed...
to support data capture for research studies,28 and export the data into Stata/SE V.16.1 for Mac, StataCorp LP (College Station, TX, USA) for analysis.

Statistical analysis

For descriptive statistics, we will report categorical data as proportions with 95% CIs and continuous data as mean values with SDs or medians with IQRs as appropriate. As part of the CONSORT diagram,18 we will report the proportion of patients who do not attend their initial cancer consultation, as well as the proportion of patients who attend their initial consultation, but decline to participate in the study, stratified by video group allocation. We will test whether the enhanced compassion video reduced the no-show rate to the initial consultation, as well as increased participation in research using the Fisher exact test. We will use Cronbach’s alpha to separately test the internal reliability of the HADS anxiety scale, HADS depression scale and the 5-item compassion measure among our cohort. We will test whether the enhanced compassion video group perceived the video oncologist as more (or less) compassionate, as measured by the 5-item compassion measure, than the standard introduction video group using the Wilcoxon rank-sum test.

For the primary outcome, we will use the Wilcoxon rank-sum test to test for a difference in the HADS anxiety scale between the two video groups. We will also perform a sensitivity analysis dichotomizing the HADS anxiety scale into low (<8) and moderate/high (≥8). A cutoff point of 8 on the HADS subscales has been defined as the optimal cut-off point for diagnosis screening and is commonly used to define clinically significant symptoms in research studies.25 29

We will use the Fisher exact test to test whether the proportion of patients with clinically significant symptoms differed between the two video groups. For our secondary outcome measure, we will repeat the same analyses described above using the HADS depression scale in place of the HADS anxiety scale. We will perform the above analyses using intention to treat methodology. The analyses will be repeated in a per protocol fashion excluding patients who state they did not watch the video prior to presentation to the cancer centre.

To test whether the relationship between video group and anxiety severity differs among prespecified subgroups we will perform separate multivariable linear regression models with the HADS anxiety scale as the dependent variable, and entering the following patient characteristic along with an interaction term between video group and the characteristic as independent variables: (1) age (decile), (2) sex (male vs female), (3) race (white vs non-white), (4) ethnicity (Hispanic vs non-Hispanic) and (5) suspected primary cancer (breast vs gastrointestinal vs pulmonary vs skin vs central nervous system vs gynecologic vs other).

Sample size calculation

Assuming an α of 0.05, power of 0.8 and an SD of 5 for the HADS anxiety scale, based on previous literature,24 26 to detect a clinical meaningful difference (previously defined as a 1.5-point difference)30 between the subjects who viewed the standard introduction video compared with the subjects who viewed the enhanced compassion video we will need 176 subjects per group. Assuming a 25% lost to follow-up (ie, non-attendance to consultation or decline to participate) to ensure accrual of the total sample size of 352, we plan to enrol 470 total subjects.

DISCUSSION

This study aims to test whether viewing compassionate statements from an oncologist prior to an initial oncology consultation will reduce the degree of anxiety among patients referred to a cancer centre. By randomising subjects to one of two introduction videos, which differ only in regard to additional compassionate statements, we will be able to test whether the compassionate statements themselves have an effect on patient anxiety.

Given anxiety has been shown to decrease the ability to concentrate,5 decreasing patient anxiety prior to their initial consultation may improve engagement with their healthcare providers and empower them to ask questions about what tests and procedures are most appropriate for them. Such improvement in the clinician–patient interaction may also result in improved clinical assessment, accurate diagnosis, as well as better counselling, therapeutic instruction and cost-effectiveness.16 This study is the first step in testing whether preconsultation compassionate statements decrease patient anxiety. If our hypothesis is correct, future research will be warranted to test the effect of preconsultation compassionate statements on other clinical outcomes such as patient retention of clinical instructions, medication compliance and cost-effectiveness. Similarly, a null study will support further research into the timing, delivery mechanism and ‘dose’ of compassion that may be required to reduce patient anxiety prior to their study visit. Regardless of our results, qualitative research is also warranted to identify other potential intervention targets to strengthen the clinician–patient relationship.

To view the videos prior to the initial oncology consultation patients must have an active email account. Thus, subjects without an email account will be excluding potentially limiting generalisability of our results. However, this study will be a first step in determining whether clinician compassion can be conveyed to patients prior to their initial oncology consultation and whether preconsultation compassion can improve patient outcomes.

Protocol amendments

Any amendments to this protocol will be described along with the rationale and date the change was implemented.

Patient and public involvement

We designed this study given previous research has demonstrated that compassionate patient care is considered one of the most important aspects of high-quality healthcare by patients and patient family members.8 31 However, individual patients were not involved in the design of this study.
Data sharing

After review and approval by our study data use committee, we will allow other researchers who submit to us a suitable protocol to have access to the complete deidentified data-sets used and/or analysed during the study, in comma separated value format together with a data dictionary.

ETHICS AND DISSEMINATION

As stated above, this study was approved by the Cooper University Health Care Institutional Review Board with alteration of the requirements of obtaining informed consent under 45 CFR 46.116(d). The results from this randomised control trial will be submitted for publication to peer-reviewed journals, and to national meetings in presentation form.

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Contributors All authors have made substantial contributions to this report. BWR supervised all aspects of the study design and takes responsibility for the article as a whole. BWR, CW, AM, GG and ST contributed to the study design and development of the video scripts. BWR provided statistical expertise. BWR, CW and ST drafted the manuscript. AM and GG: read and contributed substantially to revision of the final manuscript. BWR, CW, AM, GG and ST: approved the manuscript in its final form.

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REFERENCES

1 Dermatis H, Lesko LM. Psychosocial correlates of physician-patient communication at time of informed consent for bone marrow transplantation. Cancer Invest 1991;9:621–8.
2 Fallowfield LJ, Hall A, Maguire GP, et al. Psychological outcomes of different treatment policies in women with early breast cancer outside a clinical trial. BMJ 1990;301:575–80.
3 Jefferson L, Atkin K, Sheridan R. Non-attendance at urgent referral appointments for suspected cancer: a qualitative study to gain understanding from patients and GPs. Br J Gen Pract 2019.
4 Sheridan R, Oliver SE, Hall G, et al. Patient non-attendance at urgent referral appointments for suspected cancer and its links to cancer diagnosis and one year mortality: a cohort study of patients referred on the two week wait pathway. Cancer Epidemiol 2019;63:101588.
5 Moran TP. Anxiety and working memory capacity: a meta-analysis and narrative review. Psychol Bull 2016;142:831–64.
6 Shim E-J, Lee JW, Cho J, et al. Association of depression and anxiety disorder with the risk of mortality in breast cancer: a national health insurance service study in Korea. Breast Cancer Res Treat 2020;179:491–8.
7 Grant JL, Keer D, Simon-Thomas E. Compassion: an evolutionary analysis and empirical review. Psychol Bull 2010;136:351–74.
8 Sinclair S, Norris JM, McConnell SJ, et al. Compassion: a scoping review of the healthcare literature. BMJ Palliat Care 2016;15:6.
9 Singer T, Klimecki OM. Empathy and compassion. Curr Biol 2014;24:P875–8.
10 Stewart M, Brown JB, Donner A, et al. The impact of patient-centered care on outcomes. J Fam Pract 2000;49:796–804.
11 Stewart MA. Effective physician-patient communication and health outcomes: a review. CMAJ 1995;152:1423–33.
12 DiMatteo MR. The role of the physician in the health care environment. West J Med 1998;168:328–33.
13 Hillen MA, de Haes HJCJ, Stalpers LJA, et al. How can communication by oncologists enhance patients’ trust? an experimental study. Ann Oncol 2014;25:896–901.
14 van Vliet LM, van der Wall E, Plum NM, et al. Explicit prognostic information and reassurance about nonabandonment when entering palliative breast cancer care; findings from a scripted video-vignette study. J Clin Oncol 2013;31:3242–9.
15 Ngpty LA, Curbow BA, Wingard JR, et al. Can 40 seconds of compression reduce patient anxiety? J Clin Oncol 1999;17:371–9.
16 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med 2013;158:200–7.
17 Chan A-W, Tetzlaff JM, Gotzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ 2013;346:e7586.
18 Schulz KF, Altman DG, Moher D. Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;2010:c332.
19 Patel S, Pelletier-Baul A, Smith S, et al. Curricula for empathy and compassion training in medical education: a systematic review. PLoS One 2019;14:e0221412.
20 Roberts BW, Roberts MB, Yao J, et al. Development and validation of a tool to measure patient assessment of clinician compassion. JAMA Netw Open 2019;2:e191176.
21 Sabapathi P, Roberts MB, Fuller BM, et al. Validation of a 5-item tool to measure patient assessment of clinician compassion in the emergency department. BMJ Emerg Med 2019;19:63.
22 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361–70.
23 Hermann C. International experiences with the Hospital Anxiety and Depression Scale—a review of validation data and clinical results. J Psychosom Res 1997;42:17–41.
24 Inhester B, Beierlein V, Bultmann JC, et al. Anxiety and depression in working-age cancer survivors: a register-based study. BMC Cancer 2017;17:347.
25 McFarland DC. New lung cancer treatments (immunotherapy and targeted therapies) and their associations with depression and other psychological side effects as compared to chemotherapy. Gen Hosp Psychiatry 2019;60:145–55.
26 Park EM, Gelber S, Rosenberg SM, et al. Anxiety and depression in young women with metastatic breast cancer: a cross-sectional study. Psychosomatics 2018;59:251–8.
27 Schellekens MPJ, van den Hurk DGM, Prins JB, et al. The suitability of the hospital anxiety and depression scale, distress thermometer and other instruments to screen for psychiatric disorders in both lung cancer patients and their partners. J Affect Disord 2016;203:176–83.
28 Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)-a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–81.
29 Bjelland I, Dahl AA, Haug TT, et al. The validity of the hospital anxiety and depression scale. An updated literature review. *J Psychosom Res* 2002;52:69–77.

30 Puhan MA, Frey M, Büchi S, et al. The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease. *Health Qual Life Outcomes* 2008;6:46.

31 Trzeciak S, Roberts BW, Mazzarelli AJ. Compassionomics: hypothesis and experimental approach. *Med Hypotheses* 2017;107:92–7.