A pre-consultation compassion video to reduce anxiety among patients referred to a cancer center: a randomized control trial

Protocol

4/18/21

Participants

We will enroll adult patients scheduled for an initial cancer consultation at MD Anderson Cancer Center at Cooper. Inclusion criteria include: 1) age ≥ 18 years; 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.

Intervention, randomization and masking

All new adult patients scheduled for an initial cancer consultation at MD Anderson Cancer Center at Cooper will be randomized to receive an email containing a link for either the "standard introduction video" or the "enhanced compassion video." Subjects will receive either an information only standard introduction video (76 seconds) or an enhanced compassion video (107 seconds). The two videos featured the same oncologist (i.e. Medical Director of the cancer center) and are identical except the enhanced compassion video contains five additional compassion-focused statements. An independent statistician will generate the group assignment sequence using a parallel design, 1:1 simple randomization schedule. The randomization 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 labeled 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. When the patients arrive to the Cancer Center waiting room for his/her initial cancer consultation they will be approached by research staff to obtain written informed consent to complete the research questionnaire and for use of data.

Outcome measures

The primary outcome measure will be anxiety severity on arrival to the cancer center 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 Depression score will be analyzed as a secondary outcome.

Statistical analysis:

We will use the Wilcoxon rank-sum test to test for a difference in the HADS anxiety scale between the two video groups and quantile regression to report the median difference with 95% CI. For our secondary outcome measure we will repeat the same analyses using the HADS depression scale in place of the HADS anxiety scale. We will perform all analyses using intention to treat principle.