## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | A pre-consultation compassion intervention to reduce anxiety among patients referred to a cancer center: protocol for a randomized control trial |
| **AUTHORS** | Winn, Christine; Generosa, Grana; Mazzarelli, Anthony; Trzeciak, Stephen; Roberts, Brian |

## VERSION 1 – REVIEW

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| **REVIEWER** | Van Vliet, Liesbeth<br>Leiden University, Health, Medical, and Neuropsychology |
| **REVIEW RETURNED** | 17-Feb-2021 |

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| **GENERAL COMMENTS** | Review comments<br>I applaud the authors for setting up this simple, yet fascinating study with huge clinical potential. I have a few comments about the article & about the methodology which might help the authors. I wish them the best of luck with conducting this study.<br><br>Introduction<br>There are a few other studies worth mentioning that looked at the effect of compassionate statements during oncology-visits (also using videos and volunteer patients). E.g: Hillen et al., 2014 How can communication by oncologists enhance patient's trust (caring statements lead to more trust); van Vliet et al 2013 JCO Explicit prognostic information and reassurance for nonabandonment (compassionate statements decrease anxiety).<br>It is unclear to me whether watching a standard information video is already common-practice or not – this becomes only clear in the Methods-section, perhaps move this to the Introduction?<br>As no-show is an outcome measure, could the authors perhaps add something in the introduction about how often this occurs nowadays?<br>Please start 'the aim of the study is' in a new paragraph.<br><br>Methods<br>No need to change in manuscript, but I wonder why it was not possible to obtain IC online before watching the video?<br>I wonder whether there might be any Covid-19 changes/restrictions. E.g, are all first consultations still being done in person, or also remotely? What if it will all change to remotely; what would the implications for the study be?<br>By not including patients who do not have an email-address there is a risk of not including LHL patients – perhaps add as a limitation?<br>Manipulation: The manipulation looks really good, but I wonder whether it has been pilot-tested to ensure the second video is really perceived as being more compassionate by patients? I |

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| | assume this is not the case as the authors mention that patients were not involved. If there is still time to pilot-test it, that might be advisable just to be sure the manipulation will be successful. (especially as in the standard video there is also a section about the support of nurses).<br>Manipulation: the standard manipulation also oozes expertise, competence. I just wonder whether this might also influence outcomes such as anxiety (as it might indeed influence trust)? Something to keep in mind when interpreting the data; I assume there is no comparison data available from a group that does not receive any video?<br>Discussion<br>I am used that even protocol papers include a short discussion-section; could the authors include one (e.g. restating the aim, possible strengths and weaknesses, possible clinical implications)? |

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| **REVIEWER** | Poletti, Stefano<br>INSERM U1028, CRNL-DYCOG |
| **REVIEW RETURNED** | 10-Mar-2021 |

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| **GENERAL COMMENTS** | This protocol study addresses a crucial point in delivering cancer diagnoses and treatment and includes both human-ethical and healthcare consequences. Many studies showed the lack of compassionate care and these outcomes could shed new light on the effectiveness of such an approach. Effective doctor-patient communication is a central clinical function in building a therapeutic doctor-patient relationship, which is the heart and art of medicine. This is important in the delivery of high-quality health care. Much patient dissatisfaction and many complaints are due to breakdown in the doctor-patient relationship. In this context, a wider description of consequences (in terms of clinical assessment, accurate diagnosis, counsel appropriately, give therapeutic instructions, cost-effectiveness, sustainability, etc) should be included in the discussion section. The methods to assess the impact on anxiety and depression, as well as on "no shows", are corroborated by other results and methodologically consistent. There is just a general need of expanding and clarifying few points in the introduction (see document). The outcomes of this study could encourage different communication training to help physicians improve their communication skills (future directions). Limitations: This study would benefit from qualitative data. |

## VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. I applaud the authors for setting up this simple, yet fascinating study with huge clinical potential. I have a few comments about the article & about the methodology which might help the authors. I wish them the best of luck with conducting this study.

Response 1: We thank the reviewer for these kind words.

2. There are a few other studies worth mentioning that looked at the effect of compassionate statements during oncology-visits (also using videos and volunteer patients). E.g: Hillen et al., 2014 How can communication by oncologists enhance patient's trust (caring statements lead to more trust); van Vliet et al 2013 JCO Explicit prognostic information and reassurance for nonabandonment (compassionate statements decrease anxiety).

Response 2: We thank the reviewer for bringing these studies to our attention and we have incorporated them into our introduction section [page 4, lines 110-112].

3. It is unclear to me whether watching a standard information video is already common-practice or not – this becomes only clear in the Methods-section, perhaps move this to the Introduction?

Response 3: We now state in the introduction that the standard introduction video is being sent as part of an ongoing clinical quality initiative at our institution [page 5, line 127].

4. As no-show is an outcome measure, could the authors perhaps add something in the introduction about how often this occurs nowadays?

Response 4: We agree, and now discuss how often patients do not attend their scheduled appointment [page 4, lines 93-94].

5. Please start 'the aim of the study is' in a new paragraph.

Response 5: Done

6. No need to change in manuscript, but I wonder why it was not possible to obtain IC online before watching the video?

Response 6: We specifically decided not to obtain consent prior to watching the videos, as we wanted to keep subjects blinded to the hypotheses and the purposes of the videos until they arrived for their appointments so as to not influence their perspective of the videos and the affects the videos may (or may not) have on anxiety. We now further explain this in the methods section [page 6, lines 155-160].

7. I wonder whether there might be any Covid-19 changes/restrictions. E.g, are all first consultations still being done in person, or also remotely? What if it will all change to remotely; what would the implications for the study be?

Response 7: Our institution has implemented strict masking and social distancing policies and all initial consultants will be in person. We now state this in our methods section [page 6, lines 162-163].

8. By not including patients who do not have an email-address there is a risk of not including LHL patients – perhaps add as a limitation?

Response 8: We agree and have added this as a limitation [page 3, lines 85-86; page 12, lines 337-341].

9. Manipulation: The manipulation looks really good, but I wonder whether it has been pilot-tested to ensure the second video is really perceived as being more compassionate by patients? I assume this is not the case as the authors mention that patients were not involved. If there is still time to pilot-test it, that might be advisable just to be sure the manipulation will be successful. (especially as in the standard video there is also a section about the support of nurses).

Response 9: The reviewer is correct this intervention has not been pilot tested. As described in the methods section we plan to administer a previously validated patient-assessed measure of perceived compassion (5-item compassion measure) to test if the enhanced compassion video is perceived as more compassionate by patients.

10. Manipulation: the standard manipulation also oozes expertise, competence. I just wonder whether this might also influence outcomes such as anxiety (as it might indeed influence trust)? Something to keep in mind when interpreting the data; I assume there is no comparison data available from a group that does not receive any video?

Response 10: The reviewer is again correct, given our goal is to test specifically if the compassion language will have an effect on patient anxiety (as opposed to the effects of a video itself) we planned to have the videos be identical aside from the added compassion language. We now discuss this in our new discussion section [page 12, lines 317-321].

11. I am used that even protocol papers include a short discussion-section; could the authors include one (e.g. restating the aim, possible strengths and weaknesses, possible clinical implications)?

Response 11: We agree and have added a discussion section [page 12, lines 316-341].

Reviewer: 2

1. This protocol study addresses a crucial point in delivering cancer diagnoses and treatment and includes both human-ethical and healthcare consequences. Many studies showed the lack of compassionate care and these outcomes could shed new light on the effectiveness of such an approach. Effective doctor-patient communication is a central clinical function in building a therapeutic doctor-patient relationship, which is the heart and art of medicine. This is important in the delivery of high-quality health care. Much patient dissatisfaction and many complaints are due to breakdown in the doctor-patient relationship. In this context, a wider description of consequences (in terms of clinical assessment, accurate diagnosis, counsel appropriately, give therapeutic instructions, cost-effectiveness, sustainability, etc) should be included in the discussion section.

Response 1: We agree and now discuss the reviewer's point in our added discussion section [page 12, lines 323-335].

2. The methods to assess the impact on anxiety and depression, as well as on "no shows", are corroborated by other results and methodologically consistent. There is just a general need of expanding and clarifying few points in the introduction (see document). The outcomes of this study could encourage different communication training to help physicians improve their communication skills (future directions).

Response 2: We have added a discussion section which includes a discussion of future directions [page 12, lines 329-335].

3. Limitations: This study would benefit from qualitative data.

Response 3: We agree and now discuss the need for qualitative data in our discussion section (i.e. future directions) [page 12, lines 334-335].

Comments from document:

4. A wider perspective on patient-centered approaches would be helpful here: The impact of patient-centered care on outcomes.

Stewart M, Brown JB, Donner A, McWhinney IR, Oates J, Weston WW, Jordan J

J Fam Pract. 2000 Sep; 49(9):796-804.

Response 4: We agree and have expanded our introduction section [page 4, lines 104-110].

5. The discussion of the results should include an extensive overview on benefits of improving clinicians-patients conversations, e.g. engaging their health care provider through these conversations and empowering them to ask questions about what tests and procedures are most appropriate for them. An overview on existing proposals that enhance patient-friendly materials could also be included.

Response 5: We agree and have added a discussion section, which addresses how the pre-consultation video may improve clinician-patient conversations [page 12, lines 323-328].

6. Past reviews showed how patients expressed discontent even when many doctors considered the communication adequate or even excellent. Doctors tend to overestimate their abilities in communication. see Stewart M. A. Effective physician-patient communication and health outcomes: a review. CMAJ. 1995;152((9)):1423–1433.

Response 6: We thank the reviewer for this reference. We now discuss the findings of this review in our introduction section [page 4, lines 106-108].

7. It has also been observed how communication skills tend to decline as medical students progress through their medical education: The role of the physician in the emerging health care environment. DiMatteo MR West J Med. 1998 May; 168(5):328-33.

Response 7: We again thank the reviewer for this reference. We found its discussion regarding the importance to patients of compassionate communication to be very relevant to our study and now reference it in our introduction section [page 4, lines 108-110].

8. A clear, distinctive definition of compassion is missing.

Response 8: We now define compassion in our introduction section [page 4, lines 103-104].

**VERSION 2 – REVIEW**

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| **REVIEWER** | Van Vliet, Liesbeth<br>Leiden University, Health, Medical, and Neuropsychology |
| **REVIEW RETURNED** | 21-Apr-2021 |

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| **GENERAL COMMENTS** | I thank the Authors for addressing my comments so thoroughly and wish them all the luck with conducting this study! |