PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Discrepancy in Patient- and Oncologist-Rated Performance Status on Depression and Anxiety in Cancer: A Prospective Study Protocol
AUTHORS	Chan, Caryn ; Wan Ahmad, Wan Azman; Yusof, Mastura; Ho, Gwo Fuang; Krupat, Edward

VERSION 1 - REVIEW

REVIEWER	Wolfgang Linden University of British Columbia
REVIEW RETURNED	26-Jul-2012

THE STUDY	This paper is a proposal for an experimental study. The study question is interesting and I encourage the authors to actually run this study. They should do pilot data first to determine feasability and obtain an effect size estimate. Then they can compute power statistics and decide what sample size is needed. Protocols of studies not yet run get only published if they are for long-term clinical trials, and usually have baseline data in hand that in and of itself may be informative. A second reason for publishing a trial design is that either something innovative was done within the protocol or the researchers simply want others to know that such a study is forthcoming to prevent expensive duplication. I cannot find a single positive reason for why this proposal should be published. In fact, as an author, I'd rather not discuss my study at this stage because I would not want to encourage others to run away with my idea.
GENERAL COMMENTS	I'd willing to review the manuscript once it is complete and we have data to look at.

REVIEWER	Esther Dajczman RN.,M.Sc.A. Clinical Nurse Specialist- Pulmonary Diseases Jewish General Hospital Montreal, Quebec, Canada
REVIEW RETURNED	06-Aug-2012

THE STUDY	The authors might include the ECOG Performance status measure and the HADS measure in an appendix to the manucript.
GENERAL COMMENTS	This is a generally well written and thought out protocol. It addresses a very important clinical issue namely how to easily screen for psychological distress in a busy oncology clinic environment. The introduction, hypothesis, methodology, is well thought out in general. Of note, research question number 1, poses that if there is a discrepancy between the patient and physician's ECOG value, what is the cause. The study is not designed to verify the causes of the discrepancy between the

	ECOG evaluations, but more specifically that this discrepancy may be associated with an increased likelihood of co morbid anxiety and depression, and thus well correlated with the HADS. This is well stated in the hypothesis of the protocol. The authors do not adequately discuss the use of the distress thermometer and mention this tool only briefly in the discussion part of the manuscript. In view of its ease of use, and ability to screen for distress (ref: Prevalence of emotional distress in newly diagnosed lung cancer patients-Steinberg et al), it might therefore have been beneficial to consider correlating this simple tool in addition to the discrepancy in the ECOG scale with the HADS. This might have been able to yield a valuable piece of information, in terms of screening tools for psychological distress, and it would have been simple for the patient to have completed this alongside the ECOG, and the HADS in order to see which result is better correlated with the HADS .

VERSION 1 – AUTHOR RESPONSE

Reviewer: Wolfgang Linden
University of British Columbia

This paper is a proposal for an experimental study. The study question is interesting and I encourage the authors to actually run this study. They should do pilot data first to determine feasability and obtain an effect size estimate. Then they can compute power statistics and decide what sample size is needed.

[6] Thank you for your kind encouragement to run the study. We appreciate that you have raised several important factors and have sought to properly clarify with the help of the statistician we consulted on this. Indeed, we did run a pilot study previous to this to consider these points (referred to as 'preliminary testing' in page 5, paragraph 2, lines 13-14) from which the cronbach alpha was obtained. Pilot testing computed an r = 0.75, which using Cohen's conventions can be interpreted as a large effect size. A priori power calculation using the effect size of 0.75 with the conventional probability level of .05 in a sample size of 306 would result in an observed power of 0.99 (two-tailed).

We calculated our sample size using a ±5% error with 95% confidence, using a response rate of 50% as it gives the largest sample size. The actual response rate is actually much higher at approximately 96%, rendering feasibility a non-issue.

Although an estimated figure of 306 patients would be sufficient to test our hypothesis in a cross-sectional design, we adopted the much larger sample size of 500 to cater for drop-outs at various follow-ups points (estimated at 20-40%) and to facilitate regression analyses.

Protocols of studies not yet run get only published if they are for long-term clinical trials, and usually have baseline data in hand that in and of itself may be informative. A second reason for publishing a trial design is that either something innovative was done within the protocol or the researchers simply want others to know that such a study is forthcoming to prevent expensive duplication. I cannot find a single positive reason for why this proposal should be published. In fact, as an author, I'd rather not discuss my study at this stage because I would not want to encourage others to run away with my idea.

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Reviewer: Esther Dajczman RN.,M.Sc.A.
Clinical Nurse Specialist- Pulmonary Diseases
Jewish General Hospital
Montreal, Quebec, Canada

The authors might include the ECOG Performance status measure and the HADS measure in an appendix to the manucript.

[7] We now include the ECOG Performance status measure in an appendix. We did not include the HADS as it is registered and licensed by GL Assessment – while the HADS is free for use in individual clinical practice, reprinting it even as inclusion to the appendix may likely constitute a breach of copyright.

This is a generally well written and thought out protocol. It addresses a very important clinical issue namely how to easily screen for psychological distress in a busy oncology clinic environment. The introduction, hypothesis, methodology, is well thought out in general. Of note, research question number 1, poses that if there is a discrepancy between the patient and physician's ECOG value, what is the cause. The study is not designed to verify the causes of the discrepancy between the ECOG evaluations, but more specifically that this discrepancy may be associated with an increased likelihood of co morbid anxiety and depression, and thus well correlated with the HADS. This is well stated in the hypothesis of the protocol.

[8] We thank you greatly for your supportive feedback and recommendations. We hope to be able to run regression analyses later on to establish causality.

The authors do not adequately discuss the use of the distress thermometer and mention this tool only briefly in the discussion part of the manuscript. In view of its ease of use, and ability to screen for distress (ref: Prevalence of emotional distress in newly diagnosed lung cancer patients-Steinberg et al), it might therefore have been beneficial to consider correlating this simple tool in addition to the discrepancy in the ECOG scale with the HADS. This might have been able to yield a valuable piece of information, in terms of screening tools for psychological distress, and it would have been simple for the patient to have completed this alongside the ECOG, and the HADS in order to see which result is better correlated with the HADS.

[9] Your suggestion on adding the DT is a brilliant one. We concur that it would be indeed extremely interesting and valuable to see how the ECOG would compare against the DT, using the HADS as criterion – hence we would strongly consider doing this at either the one-year follow-up or in future studies, as the baseline and 4-6 week follow-up for this study has just been completed. Our chief focus for now is therefore on the ECOG rather than the well validated Distress Thermometer (DT) which has been extensively validated and described in other papers. We mention the DT only as a point of comparison. Hence, describing it further without actually including it in would go beyond the scope of this study.

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Lastly, we would like to thank the managing editor and reviewers for your time and effort taken to review this paper.