PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluating Holistic Needs Assessment in Outpatient Cancer Care: a Randomised Controlled Trial- the study protocol.
AUTHORS	Snowden, Austyn; Young, Jenny; White, Craig; Murray, Esther; Richard, Claude; Lussier, Marie-Therese; MacArthur, Ewan; Storey, Dawn; Schipani, Stefano; Wheatley, Duncan; McMahon, Jeremy; Ross, Elaine

VERSION 1 - REVIEW

REVIEWER	Elaine Boland Queen's Centre for Oncology and Haematology Hull and East Yorkshire Hospitals NHS Trust, UK
REVIEW RETURNED	25-Feb-2015

GENERAL COMMENTS	1) Has the NCSI Concerns checklist been validated and why did you choose that? 2) As the clinicians span over four professional groups their level of communications skills will be different (despite having training using HNA) and this will have an impact on the outcome. I feel that as a secondary outcome, the patient participation/shared decision-making and self-efficacy should be broken down to each professional group and see if there is any difference. 3) Another important outcome is whether the clinicians felt that the HNA impacted on their consultation and found it useful/ 4) Did it increase the clinic time esp in a busy oncology clinic? As this would be crucial for future use in clinical settings 5) Learning' from the consultations where a HNA is applied may crossover into their interactions with the control group – I think is a strong limitation of your study and will have an impact. Ways to overcome this could include: - Either have this as cluster randomised controlled trial of the clinics - Or else each clinic first recruit a baseline sample as controls and then go on the randomisation 6) What is the time frame for this trial?

REVIEWER	Veronica Nanton University of Warwick United Kingdom
REVIEW RETURNED	06-Mar-2015

GENERAL COMMENTS	I have enjoyed reading this well written protocol paper. Holistic Needs Assessment is increasingly widely used but evidence of its impact on the consultation is lacking. This study is timely and relevant to clinical practice which currently varies widely in approach to holistic needs assessment in cancer care.

	The authors have followed the Spirit guidelines and provide a well argued rationale for the design and for the measures used. The basis of the sample size calculation and statistical analysis plan is justified. There is an issue of clinician learning and potential contamination between intervention and control groups that the authors acknowledge and will incorporate in the analysis. My only disappointment is that while the pilot phase includes some feedback from clinicians regarding their experience with the HNA, no qualitative investigation of patients' responses to the intervention is described. These accounts would be valuable alongside the quantitative outcome data in assessing the impact of the HNA from the patient perspective. I have only minor suggestions to the authors and a few questions: MEDICODE appears to be a useful method of coding the consultations. I am not familiar with MEDICODE and all the references I have checked relate to discussions over medication. The authors have explained the two variables of dialogue ratio and preponderance of initiative and describe their intention to develop a coding framework for MEDICODE around holistic needs. I have some experience of the Roter Interaction Analysis System and understand this process but for readers who are unfamiliar with consultation coding, the development of MEDICODE from codes in the context of discussion over medication to a wider discussion over holistic needs could usefully be explained more fully. There is no mention in text (although there is a clue in the name) that MEDICODE relates specifically to discussions over medication. Lorig's self efficacy scale was developed for chronic disease but has been widely used in cancer. Cancer is now frequently described as a chronic disease but is this appropriate for all the patient groups included in this study (head and neck patients for example)? A sentence acknowledging that this is an assumption would pre-empt any criticism on this point. I suggest a more detailed description of the training given to clinicians: is this a one off session, does it involve role play, is it done in groups etc . I would like the authors to explain why the Concerns checklist has been utilised as the HNA in preference to any of the other available instruments. Will there be any assessment of clinicians' previous use of HNA? Is there any measurement of impact of the use of the HNA on consultation length or is the consultation length fixed in the two study arms? The participation of 10 sites in this trial is a considerable achievement on the part of the authors. The data to be generated may have important implications for the future of HNA in cancer follow up. I look forward to reading an account of the findings of this study.

VERSION 1 – AUTHOR RESPONSE

Reviewer Name Elaine Boland
Institution and Country Queen's Centre for Oncology and Haematology
Hull and East Yorkshire Hospitals NHS Trust, UK
Please state any competing interests or state 'None declared': None

Please leave your comments for the authors below

1) Has the NCSI Concerns checklist been validated and why did you choose that?

The NCSI Concerns Checklist has not been formally validated but it is the tool of choice of the study funders Macmillan Cancer Support UK. It is closely based on the distress thermometer that has been extensively validated.

2) As the clinicians span over four professional groups their level of communications skills will be different (despite having training using HNA) and this will have an impact on the outcome. I feel that as a secondary outcome, the patient participation/shared decision-making and self-efficacy should be broken down to each professional group and see if there is any difference.

We agree and can hopefully incorporate this into an analysis of subgroups. However, the study has been powered to primarily detect an overall difference between experimental and control group in general.

P10 We also plan to conduct subgroup analyses according to characteristics of the clinicians. For example we have obtained information on gender, profession and years of experience. These can be used to explore any potential findings in greater depth.

3) Another important outcome is whether the clinicians felt that the HNA impacted on their consultation and found it useful/

We agree. We are measuring the time taken in both groups. We removed this from the hypotheses as we could not establish what a meaningful difference in time would be. However, we are monitoring this as in our pilot study we found there to be no time difference. In relation to wider utility we plan to interview clinicians throughout the study.

4) Did it increase the clinic time esp in a busy oncology clinic? As this would be crucial for future use in clinical settings

Please see response above.

5) Learning' from the consultations where a HNA is applied may crossover into their interactions with the control group – I think is a strong limitation of your study and will have an impact.
Ways to overcome this could include:
- Either have this as cluster randomised controlled trial of the clinics
- Or else each clinic first recruit a baseline sample as controls and then go on the randomization

Whilst we hope learning will occur we disagree that this is a limitation because the intervention is the HNA, not the skills of the clinician. For example if the patient does not complete HNA prior to the consultation they (the patient) will not know that they are free to raise any concerns on the checklist. In our experience patients assume the consultation is purely 'clinical' and are thus not ready to discuss any issues outside their conception of this. From the clinician's perspective, whilst their communication skills may be improved as a function of previous HNA experience, they will still not

know what the patient's problems are, and would not be able to find out unless they completed HNA.

However, we do acknowledge that learning will occur. We have added the following sentence to the limitations section:

Due to the way we have randomised the same clinicians deliver both experimental and control treatment. There is therefore a risk of crossover learning from the experimental to the control. We could have mitigated this using a cluster randomised trial design, but this was not an option due to the increased number of participants required. Further, whilst crossover learning is a risk, we did not consider it would undermine the key objectives as the main intervention is the concerns checklist, not the skills of the clinician.

From a statistical perspective we are mitigating this effect by using analysis of covariance to fit trendlines to the data over time. In this way time can be used as a covariate to remove any effect of learning. Please see page 10.

6) What is the time frame for this trial?

Data collection will run for 12 months. (page 8)

Reviewer Name Veronica Nanton
Institution and Country University of Warwick
United Kingdom
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below
I have enjoyed reading this well written protocol paper. Holistic Needs Assessment is increasingly widely used but evidence of its impact on the consultation is lacking. This study is timely and relevant to clinical practice which currently varies widely in approach to holistic needs assessment in cancer care.

The authors have followed the Spirit guidelines and provide a well argued rationale for the design and for the measures used. The basis of the sample size calculation and statistical analysis plan is justified. There is an issue of clinician learning and potential contamination between intervention and control groups that the authors acknowledge and will incorporate in the analysis.

My only disappointment is that while the pilot phase includes some feedback from clinicians regarding their experience with the HNA, no qualitative investigation of patients' responses to the intervention is described. These accounts would be valuable alongside the quantitative outcome data in assessing the impact of the HNA from the patient perspective.

Thank you very much for your comments. As you say, we obtained qualitative feedback from patients in a previous study and plan to follow up patients in this study too. Apologies this wasn't explicit. The patients complete the study documentation and also add their email address/contact details to the form should they wish to participate in further interviews. We have added this to the protocol on page 9.

I have only minor suggestions to the authors and a few questions:

MEDICODE appears to be a useful method of coding the consultations. I am not familiar with MEDICODE and all the references I have checked relate to discussions over medication. The authors have explained the two variables of dialogue ratio and preponderance of initiative and describe their

intention to develop a coding framework for MEDICODE around holistic needs. I have some experience of the Roter Interaction Analysis System and understand this process but for readers who are unfamiliar with consultation coding, the development of MEDICODE from codes in the context of discussion over medication to a wider discussion over holistic needs could usefully be explained more fully. There is no mention in text (although there is a clue in the name) that MEDICODE relates specifically to discussions over medication.

Thank you. You are correct we have designed this as a bespoke tool for coding cancer consultations. MEDICODE was as you say developed for medicine management analysis and we have worked together to develop the coding package consistent with the aims of this study. In brief, the coding framework mirrors the broad categories of the holistic needs assessment. We recognize this is a novel system that has not been used in cancer consultations before. However, the principles of dialogue ration and preponderance of initiative are transferable to any clinical consultation, and were chosen here as the best evidence for capturing the subtle shifts in conversation most likely in a study attempting to shift the focus from clinician to patient. The following sentence has been added to the text on page 7:

MEDICODE was constructed to measure conversations about medicine management [23] and has not been used previously to analyse cancer consultations. However, the principles of dialogue ratio and preponderance of initiative are transferable to any clinical consultation, and were chosen for this study as the best way of capturing the subtle shifts in conversation hypothesised to occur.

Also page 8:

It is our intention to structure the coding framework around the theory of holistic needs assessment, coding elements of the clinical conversation according to concern discussed: Physical, Practical, Family/Relationship, Emotional, Spiritual, Lifestyle (see Figure 1).

Lorig's self efficacy scale was developed for chronic disease but has been widely used in cancer. Cancer is now frequently described as a chronic disease but is this appropriate for all the patient groups included in this study (head and neck patients for example)? A sentence acknowledging that this is an assumption would pre-empt any criticism on this point.

Thank you. We used the Lorig self-efficacy scale because of the volume of evidence supporting its use. In particular it was recommended in a review of outcome measures by Davies in 2009. We acknowledge that in attempting to use the best generic tool we may not capture the more disease specific elements of self efficacy. We have added the following sentence to the paper on page 7:

We acknowledge that a limitation of the tool is that it has not been widely used with all cancer types. However, it appears to be the best generic to