PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Health status and needs of cancer survivors attending the Sydney Survivorship Centre clinics and programmes: A protocol for longitudinal evaluation of the Centre's services
AUTHORS	Vardy, Janette; Tan, Cindy; Turner, Jane; Dhillon, Haryana

VERSION 1 - REVIEW

REVIEWER	Dr Rebecca Maguire National College of Ireland, Ireland
REVIEW RETURNED	08-Nov-2016

GENERAL COMMENTS	This paper describes a protocol for an observational single centre study for survivorship which has the potential to reveal some interesting findings. Overall the paper could benefit from greater clarification in some areas, in particular surrounding the methods and analysis. Some specific points are below: Abstract: • Recommend including a line on the overall aim(s)/objective(s) at end of intro. • The methods section should clarify the longitudinal nature of the study. • There is no mention of proposed analysis here – this should be included Weaknesses: • I presume sample size is not just determined by number of patients attending programme, but also those who consent to be involved in the research itself. Introduction: • Minor point: delete comma on page 4, line 36 • Page 5, line 18 – you note that psychological support is an important feature of most programmes. Could you elaborate on what such support might involve and provide a reference for this if possible? • Page 6, line 23 – Is the follow-up based on need (e.g. as determined by medical practitioner), the survivor's desire to participate, or some other factor? • Page 6, line 36 – It is also not clear whether all survivors are referred to the weight management clinic, or just those who are deemed overweight/obese. Please clarify. • Page 7, line 9-10 – A range of courses offered at the centre are mentioned but not described. Is there any evidence for the benefits of these activities in particular (and if not, why were they chosen as

	part of the programme)? More detail could be provided here. • A number of aims for research are listed on page 7. It is not clear whether these correspond to the aims of the specific protocol or the centre as a whole ("our major research aims to…"). If this does relate to the protocol, more detail would be needed on the statistical analysis that would ensue to meet these objectives. Methods • There is no indication of expected sample size. Sample size calculation should be mentioned (as per BMJ open guidelines an estimate of how many participants will be needed for the primary outcome to be statistically, clinically and/or politically significant should be included in any protocol) • Given that there is no control group, it is not possible to fully address the "impact" (e.g. page 9, line 50) of the programme by examining changes in measures over time (e.g. changes in QOL etc. may be due to other factors at that time). Causal language such as this should be removed within the manuscript. • While measures are listed with references to scales provided in places, more detail could be provided on what these involve (e.g. what do questionnaires comprise of, how will survivors' experience at clinic be assessed?) • The title of project includes reference to caregivers as well as survivors, however there does not seem to be many measures relating to caregivers (aside from some mention of qualitative interview). Consider removing reference to caregivers in title if this is not a core component of research or else give more details as to what measures will be taken from caregivers. • A more detailed data analysis plan could be included here. Will the various dependent variables just be examined in terms of their change over time from pre to post test, or will more complex analysis, taking into account relationships between various possible variables, (e.g. using multiple regression analyses) be undertaken? Discussion • A discussion section may not be appropriate here given the prospective nature of this study. Much of this information would be more appropriately placed in the introduction section (e.g. to provide a stronger rationale for the study itself).

REVIEWER	Gillian Prue Queen's University Belfast United Kingdom
REVIEW RETURNED	15-Nov-2016

GENERAL COMMENTS	This is a protocol of an evaluation of a multi-faceted project to evaluate the impact of a Survivorship centre clinic. While this has the potential to be an interesting study, there are a number of omissions that need to be addressed in the current protocol. Introduction: Are the aims listed the aims of the centre or of this protocol? To me these read more of a programme of research than the aim of the protocol. Would benefit from additional references. Methods: May be useful to separate this into the research question around

	those attending the clinic and a separate question on those participating in the various programmes. The methods are currently very focused on patients - what is the eligibility criteria for caregivers? how are caregivers consented to participate? Are there specific outcome measures for the caregivers? Are the ones currently listed just for patients? Are any caregiver specific scales being used - if not it may be a worthwhile consideration, or are the caregivers only included in the qualitative component? Analysis - what is the primary outcome? although the sample size is limited by attendees, it may still be possible to conduct a power calculation. The detail on how change over time will be determined needs to be included. How will the qualitative data be analysed, how will rigour be ensured? Is there an interview/focus group guide? What is the rationale for including both focus groups and interviews? Will any of the quantitative findings guide the qualitative interviews - how do the two relate? Discussion: There needs to be some discussion around the limitations of the study. With regards to the programmes component: I am not convinced about the ability to generalise the findings beyond the individuals attending the programmes. Are the programmes manualised and monitored for fidelity, if not this would appear to be more of a service evaluation than a research question as it would not be able to be reproduced in other patient/caregiver populations.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Dr Rebecca Maguire
Institution and Country: National College of Ireland, Ireland
Competing Interests: None declared

This paper describes a protocol for an observational single centre study for survivorship which has the potential to reveal some interesting findings. Overall the paper could benefit from greater clarification in some areas, in particular surrounding the methods and analysis.

Some specific points are below:

Abstract:
1. Recommend including a line on the overall aim(s)/objective(s) at end of intro.
Response: This has been added.
2. The methods section should clarify the longitudinal nature of the study.
Response: This has been added.

3. There is no mention of proposed analysis here – this should be included
Response: Details of the proposed analysis have been expanded. However, the intent of this protocol is the collection of longitudinal data to support a range of analyses, addressing specific questions at different time periods. Each analysis will be planned with aim, hypotheses, and analytical strategy pre-specified and an analyses-specific sample size calculated. We suggest that, in part, the value of this protocol paper is to provide a guide for others establishing models of survivorship care and follow-up to support embedding research evaluations within routine clinical practice in order to contribute to

the development of a stronger evidence-base for cancer survivorship care, in accordance with recommendations from IOM.

Weaknesses:
4. I presume sample size is not just determined by number of patients attending programme, but also those who consent to be involved in the research itself.
Response: This is correct. This has been clarified.

Introduction:
5 Minor point: delete comma on page 4, line 36
Response: This has been deleted.

6. Page 5, line 18 – you note that psychological support is an important feature of most programmes. Could you elaborate on what such support might involve and provide a reference for this if possible?
Response: This has been expanded and a reference added.

7. Page 6, line 23 – Is the follow-up based on need (e.g. as determined by medical practitioner), the survivor's desire to participate, or some other factor?
Response: This is determined by the original oncologist – and has been clarified.

8. Page 6, line 36 – It is also not clear whether all survivors are referred to the weight management clinic, or just those who are deemed overweight/obese (BMI>25). Please clarify.
Response: Only patients who are overweight or obese are eligible to attend the weight management clinic. This has been clarified.

9. Page 7, line 9-10 – A range of courses offered at the centre are mentioned but not described. Is there any evidence for the benefits of these activities in particular (and if not, why were they chosen as part of the programme)? More detail could be provided here.
Response: Courses are selected and offered based on there being some level of evidence for efficacy in cancer survivors. We have added a little extra detail and references have been added.

10. A number of aims for research are listed on page 7. It is not clear whether these correspond to the aims of the specific protocol or the centre as a whole ("our major research aims to…"). If this does relate to the protocol, more detail would be needed on the statistical analysis that would ensue to meet these objectives.
Response: This has been clarified. The majority relates to the aims of the centre.

Methods
11. There is no indication of expected sample size. Sample size calculation should be mentioned (as per BMJ open guidelines an estimate of how many participants will be needed for the primary outcome to be statistically, clinically and/or politically significant should be included in any protocol)
Response: As indicated above, this protocol paper describes an ongoing longitudinal study of cancer survivor experience and outcomes; as such there will be continuing analyses of the data to address specific questions at different time points. The power and sample size calculations for each question will be determined as part of the analysis planning, in advance of the analysis being undertaken. It is estimated that for major clinical endpoints a sample size of 300 participants would provide sufficient power for clinically significant results.

12. Given that there is no control group, it is not possible to fully address the "impact" (e.g. page 9, line 50) of the programme by examining changes in measures over time (e.g. changes in QOL etc. may be due to other factors at that time). Causal language such as this should be removed within the manuscript.

Response: We agree. This has been amended.

13. While measures are listed with references to scales provided in places, more detail could be provided on what these involve (e.g. what do questionnaires comprise of, how will survivors' experience at clinic be assessed?)
Response: The questionnaires we are using have all been validated in cancer patients and most are in common use. As requested we have added additional information regarding the questionnaires particularly for the less common questionnaires and the assessment of the survivors experience.

14. The title of project includes reference to caregivers as well as survivors, however there does not seem to be many measures relating to caregivers (aside from some mention of qualitative interview). Consider removing reference to caregivers in title if this is not a core component of research or else give more details as to what measures will be taken from caregivers.
Response: We agree the focus is on the survivors rather than the caregivers so we have removed the reference to caregivers in the title as suggested.

15. A more detailed data analysis plan could be included here. Will the various dependent variables just be examined in terms of their change over time from pre to post test, or will more complex analysis, taking into account relationships between various possible variables, (e.g. using multiple regression analyses) be undertaken?
Response: This has been expanded as suggested. As indicated in earlier responses this longitudinal study will support a range of analyses, of which simple descriptive and change over time analysis have been specified. In addition, more complex analysis may be planned in the future as our sample expands to provide sufficient power to assess relationship between different variables using mixed models analysis.

Discussion
16. A discussion section may not be appropriate here given the prospective nature of this study. Much of this information would be more appropriately placed in the introduction section (e.g. to provide a stronger rationale for the study itself).
Response: As suggested we have moved a couple of the paragraphs from the discussion to the introduction.

Reviewer: 2
Reviewer Name: Gillian Prue
Institution and Country: Queen's University Belfast, United Kingdom
Competing Interests: None declared

This is a protocol of an evaluation of a multi-faceted project to evaluate the impact of a Survivorship centre clinic. While this has the potential to be an interesting study, there are a number of omissions that need to be addressed in the current protocol.

Introduction:
1. Are the aims listed the aims of the centre or of this protocol? To me these read more of a programme of research than the aim of the protocol.
Would benefit from additional references.
Response: We have clarified what are the aims of the centres and the aims of this protocol. Additional references have been added to this section.

Methods:
2. May be useful to separate this into the research question around those attending the clinic and a

separate question on those participating in the various programmes.
The methods are currently very focused on patients - what is the eligibility criteria for caregivers? how are caregivers consented to participate? Are there specific outcome measures for the caregivers? Are the ones currently listed just for patients? Are any caregiver specific scales being used - if not it may be a worthwhile consideration, or are the caregivers only included in the qualitative component?

Response: As suggested parts of this section have been separated into clinic and programmes. Additional information has been added regarding the eligibility for caregivers. Questionnaires at the courses are the same for caregivers and patients. No specific caregiver scales have been used. Qualitative components will focus on the caregiver specific aspects.

3. Analysis - what is the primary outcome? although the sample size is limited by attendees, it may still be possible to conduct a power calculation. The detail on how change over time will be determined needs to be included. How will the qualitative data be analysed, how will rigour be ensured? Is there an interview/focus group guide? What is the rationale for including both focus groups and interviews? Will any of the quantitative findings guide the qualitative interviews - how do the two relate?

Response: See above for response to outcomes.
Detail of the analytical approach for the qualitative analysis has been expanded. Rigour will be ensured via use of semi-structured interview schedules, transcription, multiple readings by more than one analyst in the development of themes, co-coding and multiple coders with inter-rater reliability calculated. Member checking will also be employed with some clinic attendees invited to comment on the themes developed to confirm consistency with their own experience.
In the initial round of interviews and coding, the interview schedule will not be changed in response to the quantitative findings as this analysis will not have been done during the period the interviews and focus groups are conducted. Quantitative findings will guide purposive sampling and specific topics for exploration in qualitative components in the future.
The decision to include both interviews and focus groups is purely pragmatic. Some attendees may wish to participate in the qualitative component but be unable to attend focus group sessions due to work commitments, transport/mobility challenges, or they may be uncomfortable taking part in a group discussion. It is important that the full range of attendee experiences are captured, thus we will offer both options.

Discussion:

4. There needs to be some discussion around the limitations of the study.

Response: A section on limitations has been added to the discussion.

5. With regards to the programmes component: I am not convinced about the ability to generalise the findings beyond the individuals attending the programmes. Are the programmes manualised and monitored for fidelity, if not this would appear to be more of a service evaluation than a research question as it would not be able to be reproduced in other patient/caregiver populations.
Response: The courses are not manualised and we acknowledge that to some extent they are instructor dependent. We agree this is more of a service evaluation of the programmes we offer.

Editorial Requests:

1.Please revise your title so that it includes your study design and makes it clear that this is a protocol. This is the preferred format for the journal.

Response: This has been done.

2. Please reformat the abstract according to journal guidelines The Abstract >> Methods section should also be much more detailed/ informative.
Response: This has been expanded. See above.

3. Please reformat the 'Strengths and Limitations' section according to journal guidelines. Response: This has been done.

4. Please improve the quality of study reporting e.g. not much information is currently provided about the data analysis that will be performed.
Response: This has been done.

5.Please include an 'ethics and dissemination' section after the methods and analysis, as per journal requirements for study protocols
Response: This has been done.

VERSION 2 – REVIEW

REVIEWER	Dr Rebecca Maguire National College of Ireland, Ireland.
REVIEW RETURNED	11-Jan-2017

GENERAL COMMENTS	From reviewing the revisions of the manuscript it is clear that the author has successfully addressed all concerns raised.

REVIEWER	Gillian Prue Queen's University Belfast Northern Ireland UK
REVIEW RETURNED	26-Jan-2017

GENERAL COMMENTS	Thank you for taking the time to consider and address my previous comments on your manuscript. I have only one minor comment - I think you should consider making it clear in the title that this is a service evaluation (as you have in the text), also this may have ethical approval implications that may need consideration.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Dr Rebecca Maguire
Institution and Country: National College of Ireland, Ireland.
Competing Interests: None declared

From reviewing the revisions of the manuscript it is clear that the author has successfully addressed all concerns raised.

Reviewer: 2
Reviewer Name: Gillian Prue

Institution and Country: Queen's University Belfast, Northern Ireland, UK
Competing Interests: None declared

Thank you for taking the time to consider and address my previous comments on your manuscript.

I have only one minor comment - I think you should consider making it clear in the title that this is a service evaluation (as you have in the text), also this may have ethical approval implications that may need consideration.
Response: We have amended the title to : Health status and needs of cancer survivors attending the Sydney Survivorship Centre clinics and programmes: A protocol for longitudinal evaluation of the Centre's services

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