Author's response to reviews

Title: Enhancing return-to-work in cancer patients, development of an intervention and design of a randomised controlled trial

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Author's response to reviews: see over
Authors’ response to reviewer’s report

The authors’ responses are in italic after each reviewer comment.

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Authors: Sietske J Tamminga, Angela GEM de Boer, Jos HAM Verbeek, Taina Taskila and Monique HW Frings-Dresen

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Reviewer: Fehmidah Munir

Reviewer’s report:

This manuscript outlines a study protocol for a return to work intervention for cancer patients following CONSORT guidelines. Return to work and work ability is an area of concern for cancer patients, their families and their employers. Currently there are no interventions that have addressed this issue. Therefore this area is of importance. The protocol is written extremely well with adequate hypotheses that can be tested with appropriate analyses. My only concern is that the manuscript does not contain enough information about the training content for the nurses and whether they have taken into account other factors that could affect return to work at follow-up and very long-term follow-up. For example, treatment type, psychological factors, psychosocial factors (e.g. number of dependents etc) organisational factors (e.g. economic climate, organisational climate, support) which can all impact on return to work outcomes.

Thank you very much for your comments. The suggested change of adding more information about the training content for the nurses has been made on page 10 of the revised manuscript. Factors that can have an impact on return-to-work outcomes will be part of the training course. In addition, these factors are an important part of the content of the work-directed intervention.

Naturally its difficult to measure all such variables and I am sure the authors have considered some of the key ones.

The prognostic factors that have been taken into account are described on page 12. The rationale to select these factors as prognostic factors has been added to the revised manuscript on page 12. In addition, organisational factors such as received support from the organisation and the occupational physician will be taken into account in the process evaluation. This has been added to the revised manuscript on page 12.

These should be referred to in their sample size calculation (e.g. do they have enough participants to control for these effects?)

The suggested change of referring to prognostic factors in the sample size calculation has been made on page 9 of the revised manuscript. We have based our
sample size calculation on the primary outcome parameter return-to-work since the primary aim of the study is to determine effectiveness of the work-directed intervention on return-to-work. Furthermore, a sample size of 300 will have sufficient power to be able to control for the prognostic factors in a Cox regression analysis since we assume that 5 to 10 variables will be included in the final model (Spelten et al. 2003; de Boer et al. 2008) and a sample size of 10 per included factor in a Cox regression analysis is considered sufficient (Petrie and Sabin, 2005).

And in their effect evaluation (e.g. other measures they will include and how they will treat them).

The suggested change of referring to the prognostic factors in the effect evaluation has been made on page 11 of the revised manuscript. We will take prognostic factors into account in the effect analysis only if there are imbalances between the intervention group and the control group.