Reviewer's report

Title: Study protocol. Active video games to promote physical activity in children with cancer: a randomized clinical trial with follow-up

Version: 2
Date: 6 November 2013

Reviewer: Annelies Hartman

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MAJOR COMPULSORY REVISIONS
1) The authors aim to include children with ALL and other cancer outside the central nervous system. The treatment for different forms of cancer varies considerably (chemotherapy, radiotherapy, surgery) as does the duration of treatment. This is not reported anywhere in the manuscript, nor are the authors providing means of dealing with the potential considerable variation in the groups.

2) There are a number of outcome measures. It is unclear whether they have age/gender related scores? If not, the design needs to be adjusted so that patients and controls for age/gender. This is not reported anywhere in the manuscript.

MINOR ESSENTIAL REVISIONS:

BACKGROUND section:


p. 7 first paragraph line 2: The statement ‘The explosive popularity of these games has also inspired physiotherapists etc needs literature to support it.

p. 7 second paragraph line 1: ‘Evidence for and against active video gaming already exists’. This needs to be explored further. What is the evidence in favor? And maybe more importantly: what is the evidence against? Just mentioning one reference does not suffice here.

p. 7 second paragraph line 2: the word ‘exergaming’ needs to be explained.

p. 7 second paragraph line 5: The expression ‘naturalistic circumstances’ needs to be explained.

p. 7 second paragraph line 9: ‘The rehabilitative impact of video games has been studied etc’. Please elaborate. Which conditions? Children or adults? Etc etc.

p. 7 third paragraph line 1: the primary aim is stated, but a clearly defined study question is also needed.
The secondary areas of interest are a very general statement. The areas of interest need to be re-worded into clearly defined study questions.

Compared to the control group, who receive only a general recommendation to be active. Considering the literature on this topic it is surprising that a general recommendation to be active appears to be the standard treatment, used for the controls. Most hospitals now involve physiotherapists when motor performance problem occur. Are the controls not denied treatment in this proposal?

METHODS/DESIGN section:

In my view a coin toss is not acceptable to decide on randomization. Also, randomization should not be carried out by the researcher. Your statistics department should be able to provide you with a series of random numbers for your intervention group and numbers for the control group. The code should be supplied in a closed envelope for each participant and opened by someone who is not involved in the study. Also, this should be carried out when the participant is enrolled in the study, not after the first measurement.

Participants:

Either one of the designated hospitals. The participating hospitals should be mentioned.

Intervention:

Recommendations on physical activity and guidance on how and which games to play etc. Are the recommendations the same for every child? If not, how are the recommendations determined? This needs clarifying.

How and which games to play? Is this not the same for every child? If not, how is this determined? This needs clarifying.

This is a very general paragraph in support of the intervention. I would suggest moving this paragraph to the Background section.

The intervention of the control group does not appear to be in line with the literature written on this topic. Please explain why not.

This questionnaire has been previously used in etc'. Did the adolescents fill out the questions or their parents? Please elaborate.

Correlated relatively well'. How well? Please add the correlation coefficient plus p-value.

The measurement points are stated from baseline onwards. However, as you aim to include children with various cancers, the treatment duration will vary. Therefore 2.5 year after baseline is approximately 6 months after completion of therapy in case of child with ALL, but maybe 2 years after completion of treatment for a Wilms tumor. How will the researcher deal with this?
The revised version of the M-ABC is generally referred to as M-ABC2.

Please specify for age group parents proxy version is used and for which age the questionnaire is filed out by children.

‘...child is under 10 years old, are interviewed’. Who will be the interviewer?

In this paragraph a few additional areas of interest are mentioned. They should be added to the aims of the study and re-worded as study questions.

Sample size calculation

Do the authors mean 34 in the intervention group and 34 in the control group? Or 34 participants altogether? Also, the groups may vary considerably if children with different cancer types are included. The number of 34 therefore seems rather low. Was the potential variety in the groups considered in the power calculation?

As stated before, the randomization procedure does not seem appropriate.

Please add whether the researcher is conducting interviews, as this could affect the results.

Have the authors considered the effect of wearing the Fitbit accelerometer on the behavior of children in the control group, in the sense that it may motivate them to be more active? It would strengthen the discussion if this issue was addressed.

‘...that is somewhat higher than in routine procedures’. What is the routine procedure? And why would you consider altering this routine? That is more likely to weaken the design as you are also manipulating behavior in the control group.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests