Author's response to reviews

Title: Diet, physical exercise and cognitive behavioral training as a combined workplace based intervention to reduce body weight and increase physical capacity in health care workers. A randomized controlled trial

Authors:

Jeanette R Christensen (jrc@sport.au.dk)
Anne Faber (afh@nrcwe.dk)
Dorte Ekner (dek@nrcwe.dk)
Kristian Overgaard (ko@sport.au.dk)
Andreas Holtermann (aho@nrcwe.dk)
Karen Søgaard (ksogaard@health.sdu.dk)

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Author's response to reviews:

Dear Editor

Thank you for your reviewers constructive criticism and positive remarks. We are very pleased that they think our paper has the potential to add new knowledge on how to promote health among high-risk groups. We have revised the paper taking into account all the your suggestions and think the paper has greatly improved.

Below are the two responses to your reviewer.

Kind regards

Jeanette Reffstrup Christensen

Department of Sport Science, Aarhus University

Telephone: +45 60202798

E-mail: jrc@sport.au.dk

Response to reviewer – Evan Atlantis

The report presents findings of a cluster randomised trial to determine whether a 3-month lifestyle program improved a broad range of health outcomes in overweight female health workers compared with three (monthly) 2-hr health education seminars (control intervention). The lifestyle program showed significant benefits in weight/BMI, % body fat, blood pressure, and cardiorespiratory fitness. The authors’ concluded that their findings “show the great potential of workplace health promotion among this high-risk group” but
long-term effects remain to be investigated.

The submitted paper has the potential to add new knowledge on this topic; I raise several issues and suggestions for improvements.

Thank you for your constructive criticism and positive remarks. We are very pleased that you think our paper has the potential to add new knowledge on how to promote health among high-risk groups. We have revised the paper taking into account all your suggestions and think the paper has greatly improved.

Major:

This paper was difficult to read, lacking both structure and logical flow.

Furthermore, I respectfully suggest that the authors’ seek help with correct English grammar/usage.

Response:

Thank you for the many good suggestions for improvements in language, structure and clarification.

Action:

We have followed your suggestions and the paper has now been revised by a person with English as her mother tongue and we have checked that the manuscript follow the CONSORT guideline for reporting an RCT study. In addition, we have followed the reviewers’ suggestions for improvements and feel that the many changes and adjustments have provided more readability and logic structure.

The power calculation for sample size is not adequate. It does not account for the degree of correlation within clusters (intracluster correlation); and it does not report the standardised mean difference (effect size) anticipated between the experimental and control intervention groups.

Response:

It is correct that the power was calculated based on individuals and not clusters. This is how it is reported both in clinical trial and the design paper and is a method said by several statistics to be possible (Donner A, Klar N. Pitfalls of and controversies in cluster randomization trials. Am J Public Health 2004; 94:416-422). We do, however, report that the calculation was based on a difference in weight loss of at least 3 kg between the intervention group and the control group. Still, we can see that it will strengthen our paper to include clusters
as covariate in the statistical analyses.

The statistical analyses are also questionable. Why not use ANCOVA to determine significant between group differences in change (pre-post) or post means adjusted for baseline mean, and covariates? I suggest rethinking about the most appropriate model needed to answer the research questions.

Response:

We have followed your advice and changed the statistical analysis to ANCOVA adjusted for age, the investigated value at baseline as well as for clusters.

Action:

The statistic paragraph has therefore now been substituted with:

When comparing intervention group and reference group over time, ANCOVA analysis were performed in accordance to the intention-to-treat principle, i.e. all randomized participants are included in the analyses with missing values substituted with carried forward or backwards measured variables. Clusters, age and the investigated value at baseline are included as covariates. All results are given as mean (SD).

P-values have been altered according to the new statistical analysis, results in the paragraph “Changes after 3 months in target population” has been changed in accordance as well as significant changes in table 3.

Changes after 3 months in target population

Table 3 presents average changes in the target group from baseline to 3 months of all measures in the intervention and the reference group. A highly significant Intervention group* Test round interaction was found for weight loss, BMI, fat percentage, waist circumference and diastolic blood pressure. In the intervention group, body weight decreased from 84.2 to 80.6 kg, corresponding to a decrease in BMI from 30.5 to 29.1. Fat % fell from 40.9 to 39.3% and waist circumference decreased from 99.3 to 95.1 cm. Blood pressure was lowered from 134.1/85.2 to 126.6/79.8 mmHg. For the reference group, no significant changes were found except for an increased BMI from 30.4 to 30.7. Regarding physical capacity, no significant Intervention group* Test round interaction was found for muscle strength. VO2 max was unchanged in both groups, while an Intervention group* Test round interaction (p<0.011) was found for aerobic fitness with the intervention group increasing from 25.9 to 28.0 ml/min/kg. Regarding musculoskeletal pain, no significant Intervention group* Test round interactions were found.

The novelty of the study’s findings is not emphasized. What does this study add
to the existing knowledge-base?

Response:

This workplace weight loss approach is the first we are aware of to successfully combine three initiatives consisting of diet, physical exercise and cognitive behavioural training.

Action: This is now more clearly emphasised in the introduction:

Diet alone has shown limited effectiveness for long term weight loss maintenance (Wu et al. 313-23). Programmes combining diet and physical exercise are therefore recommended to avoid reductions in energy metabolism with dietary restrictions (Shaw et al. CD003817). Grave and colleagues suggest that weight regain is due to failure to keep up physical activity, as maintenance of physical activity is fundamental for long-term weight loss (Dalle et al. 348293). The key to maintaining physical activity is new cognitive procedures and strategies that will help weight-loser’s to build a mind-set of long-term weight control. In summary, more multidisciplinary interventions are recommended (Dalle et al. 348293) and should include a combination of the three elements - dietary change, physical exercise and cognitive behavioural training. However, only few studies have combined these initiatives (Shaw et al. CD003818) and to our knowledge, no previous studies have investigated the combined effects of these initiatives on weight loss at a high-risk group like health care workers in a workplace setting.

Minor:

Abstract

The use and interpretation of “early retirement” throughout is unclear.

Response:

We recognize that the interpretation of “early retirement” can be unclear and thank you for reminding us.

Action:

We have defined “early retirement” as “people who leave the workforce before they are entitled to state pension”. The definition is inserted in both the abstract and in the introduction, the first time mentioned. The paragraph in the abstract is altered to:

Background Health care workers comprise a high-risk workgroup with respect to deterioration and early retirement, that is people who leave the workforce before they are entitled to state pension.

And the paragraph in the introduction is altered to:
Overweight and obesity are well documented to be associated with major chronic illnesses, including hypertension, diabetes, arthritis, heart diseases, cancer and all-cause mortality [1] [2] [3]. Moreover, excessive body weight has also been shown to increase the risk for musculoskeletal pain [4], sick leave [5] and early retirement from labour market before they are entitled to state pension [6], causing high socioeconomic costs [7].

Should be 98 subjects randomised to an intervention OR control

Response:
This has now been corrected

Action:
A paragraph in the abstract has been corrected to:

Methods 98 female, overweight health care workers were cluster-randomized to an intervention group or a reference group.

The description of the lifestyle program is not sufficiently informative (i.e., dose, components).

Response:
The lifestyle program has now been more precisely and detailed described

Action:
The method section in the abstract has been altered to:

Methods 98 female, overweight health care workers were cluster-randomized to an intervention or a reference group. The intervention consisted of an individually dietary plan with an energy deficit of 1200 kcal/day (15 min/hour), strengthening exercises (15 min/hour) and cognitive behavioural training (30 min/hour) during working hours 1 hour/week. Leisure time aerobic fitness was planned for 2 hour/week. The reference group was offered monthly oral presentations. Body weight, BMI, body fat percentage (bioimpedance), waist circumference, blood pressure, musculoskeletal pain, maximal oxygen uptake (maximal bicycle test), and isometric maximal muscle strength of 3 body regions were measured before and after the intervention period.

Introduction

Correct the typographical/EndNote errors throughout.

Response and action:
We recognize mistakes in the literature list. These are now corrected.

I would use ‘non participation in the workforce’.

Response:

We have now defined early retirement as: leaving the labour market before being entitled to state pension

The statement that there is no “gold standard for weight loss maintenance” is misleading. Several consensus statements exist for individualised interventions, and for taxes, tariffs, and trade laws policies, and the built environment. Papers by Atlantis E et al, and Karin Proper could strengthen the study’s rationale.

Response:

We recognize that the statement “there is no gold standard” is questionable, and thank you for the references.

Action:

The paragraph in the introduction is therefore altered to:

Strength training has been shown to improve physical capacity and reduce musculoskeletal pain (Andersen et al. 100-04). Meanwhile, different strategies to reduce overweight have been suggested, as well as several consensus statements regarding weight loss maintenance for individualized interventions, for taxes, tariffs and trade laws policies, and the built environment (Atlantis, Barnes, and Ball 343-52) (Proper et al. 218-26).

Tables 1 and 2 should be merged succinctly.

We have carefully considered if the three tables could be combined, however we prefer to keep them separate. The three tables closely follow the flow diagram with table 1 providing background data for the whole intervention population and the predefined target group, table 2 giving background data of pain and physical capacity for the intervention and control group within the target group, and finally giving data on the primary effect measure for the target group in table 3.

Response to reviewer – Mogens Theisen Pedersen

Well written article with important results. However I have a main concern about the statistic part which could change some of the results. This is explained in the specific comments below. I suggest a minor revision before accepting the article.

Thank you for your constructive criticism concerning our paper "Diet, physical exercise and cognitive behavioral training as a combined workplace based intervention to reduce body weight and increase physical capacity in health care
workers - a randomized controlled trial”. We are very pleased that you consider our results important and we have revised the paper taking into account all your suggestions to the extent possible. How we addressed your points appears below.

P. 4. Cognitive behavioral counseling/training is presented like a concept well known to the reader. It should be more clearly defined in the article with proper references for more information. What is special with CBT compared to counseling in general? This should be elaborated more in detail and included more in the discussion. What might be the role of CBC in the successful weight loss?

Response:

We acknowledge that the cognitive behaviour training may be inadequate described, with lack of a key reference on the cognitive behaviour training and how it separates from general guidance.

Actions:

In the introduction an additional reference has been added, describing the positive effects of a combined intervention of physical exercise, diet and cognitive behavioural training for long-term weight loss, in which the cognitive behaviour training is a crucial part. The introduction is accordingly altered to:

Strength training has been shown to improve physical capacity and reduce musculoskeletal pain (Andersen et al. 100-04). Meanwhile, different strategies to reduce overweight have been suggested, as well as several consensus statements regarding weight loss maintenance for individualized interventions, for taxes, tariffs and trade laws policies, and the built environment (Atlantis, Barnes, and Ball 343-52) (Proper et al. 218-26). Diet alone has shown limited effectiveness for long term weight loss maintenance (Wu et al. 313-23). Programs combining diet and physical exercise are therefore recommended to avoid reductions in energy metabolism with dietary restrictions (Shaw et al. CD003817). Grave and colleagues suggest that weight regain is due to failure to keep up physical activity, as maintenance of physical activity is fundamental for long-term weight loss (Dalle et al. 348293). The key to maintaining physical activity is new cognitive procedures and strategies that will help weight-loser’s to build a mind-set of tong-term weight control. In summary, more multidisciplinary interventions are recommended (Dalle et al. 348293) and should include a combination of the three elements - dietary change, physical exercise and cognitive behavioural training. However, only few studies have combined these initiatives (Shaw et al. CD003818) and to our knowledge, no previous studies have investigated the combined effects of these initiatives on weight loss at a high-risk group like health care workers in a workplace setting.

Further, the paragraph "Cognitive behavioural training" page 9, has been elaborated with references to the cognitive behaviour program that the present
From a cognitive behaviour program, designed by Linton aiming to prevent chronic musculoskeletal pain (Linton and Andersson 2825-31), a specific cognitive behavioural training (CBT) tool were modified and tailored to support a change to a more physically active lifestyle and by addressing the distress and challenges involved with weight loss. Whereas general counselling are not obliged to follow specific methods, traditionally cognitive behaviour therapy aims at reflecting on dysfunctional attitudes and coping behaviours, discussing functional alternatives, and training the implementation of these in everyday life (Linton and Andersson 2825-31). This included helping the participants to make realistic weight loss targets, find personal strategies to ease hunger, continue healthy behaviours, cope with social contexts and situations involving alcohol, food etc. These elements were discussed in the groups based on a specifically tailored guideline, containing 15 exercises such as pro-and-con schemes and positive thinking strategies with homework between each session. The CBT was offered as a 15 min part of the weekly sessions.

The intervention consisting of diet, physical exercise and cognitive behavioural training during working hours one hour/week was shown to be very effective, generating a significant weight loss, decreased blood pressure and increased aerobic fitness after three months. These findings support the recommendations of combining these three initiatives for successful weight loss (Shaw et al. CD003818).

The physical training is poorly described including in reference 21. Why did the authors from the beginning expect an effect of 10-15 min of training compared to the evidence based knowledge of training progression models? What about the leisure time physical activity? Did they actually do anything? The result of using logbooks is not presented…why? Why did the authors choose the different strength test? Were they related to the training?

Response:

We recognize that the physical training could have been more meticulously described. The topic is therefore described in more details in the methods. The log books were introduced for motivation and for individual registration of training, which unfortunately does not give standardized quantitative data on dose and progression. The different strength tests were chosen as a general measure of muscular capacity.
Physical exercise training

10 – 15 minutes physical exercise training was included in the weekly session at the workplace. Focus during sessions was on strength training to increase muscle mass in the lower extremities in order to increase resting metabolism and maintain physical capacity. These exercises consisted of both one and two legged squats, with and without dumb bells and core balls, and lunges walking forward and to each side. Other exercises focused more on general strength, and included exercises for abdominal and back extension, shoulders and arms. Participants brought home a strength training program, picturing these exercises, and were encouraged to perform them twice a week at home. In addition to the brief training sessions, participants were encouraged to initiate aerobic leisure time exercises such as biking, walking, running, swimming or attending different sports in the local area for two hours weekly. The dose of the instructed physical exercises in the sessions progressed in intensity throughout the weeks of the intervention, by increasing weights and repetitions. To motivate participants and individualize feedback from the instructors log books to monitor leisure time exercises was given to the participants and were shown to the instructor at each session.

In the discussion the physical training intervention part is stressed as an important part. Is it really so important? This should be discussed in more detail in relation to my concern above.

Response:

We agree that the physical exercise is only as a part of the multiple approach and it is not possible to discuss the importance in details. The importance is now modified and in addition the lack of precise dose of the physical exercise is described as a limitation in the study.

Action:

A section is added to the limitation paragraph in the discussion:

A limitation in the study is the lack of quantitative registration of physical training doses in leisure time. The logbook was primarily used to facilitate the individual coaching and serve as a motivating factor.

Page 10/ abstract

An incremental maximal test was used to estimate VO2max…but in the abstract authors describe that a submaximal test was used. This should be clarified.

Response:

We thank the reviewer for correcting the mistake and apologize for the confusion.
Action:

Method in the abstract has been corrected to:

Body weight, BMI, body fat percentage (bioimpedance), waist circumference, blood pressure, musculoskeletal pain, maximal oxygen uptake (maximal bicycle test), and isometric maximal muscle strength of 3 body regions were measured before and after the intervention period.

Statistics

Authors used an ANNOVA to look for differences in changes between groups; but did you control for the effect of clusters? If not this should be done.

Response:

We have now altered our statistics to ANCOVA and controlled for clusters, as well as for age and the analyzed variable.

Actions:

All results have been reanalyzed and correspondingly the statistic paragraph has been substituted with:

When comparing intervention group and reference group over time, ANCOVA analysis were performed in accordance to the intention-to-treat principle, i.e. all randomized participants are included in the analyses with missing values substituted with carried forward or backwards measured variables. Clusters, age, weight and the investigated value at baseline are included as covariates. All results are given as mean (SD).

P-values have been altered according to the new statistical analysis, results in the paragraph “Changes after 3 months in target population” has been changed in accordance as well as significant changes in table 3.

Changes after 3 months in target population

Table 3 presents average changes in the target group from baseline to 3 months of all measures in the intervention and the reference group. A highly significant Intervention group* Test round interaction was found for weight loss, BMI, fat percentage, waist circumference and diastolic blood pressure. In the intervention group, body weight decreased from 84.2 to 80.6 kg, corresponding to a decrease in BMI from 30.5 to 29.1. Fat % fell from 40.9 to 39.3% and waist circumference decreased from 99.3 to 95.1 cm. Blood pressure was lowered from 134.1/85.2 to 126.6/79.8 mmHg. For the reference group, no significant changes were found except for an increased BMI from 30.4 to 30.7. Regarding physical capacity, no significant Intervention group* Test round interaction was found for muscle strength. VO2 max was unchanged in both groups, while an Intervention group*
Test round interaction (p<0.011) was found for aerobic fitness with the intervention group increasing from 25.9 to 28.0 ml/min/kg. Regarding musculoskeletal pain, no significant Intervention group* Test round interactions were found.

The same statistical test was used 17 times (table 3) to look for an intervention effect. This increases the possibility of a false positive result. The significance level therefore should be decreased (lower P).

Response:

We agree that the same statistical test was used many times and that we in principle should take this into account. Yet we found our results to be physiologically consistent and coherent. Reducing the level of significance would substantially increase the risk for a type II error. We have, however, now added this aspect in the study limitation paragraph.

Action:

A study limitation paragraph has been included:

Several ANCOVA models were carried out for testing effects of the intervention on multiple outcomes. The risk for a chance finding may therefore be present. However, reducing the level of significance would increase the risk for a type II error. This aspect ought to be included in the interpretation of the study results.

Page 14. Line 7

"the lower part of table 2 shows".......this must be a mistake?....I don’t understand.

Response:

We apologize for this mistake.

Action:

The sentence is now erased.

Table 1

Education.....what is meant by “Health care wo” ?

Response:

“Health care wo” should be “Health care workers”

Action:
Discussion

Limitations of the work are not mentioned, but should be clearly stated.

Response:

Limitations are now discussed.

Action:

A section on limitations has now been added:

A limitation in the study is the lack of quantitative registration of physical training doses in leisure time. The logbook was primarily used to facilitate the individual coaching and serve as a motivating factor. Another limitation is that in the integrated multiple intervention concept of this study the importance of each of the components cannot be evaluated. A four-armed design where each of the components as well as the combined concept is tested against a control group would have been ideal, but also unrealistic with the current resources and the workplaces available. A qualitative process analysis with focus group interview is another approach that would have been possible, but unfortunately not performed. Finally, the target group only consists of females and the results cannot be extrapolated to males.

Concerning statistics, several ANCOVA models were carried out for testing effects of the intervention on multiple outcomes. The risk for a chance finding may therefore be present. However, reducing the level of significance would substantially increase the risk for a type II error. This aspect ought to be included in the interpretation of the study results.