Author's response to reviews

Title: Pragmatic randomised controlled trial of preferred intensity exercise in women living with depression

Authors:

Patrick Callaghan (Patrick.Callaghan@nottingham.ac.uk)
Elizabeth Khalil (elizabeth.khalil@nottingham.ac.uk)
Ioannis Morres (Ioannis.Morres@nottingham.ac.uk)
Tim Carter (Timothy.carter@nottingham.ac.uk)

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Author's response to reviews: see over
Dear Editor,

RE: Pragmatic randomised controlled trial of preferred intensity exercise in women living with depression – revised manuscript following reviewers’ comments

I am grateful to the reviewers for their helpful and constructive comments and suggestions to improve the quality of this manuscript.

I enclose the revised manuscript that I would be pleased to have considered for publication in BMC Public Health. I have highlighted in red the changes I have made to the MS and I address, directly the comments the reviewers’ made below.

Reviewer’s report
Title: Pragmatic randomised controlled trial of preferred intensity exercise in women living with depression
Version: 1 Date: 8 January 2011
Reviewer: Fernando Dimeo
Reviewer's report:

Major comments:
1. The trial should evaluate patients with depression. However, the broad standard deviation suggest that at least some participants did not suffer from depression. A BDI of less than 12 does not show "light depression", but normal mood.

Although the SD in BDI scores is relatively high suggesting variation in levels of depression, the mean BDI score in the intervention arm is 26.5 that indicates moderate depression. The participants in the study had all been diagnosed as depressed a qualified GP or psychiatrist.
2. It is not clear if both groups are indeed exercising at different intensities. When I compare heart rate and RPI I do not see a substantial difference between both groups. Therefore, it seems to me that both groups exercised very similarly. However, the control group did not improve at all. The authors should provide a rationale for this difference between both groups.

We have provided a rationale on pages 3 and 4 of the revised MS. As the peak RPE scores in table 2 show, at baseline the intensity level of both groups was similar, this is what we anticipated. However, at the end of the study, the mean peak RPE score for the active comparator arm was significantly higher showing they were exercising at a higher level of intensity closer to prescribed levels, whilst the participants in the intervention arm were exercising closer to the preferred intensity levels which was the goal of the study. The exercise sessions were supervised by a qualified exercise therapist. Both the intervention and active comparator programmes received manualised psychosocial support through motivational interviewing and advice on maintaining healthy lifestyles around exercise from a qualified health psychologist. The manualised psychosocial support was based on the Transtheoretical Model of Change [12] and in particular the self-efficacy construct shown by the researchers [26] to be a strong predictor of exercise intentions and actual exercise behaviour.

3. The sample calculation predicted a n=58. However, only 38 participants were recruited. The authors should explain this point.

We explain this point under limitations in the revised MS on page 10

Minor comments:
4. Please change the abstract to include means and standard deviation of the scores.

We have now added these data into the abstract, pls see page 2 under results.

5. Please provide the criteria for exercise in the intervention group (how high was the RPE?) and also the criteria for the control group (duration, intensity, heart rate).

As noted above, we have done this on pages 3&4

6. The "Discussion" seems to lack a source (XX).

Our apologies, we have now added this source on page 9, first paragraph.

Referee 2

1) There is no theoretical rationale for the manualized intervention. The investigators remark that they used a manualized psychosocial support through motivational interviewing and advice on healthy lifestyles around exercise as the intervention, with the primary intervention component preferred intensity. Without a theoretical rationale, the report falls short of a) describing the rationale for the
age range, the rationale for including only women

We have added this to page 4: The manualised psychosocial support was based on the Transtheoretical Model of Change [12] and in particular the self-efficacy construct shown by the researchers [26] to be a strong predictor of exercise intentions and actual exercise behaviour.

2) The outcomes, Physiological, psychological, and social well being were not specified to which scales measures which outcome.
We have added this to page 9 of the revised MS under intensity and depression outcomes.

3) The intervention mediators were not identified: this leads to problems in the reporting- what part of motivational interviewing and social support was hypothesized to impact self esteem?

The focus of the study was the impact of preferred versus prescribed intensity. Both arms of the trial received MI and social support. This was not an explanatory trial. It was a pragmatic trial. Our secondary outcome was to investigate whether preferred intensity impacted on self-esteem. We hypothesise post-hoc that participants who choose their exercise intensity levels, i.e. preferred intensity gain in self-esteem.

Why was Becks Inventory selected to measure depression?

We have provided a rationale for the use of the BDI on page 7. We used the BDI as it is a measure of depression widely used in research where depression scores are a primary outcome measure and to allow us to better compare our results with previously published systematic reviews and trials.

4) If the participants were exercised in cohorts of about 5, how did the investigators know that it was intensity that contributed to adherence and not the social interaction of the cohort members?

We cannot exclude fully this possibility, but it is unlikely given that the intervention and control arms exercise in groups and both received the manualised social support and MI.

2) Adherence was measured by attendance> It is unclear what intensity the women DID exercise at, although mean and peak HR was reported, it is unclear how the women actually exercised.. the large SD in the intervention group shows that the prescription might not have been adhered to.

We address this issue above and in detail on pages 3 and 4 of the revised manuscript. As the peak RPE scores in table 2 show, at baseline the intensity level of both groups was similar, this is what we anticipated. However, at the end of the study, the mean peak RPE score for the active comparator arm was significantly higher showing they were exercising at a higher level of intensity closer to prescribed levels, whilst the participants in the intervention arm were exercising closer to the preferred intensity levels which was the goal of the study. The exercise
sessions were supervised by a qualified exercise therapist. Both the intervention and active comparator programmes received manualised psychosocial support through motivational interviewing and advice on maintaining healthy lifestyles around exercise from a qualified health psychologist. The manualised psychosocial support was based on the Transtheoretical Model of Change [12] and in particular the self-efficacy construct shown by the researchers [26] to be a strong predictor of exercise intentions and actual exercise behaviour.

3) The inclusion criteria state those women who were being monitored by or receiving treatment for depression would be included. This raises questions regarding the diagnostic criteria for monitoring or treatment, compounded by the sample description of large variance in medication or/and therapy for depression, variance in the presumed severity of depression among the participants.

The variation in BDI scores was similar at baseline in both arms. All participants had been diagnosed with depression previously by a qualified GP or psychiatrist and all had taken anti-depressant medication. This is a standardised and widely used measure of depression in clinical studies.

4) The investigators report that a qualitative study was conducted to show the value of preferred intensity on improved outcomes, but the details of this are lacking and the results do not explain the intervention results, particularly as it is not explained what intensity the women actually exercised at.

We have inserted a paragraph about the qualitative element on page 4 of the revised MS. In addition to the pragmatic trial, we added a qualitative component to the study in the form of focus groups with participants from the intervention and active comparator arms of the study. The purpose of this component was to provide information on the processes that might help to explain the quantitative outcomes, a technique used and recommended by previous researchers conducting pragmatic trials [27]. For reasons of space, we do not report the results of the qualitative study here, but refer to it in the discussion where it helps to elucidate our findings.

5) The discussion does not relate the results to the research to guide the reader how this work impacts the science and moves it forward.

We have addressed this on page 10 under ‘strengths’ of the revised MS.

Yours sincerely,
Patrick Callaghan

RN, BSc, MSc, Ph.D, C.Psychol. CHSci, FHEA

Professor of Mental Health Nursing & Director of Research