Author's response to reviews

Title: Study protocol for patient response to spinal manipulation - a prospective observational clinical trial on physiological and patient-centered outcomes in patients with chronic low back pain

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Version: 4
Date: 1 July 2014

Author's response to reviews: see over
Dear Editorial Staff,

I am writing to you in response to the request of the following information:

“Please confirm whether informed consent for the publication of the images featured in your figures was obtained from the patients shown, and include a statement to this effect in your manuscript. Please note that we reserve the right to request proof of this consent at any point”.

The photographic images featured in the manuscript were all taken on research personnel. No participants were involved. This is the reason we used the word “illustration” in the titles for figures 1 and 2. To avoid potential confusion, we have updated the title for figure 4 to make it consistent with figures 1 and 2 (pp 45, line 26 highlighted in yellow, also shown here for your convenience).

(old) Figure 4 Participant placement for segmental load assessment during side-lying high-velocity spinal manipulation.

(new) Figure 4 Illustration of segmental load assessment during side-lying high-velocity spinal manipulation.

The original cover letter and rev1 cover letter are attached below for your reference. If you have any additional questions and requests, please let me know. Thanks.

Sincerely yours,

Ting Xia, PhD
Palmer College of Chiropractic
ting.xia@palmer.edu
June 13, 2014

Dear Editorial Staff,

I am writing to you in response to the request of the following modification:

“Thank you for providing us with documentation showing that your institutional ethical review board approved your study. However, we would ask you to revise the ethics statement in your manuscript in order to render it completely clear that your trial has received this approval. The full name of your review board should also be included in this statement.”

To address the request, on page 10, line number 4, Section Methods/Design → Study Population, an ethics statement is added (highlighted) as the first sentence:

“Ethics approval was obtained from the Palmer College of Chiropractic Institution Review Board (IRB) with the Assurance Number - X2011X141.”

The original cover letter is attached below for your reference. If you have any additional requests, please let me know. Thanks.

Sincerely yours

Ting Xia, PhD
Palmer College of Chiropractic
ting.xia@palmer.edu
June 12, 2014

Dear Editorial Staff,

I am pleased to submit the manuscript “Study protocol for patient response to spinal manipulation – a prospective observational clinical trial on physiological and patient-centered outcomes in patients with chronic low back pain” to BioMed Central’s Complementary and Alternative Medicine. I believe that this manuscript describes an original and innovative clinical trial and is well suited to the BMC Complementary and Alternative Medicine’ scope and readership. This trial is registered in ClinicalTrials.gov, with the ID number of NCT01670292.

The work is funded by National Center for Complementary and Alternative Medicine, National Institute of Health, Grant Number 5U19AT004663. The study protocol was approved by the Palmer College of Chiropractic IRB (X2011X141). Copies of official documents are attached below.

Sincerely,

Ting Xia, PhD
Assistant Professor
Palmer College of Chiropractic Research
Grant Number: 5U19AT004663-05

Principal Investigator(s):
CHRISTINE Marie GOERTZ, PHD

Project Title: Developmental Center for Clinical and Translational Science in Chiropractic

Tom Tiemeier
VICE CHANCELLOR FOR ADMIN
PALMER COLLEGE OF CHIROPRACTIC
1000 BRADY STREET
DAVENPORT, IA 52804

Award e-mailed to: grimm_k@palmer.edu

Budget Period: 06/01/2012 – 05/31/2013
Project Period: 06/01/2008 – 05/31/2014

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $261,422 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to PALMER COLLEGE OF CHIROPRACTIC in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the “Terms and Conditions” is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Center For Complementary & Alternative Medicine of the National Institutes of Health under Award Number U19AT004663. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with 42 CFR Part 50 Subpart F. Subsequent to the compliance date of the 2011 revised FCOI regulation (i.e., on or before August 24, 2012), Awardees must be in compliance with all aspects of the 2011 revised regulation; until then, Awardees must comply with the 1995 regulation. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

George Tucker
Grants Management Officer
December 7, 2011

Ting Xia, PhD
Palmer College of Chiropractic
Davenport Campus

Re: IRB Assurance # X2011X141

Dear Dr. Xia:

On December 7, 2011, the Palmer Chiropractic Research Institutional Review Board (IRB) Chairperson reviewed the amended application for the study:

Patient Response to Spinal Manipulation (PRiSM)

and approved this study for one year, after which time you will be required to complete a Progress Report on an annual basis, or more often as necessary, so that the IRB may consider a continuation of your study.

The Board is fully aware of the regulations governing the Institutional Review Board (Title 45, Code of Federal Regulations, Part 46) and believes that its operations are in compliance with those regulations.

Sincerely,

Ronne L. Firth, DC, DACBR, Chairperson
Institutional Review Board
Palmer Chiropractic Research

RLF/kkm