



Published in final edited form as:

Pain. 2009 March ; 142(1-2): 164–165. doi:10.1016/j.pain.2008.12.025.

Response to Keele Team's Response Letter

Steven Z. George, PT, PhD and

Assistant Professor, Department of Physical Therapy, Center for Pain Research and Behavioral Health, University of Florida

Michael E. Robinson, PhD

Professor, Department of Clinical and Health Psychology, Center for Pain Research and Behavioral Health, University of Florida

We would like to thank Hill et al (7) for taking the time to provide feedback on our recent publication in *Pain* (4). I would also like to thank the Editor for providing us the opportunity to respond to their comments.

Our clinical trial investigated the addition of behavioral treatments (graded exercise and graded exposure) to physical therapy determined by clinical prediction rules. Results from the trial suggest no additional benefit from the behavioral treatments for patients with acute/sub-acute low back pain at 4-week and 6-month outcomes (4). Hill et al (7) suggest that one conclusion drawn from our data is that psychosocial interventions should be put “out to pasture – page XXX.” We would like to clarify that these are their words, not ours. Such a strong recommendation is unwarranted based on data from a single clinical trial. Our own interpretation of these data included several other equally feasible reasons for our null findings and our suggestions for future study included methodology that incorporates psychosocial interventions (4).

Differences in interpretation aside, a primary issue that Hill et al (7) seem to have with our clinical trial is that the psychosocial sub-groups were determined in an “oversimplified” fashion. On this point we agree with the authors. In comparison to data available in 2008 for primary care (6) and physical therapy settings (3), the approach used to identify psychosocial sub-groups was simplified. In contrast, there were available data for physical therapy clinical prediction rules when this trial was being planned (1,5). We do, however, take umbrage with the description of this psychosocial sub-group identification as “arbitrary”. The same cut off score was used in a previous clinical trial reported by George et al (2). In this trial a differential treatment effect was observed such that those with elevated fear-avoidance beliefs had a greater benefit from graded exercise supplemented physical therapy. We believe the use of the same cut off score was an appropriate and necessary methodological choice for the follow up trial in which we attempted to replicate previously observed treatment effects.

A secondary issue that Hill et al bring up is that our clinical trial was potentially underpowered, an important concern when null findings are reported. We disagree with the authors on this point. The prospective power analyses were based on effect sizes observed in our trial reported in 2003 (2). The observed effect sizes and power for the current trial were calculated, and were much smaller than in the previous trial. These data were reported to

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

demonstrate how quite small these effects were, not to justify the need for larger studies in this area. The current trial was adequately powered to detect clinically meaningful effects, but not adequately powered to detect statistical significance of miniscule effects.

Future study will determine if larger treatment effects are associated with more refined ways of determining psychosocial sub-groups, in comparison to readily available clinical prediction rules. This is a point we feel was made quite clearly in our manuscript; “Future study in patients with LBP should focus on improving the identification of patients at risk for developing chronic LBP and refining specific psychological targets that optimally reduce pain intensity in acute and sub-acute phase – page 157”(4).

Sincerely,

Reference List

1. Childs JD, Fritz JM, Flynn TW, Irrgang JJ, Johnson KK, Majkowski GR, Delitto A. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. *Ann Intern Med* 2004;141(12):920–8. [PubMed: 15611489]
2. George SZ, Fritz JM, Bialosky JE, Donald DA. The effect of a fear-avoidance-based physical therapy intervention for patients with acute low back pain: results of a randomized clinical trial. *Spine* 2003;28(23):2551–60. [PubMed: 14652471]
3. George SZ, Fritz JM, Childs JD. Investigation of elevated fear-avoidance beliefs for patients with low back pain: a secondary analysis involving patients enrolled in physical therapy clinical trials. *J Orthop Sports Phys Ther* 2008;38(2):50–8. [PubMed: 18349490]
4. George SZ, Zeppieri G Jr, Cere AL, Cere MR, Borut MS, Hodges MJ, Reed DM, Valencia C, Robinson ME. A randomized trial of behavioral physical therapy interventions for acute and sub-acute low back pain (NCT00373867). *Pain* 2008;140(1):145–57. [PubMed: 18786762]
5. Hicks GE, Fritz JM, Delitto A, McGill SM. Preliminary development of a clinical prediction rule for determining which patients with low back pain will respond to a stabilization exercise program. *Arch Phys Med Rehabil* 2005;86(9):1753–62. [PubMed: 16181938]
6. Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, Hay EM. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008;59(5):632–41. [PubMed: 18438893]
7. Hill JC, Foster N, Main CJ, Hay EM. In response to a randomized trial of behavioral physical therapy interventions for acute and sub-acute low back pain. *Pain*.