Author's response to reviews

Title: The IGNITE (Investigation to Guide New Insight into Translational Effectiveness) Trial: Protocol for a Translational Study of an Evidenced-based Wellness Program in Fire Departments

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Author's response to reviews:

This is an addendum to the initial cover letter submitted with the manuscript, “The IGNITE (Investigation to Guide New Insight into Translational Effectiveness) Trial: Protocol for a Translational Study of an Evidenced-based Wellness Program in Fire Departments.”

Implementation Science is the first and only journal to which this manuscript has been submitted.

Perhaps there is confusion because of a previously submitted a manuscript, "Beta Testing as a Needed Translational Step: A Qualitative Dissemination Study of an Evidence-based Worksite Health Promotion Program for Fire Fighters." That manuscript described a completed project, which was a qualitative study of sequential implementation of the PHLAME health promotion program in six fire departments across the US and how the findings were used to refine the program. That manuscript described a completed study and its findings. The conclusion was that beta-testing may be an important and often overlooked step when going from efficacy to effectiveness trials.

The study described in the previous manuscript was concluded prior to receiving the funding from the National Institutes of Health ARRA Challenge Topic “Pathways for Translational Research,” that is supporting the protocol described in this manuscript.

Although the prior and current submission both involved the PHLAME health promotion program, the study protocol in the current manuscript differs completely from the prior submission. In the current manuscript, we describe a prospective assessment of adoption, installation, use and outcomes of a safety
and wellness program for firefighters in 12 departments in the Pacific Northwest. The protocol is to define a model of worksite translation using a mixed methods assessment, including quantitative mediation analyses.

Your email also requested information on ethical issues. Those were included with the manuscript prior to the references. We attempted to follow the Instructions for Authors and the format demonstrated by Implementation Science published articles. If additional information is required, we would be happy to provide it.

Again, this manuscript is a new, original description of a recently funded study, 5RC1NR011793. Previous work to establish the program’s efficacy and beta-testing are not described in this manuscript, although findings are mentioned in the Background section and citations provided, and that prior funding also was acknowledged (5R01AR045901 and R01 CA105774).

Ethical Aspects

The Institutional Review Board of the Oregon Health & Science University approved the study in August of 2009. Interviews and focus group transcripts are anonymous. After the research assistant(s) who collected the data listens to and reviews transcripts for accuracy, names are removed and those transcripts are only identified by site. Individual surveys and measurements are confidential with a secure code book maintained by the investigator and data manager. Participating departments will be provided summative information about their site and de-identified summary data concerning other departments.

Competing Interests

PHLAME is a program on the Cancer Control P.L.A.N.E.T. (http://cancercontrolplanet.cancer.gov/) site for research-tested programs, and it is distributed through the Center for Health Promotion Research at Oregon Health & Science University (OHSU). OHSU and Elliot, Goldberg, and Kuehl have a financial interest from the commercial sale of technologies used in this research. This potential conflict of interest has been reviewed and managed by the OHSU Conflict of Interest in Research Committee.

Authors’ Contributions

DLE is Principal Investigator on the project and prepared the initial draft of this manuscript. DLE, KSK, ELM, CAD and LG formulated the study protocol and contributed to drafting the manuscript. DPM assisted in protocol development was instrumental in the quantitative assessment components; JE assisted with a perspective from organizational psychology; and KCF provided a community partner aspect. All authors read and approved the final manuscript.

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Thanks you for the opportunity to clarify information, and please let me know if additional details are required.

Sincerely yours,

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