Author's response to reviews

Title: Improving chronic disease prevention and screening in primary care: results of the BETTER pragmatic cluster randomized controlled trial

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Author's response to reviews: see over
Dear BMC Family Practice Editors,

Re: Improving chronic disease prevention and screening in primary care: results of the BETTER pragmatic cluster randomized controlled trial

On behalf of my coauthors, I am submitting this manuscript for consideration for publication in the British Medical Journal. In this manuscript we report the results of the trial Building on Existing Tools to Improve Chronic Disease Prevention and Screening in Primary Care (the BETTER Trial), a pragmatic factorial randomized controlled trial set in primary care practices in Ontario and Alberta, Canada. The objective of the trial was to test an intervention to improve prevention and screening through an approach that integrated prevention and screening for heart disease, diabetes, colorectal cancer, breast cancer and cervical cancer, and associated lifestyle factors. We conducted a comprehensive review of the literature to identify prevention and screening actions based in primary care for which there was high quality evidence that they lead to improved outcomes. Through this process we identify 28 actions to be included in the trial.

The intervention is based on a model of practice facilitation, which is an evidence-based strategy to improve the quality of primary care (Developing and running a primary care practice facilitation program: a how-to-guide. AHRQ Publication No. 12-0011). The BETTER Trial involved two levels of facilitation:

1. Practice-level: this involved a Practice Facilitator (PF) who supported the practice to improve their processes for prevention and screening. The PF followed the traditional model of practice facilitation whereby a trained individual external to the practice supports several practices currently.

2. Patient-level: this involved a Prevention Practitioner (PP) who held a dedicated prevention visit with each participating patient at which the patient received a tailored ‘prevention prescription’. To our knowledge this is unique in that the PP was a healthcare practitioner (e.g., a nurse) identified from within the practice and trained by BETTER in chronic disease prevention of screening. Based on our preliminary consultations, this aspect is important for generalizability since the practices did not have to identify and fund an external person. (We are exploring this further through a post-trial qualitative study we are currently conducting with the participating practices.)

We developed a range of tools to assist the Facilitators in their roles. The tools can be viewed at the website: http://www.betterproject.ca. Please note that this website is expected to migrate to http://better.utoronto.ca/ in mid July 2013. Videos of the application of these tools can be viewed at UofTBetterProject on YouTube. These tools integrated all of the actions and showed the interrelationship between risk factors and lifestyle factors with multiple chronic conditions, and served as teaching tools for Facilitators and patients.

The factorial design allowed us to determine the effect of the PF alone, PP alone, or both PF and PP compared to controls. We also conducted a cost-effectiveness analysis alongside the trial which considered the costs of the intervention (practice-level with a PF and patient-level with a PP) and the cost of additional maneuvers accomplished. We studied patients with moderate
mental health problems as a separate stratum. The results show that, compared to controls, the PP intervention was effective with (adjusted analysis) 32% more actions accomplished by patients overall (P<0.001): 36% for general health patients and 25% for mental health patients (both P<0.001) at the cost of CAN$26.43 per additional action accomplished.

This study is unique in several ways:
1) Our approach integrated the major chronic diseases (including cancers) instead of focusing on just one or two – this approach is more consistent with the realities of practice in primary care.
2) For the patient-level intervention, we tested an adaption of the usual approach to facilitation in that the PP was identified from within the practice and dedicated one day per week to the role of PP – this makes it more practical for primary care since they do not have to employ an external person or link with other primary care practices to share support of an external person. (Our PF role followed the more traditional approach of an external Facilitator supporting several practices).
3) The PP had direct patient contact – in the usual approach Facilitators function only at the level of the practice without direct patient contact.
4) We conducted a cost-effectiveness analysis to determine the actual cost per action accomplished.
5) We studied patients with moderate mental illness as a separate stratum because this is a particular vulnerable population with high prevalence in primary care.

The trial was funded by the Canadian Partnership Against Cancer and the Heart and Stroke Foundation of Canada. None of the authors have any conflicts of interest.

The results of the trial were presented at the North American Primary Care Research Group meeting in New Orleans, December 2012. Please see abstract at the end of this letter.

A list of potential reviewers is also provided at the end of the letter.

Thank you for considering this manuscript for publication in BMC Family Practice.

Yours sincerely,

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**Title:** Building on Existing Tools to Improve Chronic Disease Prevention and Screening: Results of the BETTER Trial

**Context:** Primary care is the setting for most chronic disease prevention and screening (CDPS) maneuvers. Evidence-based approaches exist to improve CDPS, but are inconsistently applied. 

**Objective:** To improve CDPS in primary care for cardiovascular disease, diabetes, cancer, and lifestyle factors.

**Design:** A two-way factorial cluster pragmatic randomized control trial.

**Setting:** 8 urban Primary Care Team (PCT) practices in Toronto and Edmonton, Canada; 4 primary care physicians (PCPs) from each PCT yielding 32 PCPs.

**Patients:** Active adult patients aged 40-65 rostered to a participating PCP were eligible.

**Intervention:** A multi-faceted intervention targeted at two levels: 1) practice-level intervention involving a Practice Facilitator (PF) and 2) patient-level intervention involving a Prevention Practitioner (PP). Participating PCPs were randomly assigned to 4 arms: 1) PF only, 2) PP only, 3) PP and PF, or 4) control.

**Main outcome:** A 28 component composite Summary Quality Index (SQUID) of evidence-based CDPS maneuvers, established by a comprehensive review of the literature. The individual patient-level SQUID was the primary outcome and defined as the proportion of maneuvers for which the patient was eligible at baseline, that had been met (according to pre-defined targets) at follow-up.

**Results:** 789 participants were enrolled, 12 discontinued, and 777 were analyzed. Participants were 72% female, mean age 53.2 (±6.8), and 84% Caucasian. Baseline variables were balanced across randomization groups. Analysis was by Generalized Estimation Equations method. Control patients accomplish 21% of eligible maneuvers, compared to 28% in the PF arm (p>0.05), 54% in the PP arm (p<0.05), and 58% in the PP and PF arm (p<0.05).

**Conclusion:** Participants receiving the patient-level intervention involving a PP accomplished significantly more of their eligible maneuvers. This trial is unique in using an intervention that targets all CDPS maneuvers in an integrated approach and uses a facilitator (PP) drawn from within the PCT trained in CDPS.

Keywords: Chronic disease, prevention, screening, randomized controlled trial

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