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From efficacy to effectiveness: lessons learned from the Practice-Based Opportunities for Weight Reduction (POWER) trial

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Despite the encouraging results of behavioral weight-loss interventions in efficacy trials, primary care providers (PCPs) have expressed a lack of confidence that proven weight management models can be implemented in a primary care setting [1]. The Practice-Based Opportunities for Weight Reduction (POWER) trial conducted at Johns Hopkins University (MD, USA) compared the effectiveness of two behavioral weight-loss programs to a self-directed control group over 24 months among obese adults with at least one cardiovascular disease risk factor. In contrast to traditional efficacy studies that often enrolled convenience

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populations, POWER enrolled obese patients from primary care clinics and delivered interventions that could potentially be integrated into routine medical care. As a comparative effectiveness trial, our findings should be directly applicable to routine medical care and should inform patients, healthcare providers and delivery systems of effective treatment options [2]. This article highlights lessons learned from the design and implementation of the POWER trial.

Details of the study design have been published [3,4]. Participants were obese patients from one of six participating primary care clinics, who had at least one cardiovascular risk factor (hypertension, hypercholesterolemia, or diabetes), regular internet access and basic computer skills (i.e., the ability to enter data into a website and send/receive email). Participants were randomized to one of three groups: control condition, remote intervention and in-person intervention. The primary outcome was weight loss at 24 months after randomization.

The two behavioral interventions were based on previous trials conducted by the Hopkins investigative team that demonstrated the efficacy of lifestyle interventions in achieving and maintaining weight loss and improving cardiovascular disease risk factors [5-8]. The group receiving in-person support was offered group sessions, individual sessions (telephonic and in-person) and web support. The group receiving remote support was provided telephonic sessions and web support with no face-to-face contact. These active intervention groups were compared with the self-directed control group. A summary of the intervention recommendations and contact schedule have been published [3,4]. PCPs provided general encouragement for intervention participation and reviewed a one-page report of the participant's progress at regularly scheduled clinic visits for those in the active interventions.

The main results have been published and a brief review follows [4]. Of the 415 randomized participants, 64% were women and 41% were African-American; mean (standard deviation) age was 54 (10.2) years, and mean (standard deviation) BMI was 36.6 (5.4) kg/m². The median number of completed coaching sessions in the remote support arm was 14 during the first 6 months (15 sessions were offered), and 16 during months 7–24, when 18 sessions were offered. The median number of completed coaching contacts for the in-person arm was 14 during the first 6 months (21 sessions were offered), and 16 during months 7–24, when 36 sessions were offered. The group receiving in-person support completed few group sessions, and attendance dropped over time. At 24 months, standardized weights were obtained from 95% of the sample. Mean weight change from baseline to 24 months was -0.8 kg in the control condition, -5.1 kg in the in-person support arm ($p < 0.001$ vs control) and -4.6 kg in the remote support arm ($p < 0.001$ vs control). There was no significant difference in weight change between the two active intervention groups.

Upon completion of the trial, the investigative team identified several 'lessons learned', that should be applicable to other effectiveness trials.

A set of explicit guiding principles was extraordinarily useful as we transitioned from conducting efficacy trials to effectiveness trials. These principles were intended to maximize the generalizability of trial findings, thereby enhancing the dissemination potential of the

interventions. These principles, which were explicitly stated in the trial's protocol, were as follows:

- Maximize trial generalizability by reducing screening burden (number of in-person visits and data collection elements), exclusion criteria, number of follow-up visits and logistic hurdles related to enrollment in the intervention;
- Design interventions that could be implemented in a variety of healthcare settings. There are substantial structural barriers to the delivery of behavioral interventions in primary care settings (e.g., lack of space and appropriately trained staff). In this context, the interventions should directly involve clinicians but place low burden on their office operations;
- Provide interventions in an efficient manner using the internet and telephonic sessions;
- Design interventions that would be applicable when the trial ends in 2011. We reasoned that access to and use of the internet was becoming commonplace and eventually would be ubiquitous. Given these considerations and the need to maintain frequent, efficient contacts over the long-term, we decided that both interventions would use a study-specific website and that participants must have routine internet access and basic computer skills.

Enhancing generalizability required fundamental changes in our approach towards implementation, not merely relaxed enrollment criteria. To increase generalizability, we minimized exclusion criteria and reduced participant burden by offering questionnaires online and by obtaining follow-up data in the primary care clinics and other settings. While many of the inclusion and exclusion criteria for this trial were similar to those of previous efforts, we relaxed other criteria, did not include a run-in period or adherence test, and did not require attendance at intervention sessions. Yet, the most fundamental difference between this trial and earlier efficacy trials was the spirit in which the enrollment criteria were applied. Whereas earlier efficacy trials did not enroll individuals for whom there was a concern about follow-up or intervention adherence, a key message to trial staff was “when in doubt, enroll”. Still, similar to our previous efficacy trials, every effort was made to obtain a final weight measurement even among those who did not participate in earlier follow-up visits. In this manner, we minimized the need for imputed data in the primary analyses and maintained strong internal validity.

Early and sustained involvement of key stakeholders was crucial to the success of the trial. In POWER, the key external stakeholders were the medical directors of the participating clinics and Healthways (TN, USA), the company that developed the website for the active interventions and that provided the coaches for the group receiving remote support.

The medical directors had a vital role in both data collection and intervention efforts. Medical directors of the participating clinics met monthly with study investigators and senior staff. This resulted in high-level buy-in and established realistic expectations regarding PCP involvement in the interventions and data collection. Across all centers, 46 providers agreed to participate; only one provider declined. The medical directors also

helped design the weight progress report, which provided a guide for PCPs to encourage the active participation of their patients in the weight-loss intervention. Regular meetings with the medical directors also contributed to our high follow-up rates (e.g., medical clinic staff collected outcome data on challenging participants) and facilitated smooth interactions between medical clinic staff and the intervention team.

Healthways, a company with expertise in remote delivery of disease management programs, provided logistical support for the development and maintenance of the intervention website. They contributed to refinements of the online self-monitoring features and helped to ensure that the contact frequency in the remote arm was feasible in a pay-for-service environment. Healthways also provided coaching staff for the group receiving remote support only.

Intervention flexibility was necessary to meet individual participant needs. The current trial incorporated flexibility in both intervention delivery modality (telephone, internet, groups and individual face-to-face) and the topics addressed during coaching sessions. Although bimonthly contacts were originally scheduled for the remote support arm during months 7–24, the frequency pattern was changed to monthly contacts after positive feedback from both participants and coaches during the initial months of the study. Many of the participants in the in-person arm expressed interest in having both telephone and in-person contacts, and we provided this flexibility in the delivery of individual sessions. There was also flexibility within the coaching sessions. Coaches were trained to use motivational interviewing to address ambivalence and encourage patients in developing their motivation to change. Coaching guides for both interventions recommended talking points corresponding with the online modules, but coaches were encouraged to address the most pressing weight management issue presented by the participant.

In conclusion, POWER is one of the few comparative effectiveness trials that tested successful weight-loss strategies in the primary care setting. One of the most salient differences between this comparative effectiveness study and earlier efficacy trials was the substantial involvement of external partners who assisted with study design and implementation. Another difference was the high degree of flexibility in delivering the interventions, which allowed the coaches to better meet the needs of the participants. These adaptations were essential to the success of the study, the generalizability of the results, and the potential feasibility of the interventions in a variety of settings, including a pay-for-service environment.

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Healthways, Inc. developed the website for both interventions used in the POWER trial in collaboration with Johns Hopkins investigators and provided coaching effort for the transtelephonic intervention. Healthways also provided some research funding to supplement NIH support. Under an institutional consulting agreement with Healthways, the Johns Hopkins University received fees for advisory services to Healthways during the POWER trial. Faculty members who participated in the consulting services received a portion of the University fees. On the basis of POWER trial results, Healthways developed and is commercializing a weight-loss intervention program called Innergy™. Under an agreement with Healthways, Johns Hopkins faculty monitor the Innergy program's content,

and process (staffing, training and counseling) and outcomes (engagement and weight loss) to ensure consistency with the corresponding arm of the POWER Trial. Johns Hopkins receives fees for these services and faculty members who participate in the consulting services receive a portion of these fees. Johns Hopkins receives royalty on sales of the Innergy program.

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