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DOI: 10.2337/dc06-1575

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## Translating the Chronic Care Model Into the Community: Results From a Randomized Controlled Trial of a Multifaceted Diabetes Care Intervention

Response to Belalcazar and Swank

We read Belalcazar and Swank’s response (1) to our article with great interest. They have valid concerns regarding potentially biased estimates of treatment effects in small translational research studies where circumstances and environments are not as easily controlled as they are in efficacy-based research (2).

Our study (3) was a pilot, randomized, controlled trial of a multifaceted diabetes care intervention. Eleven primary

care practices and their patients ( $n = 762$ ), all from the same underserved community, were block randomized to one of three study groups before the start of the intervention. Practices were randomized instead of individual patients to ensure consistent delivery of the intervention for all patients and to eliminate contamination of the intervention between patients in the same practice (4).

Given the small number of practices randomized and the small sample of patients evaluated, the authors are correct that the study groups may be imbalanced with respect to several factors, even when the  $P$  values, which depend on sample size, are not statistically significant. To address this concern, we identified the most important and best “fitting” covariates (age, insulin, baseline metabolic value, study group, and the nesting of practices within study group) with a series of analytical techniques and a review of the literature and then adjusted for these variables when analyzing differences between study groups. We acknowledge the authors’ suggestion about adjusting for ethnicity; however, with 10 nonwhite subjects in the study, this was not feasible. Despite the small sample size, statistically significant differences between study groups were observed, lending further credence to our results.

The authors suggest using propensity scores to correct for differences in baseline characteristics among study groups (4). In observational studies, in which the selection of an intervention (e.g., insulin use) depends on various patient factors, using a propensity score, the estimated probability of receiving one of the interventions based on the patient-specific factors, can greatly reduce selection bias. As our study was a randomized controlled trial, we do not have variables that are truly related to the probability of receiving a particular intervention, since the interventions were randomly assigned a priori. Thus, a propensity score cannot be applied to this study. It may be possible to create an alternative composite score that would encompass several risk factors in future analyses of these types of interventions.

Variations on the multifaceted diabetes care intervention described in our article are currently being studied in a variety of settings, both locally and nationwide. Unfortunately, the majority of these efforts suffer from small sample size and a lack of randomization (5). In these studies, the use of propensity scores may enhance the validity of the results.

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DOI: 10.2337/dc06-1739

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## Intensive Insulin Therapy in the Intensive Care Unit: Assessment by Continuous Glucose Monitoring

Response to De Block et al.

I read with interest the article by De Block et al. (1). Indeed, reliable devices recording continuously interstitial glucose concentrations (IGCs) may be an alternative to frequent glucose monitoring, especially in patients of intensive care units (ICUs) in whom normoglycemia has become a major target. However, all factors influencing the complex kinetics of