Comment on Pladevall et al, "A Randomized Controlled Trial to Provide Adherence Information and Motivational Interviewing to Improve Diabetes and Lipid Control"

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letter to the editor

It is with great interest that we read the recent article by Pladevall et al (*The Diabetes Educator*, doi: 0145721714561031).[1] We would like to commend the authors for undertaking a large and ambitious trial with the goal of improving medication adherence and diabetes and lipid control with the use of adherence feedback and motivational interviewing (MI). The intervention, as tested, failed to improve diabetes medication regimen adherence and diabetes/lipid control. Unfortunately, these results are potentially misleading due to methodological shortcomings.

First, we have concerns over the internal validity of the study intervention. Patients were randomized to 1 of 3 conditions: (1) usual care (UC), (2) adherence information (AI), or (3) AI plus MI. Patients randomized to receive AI plus MI first received AI from their primary care physician and then received MI to promote medication adherence from health care professionals working in an independent adherence clinic. The adherence intervention involved the physician electronically receiving feedback on medication refills (adherence) and discussing this with the patient. Providing feedback on what one has not done (not refilling prescription in a timely manner) may well amount to unilateral advice giving and come across in a judgmental manner, contrary to a key MI principle of collaborative agenda setting. In 2003, the World Health Organization identified standards for managing adherence issues, including: patients need to be supported, not blamed; adherence is simultaneously influenced by several factors, and solving problems related to these factors is necessary; adherence is a

dynamic process that needs to be followed up; and health professionals need to be trained in adherence.[2] It is unclear if these standards were followed, calling the adequacy of the intervention into question. Further, this intervention may have resulted in carryover effects that unintentionally sabotaged subsequent MI sessions. On a similar note, it was reported that health care professionals delivering MI had delegated authority to make medication adjustments, but it was not reported whether this was performed unilaterally or using a shared decision-making model with the patients. Overall, given that the adherence clinics were a separate entity and not integrated into the primary health care team, it may not be surprising that this disconnect would contribute to poor uptake/engagement in the intervention.

Second, we have concerns over the content of the MI intervention, training of MI providers, and documentation of treatment fidelity. Insufficient information about the MI intervention was provided to determine the content of information discussed and allow for replication. In addition, several important aspects of the MI-specific training provided to interventionists were not adequately reported, making it difficult to discern whether MI training resulted in a reliable change in adherence communication delivered to patients. Mainly, the length and format (eg, individual, group, workshop) of MI-specific training and the objective tools used to evaluate MI proficiency following training were not reported, making it difficult to discern provider competency prior to study implementation. Further, there was no mention of ongoing supervision and training of the MI coaches. A lack of ongoing training and supervision is concerning considering empirical evidence reports that it is difficult to suppress prior counseling habits[3] and MI has been recognized as a highly complex clinical skill that takes considerable time to learn and master.[4] Furthermore, the authors did not appear to verify the integrity with which MI was delivered in order to clarify the degree of fidelity to the MI approach. This is surprising given the availability of assessment tools[5] and recommendations to do so by the Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological trials.[6] At present it is unclear whether a single MI training course can be effective in changing daily practice of health professionals, with a recent cluster randomized controlled trial reporting that MI training to improve routine diabetes care in general practice had a minimal impact on day-to-day practice measured at 1-year follow-up.[7]

The selection of participants was also a concern as there was some discrepancy between the behavior of interest (ie, medication adherence) and participant inclusion criteria (ie, elevated levels of A1C and LDL-C). One key tenet of any behavioral trial is that the problematic behavior is present at the onset of the trial.[8] Pladevall et al[1] enrolled any participant with elevated levels of A1C and LDL-C. There were no inclusion parameters for medication adherence. This is surprising given that the intervention focused on the dissemination of adherence information. Such an enrollment strategy relies on an inappropriate assumption that elevation of A1C and LDL-C is directly related to medication adherence. Thus, it is possible that some patients were enrolled in the trial despite having no problems with adherence that would dilute any treatment effects, which given the very high adherence reported at baseline would seem to be the case.

In conclusion, we believe that there is insufficient evidence from this trial to conclude that the MI intervention was not efficacious and hope that this letter will help guide future intervention designs.

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