

Jun 23, 2008

RE: NRES-D-08-00086, titled "Translating the Diabetes Prevention Program to Primary Care: A Pilot Study"

Dear Dr. Whitemore,

Recently you sent your manuscript for consideration by Nursing Research. The review of your manuscript is complete and the comments of the reviewers are listed below along with a checklist for style. The reviewers were very positive in their comments. Please make the changes they recommend. Think about what information could appear on the Web site and let me know what you think when you resubmit. When I read the revised manuscript I will think about this also. Perhaps, I will have a recommendation about this later in the editorial process. You may revise your manuscript based on the reviews and resubmit the manuscript to Nursing Research for further consideration. I will verify that this has been done upon receipt of the revised manuscript.

Please include with your revised submission an itemized, point-by-point response to the comments of the reviewers. The revisions should be completed by Sep 21, 2008 to avoid being considered as a new submission.

To submit a revision, go to <http://nres.edmgr.com/> and log in as an Author. You will see a menu item called "Submission Needing Revision." Please click on this item to obtain your submission record and begin the revision process.

With Kind Regards,

Molly C. Dougherty, PhD, RN, FAAN  
Editor  
Nursing Research

Reviewer Comments:

Reviewer #1:

This article is very notable at this time of emphasis on evidence based practice and translational research. It has the potential to be a landmark publication with more attention to these aspects. I will endeavor to point out instances where the author(s) could better position the significance of the study in terms of these trends.

To have undertaken this design was major and creative. We can all become encouraged about the acceptability of modifying a protocol to suit local needs. The diversity of the sample (only 52% White) was a major achievement—with some caveats. See Sample. We need to strongly encourage nurse researchers willing to take on this kind of challenge.

Problem statement

Was it page 5 line 5-7? Would like a strong statement that tells the puzzle to be solved by the study. I think your problem is not how to provide programs but what the nature of the program should be—which model is more effective. The "how" is using NPs and variation on the DPP

Literature review

Use of nursing literature as cornerstone is very desirable—Satterfield et al..

From my perspective the literature review was inadequate. It was good to know that there has been some preliminary evidence for efficacy, p.3 and that NPs are known to do health promotion (p.4).

However, I would have like to learn more about how "lessons learned" were abstracted from previous community based interventions, if not for diabetes, for lifestyle. The Cochrane database has two studies that might contribute to improving future work and the Google link to citations for the Satterfield et al. 2003 paper offer some relevant resources. In translational research, appreciating nuances of implementation and setting is very important.

I think that the report of the results of the DPP would be as important as the 1999 article on the design. See Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin Diabetes Prevention Program Research Group N Engl J Med. 2002 Feb 7;346(6):393-403

Another variable that I wished to see in the literature review was "motivational interviewing."

See citations on exercise in Discussion. APA style restricts new citations, but most articles seem to have them anyway. However, would the conceptual framework of the intervention have been clearer if that content was introduced here?

What is evidence for its success? Difficulty of learning? Lessons learned in training novices.... See notes on Theoretical Framework.

#### Theoretical Framework

The use of the RE-Aim framework was useful in understanding elements of design and data collection. Were there any interventions in the literature that used this framework—I think so.

However, this was not the conceptual framework for the protocols of content for the two groups, nor does it describe beliefs and assumptions about how change happens. This omission may explain some of my puzzles about the manuscript mentions of motivational interviewing—why selected? Theory of how it works? Was it foundation of DPP or authors views of how change happens? Research on its effectiveness, etc.

#### Sample

Please tell us how many sites were contacted and how many refused. I think that sites were the unit of recruitment, not individual NPs—yes?

Consort table was excellent resource. Why did so many withdraw from treatment early on?

The race differences were very important, and significant statistically. The discussion might include a return to the literature on Diabetes programs for Hispanic individuals and for Blacks. What has experience been in achieving outcomes? What lessons learned from other studies and from this experience that could inform the full study (this was a pilot) and could assist others ready to try similar programs. This sample was also more diverse on reported income than many studies, please explore how this might affect future results when n is large enough for analysis. Also what modifications were done for these drastically different groups?

Were any of the sites affiliated with university?

Another important demographic in a contemporary study is computer access and email use. Very important in this study as p.17 mentions dropping phone sessions and using email. Was this population 100% on email at start? Had they been counseled or followed in any way by email in these NP practices before the study? Was this new mode of connection important? For the next study, please track Internet behaviors if this population is so connected that email could substitute for phone calls.

#### Methods section

I missed statement of IRB activities and approval.

The content on p. 8 was particularly useful for reminding the reader of the requirements and demands of translational research—modifying to fit setting and population

Thank you for the succinct protocol inclusion.

p.8 line 18-21: I found myself wishing for the rationale for the truncated contact hours compared to DPP

#### Outcome measures

Outstanding to use the RE-Aim framework for design of procedures and selection of outcome measures. Excellent plan to do individual and organizational level data. Not sure that p.9 line 23

content goes in measures or procedures. Editor's call.

Data on measuring waist circumference was very helpful.

The HOMA assessment I presume was to match the DPP criteria. Throughout the manuscript, I suggest you keep the reader linked to the "translational" aspect—what you mirrored and what you modified.

Reach

To establish reach, one would plan to look at retention and attrition characteristics compared to recruitment.

Implementation

Thank you for the internal consistency check

Organizational measures

A great plan. Are these also indicators of fidelity?

Efficacy

A great triumvirate of variable types. For behavioral, do you mean nutrition patterns? Attitudes? Information? Same with exercise. Why no lab data at time 2—ok, just explain why behavioral and other outcomes done. Money? Time? Again what is the guidance for other translational studies on dropping one set of indicators?

Data analysis

The detail provided here was excellent.

Discussion

p.9 we learn that fidelity was tracked, I would like more detail on the findings, again important to getting good replication in other settings. What was missing in the standard care protocol? (p. 13) Same with 76% implementation of the lifestyle protocol. Not clear what you mean when you say implementation improved over time—from 76% . Maybe in this kind of study, more detail is essential! What strategies would the authors recommend for the lack of time to complete the protocol due to client needs (p.13 lines 8-10). Were these deviations tracked? Could meeting needs enhance adherence? Retention? Outcomes? I know the sample size was too small for testing these effects, but what qualitative data is available? What plans for full study to accommodate the imperatives of client need vs. protocol. Maybe have back up materials, phone checks for those missed parts of the protocol.

What were the real challenges of the motivational interviewing? P. 17 line 12 shows a persistent faith in motivational interviewing? What is data on success related to your outcomes?

p.16 I would like more detail on this study group's exercise behavior. Table 2 shows that the average minutes of exercise (139.7) at baseline was very close to the 150 minute ideal and that from a practical perspective, the control group at 129.5 minutes was very close. The changes table do not give much insight into what happened. Given that p.15-16 spends so much time on exercise, it would be useful to give more data and more analysis.

RE-AIM

Please revisit p. 5 lines 1-8 and give us your conclusion on the extent to which you met the criteria for achieving the major premise of the model.

Introduction of new citations. Strictly speaking, new work should not be added here in APA style.

This study is so very important on many levels. I am recommending that the journal give adequate space to allow discussion of the details that are so critical to translational research—ang that the authors provide them!

Writing style

Abstract

P1. line 13—the phrase "however, the average ..." is a puzzle.

p.2 spell out T2D first time

p. 2 line 11, I like "progression" rather than development here and that parallels, lines 18-19

p.2 line 13, watch subject verb choice, now says that individuals can be delayed if not prevented

p.3 line 13 please rephrase "variable programs" Did you mean programs with varying treatment models?

p.7 APA recommends avoiding anthropomorphism, see line 22: the change program intended to maximize... I think the investigators had intentions

Please search the document for the word "however." A. usually it starts a sentence and is awkward in a compound sentence, like p. 7, line 20. make two sentences. "However" is an alert that things are not as expected. Sometimes the authors use is a puzzle, see abstract

Statistical data:

Check p values. See p.14 as an example. Does the author really mean  $p <$  rather than  $p =$ ? Rarely does  $p =$  exactly .05.

Reviewer #2: This is a challenging question and a difficult study to carry out. Clinician behavior is notably quite resistant to change. The author(s) are to be congratulated for their efforts. Program evaluation hinges on fidelity to treatment protocols, representativeness of the population of interest and feasibility of its use in clinical practice. Efforts were made at address the questions of fidelity and population representativeness. Not addressed were the characteristics of the NPs and the clinical site and importantly their abilities to carry out the treatment. An analysis of NP x treatment as well as site x treatment analysis would answer this question, i.e., differences in outcome by NP provider. For instance was one NP particularly successful or not successful in promoting the behavioral change in their clients. Given the small number of client participants, presentation of the power analyses would be helpful in interpreting the findings.

It was not clear to me that the feasibility of implementing this program was indeed supported. It was noted that with considerable assistance the NPs were able to carry out the protocol. So the question really hinges on what does feasibility mean. I think it can be said that with the significant support of the research staff, the protocol was implemented.

I agree that the results are encouraging supporting continued efforts in the refinement of the program. Were participants (NPs and clients) asked what they found helpful or not helpful to assist with refinement of the program? I did note that NPs found motivational interviewing challenging but were their other techniques used? Was there analysis evaluation of the effects of frequency of NP client interactions?

Not specifically stated was whether clients gave their consent to participate in this project.

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CHECKLIST FOR STYLE

Title Page --

Supply affiliation and professional title for each author.

Supply running head of less than 50 characters (no abbreviations).

Provide corresponding author information on title page.

Abstract --

Supply 2-3 keywords; use MeSH guidelines if possible.

Acknowledgments --

Supply the titles of those acknowledged.

References --

Update reference list using APA 5th Ed. format. In particular,

Use up to 6 authors in the ref. list (ie, Posner...)

Update in-text citations using APA 5th Ed. Format (The Publication Manual of the American Psychological Association, 5th Edition, pp. 208-209). In particular:

On first citation of a reference, list all authors if there are less than 6. For following citations, use first author followed by et al.

Correct Fairbanks publication date on p. 4.  
What is correct spelling for Zayes? or Zayas?

The following references are not cited in the text. Remove from reference list or add to text:  
Mundinger et al.

Tables --

Format tables according to APA 5th Ed.

Define all abbreviations used in table(s) in a note below each table with superscript letters, not numbers.