Reviewer's report

Title: Development of a complex oral health care intervention after stroke: using a mixed methods pilot study to inform the design of a randomized controlled trial.

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Reviewer: Joseph Gallo

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Development of a complex oral health care intervention after stroke: Using a mixed methods pilot study to inform the design of a randomized controlled trial by Brady et al. (March 2011)

The investigators describe the development of an intervention using mixed methods to inform the design. They focus on stroke as a condition in which oral care may fall off in competition with other patient needs. They conceptualize the effort to improve care under three dimensions: “patients, staff, and services.” In developing an intervention that would have an impact on health outcomes, they realize that they need to attend to factors at each level, some of which they may not anticipate. Hence, the choice to evaluate the pilot intervention with mixed methods was appropriate. The authors are to be commended for involving the stakeholders -- who will be asked to carry out the intervention -- in the design phase of the intervention development.

My comments come under three rubrics: (1) the conceptual framework; (2) the use of mixed methods; and (3) general comments on the presentation.

The conceptual framework

The authors do not discuss notions around “efficacy,” “effectiveness,” or “implementation” research which has received attention recently to increase the public health impact of interventions. Specifically, effectiveness research occurs in “real-world” settings (Glasgow & Emmons, 2007) but to influence public health, interventions found to be effective must be implemented well (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005). Considering the environment where an intervention will be carried out -- such as when the intervention is designed -- is critical and is well illustrated by the study. The authors should consider where their intervention stands on the efficacy - effectiveness - implementation continuum.

The use of mixed methods

The rationale for using mixed methods should be more explicit (see Tashakkori & Teddlie, 2008 for a list of reasons for mixed methods). In general, the authors do not tap a now considerably developed literature on mixed methods (Tashakkori & Teddlie, 2010).
The authors state that they do not intend to use mixed methods in the next phase of the research. While such an approach is standard, if resources permit they should reconsider that decision, since in new sites with new providers and patients, new themes regarding the intervention design (e.g., related to failure to carry through with the intervention) may continue to emerge.

The authors provide “quantitative” and “qualitative” findings within each level of the hierarchy. This is an exemplary way to present the results although as they mention that a “standard” approach would be to separate the two strands of the research. What they do not attempt is to mix the methods at the level of the analysis. An example would be to examine the statements made by providers or patients with low levels of knowledge about oral health, or among persons whose knowledge does not improve over time.

Other general comments

Table 1, please spell out abbreviations (the abbreviations used in the table are not included in the list of abbreviations provided on page 31).

Table 2, for the non-specialist reader, should you provide the “right” answers in the table (e.g., in the first column after the items, state whether the item is “true” or “false”)?

In Tables 4 and 5 the numbers of patients over time are very small as are the differences in the item scores, but the p-values indicate high statistical significance. Perhaps a better strategy would be to simply show the data without statistical tests since the small sample size may lead to misleading p-values due to violations of the models upon with the p-values are based. Were the p-values based on exact methods?


