

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Effects of the First Line Diabetes Care (FiLDCare) self-management education and support project on knowledge, attitudes, perceptions, self-management practices and glycemc control: A quasi-experimental study conducted in the Northern Philippines
<b>AUTHORS</b>	Ku, Grace Marie; Kegels, Guy

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Chen-Yen Wang University of Hawaii at Manoa USA
<b>REVIEW RETURNED</b>	30-Apr-2014

<b>GENERAL COMMENTS</b>	<p>1). Lack of validity and reliability and psycho matrix of questionnaires</p> <p>2). One Page 14, percentage and number of participants who improved, no change, or worsen their HbA1c were not match</p> <p>a. 60.4% (99/164)</p> <p>b. Result of 7/164 should be 4.3% (164-99-58 =7)</p> <p>c. Result of 58/164 should be 35.4, not 31.7%</p> <p>3). What was the optimal pre- implementation HbA1c level?</p> <p>4). 41% of participants who had HbA1c less than 7% at the baseline and decreased A1c at post-implementation. Did they experience hypoglycemia? If yes, what was the frequency? Hypoglycemia has been associated with cardiovascular risks.</p> <p>5). Did the researcher analyze changes in A1c for participants with optimal pre-implementation A1C only?</p> <p>This study is important for diabetes management in the developing countries. Researchers have clear understanding of existing system and innovation to improve it.</p> <p>Please double check numbers in the result section as well as analyze outcomes based on A1C at the baseline.</p> <p>For example,</p> <p>** Changes in outcomes in participants with A1c less than or equal to 7% at the baseline.</p> <p>** Changes in outcomes in participants with A1c greater than 7% at the baseline.</p> <p>Then compare the differences.</p>
-------------------------	---

<b>REVIEWER</b>	Jie Hu
-----------------	--------

	University of North Carolina at Greensboro U.S.A.
<b>REVIEW RETURNED</b>	03-Jun-2014

<b>GENERAL COMMENTS</b>	<p>The paper is poorly organized and written although the study is important. I have a major concern on how HbA1C was categorized and analyzed before and after intervention in the study that might make significant findings. I would not recommend for publication.</p> <p>Abstract: The word “practice” is confusing, do you mean diabetes self-management?</p> <p>Strengths: the first strength listed doesn't reflect the study purpose or outcomes. Statistical analyses methods would not be considered as strength of the study. Strengths should include the contribution of the study to diabetes knowledge, research, and clinical practice.</p> <p>Introduction: What are the prevalence and mortality of diabetes in Philippines? Introduction is not logical congruent, for example, the last paragraph needs to be moved to methods section. A paragraph at least consists of two sentences, on page 5, lines 48-52 only has one sentence.</p> <p>Background: The authors didn't provide a review of literature on diabetes knowledge, attitude, and perception in this population instead of a background of country and population where the study was conducted, which can be moved to methods section. It is hard to know what has been done regarding study outcomes and what is the gap in this area without presenting a review of literature on study concepts/outcomes. What types of intervention have been conducted in this population?</p> <p>Methods: Definition of HbA1C: Based on the description of categorization of changes in HbA1C, an unchanged HbA1C after intervention is categorized as decrease in HbA1C. I would suggest that use parametric statistical analysis to screen significant changes in HbA1C level between pre and post-tests before performing logistic regressions. Measure on social support was included in the methods section but the authors had never addressed the concept/variable as a study outcome.</p> <p>Results: Descriptive statistics on HbA1C level with a continuous variable for comparison of pre and post tests have been used in the table and results as well as discussion sections, but parametric statistical analyses were not used for screening the data given the fact that the study had an adequate sample size.</p> <p>Discussions: Some discussions are not logically connected with the study results, for example, discussion of gender difference as a subtitle, but the authors have never mentioned it in the review of literature or introduction.</p> <p>In summary, it is a good intervention study using a large sample. However, the paper lacks logical congruency. I would suggest that authors provide concise introduction of prevalence of diabetes in this population and a comprehensive review of literature related to the study concepts/outcomes. Terms and variables measured in the study need to be consistently used in the paper, for example, the title and abstract used "practice" as one of the outcomes, but in the methods section, it refers to diabetes self-management. The entire paper needs to be better organized.</p>
-------------------------	--

## VERSION 1 – AUTHOR RESPONSE

Reviewer Name Chen-Yen Wang  
Institution and Country University of Hawaii at Manoa  
USA

1). Lack of validity and reliability and psycho matrix of questionnaires

- As mentioned in the manuscript, we adapted previously validated questionnaires. We tested internal consistency reliability of the questions in a previous study involving people with diabetes in the Philippines, which was published elsewhere. We now refer to this in the text (ref. 21).

2). One Page 14, percentage and number of participants who improved, no change, or worsen their HbA1c were not match

a. 60.4% (99/164)

b. Result of 7/164 should be 4.3% (164-99-58 =7)

c. Result of 58/164 should be 35.4, not 31.7%

- We apologize for the typographical error. The number of people whose HbA1c worsened should be 52 (31.7%) not 58. We have corrected the error and have likewise inserted the number of people whose HbA1c remained unchanged (13 / 7.9%).

3). What was the optimal pre- implementation HbA1c level?

- As we have mentioned in the definitions, “Good control of diabetes was defined as having HbA1c <7.0% (<53mmol/mol).” For more clarity, we have inserted the sentence “This was considered as the optimal level in both pre-implementation and post-implementation determinations.”

4). 41% of participants who had HbA1c less than 7% at the baseline and decreased A1c at post-implementation. Did they experience hypoglycemia? If yes, what was the frequency? Hypoglycemia has been associated with cardiovascular risks.

- None of the study participants reported any episodes of hypoglycemia. We have inserted a sentence referring to this in the last part of the 5th paragraph under the heading “Results”.

5). Did the researcher analyze changes in A1c for participants with optimal pre-implementation A1C only?

- During our preliminary statistical analysis, we analyzed our pre-implementation data based on optimal/suboptimal pre-implementation HbA1c and our post-implementation data based on optimal/suboptimal post-implementation HbA1c. However, we deemed that it would be better to present our findings based on improvement/deterioration of glycemic control as measured by a decrease or an increase in HbA1c levels rather than achievement/non-achievement of optimal HbA1c in congruence with our hypothesis. We chose changes in HbA1c levels (decreased/unchanged/increased) rather than the “optimal/suboptimal” groupings as risks are more often measured based on changes in HbA1c (eg, 1% reduction in HbA1c can lower the risk, etc.). Furthermore, as would be the case in any study regarding comparisons in glycemic control after an intervention, reductions/no change/increase in HbA1c were noted whether the HbA1c of our study participant were categorized as optimal or not (as shown in Table 3). Nevertheless, we have now added the results of our statistical analysis based on optimal/suboptimal pre- and post-implementation HbA1c in the revision version (under subheadings “Baseline Results” and “Post-implementation results” and in Table 4).

This study is important for diabetes management in the developing countries. Researchers have clear understanding of existing system and innovation to improve it.

- Thank you.

Please double check numbers in the result section as well as analyze outcomes based on A1C at the

baseline.

For example,

\*\* Changes in outcomes in participants with A1c less than or equal to 7% at the baseline.

\*\* Changes in outcomes in participants with A1c greater than 7% at the baseline.

Then compare the differences.

• Thank you. We have done these.

-----

Reviewer Name Jie Hu

Institution and Country University of North Carolina at Greensboro U.S.A.

The paper is poorly organized and written although the study is important. I have a major concern on how HbA1C was categorized and analyzed before and after intervention in the study that might make significant findings. I would not recommend for publication.

• We have attempted to reorganize the article in this revision version.

• We are sorry that we were not clear enough in defining how pre- and post-implementation HbA1c was categorized. As we have mentioned in the definitions, "Good control of diabetes was defined as having HbA1c <7.0% (<53mmol/mol)." For more clarity, we have inserted the sentence "This cut-off was considered as the optimal level in both pre-implementation and post-implementation determinations."

• We now include additional analysis of pre- and post-implementation HbA1c, which may be found under subheadings "Baseline Results" and "Post-implementation results" and in a new paragraph (4th paragraph) under the subheading "Changes in measured endpoints" under "Results. A new table (Table 4) was likewise added.

Title: The title of the paper needs to be concise.

• We have modified the title.

Abstract: The word "practice" is confusing, do you mean diabetes self-management?

• We have appended the word "self-management" to the word "practice" in the abstract and, where applicable, we replaced "self-care" with "self-management" throughout the text for consistency and to avoid any confusion.

Strengths: the first strength listed doesn't reflect the study purpose or outcomes. Statistical analyses methods would not be considered as strength of the study. Strengths should include the contribution of the study to diabetes knowledge, research, and clinical practice.

• The first strength listed refers to the purpose of the study – the implementation of a diabetes self-management education and support project that was adapted to the capabilities and resources of a low-middle income country health system – the concept of which may positively contribute towards improving chronic care in the Philippines and which may serve as an inspiration for other LMIC health systems who face the same burden.

• Although methods of statistical analysis cannot be directly attributed as a strength of the research done, the strategies for analysis of the data and results may be considered as contributory to the overall strength of the paper. The analytical techniques utilized may serve as an example and an inspiration to other researchers who may be conducting similar research, albeit in other fields.

Introduction: What are the prevalence and mortality of diabetes in Philippines? Introduction is not logical congruent, for example, the last paragraph needs to be moved to methods section. A paragraph at least consists of two sentences, on page 5, lines 48-52 only has one sentence.

- We have improved the Introduction, added the lacking information under the subheading “Diabetes in the Philippines” under the “Background” section of the “Introduction” and moved the study setting descriptions to the “Methods”. We have merged some paragraphs including the single-sentence paragraph noted.

Background: The authors didn’t provide a review of literature on diabetes knowledge, attitude, and perception in this population instead of a background of country and population where the study was conducted, which can be moved to methods section. It is hard to know what has been done regarding study outcomes and what is the gap in this area without presenting a review of literature on study concepts/outcomes. What types of intervention have been conducted in this population?

- We now mention KAP studies on people with diabetes in the Philippines under the subheading “Diabetes in the Philippines” in the Background section of the Introduction.

- May we point out that in our previous version, we have a sentence regarding the state of diabetes care in the Philippines, particularly in the local government health units, which reads: “Similar to most LGHU in the Philippines, organized care aiming at self-management education and support for chronic conditions is non-existent in both the Batac City and Pagudpud government health units”. In the revision version, we have restated this sentence as “Organized care aiming at self-management education and support for chronic conditions is non-existent in most LGHU. Before the presently reported FiLDCare project, this was also the case in the study sites.” which is now the last sentence in the subheading “The Philippine primary healthcare system” under the section “Background” of the “Introduction”.

- We moved the information on the study sites to “Methods” under the subheading “Study setting”

Methods: Definition of HbA1C: Based on the description of categorization of changes in HbA1C, an unchanged HbA1C after intervention is categorized as decrease in HbA1C. I would suggest that use parametric statistical analysis to screen significant changes in HbA1C level between pre and post-tests before performing logistic regressions. Measure on social support was included in the methods section but the authors had never addressed the concept/variable as a study outcome.

- We categorized the HbA1c as such based on the observation that the natural history of diabetes is for glycemic control to deteriorate through time if no interventions are done (De Frozo 2009), hence an unchanged HbA1c can be said as “non-deterioration” of glycemic control. We re-categorized the changes in HbA1c into two variables for regression analysis.

- The data we collected are not normally distributed, hence we opted to use the non-parametric counterparts of parametric statistical analysis in our manuscript as these would have greater efficiency than the parametric tests on non-normal distributions. We retained non-parametric analysis for the actual values/ratings (results of the Wilcoxon signed rank test, used instead of the paired T-test, are presented in Tables 2, 5a and 5b). We have however now used the two independent samples T-test in the analysis of the changes in the outcomes. A new table is added in the revision, which contains parametric analysis comparing the changes in the measured variables based on pre- and post-implementation glycemic control (Table 4) and we revised the statistical analysis of the changes in the measured outcomes listed in the last column of the original manuscript’s Table 4b (now Table 5b in the revision version).

- May we mention that during preliminary statistical analysis, we ran parametric statistics including multifactorial analysis of variance (using an alpha of 0.05, with duration of the condition and gender as

confounders) and identified duration of diabetes ( $p=0.004$ ), gender ( $p=0.041$ ), and fear of the condition ( $p=0.047$ ) as significant variables associated with improvement/decrease in glycemia but, for purposes of using the proper statistical methods, we retained the nonparametric analysis of the actual values.

- In performing logistic regression, we initially conducted bivariate analysis before running multivariate analysis, as described under “Statistical Analysis” in “Methods”.

- We have inserted sentences regarding support from family and friends in the “Discussion” and “Conclusion”.

- o Under the subheading “Changes in knowledge, attitudes and perceptions”, the sentences “Another possible effect of the DSME/S sessions is the recognition of the things that have to be done for the condition and the need for social support to accomplish some of these. As the person with the condition learns of the various activities to be undertaken for self-care and self-management, previously perceived adequate support given by family and friends may now be perceived as inadequate, hence the negative change in this rating. Involvement of the family and friends in the DSME/S sessions was limited, and strategies to include the people around the person with diabetes in future DSME/S activities need to be developed further.” were inserted after the discussion on “diet adherence” and before the discussion of “fear”.

- o At the end of “Conclusion” the sentence “Inclusion of and a more active participation of family and friends as well as other members of the community in DSME/S activities should be considered, as this may help improve the social support that most people with diabetes need.” was added.

Results: Descriptive statistics on HbA1C level with a continuous variable for comparison of pre and post tests have been used in the table and results as well as discussion sections, but parametric statistical analyses were not used for screening the data given the fact that the study had an adequate sample size.

- Please refer to our answers under “Methods” above.

Discussions: Some discussions are not logically connected with the study results, for example, discussion of gender difference as a subtitle, but the authors have never mentioned it in the review of literature or introduction.

- We have attempted to improve the structure of our manuscript.

- The gender difference and the differences according to the duration of diabetes were findings identified during statistical analysis. These were not in the original objectives of the research.

In summary, it is a good intervention study using a large sample. However, the paper lacks logical congruency. I would suggest that authors provide concise introduction of prevalence of diabetes in this population and a comprehensive review of literature related to the study concepts/outcomes. Terms and variables measured in the study need to be consistently used in the paper, for example, the title and abstract used “practice” as one of the outcomes, but in the methods section, it refers to diabetes self-management. The entire paper needs to be better organized.

- Thank you. We tried to improve the content and structure of the paper and we hope that it is now acceptable.

- We have added a subheading “Diabetes in the Philippines” under “Background” in the “Introduction” to provide the essential information regarding diabetes in this population. We also mention a couple of KAP studies done on people with diabetes in the country in this part of the manuscript.

- We have replaced the word “self-care” with the word “self-management” where applicable.

We thank our reviewers for their time in going over our manuscript and giving valuable inputs that could improve the structure and content of our submission.

We hope that we were able to address the questions, comments, and recommendations in our revision version.

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Chen-Yen Wang University of Hawaii, Manoa
<b>REVIEW RETURNED</b>	23-Jul-2014

<b>GENERAL COMMENTS</b>	Authors have revised the manuscript based on reviewers' comments.
-------------------------	---