

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.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Interventional study to improve Diabetic Guidelines Adherence using mobile health (m-Health) Technology in Lahore Pakistan
AUTHORS	Hashmi, Noreen; Khan, Shazad

VERSION 1 – REVIEW

REVIEWER	Lubna Daraz, PhD Mayo Clinic, USA.
REVIEW RETURNED	12-Dec-2017

GENERAL COMMENTS	<ul style="list-style-type: none">•The manuscript needs a major review of grammar, consistency, and flow.•The organization of the manuscript requires major revision. <p>Some examples:</p> <ol style="list-style-type: none">1. Use consistent keyword for “m- health” through the manuscript.2. Change ‘evidenced based’ to ‘evidenced-based’.3. Introduction: the Last sentence needs edit: “Our study checked if m-health technology using short messaging service (SMS) can improve the knowledge and practice of ADA preventive care guideline 8 recommendations among physicians”. <p>Numerous errors in grammar throughout the manuscript.</p>
-------------------------	---

REVIEWER	Mahmoud M. Radwan Palestinian Ministry of Health, Palestine, Gaza. PhD Health Policy
REVIEW RETURNED	19-Dec-2017

GENERAL COMMENTS	<p>Many thanks for the opportunity to review this manuscript that addresses an interesting issue, to investigate if m-health regular SMS reminder can improve the knowledge and adherence to ADA preventive care guideline recommendations.</p> <p>I have the following comments:</p> <p>Background:</p> <ul style="list-style-type: none">- Please shortly mention the prevalence/burden of DM in Pakistan.- Please cite a reference for the sentence "Studies have shown that current educational methods may result in significant gaps in physician knowledge for diabetes management"- Please provide more details on the available evidences of the m-health SMSs' effects on guideline adherence. <p>Methodology:</p> <ul style="list-style-type: none">- Would you please describe the characteristics and experiences of the medical house officers /post graduate trainees (PG trainees)? Have they formal responsibilities and duties to decide the
-------------------------	--

	<p>appropriate care for the diabetic patients?</p> <ul style="list-style-type: none"> - Would you please provide more details about the questionnaire development (adaptation) ? Did you translate it to Urdu "Pakistani language? Did you check the psychometric properties of the questionnaire..please mention if yes or no. - I can suggest to include the questionnaire as a supplementary file - Please give a reference for the sentence " The external construct validity was analyzed by checking empirical hypotheses derived from the literature" - Did you encourage the participants for expressing any queries encountered in response to the SMS messages.? please mention if yes or no. <p>Results:</p> <ul style="list-style-type: none"> - It could be suggested to provide more descriptions for the analyzed data within each table <p>Discussion:</p> <ul style="list-style-type: none"> - After reviewing the discussion part and since guidelines adherence are often influenced by many factors that can hinder or enable its implementation, I can recommend you to test the correlation between the knowledge and the adherence to diabetic recommendations (practice) post intervention in the interventional group. - Thank you.
REVIEWER	Bruce A. Perkins University of Toronto Canada
REVIEW RETURNED	21-Dec-2017
GENERAL COMMENTS	<p>I read with great interest this paper intended to take results of the TRIAD study toward implementation science methods. The authors conduct a "quasi-experimental" design which appears to return to standard clinical trial methodology by randomizing 62 physicians to a physician-centered SMS-based reminder system using ADA guideline concepts. They find that this intervention has overall benefits for knowledge and practice.</p> <p>Though I feel strongly that the authors have chosen an extremely important area of study, and that they have applied a very creative and feasible intervention that could be generalized broadly, I have some fundamental concerns with the study itself and additionally to the study reporting:</p> <ol style="list-style-type: none"> 1. Trial Design, Justification for a Clinical Trial and Detailed CONSORT Reporting. In reading the introduction, I felt that the authors were justifying an implementation science design, but instead they use an RCT design that is described as "quasi-experimental". I found this difficult to follow. Randomization may actually refer to randomization at the institution (rather than physician) level, but it is not described as a cluster randomization trial and there would be only two clusters in this case. Sample size and power is not described from this perspective. Physician losses to follow-up are not described according to randomization group, only in total. 2. Choice of Outcome measure. The outcome measures are not patient-centered (for example A1c, LDL, BP, "balanced scorecard" measures. This is an critical point that needs to be justified. Physician knowledge is one aspect, but patient outcomes would be a more reassuring measure of efficacy/effectiveness. 3. Inconsistencies in the Description of the Primary Outcome measure. There is inconsistency in Abstract and Statistics sections for primary outcome – It is stated to be the composite score in the 13

	domains, but Abstract and Results describe the components first. If indeed the components are the primary outcome, should there not be a multiple comparison adjustment? 4. Scale-up plans. These are alluded to in Abstract, but not in Discussion.
--	---

VERSION 1 – AUTHOR RESPONSE

Editor Comments to Author:

- Please include the study design and setting in the title. This is the preferred format of the journal.
Done Please see title on page 1 and 2

Please complete and include a STROBE checklist, ensuring that all points are included and state the page numbers where each item can be found. The checklist can be downloaded from here: <http://www.strobe-statement.org/?id=available-done> Please see supplementary file

Please do not include the cover letter as part of your manuscript. This has already been included on the system. Deleted

- Please give a more detailed description of the background literature on this subject in the Introduction section. What is the rationale for performing this study? Done please see page 3

-
How was the random picking of the hospitals and participants performed? information added in the methodology section. We picked up the two hospitals randomly by pick out of hat method after listing all the public hospitals in Lahore but we not randomize the individual physicians in each hospital who were our basic study units. It was not possible to randomize the individual physicians as we were concerned about contamination bias and the number of available physicians in each unit. Since this was an experimental study with a control group we labeled it as quasi-experimental and not randomized experimental trail. We calculated sample size based on the individual units and not on clusters. Please see methodology section as well.

Also references for quasi-experimental study design

1. Robson, Collin. Real World Research. 2nd edition. UK :Blackwell publishing;2002. Chapter 5:Fixed designs Quasi experiments:133-146.

2. Types of Designs available from <https://www.socialresearchmethods.net/kb/destypes.php>

-
Please ensure that your manuscript is thoroughly proofread and copyedited by a native English speaker prior to resubmission, to check for any errors in language and presentation. Done

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Lubna Daraz, PhD

Institution and Country: Mayo Clinic, USA.

Please state any competing interests or state 'None declared': None declared.

Please leave your comments for the authors below

- The manuscript needs a major review of grammar, consistency, and flow. Improved
- The organization of the manuscript requires major revision. Improved

Some examples:

1. Use consistent keyword for "m- health" through the manuscript.
2. Change 'evidenced based' to 'evidenced-based'.
3. Introduction: the Last sentence needs edit: "Our study checked if m-health technology using short messaging service (SMS) can improve the knowledge and practice of ADA preventive care guideline 8 recommendations among physicians". Corrected

Numerous errors in grammar throughout the manuscript. Corrected

Reviewer: 2

Reviewer Name: Mahmoud M. Radwan

Institution and Country: Palestinian Ministry of Health, Palestine, Gaza. PhD Health Policy

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

Many thanks for the opportunity to review this manuscript that addresses an interesting issue, to investigate if m-health regular SMS reminder can improve the knowledge and adherence to ADA preventive care guideline recommendations.

I have the following comments:

Background:

- Please shortly mention the prevalence/burden of DM in Pakistan.

Prevalence given please see introduction first paragraph Page 3

Please cite a reference for the sentence "Studies have shown that current educational methods may result in significant gaps in physician knowledge for diabetes management"

George JT, Warriner DA, Anthony J, Rozario KS, Xavier S, Jude EB, McKay GA: Training tomorrow's doctors in diabetes: Self-reported confidence levels, practice and perceived training needs of post-graduate trainee doctors in the UK. A multi-centre survey.

BMC Med Educ 2008, 8:22-6920-8-22

George JT, Warriner D, McGrane DJ, Rozario KS, Price HC, Wilmot EG, Kar P, Stratton IM, Jude EB, McKay GA, TOPDOC Diabetes Study Team: Lack of confidence among trainee doctors in the management of diabetes: The trainees own perception of delivery of care (TOPDOC) diabetes study.

QJM 2011, 104(9):761-766

References added in the text page 3

-

Please provide more details on the available evidences of the m-health SMSs' effects on guideline adherence.

Williams AD. Use of a text messaging program to promote adherence to daily physical activity guidelines: a review of the literature. *Bariatric Nursing and Surgical Patient Care*. 2012 Mar 1;7(1):13-6.

Zurovac D, Sudoi RK, Akhwale WS, Ndiritu M, Hamer DH, Rowe AK et al. The effect of mobile phone text-message reminders on Kenyan health workers' adherence to malaria treatment guidelines: a cluster randomised trial. *The Lancet*. 2011 Sep 2;378(9793):795-803.

Zurovac D1, Larson BA, Sudoi RK, Snow RW. Costs and cost-effectiveness of a mobile phone text-message reminder programmes to improve health workers' adherence to malaria guidelines in Kenya. *PLoS One*. 2012;7(12):e52045. doi: 10.1371/journal.pone.0052045. Epub 2012 Dec 18.

References added in the text page 3

Please see the introduction and discussion as well

Methodology:

- Would you please describe the characteristics and experiences of the medical house officers /post graduate trainees (PG trainees)? Have they formal responsibilities and duties to decide the appropriate care for the diabetic patients?

The House officers and PG trainees are working medical ward. The house officers are doing mandatory internship of 6 months in medicine are fresh medical graduates. They work independently but are supervised by post graduate trainees and other senior faculty members for complicated cases. The post graduate trainees are physicians who have basic medical graduation degree of MBBS and now are pursuing FCPS(Fellowship of college of physician and surgeons Pakistan) in medicine. They have formal responsibilities and duties to take care of both inpatient and outpatient

diabetics. They work independently but are supervised by senior faculty members for complicated cases.

Would you please provide more details about the questionnaire development (adaptation) ? Did you translate it to Urdu "Pakistani language? Did you check the psychometric properties of the questionnaire..please mention if yes or no.

We used the original questionnaire and added the demographic section and did not change the language of the original questionnaire as all the study participants were physicians who could understand and speak English as it is used to teach medical education in our country. We did not check in detail the psychometric properties of the questionnaire as this question was developed and tested by Center For Disease Control USA. The Guttman scale was reported in the article. Please see page5

I can suggest to include the questionnaire as a supplementary file:
Questionnaire included as a supplementary file

Please give a reference for the sentence " The external construct validity was analyzed by checking empirical hypotheses derived from the literature"

This sentence just meant that we used pertinent literature review to make sure that the external construct validity of the questionnaire covers all the aspects related to the important aspects of the study variables. The sentence was deleted from the text due to its potential ambiguity.

Did you encourage the participants for expressing any queries encountered in response to the SMS messages.? please mention if yes or no.
yes

Results:

- It could be suggested to provide more descriptions for the analyzed data within each table
Tables changed and more description given please see table 2 pages 6,7 and pages 10,11

Discussion:

- After reviewing the discussion part and since guidelines adherence are often influenced by many factors that can hinder or enable its implementation, I can recommend you to test the correlation between the knowledge and the adherence to diabetic recommendations (practice) post intervention in the interventional group.

Confounder analysis and correlation between knowledge and the adherence to diabetic recommendations (practice) post intervention in the interventional group added in the results page 10,11 and discussion section

- Thank you.

Reviewer: 3

Reviewer Name: Bruce A. Perkins

Institution and Country: University of Toronto, Canada

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

I read with great interest this paper intended to take results of the TRIAD study toward implementation science methods. The authors conduct a "quasi-experimental" design which appears to return to standard clinical trial methodology by randomizing 62 physicians to a physician-centered SMS-based reminder system using ADA guideline concepts. They find that this intervention has overall benefits for knowledge and practice.

Though I feel strongly that the authors have chosen an extremely important area of study, and that they have applied a very creative and feasible intervention that could be generalized broadly, I have some fundamental concerns with the study itself and additionally to the study reporting:

1. Trial Design, Justification for a Clinical Trial and Detailed CONSORT Reporting. In reading the introduction, I felt that the authors were justifying an implementation science design, but instead they use an RCT design that is described as “quasi-experimental”. I found this difficult to follow. Randomization may actually refer to randomization at the institution (rather than physician) level, but it is not described as a cluster randomization trial and there would be only two clusters in this case. Sample size and power is not described from this perspective. Physician losses to follow-up are not described according to randomization group, only in total.

Even though we picked up the two hospitals randomly by pick out of hat method after listing all the public hospitals in Lahore but we not randomize the individual physicians in each hospital who were our basic study units. It was not possible to randomize the individual physicians as we were concerned about contamination bias as well as availability of the physicians. Since this was an experimental study with a control group we labeled it as quasi-experimental and not randomized experimental trail. We calculated sample size based on the individual units and not on clusters. Please see methodology section

Also references for Quasi-experimental study design

1. Robson, Collin. Real World Research. 2nd edition. UK :Blackwell publishing;2002. Chapter 5:Fixed designs Quasi experiments:133-146.

2. Types of Designs available from <https://www.socialresearchmethods.net/kb/destypes.php>

We have added the data of physicians losses to follow-up in the revised text. Please see page

2. Choice of Outcome measure. The outcome measures are not patient-centered (for example A1c, LDL, BP, “balanced scorecard” measures. This is an critical point that needs to be justified. Physician knowledge is one aspect, but patient outcomes would be a more reassuring measure of efficacy/effectiveness.

This study was not designed to look at the patient outcome as much as we would have liked to check them. We could not measure the patient outcomes because of infrequent patient's follow-ups, small duration of study , and limited resources to check the patient outcomes including laboratory workup as the patient population in public hospitals are mostly poor with lack of resources. The study was not funded externally and the primary author used her private funds to conduct the whole study. We did ask 181 patients who were seeking their diabetic care in the two hospitals during the same time the interventional study was being done about their diabetic preventive care and this study is being published as well.

Ours was an exploratory study Future studies with better resources should check primary patient outcomes instead of process outcomes

3. Inconsistencies in the Description of the Primary Outcome measure. There is inconsistency in Abstract and Statistics sections for primary outcome – It is stated to be the composite score in the 13 domains, but Abstract and Results describe the components first. If indeed the components are the primary outcome, should there not be a multiple comparison adjustment?

The change in composite score was the primary outcome we looked at and changes have been made in the article to reflect that first. Please see the changes made in the abstract, result, discussion, and conclusion section

4. Scale-up plans. These are alluded to in Abstract, but not in Discussion. Scale up plans added Please see page 13

VERSION 2 – REVIEW

REVIEWER	Lubna Daraz Mayo Clinic. United States.
REVIEW RETURNED	02-Feb-2018

GENERAL COMMENTS	Thank you for making the revisions. Please use the word 'evidence-based' consistently throughout the manuscript. There is still inconsistency in the format especially in the Abstract, for example, the alignment of the paragraphs, use of spaces etc. Please use 'the' before " American Diabetic Association preventive...." in Abstract. Inconsistent use of "m-Health/m-health".
-------------------------	--

REVIEWER	Mahmoud M. Radwan Ministry of Health- Palestine
REVIEW RETURNED	04-Feb-2018

GENERAL COMMENTS	Thanks for the authors for considering almost all the comments. I am still recommending the authors to mention in the manuscript (upon their reply) that the house officers/ post graduate trainees have formal responsibilities and duties to decide the appropriate care for the diabetic patients in both two hospitals. Thank you.
-------------------------	--

VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Lubna Daraz

Institution and Country: Mayo Clinic. United States.

Please state any competing interests or state 'None declared': None declared.

Thank you for making the revisions. Please use the word 'evidence-based' consistently throughout the manuscript. There is still inconsistency in the format especially in the Abstract, for example, the alignment of the paragraphs, use of spaces etc. Please use 'the' before " American Diabetic Association preventive...." in Abstract. Inconsistent use of "m-Health/m-health".

Corrections made:

- 1.Added word "the" before American Diabetic Association preventive guidelines in the manuscript
- 2 .m-Health used consistently and changes made in the manuscript
- 3.Formatting of the document done

Reviewer: 2

Reviewer Name: Mahmoud M. Radwan

Institution and Country: Ministry of Health- Palestine

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

Thanks for the authors for considering almost all the comments.

I am still recommending the authors to mention in the manuscript (upon their reply) that the house officers/ post graduate trainees have formal responsibilities and duties to decide the appropriate care for the diabetic patients in both two hospitals. Thank you

Correction made: Statement about house officers/ post graduate trainees formal responsibilities was added on page 4