

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)	Patient confidence regarding secondary lifestyle modification and knowledge of “heart attack” symptoms following percutaneous revascularization in Japan: A cross-sectional study
AUTHORS	Kitakata, Hiroki; Kohno, Takashi; Kohsaka, Shun; Fujino, Junko; Nakano, Naomi; Fukuoka, Ryoma; Yuasa, Shinsuke; Maekawa, Yuichiro; Fukuda, Keiichi

VERSION 1 – REVIEW

REVIEWER	Soo Hoo Soon Royal North Shore Hospital Sydney, Australia
REVIEW RETURNED	25-Sep-2017

GENERAL COMMENTS	<ol style="list-style-type: none">1. The study objective is clearly stated.2. The abstract is complete and accurately summarises the study.3. The study design addresses the research question.4. The methodology is appropriate for the study purpose but for replication of the study, there is insufficient information provided in the manuscript on the construction and content validity of the survey questionnaire. There was detailed illustration on the domains of the questionnaire (Table 1), but there was no mention whether the questionnaire was pilot-tested prior to administration or whether it was derived from another tool. It was also unclear if data collection was conducted immediately after attendance at an individual or group educational program (such as an in-hospital cardiac rehabilitation session) or were patients just given printed discharge instructions on lifestyle modification. This may impact on participants' interpretation of “confidence” regarding the type of activities they were actually shown to perform and what they feel they can accomplish at a later date based on pre-discharge instructions. More information on this would be useful in the methods section in order to link into the discussion and the limitations of the study.5. The research ethics were addressed appropriately.6. The study outcomes were clear.7. Statistical application was appropriate and it would be useful to mention how many models were constructed for the elimination of multiple confounding variables.8. Some supporting references are dated (for example Ref. No.7 King et al., 2007 and Ref no: 9 Lockyer et al ; 2005) as more current publications are available.9. The results are presented clearly.10. The results address the study objectives.
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	<p>11. The results justify the conclusion.</p> <p>12. The study limitations were not discussed adequately. The authors had provided an explanation that high confidence levels were associated with patients who had previous heart attacks (27%) as shown in the demographic profile. However, a much higher proportion (40.5%) of the study sample had a previous PCI and discussion on this difference is important to support the findings. Description of the study sample (page 7) indicated that 3 times more patients (76.7%) had stable angina compared to 23.3% with ACS and was primary PCI performed for the ACS group by comparison to elective PCI? If so, could this influence and define patient behavioural responses? Additional clarification in the sample description could add weight to the discussion and study limitations.</p> <p>13. 14. 15. Yes for these 3 questions.</p> <p>Additional comments:</p> <p>The authors may also consider expanding the introduction and the discussion to include more critical appraisal and stronger argument (with additional evidence and references on similar studies in Japan or for other cultural groups) as this will highlight the need for this study to be conducted and therefore support the uniqueness of the findings.</p> <p>Overall, this is an interesting study exploring the knowledge and behavioural aspects of lifestyle modifications of PCI patients within a cultural context. I would recommend revising the title to exclude the phrase "Real-world perspectives" as it is essentially an observational survey study on PCI patients' confidence and knowledge and to add in "following percutaneous coronary revascularization in Japan" at the end of the title. This would reflect the culture-specific setting of the study population.</p>
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REVIEWER	Danielle Mosby Medstar Health National Center for Human Factors in Healthcare; United States of America
REVIEW RETURNED	29-Sep-2017

GENERAL COMMENTS	<p>Abstract page 1</p> <ul style="list-style-type: none"> -Line 6: I think it would be better to say "to assess patient perspectives on secondary lifestyle modification and knowledge of 'heart attack'" -Line 21: Please only describe the patients who were included in the study (236). Additionally, I would alter to have the sentence reflect "two hundred and thirty six consecutive CAD patients who underwent PCI completed the questionnaire." -Line 35: Please clarify the primary outcome measure <p>Abstract page 2</p> <ul style="list-style-type: none"> -Line 16: Please revise last sentence as it is currently choppy. I suggest "These gaps need to be further studied and disseminated to further improve cardiovascular care." <p>Strengths and Limitations</p> <ul style="list-style-type: none"> -Please use this format <p>Strengths: Limitations:</p>
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	<p>-Current format is difficult to understand.</p> <p>Introduction -First sentence is a run-on sentence and needs to be corrected. -Last paragraph: please update objective to reflect objective in abstract, and explain what you mean by conception gap</p> <p>Methods -Paragraph two, sentence two needs to be re-written as it is confusing. Perhaps by saying 55 patients in this cohort were diagnosed with acute coronary syndrome, and 181 patients were diagnosed with stable angina.</p> <p>Table 1 -Please add in the likert scales you used for clarification. It is also redundant to have No. of questions listed, you can remove that for more space. -For domain 1, can you explain why you chose a likert scale using the terminology never-useful, not useful, little useful, useful, very useful, not provided with educational program? This domain was meant to rate their satisfaction, and I believe that this would skew the results as useful and satisfaction mean two different things.</p> <p>Table 2 -Please explain why you are giving demographic information on people who were excluded. Please only provide patient characteristics on the 236 patients</p> <p>Discussion -Additional references on the sex differences would better support your findings</p> <p>Conclusion -This paragraph is bare and needs to be fleshed out more.</p> <p>References -No issues</p> <p>Figures -In addition to having a figure legend, please put titles with the figures</p> <p>Strobe Statement -Should this have track changes?</p>
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VERSION 1 – AUTHOR RESPONSE

October 31, 2017

Trish Groves, MD
Editor in Chief, BMJ Open

Dear Dr. Groves,

We are pleased to submit a revised version of our manuscript, entitled “Patients’ confidence with regard to secondary lifestyle modification and knowledge of “heart attack” symptoms following percutaneous revascularization in Japan: A cross-sectional study” for publication in BMJ open.

The manuscript has been rechecked and appropriate changes have been made in accordance with the reviewers’ suggestions. The responses to their comments have been prepared and given below.

We thank you and the reviewers for your thoughtful suggestions and insights, which have enriched the manuscript and produced a better and more balanced account of the research. We hope that the revised manuscript is now suitable for publication in your journal.

Response to Editorial Comments and Requests

- Regarding the following comment from reviewer 1: "13. 14. 15. Yes for these 3 questions.": The reviewer is referring to a series of questions that reviewers complete, which is normally only seen by the editorial team. The questions that the reviewer is referring to are as follows:

13. Is the supplementary reporting complete (e.g. trial registration; funding details; CONSORT, STROBE or PRISMA checklist)?

We have described the trial registration and funding details, and also followed the reporting guidelines stated in the STROBE checklist for cross-sectional studies (please see the attached file for the details).

14. To the best of your knowledge is the paper free from concerns over publication ethics (e.g. plagiarism, redundant publication, undeclared conflicts of interest)?

We declare that the paper is free from concerns over publication ethics.

15. Is the standard of written English acceptable for publication?

We asked native speakers of English to proofread our revised manuscript.

- Please revise your title so that it includes your study design and setting. This is the preferred format for the journal.

According to the suggestion from the editor and reviewer 1, we revised the title to “Patients’ confidence with regard to secondary lifestyle modification and knowledge of heart attack symptoms following percutaneous revascularization in Japan: A cross-sectional study.”

- The manuscript contains some typographical errors in the manuscript and needs to be carefully proofread.

We sincerely apologize for the typographical errors in the original manuscript. After our thorough revision, native speakers of English proofread our revised manuscript.

- The dataset analyzed is quite old now. Are your findings still relevant?

Thank you for your thoughtful comment. We would like to bring up the following points in response:

1. The characteristics of patients treated with PCI have been consistent during the last 5 years in Japan. According to reports from the national registry database (Japanese PCI Registry [J-PCI]),

patient characteristics have not shown any major change between 2012 (n = 186,770 [1]) and 2016 (n = 243,436 [2]) in terms of age; sex; coronary risk factors; and history of PCI, CABG, and MI. The same trend was also confirmed from our published data (J Am Coll Cardiol 2013;62:1260, PLoS One 2017;12(8):e0182687), which were derived from the Japan Cardiovascular Database-Keio Interhospital Cardiovascular Studies registry (also a multicenter registry build in collaboration with US NCDR CathPCI). We believe that these findings indicate that our study population reflects the current patients with CAD.

2. During the last 5 years, there have been increasing reports that focused on the discordance between patients and health-care practitioners in the recognition of secondary prevention or symptoms in patients with CAD (J Am Coll Cardiol 2015;66:1949–57, Circ Cardiovasc Qual Outcomes 2016;9:554–9, Am Heart J 2016;175:94–100). Our data are in the line with these findings, suggesting that closing these perception gaps between patients and health-care practitioners is a universal challenge that needs to be overcome in this field. These patient perspectives could change (e.g., owing to the development of new educational programs or campaigns). Therefore, the time trend in confidence needs to be surveyed regularly in the future. We described this issue in the Discussion section (page 19, 2nd paragraph).

[1]; http://www.cvit.jp/files/registry/data_manager/2013/0712005066/01_j-pci2012.pdf

[2]; http://www.cvit.jp/files/registry/data_manager/2017/document-02.pdf

- Please state the specific name of ethics committee that approved the study in the methods section along with the approval number (if applicable).

We added those details in the revised manuscript (page 8, 1st paragraph).

- The table of results should not be in the methods section. Please move the relevant tables to the results section.

Thank you for your kind suggestion. We have moved Tables 2 and 3 to the Results section.

- The reporting of the study's methods needs improving. For example, where does the questionnaire used come from? Was it designed specifically for this study? Was it pilot tested? Was it assessed for validity and reliability?

Thank you for your thoughtful question. The questionnaire was originally designed after in-depth discussion among the board-certified cardiologists and nurses in our institute specifically for this study, and was largely based on the recommendations from the Japanese Circulation Society (JCS) guidelines (Circ J 2013; 77: 231, Circ J 2012; 76: 1024, <http://www.j-circ.or.jp/guideline/> [in Japanese]). The recommendations from JCS are in line with AHA/ACC or ESC guidelines or statements (Circulation 2007; 115: 2675, Eur Heart J 2008; 29: 2909, Circulation 2004; 110: 588) but includes more targeted comments for Japanese physicians.

Within the section of patient education, the JCS guideline for 'Secondary Prevention in Coronary Artery Disease' stated that patients should be fully educated to understand lifestyle modification as well as action and recognition of acute symptoms of MI, angina, and other cardiovascular diseases (Circ J 2013; 77: 231). Incorporating above, we first generated two major domains; (1) lifestyle modification, and (2) action and recognition towards heart attack. The components of lifestyle modification were initially chosen from this JCS guideline Class I recommendations (plus Class IIa if no Class I recommendations are available) (Circ J 2013; 77: 231). The latter questionnaires for action and recognition towards heart attack were specifically developed from the investigators for the present study. We chose the words heart attack that was commonly used in clinical practice, not

medical jargon (e.g., myocardial infarction, angina), which could help the patients understand the questionnaire with ease (JAMA Intern Med 2013; 173 1715).

In order to evaluate and validate the preliminary questionnaire, we then conducted pilot study with 17 patients (not included in the final analysis). Upon reviewing the responses, we came to wonder how much degree patients considered our educational program itself useful. Therefore, the main adjustments were made with the addition of questions related to the usefulness of our hospital education program.

The relationship between the patients' confidence level about lifestyle modification and their actual postdischarge behaviors or long-term clinical outcomes have not been analyzed, and these will need to be evaluated in the future in a large multicenter study with long-term follow-up.

We described these points in the Methods (page 9, 2nd paragraph) and Discussion (limitation) sections (page 20, 2nd paragraph) of the revised manuscript.

- What was the response rate?

The response rate was 99.6%. We excluded one patient who did not answer adequately (most of the answers were left blank) from our study.

Response to Reviewer 1: Dr. Soo Hoo Soon

Thank you very much for your thorough review of our manuscript. We agree with your constructive comments and we have revised the manuscript accordingly.

1. The study objective is clearly stated.
2. The abstract is complete and accurately summarizes the study.
3. The study design addresses the research question.
4. The methodology is appropriate for the study purpose but for replication of the study, there is insufficient information provided in the manuscript on the construction and content validity of the survey questionnaire. There was detailed illustration on the domains of the questionnaire (Table 1), but there was no mention whether the questionnaire was pilot-tested prior to administration or whether it was derived from another tool. It was also unclear if data collection was conducted immediately after attendance at an individual or group educational program (such as an in-hospital cardiac rehabilitation session) or were patients just given printed discharge instructions on lifestyle modification. This may impact on participants' interpretation of "confidence" regarding the type of activities they were actually shown to perform and what they feel they can accomplish at a later date based on pre-discharge instructions. More information on this would be useful in the methods section in order to link into the discussion and the limitations of the study.

Thank you for your thoughtful question.

First of all, in order to evaluate and validate the preliminary questionnaire, we conducted pilot study with 17 patients (not included in the final analysis). Upon reviewing the responses, we came to wonder how much degree patients considered our educational program itself useful. Therefore, the main adjustments were made with the addition of questions related to the usefulness of our hospital education program. We described these points in the Methods (page 9, 2nd paragraph)

Data collection was conducted immediately after a group education program. Patient education was performed by nurses and nutritionists by using video and literature materials for lifestyle modification and nutritional guidance, which was followed by face-to-face counseling by a nurse. We added this

information about the process of patient education as well as the collection of the questionnaires in the revised manuscript (page 7, 1st paragraph).

We would also like to add that the questionnaire was originally designed after in-depth discussion among the board-certified cardiologists and nurses in our institute specifically for this study. The discussion was largely based on the recommendations from the Japanese Circulation Society (JCS) guidelines (Circ J 2013; 77: 231, Circ J 2012; 76: 1024, <http://www.j-circ.or.jp/guideline/> [in Japanese]). Specifically, in the section of patient education, the JCS guideline for 'Secondary Prevention in Coronary Artery Disease' stated that patients should be fully educated to understand lifestyle modification as well as action and recognition of acute symptoms of MI, angina, and other cardiovascular diseases (Circ J 2013; 77: 231). Therefore, as for construction of the questionnaires, we first generated two major domains; lifestyle modification, action and recognition towards heart attack. The components of lifestyle modification were initially chosen from this JCS guideline: recommendation of Class I (plus Class IIa if no Class I recommendations are available) (Circ J 2013; 77: 231). The latter questionnaires for action and recognition towards heart attack were specifically developed for the present study. We chose the words heart attack that was commonly used in clinical practice, not medical jargon (e.g., myocardial infarction, angina), which could help the patients understand the questionnaire with ease (JAMA Intern Med 2013; 173 1715).

5. The research ethics were addressed appropriately.

6. The study outcomes were clear.

7. Statistical application was appropriate and it would be useful to mention how many models were constructed for the elimination of multiple confounding variables.

Thank you very much for your valuable suggestion. In the original article, the covariates were chosen according to their clinical relevance and based on the results of previous studies (Heart 2017;103:1588, BMC Public Health 2016;16:1174, J Am Heart Assoc 2017;6:e006486) as well as the univariate analysis results in our cohort (parameters with statistical significance, $p < 0.05$).

As mentioned in the aftermentioned comment, we constructed several models including previous PCI, MI, and ACS separately. Patients who had high confidence in their awareness about heart attack were associated with previous MI and previous PCI, but not ACS, although the association with previous MI was more statistically significant than that with previous PCI. In the revised manuscript, we added the multivariate regression analysis data (page 13, 1st-3rd paragraph; pages 15-16, Table 3A and 3B) in the Results section, and discussed this point in the Discussion section (page 20, 1st paragraph).

8. Some supporting references are dated (for example Ref. No.7 King et al., 2007 and Ref no: 9 Lockyer et al ; 2005) as more current publications are available.

Thank you for your kind suggestion. We cited recent articles (Mahajan K, et al. Int J Cardiol 2017;248:1–6; Kawamoto KR, et al. Curr Atherosclerosis Rep 2016;18:73) in the revised manuscript, which are consistent with the previous ones.

9. The results are presented clearly.

10. The results address the study objectives.

11. The results justify the conclusion.

12. The study limitations were not discussed adequately. The authors had provided an explanation that high confidence levels were associated with patients who had previous heart attacks (27%) as shown in the demographic profile. However, a much higher proportion (40.5%) of the study sample

had a previous PCI and discussion on this difference is important to support the findings. Description of the study sample (page 7) indicated that 3 times more patients (76.7%) had stable angina compared to 23.3% with ACS and was primary PCI performed for the ACS group by comparison to elective PCI? If so, could this influence and define patient behavioural responses? Additional clarification in the sample description could add weight to the discussion and study limitations.

We totally agree with the reviewer's comment. Naturally, patients with previous PCI had more previous MI than those without previous PCI (46.9% vs. 13.6%, $p < 0.001$). Furthermore, among 55 patients with ACS, 6 patients (10.7%) had previous PCI. On the other hand, among 181 patients with stable angina, 90 patients (49.7%) had previous PCI. Thus, patients with previous PCI were more often diagnosed with stable angina.

The collinearity test for these variables (previous PCI, previous MI, and ACS) revealed significant correlation coefficients among these variables ($r > 0.03$). Therefore, we constructed several models including each variable separately (models 1–3). Patients who had high confidence in their awareness about heart attack were associated with a previous MI and previous PCI, but not ACS, although the association with previous MI was more statistically significant than that with previous PCI. In the revised manuscript, we added the detailed demographic data (page 7, 2nd paragraph; page 14, Table 2) and the results of multivariate regression analyses (pages 15-16, Table 3A and 3B) in the Results section.

Determinants of high confidence in precise recognition of heart attack

Variables	OR	95% CI	p Value
Model 1 (Table 3B in the original article)			
Previous MI	2.51	1.29–4.91	0.007
Model 2			
Previous PCI	2.04	1.09–3.80	0.026
Model 3			
ACS	0.91	0.43–1.92	0.80

Standard covariates = age, male, obesity, education level, coronary risk factors (hypertension, dyslipidemia, diabetes mellitus).

Model 1 = standard covariates + previous MI (Table 3B in the original manuscript).

Model 2 = standard covariates + previous PCI.

Model 3 = standard covariates + ACS.

Patients with a history of MI or PCI were associated with high confidence in their precise recognition of heart attack, possibly because of their previous experience of heart attack, PCI, or repeated education. It is difficult to conclude which factors affect the confidence level about heart attack from our data; however, education focusing on heart attack in patients with CAD without previous MI or PCI is recommended. We described these points in the Discussion section (page 20, 1st paragraph).

13. 14. 15. Yes for these 3 questions.

We answered these three questions in the section "Response to editorial comments and requests."

Additional comments:

The authors may also consider expanding the introduction and the discussion to include more critical appraisal and stronger argument (with additional evidence and references on similar studies in Japan or for other cultural groups) as this will highlight the need for this study to be conducted and therefore support the uniqueness of the findings.

Thank you for your constructive comment. Recently, patients' perspective on their lifestyle modification or disease recognition has been the subject of much research in the field of cardiovascular diseases. We added several references in the Introduction section (Kelly JP, et al. JACC 2015;65:1668–82; Donahue KE, et al. Prevent Chronic Dis 2014;11:E69) (page 5, 3rd paragraph).

We demonstrated the association of female sex with high confidence in lifestyle modification. Interestingly, knowledge and awareness of lifestyle modification among women is rather inadequate in a nationwide survey from the United States. Consistent with this variation, there were regional variations in the sex difference in the achievement of lifestyle modification. Although lifestyle modification for the secondary prevention of CAD was generally worse in women than in men, Asian women were more likely than men to be adherent to lifestyle modification, especially in terms of adequate physical activities, with opposing results in Europe and the Middle East. These findings suggest that our conclusion could be unique to Japan, and these assessments are warranted to clarify which subpopulation should be targeted for education programs in each region. We added these points in the Discussion section of the revised manuscript (page 19, 2nd paragraph).

Overall, this is an interesting study exploring the knowledge and behavioural aspects of lifestyle modifications of PCI patients within a cultural context. I would recommend revising the title to exclude the phrase "Real-world perspectives" as it is essentially an observational survey study on PCI patients' confidence and knowledge and to add in "following percutaneous coronary revascularization in Japan" at the end of the title. This would reflect the culture-specific setting of the study population.

Thank you for your comment. According to your suggestion and the comment by the editor, we revised the title to "Patients' confidence with regard to secondary lifestyle modification and knowledge of heart attack symptoms following percutaneous revascularization in Japan: A cross-sectional study."

Response to Reviewer 2: Dr. Danielle Mosby

Thank you very much for your thorough review of our manuscript. We agree with your comments and we have revised the manuscript accordingly. We hope that the revised manuscript meets your expectations and is now suitable for publication.

Abstract page 1

-Line 6: I think it would be better to say "to assess patient perspectives on secondary lifestyle modification and knowledge of 'heart attack'"

Thank you for your kind suggestion. We revised the text following your recommendation (page 2, 1st paragraph).

-Line 21: Please only describe the patients who were included in the study (236). Additionally, I would alter to have the sentence reflect "two hundred and thirty six consecutive CAD patients who underwent PCI completed the questionnaire."

Thank you for your suggestion. We revised the manuscript accordingly, and changed the demographic data in the Abstract.

-Line 35: Please clarify the primary outcome measure

Thank you for your comment. The primary outcome assessed was the patients' confidence level about lifestyle modification and recognition of heart attack symptoms based on the original questionnaire. We precisely described this point in the Abstract.

Abstract page 2

-Line 16: Please revise last sentence as it is currently choppy. I suggest "These gaps need to be further studied and disseminated to further improve cardiovascular care."

Thank you for your kind suggestion. We revised the last sentence as you suggested.

Strengths and Limitations

-Please use this format

Strengths:

Limitations:

-Current format is difficult to understand.

Thank you for your kind suggestion. We revised the section on strengths and limitations as you recommended.

Introduction

-First sentence is a run-on sentence and needs to be corrected.

According to your suggestion, we split the first sentence into two sentences to correct the run-on sentence.

-Last paragraph: please update objective to reflect objective in abstract, and explain what you mean by conception gap.

Thank you for comment. We updated the objective within the Introduction section to reflect the revised objective in the Abstract (page 5, 3rd paragraph to page 6, 1st paragraph).

The conception gap between health-care providers and patients means the mismatch between what health-care providers thought patients were confident about and what the patient was actually confident about in terms of lifestyle modification or heart attack recognition. We believe that the understanding of this perception gap will help identify imbalances in the composition of patient education programs, as well as assess their appropriateness. We described this point in the revised manuscript (page 5, 3rd paragraph to page 6, 1st paragraph).

Methods

-Paragraph two, sentence two needs to be re-written as it is confusing. Perhaps by saying 55 patients in this cohort were diagnosed with acute coronary syndrome, and 181 patients were diagnosed with stable angina.

Thank you for your kind suggestion. We revised the manuscript according to your comment (page 7, 2nd paragraph).

Table 1

-Please add in the likert scales you used for clarification. It is also redundant to have No. of questions listed, you can remove that for more space.

According to your suggestion, we added the Likert scale in Table 1 and removed the data on No. of questions.

-For domain 1, can you explain why you chose a likert scale using the terminology never-useful, not useful, little useful, useful, very useful, not provided with educational program? This domain was meant to rate their satisfaction, and I believe that this would skew the results as useful and satisfaction mean two different things.

Thank you for your valuable question. We recognized our incorrect translation in the Japanese questionnaire for domain 1. This domain was meant to rate the usefulness, not the patient satisfaction, of the educational program, and we have corrected the description in Table 1. We sincerely apologize for the misinterpretation.

Table 2

-Please explain why you are giving demographic information on people who were excluded. Please only provide patient characteristics on the 236 patients

Thank you for your kind suggestion. We agree that the demographic data of the included populations should be described. In the revised manuscript, Table 2 shows the characteristics of the 236 patients.

Discussion

-Additional references on the sex differences would better support your findings

As noted in a previous comment, despite the association of female sex with high confidence level in lifestyle modification in our Japanese study population, the knowledge and awareness of lifestyle modification among women is inadequate in a nationwide survey from the United States (JACC 2017;70:12–32). Consistent with these regional variations, although lifestyle modification for the secondary prevention of CAD was generally worse in women than in men, Asian women were more likely than men to be adherent to lifestyle modification, especially in terms of adequate physical activities, with opposing results in Europe and the Middle East (Heart 2017;103:1587–94). These findings suggest that there are regional variations in the sex difference in the attitude and achievement of lifestyle modification. Therefore, we emphasized that these assessments are warranted to clarify which subpopulation should be targeted for education programs in each region. We added these points in the Discussion section of the revised manuscript (page 19, 2nd paragraph).

Conclusion

-This paragraph is bare and needs to be fleshed out more.

Thank you for your comment. We described the details of the substantial disparities in the confidence level about lifestyle modification, as well as awareness of heart attack in the revised manuscript (page 21, 1st paragraph).

References

-No issues

Figures

-In addition to having a figure legend, please put titles with the figures

Thank you for your kind suggestion. We added titles with the figures.

Strobe Statement

-Should this have track changes?

We have deleted the tracked changes in the revised manuscript.

We hope our revised manuscript is now acceptable for publication in the BMJ open. Please contact me if you have any questions regarding the manuscript.

Yours sincerely,

Takashi Kohno, MD

Department of Cardiology, Keio University School of Medicine, Tokyo, Japan

VERSION 2 – REVIEW

REVIEWER	Soo Hoo Soon yeng Royal North Shore Hospital, Sydney. Australia.
REVIEW RETURNED	12-Nov-2017

GENERAL COMMENTS	<p>Reviewer comments:</p> <p>The authors have made substantial changes in this revision to provide a more in-depth description of the research including information on the design of the study. The following changes are recommended:</p> <p>i) Please add in the SPSS version used on Page 11(Line 21).</p> <p>ii) There is more detail provided in the manuscript now for a pilot study on Page 9 but how was the sample size determined? Was a power analysis conducted and if so, please describe in brief as this detail will support the validity of the design, particularly when the authors mentioned “statistical power” on Page 20 (Line 33).</p> <p>iii) Under the Results section on Page12 (Line 12) please revise the sentence “Approximately 70% of patients considered their lifestyle modification program as useful (Very useful 26%,Useful 45%,Not useful 5%)”. List only what is useful but the percentages still do not add up to 70% of the study group - please correct.</p> <p>iv) The next sentence describing the usefulness of nutritional guidance does not add up to 70% either - please correct. Please delete “Little useful”, Not useful” and “Never useful” as they are a distraction.</p> <p>v) The 2 models shown on Tables 3A and 3B (Pages 49 and 50) used for multivariate regression analysis did not contain details of their predictive strength. Further information on why these models were accepted would be useful to support the analysis and its findings.</p> <p>vi) Paragraph 2 of the Results section on Page 20 (Lines 27 to 29) reports “low confidence” but the brackets contains “(confident or completely confident , <50%)”. Is this a reporting error?</p> <p>vii) The conclusion on Page 55 (Line 16) stated “substantial gap....and a history of MI”. Please add the words “and PCI” beside “MI” as your study results indicated a high knowledge level with these 2 groups and not just MI.</p> <p>viii) There are errors in spelling/grammar and overall sentence construction and flow could improve with further English language editing. On Page 43 (Line 42) for example, please use the singular</p>
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	<p>form of “word” instead of “words” and add in the quotation “heart attack” as one description. Please remove “and” after the word “PCI” in the abstract subheading for participants on page 2 (Line 18).</p> <p>Overall the manuscript has improved; its contents are more concise and all relevant tables are looking better than before. Thank you for making the corrections.</p>
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VERSION 2 – AUTHOR RESPONSE

December 15, 2017

Trish Groves, MD
Editor in Chief
BMJ Open

Dear Dr. Groves,

We are pleased to submit a revised version of our manuscript, entitled “Patient confidence regarding secondary lifestyle modification and knowledge of “heart attack” symptoms following percutaneous revascularization in Japan: A cross-sectional study” for publication in BMJ Open.

The manuscript has been rechecked and appropriate changes have been made in accordance with the reviewers’ suggestions. The responses to their comments have been prepared and given below.

We thank you and the reviewers for your thoughtful suggestions and insights, which have enriched the manuscript and produced a better and more balanced account of the research. We hope that the revised manuscript is now suitable for publication in your journal.

Editorial Request:

Thank you for clarifying the response rate in your rebuttal letter. However, can you also include this information in the manuscript?

Thank you for your comment. According to your suggestion, we added the response rate to the methods section (page 7, 2nd paragraph).

Reviewer's Comments to Author:

Reviewer: 1

Reviewer Name: Soo Hoo Soon Yeng

Institution and Country: Royal North Shore Hospital, Sydney. Australia.

Competing Interests: None declared.

The authors have made substantial changes in this revision to provide a more in-depth description of the research including information on the design of the study. The following changes are recommended:

i) Please add in the SPSS version used on Page 11 (Line 21).

Thank you for your comment. We added the version of SPSS used in the study to the statistical analysis section.

ii) There is more detail provided in the manuscript now for a pilot study on Page 9 but how was the sample size determined? Was a power analysis conducted and if so, please describe in brief as this detail will support the validity of the design, particularly when the authors mentioned “statistical power” on Page 20 (Line 33).

Thank you for your suggestions. We performed the pilot phase of our study to test for the acceptability (lack of ambiguity) of our questionnaire. Furthermore, as patient-based surveys are scarcely performed in Japan, the feasibility and applicability of the research platform had to be tested. Hence, no power analysis or sample size calculation was performed in the present study. We describe this issue in the limitations section in the revised manuscript (page 21, 2nd paragraph).

No formal power analysis of the results of the pilot study to determine the optimal sample size was performed. Consequently, its statistical power may not have been sufficient to detect any negative outcomes.

iii) Under the Results section on Page 12 (Line 12) please revise the sentence “Approximately 70% of patients considered their lifestyle modification program as useful (Very useful 26%, Useful 45%,Not useful 5%)”. List only what is useful but the percentages still do not add up to 70% of the study group - please correct.

Thank you for your comment. We only listed the patients who considered their lifestyle modification program to be useful in the revised manuscript (page 12, 1st paragraph); 71% of patients considered the program they received as useful.

Approximately 70% of patients considered their lifestyle modification program as useful (very useful, 26%; useful, 45%).

iv) The next sentence describing the usefulness of nutritional guidance does not add up to 70% either - please correct. Please delete “Little useful”, “Not useful” and “Never useful” as they are a distraction.

We only listed the patients who considered the nutritional guidance they received as useful in the revised manuscript (page 12, 2nd paragraph); 72% of patients considered the nutritional guidance they received as useful.

Nutritional guidance was also considered useful by approximately 70% of the patients (very useful, 28%; useful, 44%).

v) The 2 models shown on Tables 3A and 3B (Pages 49 and 50) used for multivariate regression analysis did not contain details of their predictive strength. Further information on why these models were accepted would be useful to support the analysis and its findings.

Thank you for your comments. We used c-statistics to assess the predictability of the above models. With respect to the predictability of a low confidence level in lifestyle modification (Table 3A), the c-

statistics of models 1 and 2 were 0.72 (95% CI 0.65–0.80) and 0.72 (95% CI 0.64–0.79), respectively. With respect to the predictability of a high confidence level in the precise recognition of heart attack (Table 3B), the c-statistics of models 1 and 2 were 0.67 (95% CI 0.59–0.75) and 0.65 (95% CI 0.57–0.73), respectively. We added the description of these predictability levels to the methods (page 11, 1st paragraph) and results sections (page 13, 1st and 3rd paragraph).

vi) Paragraph 2 of the Results section on Page 20 (Lines 27 to 29) reports “low confidence” but the brackets contains “(confident or completely confident , <50%)”. Is this a reporting error?

We appreciate your comment and sincerely apologize for this incorrect description. We precisely describe the revisions made to the manuscript below (page 12, 2nd paragraph).

The patients were divided into confident (confident or completely confident) and low confidence groups (not confident or less confident).

vii) The conclusion on Page 55 (Line 16) stated “substantial gap....and a history of MI”. Please add the words “and PCI” beside “MI” as your study results indicated a high knowledge level with these 2 groups and not just MI.

Thank you for your kind suggestion. We revised the manuscript as recommended (page 22, 1st paragraph).

viii) There are errors in spelling/grammar and overall sentence construction and flow could improve with further English language editing. On Page 43 (Line 42) for example, please use the singular form of “word” instead of “words” and add in the quotation “heart attack” as one description. Please remove “and” after the word “PCI” in the abstract subheading for participants on page 2 (Line 18).

We apologize for the errors in spelling/grammar in the manuscript. Although an English native speaker proofread the previous version of the manuscript, some errors remained. We revised our manuscript and performed thorough checks based on your suggestions. Furthermore, another English native speaker proofread the revised manuscript.

Overall the manuscript has improved; its contents are more concise and all relevant tables are looking better than before. Thank you for making the corrections.

We hope that our revised manuscript is now acceptable for publication in BMJ Open. Please contact me if you have any questions regarding the manuscript.

Yours sincerely,

Takashi Kohno, MD

Department of Cardiology
Keio University School of Medicine
Tokyo, Japan

VERSION 3 – REVIEW

REVIEWER	Soo Hoo Soon Yeng, RN PhD Royal North Shore Hospital, Sydney, Australia.
REVIEW RETURNED	22-Dec-2017

GENERAL COMMENTS	<p>Thank you for revising this manuscript which now contains better statistical description and more coherence than the first submission. I would recommend just two minor corrections as below:</p> <ol style="list-style-type: none">1. The addition (“s”) to the word “model” (Page 13, Line 18 and Line 51) to indicate both models (pleural instead of singular). This has, in fact, been listed as a correction in your recent response to question (v) and I feel that it may be just an oversight during in-text corrections.2. The discussion section on gender differences (Page 19, Lines 38 to 46) states that “Although a high confidence in lifestyle modification was associated with the female sex in patients with CAD in Japan according to our data.....”. This result was not reflected in the analysis, which showed that only male sex was associated with lower confidence levels on lifestyle modification. I would suggest either correcting this sentence for accuracy or removing it as supporting evidence in the discussion. <p>I have no other comments for the rest of the manuscript contents and my best wishes to the authors for their time and dedication in conducting this interesting study.</p>
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VERSION 3 – AUTHOR RESPONSE

January 26, 2018

Trish Groves, MD
Editor in Chief
BMJ Open

Dear Dr. Groves,

We are pleased to submit a revised version of our manuscript, entitled “Patient confidence regarding secondary lifestyle modification and knowledge of “heart attack” symptoms following percutaneous revascularization in Japan: A cross-sectional study” for publication in BMJ Open.

The manuscript has been rechecked and appropriate changes have been made in accordance with the reviewers’ suggestions. The responses to their comments have been prepared and given below.

We thank you and the reviewers for your thoughtful suggestions and insights, which have enriched the manuscript and produced a better and more balanced account of the research. We hope that the revised manuscript is now suitable for publication in your journal.

Editorial Requests:

Can you please make it clearer why the first two bullet points of the 'strengths and limitations' section (page 4) are specific strengths of your study? They appear to be a summary of what you did rather than specific strengths of the study's design and methods.

Thank you for your valuable comments. We have reconsidered the strengths of our study, and made the following revision.

Strengths:

- To date, many trials have focused on improving clinical outcomes in CAD patients via various interventions; however, few studies have investigated the patients' perspectives, which this survey unveils.
- This study enables medical providers to address the needs of the patient through a more comprehensive understanding of the latter's perspectives, resulting in improvement of clinical outcomes.

Reviewer's Comments to Author:

Reviewer: 1

Reviewer Name: Soo Hoo Soon Yeng, RN PhD

Institution and Country: Royal North Shore Hospital, Sydney, Australia.

Competing Interests: None declared.

Thank you for revising this manuscript which now contains better statistical description and more coherence than the first submission. I would recommend just two minor corrections as below:

1. The addition ("s") to the word "model" (Page 13, Line 18 and Line 51) to indicate both models (plural instead of singular). This has, in fact, been listed as a correction in your recent response to question (v) and I feel that it may be just an oversight during in-text corrections.

Thank you for your comment. We have added "s" to the word "model" as per your suggestion.

2. The discussion section on gender differences (Page 19, Lines 38 to 46) states that "Although a high confidence in lifestyle modification was associated with the female sex in patients with CAD in Japan according to our data.....". This result was not reflected in the analysis, which showed that only male sex was associated with lower confidence levels on lifestyle modification. I would suggest either correcting this sentence for accuracy or removing it as supporting evidence in the discussion.

Thank you for your thoughtful comment. We have revised the sentences as follows.

While our study revealed that the male sex was associated with low confidence in lifestyle modification for CAD in Japan, a nationwide survey from the United States demonstrated that women have less knowledge and awareness of cardiovascular disease than men.

We hope that our revised manuscript is now acceptable for publication in BMJ Open. Please contact me if you have any questions regarding the manuscript.

Yours sincerely,

Takashi Kohno, MD

Department of Cardiology
Keio University School of Medicine
Tokyo, Japan