

## Review report

**Final title:** Mental health status and associated factors prevailing among the patients having orofacial clefts in Bangladesh: A mixed method study

**Title at submission:** Psychological distress and associated factors prevailing among the patients having orofacial clefts –A mixed method study



## ROUND 1

**Reviewer:** Helal Uddin Ahmed, ORCID: [0000-0003-4106-218X](https://orcid.org/0000-0003-4106-218X)

### Overview

The article is well written and time demanding. Need some minor revision and later another research will be done to explore the QoL among the person with orofacial clefts before and after intervention. And those who have psychological distress need to psychosocial intervention.

### Correspondence

Tanzila Rafique  
[tanzila\\_rafique@bsmmu.edu.bd](mailto:tanzila_rafique@bsmmu.edu.bd)

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### Responsible editor

M Mostafa Zaman  
0000-0002-1736-1342

### Reviewer

Helal Uddin Ahmed  
0000-0003-4106-218X  
Anonymous

### Keywords

*cleft lip and cleft palate, DASS-21, depression, anxiety, stress*

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### Ethical approval

Approved by IRB of Bangabandhu Sheikh Mujib Medical University (No. BSMMU/2018/3022, dated 12 Mar 2018).

### Trail registration number

Not applicable

### Declaration

None

- |   |                 |  |
|---|-----------------|--|
| 1 | <b>Comment</b>  | Is the title appropriate? = <b>No</b><br>Line 2: Can add the place of study like '3 specialized hospitals of Dhaka, Bangladesh'  |
|   | <b>Response</b> | Title name has been changed to: 'Mental health status and associated factors prevailing among the patients having orofacial clefts in Bangladesh- A mixed method study.'<br>Line no: 2-3<br>Place of the study has been added as per suggestion<br>Line no:42-43 |
| 2 | <b>Comment</b>  | Does the abstract provide a complete and accurate description of the content of the article? = <b>No</b><br>Line 46: No need to add references to DAS 21 in the abstract.  |
|   | <b>Response</b> | Have been thoroughly described providing the accurate description of the article content. Reference for DASS 21 has been removed from abstract.<br>Line no: 46<br>Changed have been carried in the result section out as per feedback.<br>Line no: 50-51         |
| 3 | <b>Comment</b>  | Are the study objective(s) clearly stated and logical? = <b>No</b><br>Line 101: it reflects a national survey as stated 'CL/P patients in Bangladesh'. It should be specifying the place of study.   |
|   | <b>Response</b> | Study objective(s) have been clearly stated<br>Line: 39-41; 94-95<br>Study place has been mentioned.<br>Line no: 102-106   |
| 4 | <b>Comment</b>  | Are the methods described in sufficient detail so that the study could be reproduced? = <b>No</b><br>Line 130: Please describe the DASS 21 with reference. Add more 2/3 lines about this scale. It has been validated in Bangladesh. Please mention it.          |
|   | <b>Response</b> | Have been sufficiently mentioned.<br>Line: 101-119<br>Detailed have been given<br>Line no: 107-109   |
| 5 | <b>Comment</b>  | Are the table(s) and figure(s) clear and appropriate to address the objective(s)? = <b>No</b><br>Line 435-436: Figure 1 is not clear to me and not self-explanatory. No legend about treated and non-treated groups.   |
|   | <b>Response</b> | Legend about treated and non-treated group has been given in figure<br>Line no: 446-447  |
| 6 | <b>Comment</b>  | Are the references appropriate in number and up to date? = <b>No</b><br>Among 13 references, 7 are more than 12 years old.   |
|   | <b>Response</b> | Changed have been carried out<br>Line no: 384-415  |

**Reviewer: Anonymous**

- 7 **Comment** Is the title appropriate? = **No**  
The study entitled "Psychological distress and associated factors prevailing among the patients having orofacial clefts—A mixed-methods study" should mention the study place as it was conducted only at two super-specialized hospitals in Bangladesh. Furthermore, in the study, the researcher compared the psychological stress between treated and untreated patients with cleft lip/palate.
- Response** Title have been changed.  
Line no: 2-3  
The study sample were collected from the Dept. of Orthodontics of Bangabandhu Sheikh Medical University, Sheikh Hasina National Institute of Burn and Plastic Surgery, Bangladesh and Bangladesh Specialized Hospital, Dhaka Bangladesh. Cleft lip/palate patients from all over the country used to visit in these hospitals. Therefore, sample taken from these tertiary level hospitals, including the BSMMU and Dhaka medical college were considered as representative sample of Bangladesh.
- 8 **Comment** Does the abstract provide a complete and accurate description of the content of the article? = **No**  
The study objective was not mere exploration but comparison and prediction of associated factors according to the result section. [line 40-41 vs 51-59] Study design, type of sampling, study period, statistical analysis, and software used should be mentioned in the method section of the abstract. [The mixed method is the data collection approach, not an epidemiological study design]. References should not be included in the abstract, and the validity of the tool should be reported in terms of Cronbach's alpha. Result-section of the abstract should include a brief description of the demography and disease characteristics, e.g., duration of disease, type of disease, treatment modalities, etc. [line 42-59].  
"The findings were explained by qualitative evidence." should be changed to "The findings were confirmed or supported by qualitative evidence.". Conclusion remarks are misleading, as it seems significant psychological impacts of cleft lip and palate were found among patients of treated and untreated respondents. [It can be written as such; there were statistically significant differences in psychological distress (anxiety, depression, stress) between treated and untreated patients of cleft lip/palate.]  
"Poor treatment facilities in the peripheral areas, awareness and improper information regarding the available treatment options, health system responsiveness, social classes, financial supports, travel"costs—these variables were not found in quantitative analysis.
- Response** Specific changes have been carried out, and information has been given in the mentioned areas as per specific feedback. Abstract has been changed accordingly. Study design, type of sampling, study period, statistical analysis, and software used should be mentioned in the method section of the abstract.  
Line: 42-49  
References have been removed in the abstract, and the validity of the tool should be reported in terms of Cronbach's alpha.  
Line: 45-47  
Information in the result section of the abstract has been added.  
Line: 50-56  
The conclusion has been changed  
Line: 57-58
- 9 **Comment** Are the methods described in sufficient detail so that the study could be reproduced? = **No**  
Study period and epidemiological study design should be included.  
Sample size determination should be reported.  
Data editing and analyzing software should be mentioned.  
DASS 21 should be described in detail in terms of scoring and application as it is a self-reported psychometric scale.  
Statistical analysis should include assumptions and reporting characteristics of the specific test.
- Response** Study period and epidemiological study design have been mentioned.  
Line no: 103-104  
Sample size determination have been given.  
Line no: 113-115  
Data editing and analysing software have been mentioned  
Line no: 169-170  
DASS 21 have been described in details.  
Line no: 134-149
- 10 **Comment** Is the study design robust and appropriate to the stated objective(s)? = **No**  
Author mentioned the study design as mixed-method study. In my opinion, it is a data collection method, not an epidemiological study type.  
A cross-sectional comparative study/or a quasi-experimental study (assuming treatment as intervention) may suit well.
- Response** Study design has been revised.

- 11 **Comment** Are statistics used appropriately and described fully? = **No**  
 If psychological distress is the outcome variable and treatment is the key exposure adjusted for sociodemographic and other variables, then anxiety, depression, and stress should be in the column and others in the row.  
 Primarily, bivariate analysis such as chi square, t test, and ANOVA should be done following the quality of the data and assumption of the specific tests.  
 Statistics should be reported with their values, such as chi, t, and F, and should include the degree of freedom or confidence interval as appropriate along with the p value.  
 Factors that showed statistical significance in bivariate analysis should be included in the linear regression model to find out the best predictors adjusted for the confounders.  
 Models should be described briefly.  
 For linear regression, a test of normality is mandatory. LR should be reported with a beta coefficient with a CI and p value. Factors that are not significant can be omitted from the table for easy understanding. [line 423, 431, 434]

**Response** Statistics have been described thoroughly.  
 Line no: 169-183

- 12 **Comment** Are the table(s) and figure(s) clear and appropriate to address the objective(s)? = **No**  
 Line 435-436: Figure 1 is not clear to me and not self-explained. No legend about treated and non-treated group.

**Response** Have been incorporated and changed as per the feedback provided.

- 13 **Comment** Are the conclusions drawn supported by the results/ data? = **No**  
 Conclusion remarks are totally out of context in terms of the objectives and results of the study. It is more like a recommendation, and it should be rewritten following the objective and findings of the study. A future study with a representative sample and a better design may be recommended. [line 349-352]

**Response** Study conclusion have been changed.  
 Line No: 355-359

- 14 **Comment** Is the storytelling straightforward, clear (i.e., does not impede scientific meaning or cause confusion), and logical? = **No**  
 At the beginning, researchers started with exploration of prevailing (prevalence) psychological distress and associated factors among two groups of respondents (according to title); in the middle, they compared the outcome between two groups as well as predicted the important factors using linear regression; and lastly, they concluded, "The modern treatment of cleft surgeries and orthodontic treatments should be made accessible to all, and this information should be widely publicized so that everyone is aware of the issues at each level of the community. Nationwide public education campaigns should be spearheaded by the government and NGOs to increase the knowledge of CL/P in the country!" [Lines 40-41 and 101-102, 170-173 and 180-182, 349-353]

**Response** Story telling has been revised.

- 15 **Comment** Language and grammar should be checked meticulously before submission of an article. Respected authors may utilize different software for the purpose.  
 Strength and limitations should be mentioned in a paragraph at the end of the discussion.

**Response** Have been added to the discussion.  
 Line no: 350-354

**Editor: M Mostafa Zaman, ORCID: 0000-0002-1736-1342**

- 16 **Comment** The Discussion section's first paragraph should have highlights of the study such major findings. Strengths could be mentioned here as its selling point. Please revise the first paragraph.  
 There is large repetition of results.  
 Conclusion should be aligned with the objective.

**Response** The Discussion section's first paragraph has been revised as suggested by esteemed reviewer (Line 248-251). Discussion section has been revised to avoid any repetition of results. Conclusion has been aligned with the objective (Line 283-287).

- 17 **Comment** The manuscript's primary problem is the statement of the objective and then adherence to it for statistical analysis. I understood that the objective is to determine the prevalence of psychological distress among hospital patients with cleft palate and identify factors associated with it. The authors should answer first if this understanding is correct.  
 If the above understanding is correct and the dependent variable is quantitative, multivariate linear regression should be done. In such a case, there should not be a reference category. A reference category is used in the case of logistic regression, where the dependent variable is a categorical variable (yes/no). For example, if the analysis is done for two categories of patients, depressed or not depressed, then the analysis should be a logistic regression. The authors need to clear this confusion first in the statistical analysis section.

**Response** Many thanks for your comment. We have now used generalized linear regression model considering the dependent variable as continuous scores for depression, anxiety, and stress. We have now also removed the label of "reference" category to avoid confusion. However, in linear regression model the estimated coefficient is compared whether it is different from zero or not and to avoid perfect multi collinearity all levels in a category are not included while estimating the coefficient. Thus, one level will be omitted from each categorical variable and now we have included the omitted level of categorical variable in the model as missing.  
 Line no: 440-443

- 18    Comment    Lines 56-57: "The findings were explained by qualitative evidence"; what findings and qualitative evidence are you talking about?
- Response    For the quantitative part, participants' mental health status was assessed by the DASS 21 scale which is a validated and translated questionnaire. The validity of this tool was reported in terms of Cronbach's alpha.
- While for the qualitative part, information regarding the mental health status were assessed by following the preformed Interview guidelines. As the two data collection methods were different, therefore, to support the findings of DASS 21, the IDIs were carried out to find other insights and factors those can be find by the quantitative study alone and results of the two studies were compared.
- 19    Comment    Highlights: I suggest three bullet points: the problem statement, your key findings, and the implications of this study's findings.
- Response    Have been changed as per suggestions.
- Line no: 61-71
- 20    Comment    Methods: It is not clear how the determinants of psychological distress are determined, e.g., family income, and peri-urban living area. How sure are the authors about the family income data? Has it been factored in by all sources of income accounting and the number of family members dependent on it?
- Response    The word "distress" has been replaced by the 'mental health status' in the changed title of the study. Our study found that the factors like participants' social classes, living area types, family incomes etc. were related with the treatment seeking status, which ultimately affects their mental health. All the participants tentatively shared their average monthly family incomes to provide ideas regarding their financial conditions
- 21    Comment    Table 1: Why is the 95% confidence interval data necessary for the background data? Are you trying to justify the representativeness of the participants? I believe this is not the case. Simple descriptive data here would suffice. You have many categories for age, marriage, education, and living areas. Some categories have a small number of subjects for a meaningful analysis. I suggest merging them with similar/closer groups so that the groups have a meaningful number of subjects. This should be done for all other tables too.
- Response    Table 1 has been revised.
- 22    Comment    Table 3: Are you presenting linear or logistic regression analysis data here? The reference category has created this confusion, as seen in a relevant comment above.
- Response    We would like to clarify that the dependent variables were depression, anxiety, and stress. We have performed chi-squared tests for categorical variables
- with more than two levels and tests of proportion for variables with two levels.
- We have now included the factors in the regression model which were statistically significant in
- the bivariate tests. We have reported log likelihood ratio value for each of the models. We performed Shapiro wilk tests for testing the normality of the data and found that the distribution was not normal due to lower observation and having two groups of population. As the depression, anxiety, and stress were continuous scores, we have treated them as continuous variables for better interpretation of the findings. We have used generalized linear model to avoid the strict assumption of normality for the error term.
- 23    Comment    Finally, you have separate results for depression, anxiety and stress. How do you fit these into your objective of determining distress prevalence? Your dependent variables do not include distress. In such a situation, should you change your object to depression, anxiety and stress? Please decide prudently.
- Response    Changes have been carried out.
- Line no: 486-489

## ROUND 2

### Reviewer: Anonymous

- 1    Comment    In the abstract section you mentioned "This study assessed the psychological distress present among the adult cleft lip and/or cleft palate patients and the factors related to these issues. [Line 40-41]
- But in the last paragraph of the introduction section, you mentioned "The current study assessed the mental health status among the adult treated and untreated groups of CL/P patients in Bangladesh". [Line 94-96].
- In result section, you actually compared anxiety, depression and stress between treated and untreated patients. So in my opinion, your aim was to compare the mental health status between treated and untreated.
- And you correctly stated it in your conclusion, "There were statistically significant differences in mental health status between treated and untreated patients of cleft lip/palate."
- So, stay consistent with your write-up throughout. The study entitled "Psychological distress and associated factors prevailing among the patients having orofacial clefts—A mixed-methods study" should mention the study place, as it was conducted only at two super-specialized hospitals in Bangladesh. Furthermore, in the study, the researcher compared the psychological stress between treated and untreated patients with cleft lip/palate.
- Response    Many thanks for your comments. Specific changes have been carried out all over the text according to the of study objectives and findings. The study objectives were written as, "This study assessed the mental health status among the adult treated and untreated groups of CL/P patients in Bangladesh and the factors related to these issues".
- Line no: 40-41
- 2    Comment    Method section should be corrected. [Line 151-160]
- In this section, you should not define depression, anxiety, and stress. Instead, you should operationalize the conditions in contexts of DASS items and scores. For example, you should specify which items and scores are used to interpret what mental status.

**Response** Has been written as per guidance.  
Line no: 439

- 3 **Comment** The bar charts are not clear to me. You put percentages on the Y axis and depression, anxiety, and stress with severity on the X axis, however when I tried to aggregate all percentages, no charts showed 100%. [ Line 196-197, 452] Briefly describe the bar chart with frequency and percentage in the result section.

**Response** The bar has been described in the result section.  
Line no: 215-217

- 4 **Comment** In Table 2 you need not present item-wise reliability coefficient against each item of the scale, instead mention the reliability of the depression, anxiety, and stress subunits.

**Response** We have updated the analysis as per suggestion. The item-wise reliability coefficient against each item of the scale have been removed and the depression, anxiety, and stress subunits were given by calculating the average of Cronbach's alpha for each domain.  
Line No: 425-426

- 5 **Comment** Regarding the Multivariate Generalized Linear Model, you should specify the model.  
If your Outcome measure is numerical, then your choice shall be either linear or gamma with log link. When the data generates a positive skew—that is, a small number of very high values—“Gamma with the log-link” may be preferable

**Response** Thanks for your comments. We used a generalized linear model (GLM) with a Gamma distribution and log link function was to model the relationship between dependent variables (e.g., depression, anxiety, or stress scores) and the predictors, which include including, e.g., age group, gender, marital status, education level, occupation, areas. The Gamma distribution is appropriate for continuous positive data with skewed distributions, while the log link function ensures that the predicted values remain positive. The model can be expressed as:

$$Y_i = \exp(\beta_0 + \beta_1 \text{AgeGroup}_i + \beta_2 \text{Gender}_i + \beta_3 \text{MaritalStatus}_i + \beta_4 \text{Education}_i + \beta_5 \text{Occupation}_i + \beta_6 \text{Area}_i + \epsilon_i)$$

where:

$Y_i$  represents the outcome variable (e.g., depression, anxiety, or stress score for i-th individual),  $\beta_0$  is the intercept,  $\beta_1, \beta_2, \dots, \beta_6$  are the coefficients for the predictors,  $\epsilon_i$  is the error term. In the regression model, we have included the predictor variables which were statistically significant in the bivariate analysis.

Line no: 189-206

- 6 **Comment** Present the parameter estimates with their standard errors, and significance levels.

**Response** We have added the parameters and confidence interval along with level of significance  
Line No: 432-435

- 7 **Comment** Interpret the results, highlighting the significance of the findings and their implications.

**Response** Results and highlights have been revised accordingly.  
Line No: 226-237

**Editor: M Mostafa Zaman, ORCID: 0000-0002-1736-1342**

- 8 **Comment** The background characteristics' determination is not described. For example, how was the income data were collected; how valid were they?

**Response** Many thanks for your comments. The income data were collected based on the verbal information from the respondents, which might not be their exact income data.  
Therefore, we have decided to remove this variable from the analysis part.

- 9 **Comment** How did the authors define peri-urban areas?

**Response** Thanks for your comment. By the term “peri urban” area, we wanted to mean that area which are higher than rural but lower than urban. Therefore, we included this category with rural during analysis.

- 10 **Comment** Many variables small numbers for sub-categories. A meaningful analysis for them are not possible. I suggest merging them to make fewer categories. These variables have been relatedly compared for three indicators (depression, anxiety and stress). Therefore, correction of p values for multiple testing (e.g., Bonferoni correction) is necessary.

**Response** Many thanks for your comments. We have now revised the categories and changed accordingly.  
Line No: 432-434