Author's response to reviews

Title: "Decision-making capacity for research participation among addicted people: a cross-sectional study"

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Author’s response to reviews:

We would like to first thank the editor and the reviewers for their efforts and for identifying both the strong and weak points of our manuscript. We trust that our responses to the reviewers’ suggestions will render the manuscript suitable for publication in BMC medical ethics.

Reviewer(s)' Comments to Author:

1. Some spelling errors:
   a. P4 line 16: populations.
      We have edited this spelling error as the reviewer suggests
   b. P15 line 20: confirm.
      We have edited this spelling error as the reviewer suggests
   c. Figure 1 contains many language mistakes.
      We have edited the language mistakes the reviewer suggests

2. Results p 13: the authors did not explain clearly, why they chose to enter only some of the factors that were significantly associated with incapacity in the logistic regression model and others, like educational level, CGI, GAF, MMSE, not. Shouldn't all significantly related factors be entered stepwise? How do the authors think this would influence the outcomes?
For independent variable selection, we are guided by accepted theory, previous empirical investigations, clinical considerations, and preliminary statistical performance. We included the variable gender by its univariate results and the variable MMSE score by a combination of its statistical performance and past research.

We chose to include only these two variables because of sample size constraints. As literature suggests, for every independent variable, there should be no fewer than 10 outcomes for each binary category (e.g., capacity / lack of capacity), with the least common outcome determining the maximum number of independent variables. As in the lack of capacity group there were only 17 patients, we only entered two variables for avoiding an overfit model. Too many independent variables in the model may lead to a mathematically unstable outcome, with decreased generalizability beyond the current study sample.

We explain in the manuscript the reasons for the limited number of variables included.

(Included in Methods section, page 11)

To avoid an overfit model we followed the rule which states that for every independent variable, there should be no fewer than 10 events per covariate [34]

We better explain our selection criteria in the manuscript and we state the small sample size as a potential limitation. Further research with a larger sample would allow confirming all univariate associations in the logistic regression model.

(Included in Results section, page 13)

The stepwise logistic regression model included relevant variables that were significantly associated with lack of capacity on univariate analysis. We chose MMSE scores by its statistical performance and because impaired cognition is well-recognized as a limitation to the research participation clinical importance. Gender was selected by its apparent high OR.

(Included in Discussion section, page 18)

Limitations

There are a number of limitations that should be considered when interpreting the results. First, our findings are based on data collected from a limited number of subjects in a specific research context in an urban located centre, which may limit the generalizability of the findings. Further research is necessary to assess our results in other settings and participant groups. Studies with larger sample sizes would also allow investigators to conduct multiple-regression analyses with a greater number of independent variables in order to confirm all the univariate associations in the logistic regression model.