Author’s response to reviews

Title: "Decision-making capacity for research participation among addicted people: a crosssectional 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:

Reviewer #1:

Thank for this much improved paper from its original version – well done. It seems necessary that only one reference must be added in this manuscript.

Thank you so much for all your help.

You stated that there are no studies in the literature about why living status may be linked to lack of capacity. In an our study, there was a statistically significant difference between MacMAC-T reasoning scores and living status (living alone or with someone) of psychiatric patients. Also please refer to this study in your manuscript. (Er RA; Sehiralti M, Aker AT. (2013). Preliminary Turkish study of psychiatric inpatients'competence to make treatment decisions. Asia Pasific Psychiatry. 5(1):E9-E18).

We read the abstract but not the whole article and we didn’t realized you did already find an association between living status and lack of capacity. We apologise for not having included the study earlier. We have added this reference in the manuscript (reference number 40) and we have rewritten the paragraph adding the aclaration the reviewer 2 suggests.
Mental capacity is also univariately associated in our study with living status. People who live with their parents or in an institution were more likely to lack capacity than those who live alone or with their families although we didn’t confirmed this association in the logistic regression model. As literature suggests, living status may be linked to lack of capacity: given that the level of functionality corresponds to competence, is it possible that living alone reflects functionality [40]. We interpret living status as an indicator of psychosocial deterioration. The chronic use of drugs can cause significant cognitive deficits that may impair addicted people’s capacity to take care of themselves or to live by their own so is more difficult for people with SUD to achieve emancipation.

Reviewer #2:

The authors used the comments for improvement.

Thank you for your priceless help to make this possible.

1. There are some minor language issues that could be improved:
   a. Page 2 line 8: carried out at a community based
      We have edited this language issue as the reviewer suggests
   b. Page 2 line 9, the authors might add: Health Centre in Spain.
      We have edited this language issue as the reviewer suggests
      We have edited this language issue as the reviewer suggests
   d. Page 4-5, lines 12-25 and 1-4: IC instead of CI, and the paragraphs need some language editing.
      We have edited this language issue and we have checked the paragraphs as the reviewer suggests.

(Included in Background section, pages 4-5)

In Spain, there are no defined guidelines as to who should assess patient decision-making competence or how such assessments should be accomplished. Spanish laws about IC in biomedical research touch upon a subject's decision-making capacity and indicate those situations where the capacity is limited without define it or specify defining or specifying how to assess it should be assessed [5,6]. Laws emphasise the necessity of justifying the inclusion of “vulnerable populations” in research, without specifying who these
vulnerable population are [7]. There are no specific regulations related to concerning the research participation of patients with psychiatric or addictive disorders. Proxy consent in research will be necessary if (a) persons are younger than 18 years of age (except for emancipated minors who are regarded as capable of making decisions); (b) the physician responsible ascertains that the patient's ability to take part in the decision-making process is impaired; or (c) the patient is legally incompetent [5,6]. A person is considered legally incompetent if he is unable to understand or communicate information to meet essential requirements of physical health, safety or property management. In Spain, the courts are responsible for determining the legal competence of an individual basing their judgement on two medical reports.

e. Page 10 line 18: transcribed.

We have edited this language issue as the reviewer suggests

f. Page 13 line 15: choose.

We have edited this language issue as the reviewer suggests

2. Now it reads as if all NPCs had no Axis I diagnoses (as this was an exclusion criterion), and all SUD patients did have co-morbid psychiatric disorders (table 1). Could the authors explain how this should be interpreted in light of capabilities? Could this mean that diminished capacities on Understanding and Appreciation are not evidently related to SUD, but to mental health disorders in general?

Indeed, all NPCs did not have Axis I diagnoses but not all SUD patients had co-morbid psychiatric disorders. We want to clarify this point because the way this data are presented in table 1 have resulted confusing: the proportion of psychiatric diagnoses in each SUD group cell is not the proportion of comorbidity of each SUD group but the proportion of each psychiatric diagnoses within the SUD people who also have a co-morbid disorder. For example, within people who used alcohol (n=12), only 9 had a comorbid mental disorder; 66.67% of this people (n=6) had a mood disorder and 3 patients (33.3%) had an anxiety disorder. To avoid this misunderstanding we have rewritten the results in the table adding a fourth category called “no psychiatric diagnosis” and specifying the percentage of psychiatric diagnoses in each SUD group as a whole.

In any case, comorbidity is usually high in SUD people, up to 70% of patients in Spanish substance misuse services have dual pathology [41]. These patients may have dual deficits in decisional capacity although we didn’t find significant differences between patients with and without dual diagnoses in our study in terms of lack of capacity.

We have added a paragraph explaining the possible influence of comorbid diagnoses.
(Included in Discussion section, page 16)

Most patients in our study have also a psychiatric disorder. In Spanish substance misuse services up to 70% of patients have co-morbid psychiatric disorders. These patients with dual diagnosis may have dual deficits in decisional capacity—compounded by impaired response to short-term versus long-term gains and losses and those secondary to cognitive impairment associated with psychiatric disorders that can influence the decisional process [19]. However, we didn’t find significant differences between patients with and without dual diagnoses in our study in terms of lack of capacity. These results will have to be explored in further research.

3. Table 1: An explanation of superscript a, b and c is lacking.

The reviewer is right; the explanation is lacking. We have added that information in the table legend.

4. There is unclarity in the use of the word 'consent' throughout the text. E.g. page 13, lines 10, 12, 20 and 22: do the authors mean consenting, or being capable?

We mean “being capable”. We have edited “consent” as the reviewer suggests.

5. Page 13, line 19: the writing 'slightly non-significant' might be a way to conceal the result, which in fact is non-significant. Also page 15, line 22.

We have removed the writing the reviewer suggests.

6. Page 15, last paragraph on living status: The authors might elucidate that living status was only associated univariately with mental capacity. There was a significant difference between NPCs and SUD patients regarding living status. Living status was therefore not included in the stepwise logistic regression model.

The reviewer is right, living status was only associated univariately with mental capacity, the significant difference between NPCs and SUD patients regarding living status wasn’t confirmed in the multivariate analysis. We have elucidated this issue in the paper.

(Mental capacity is also univariately associated in our study with living status. People who live with their parents or in an institution were more likely to lack capacity than those who live alone or with their families although we didn’t confirmed this association in the logistic regression model. As literature suggests, living status may be linked to lack of capacity: given that the level of functionality corresponds to competence, is it possible that living alone reflects functionality [40]. We interpret living status as an indicator of psychosocial deterioration. The chronic use of drugs can cause significant cognitive...
deficits that may impair addicted people’s capacity to take care of themselves or to live by their own so is more difficult for people with SUD to achieve emancipation.

7. Figure 1: Preferably, the flow chart should present the eligible patients per group. This figure seems a bit unfinished.

We have changed and completed the figure 1 as reviewer suggests.

8. Table 3: Combining the patient group and the control group does not really make sense. Comparing them would make sense. This misunderstanding is carried on through the whole article.

In order to avoid this misunderstanding, we compared patient group and control group (in text, page 12 and in table 2) but we only included in table 3 SUD people with and without capacity to consent to research. We will no longer combine control and patient group in the article.

(Included in Results section, page 13)

32.69% of the participants patients (n=17), lacked research-related decisional capacity, based on a judgement guided by the MacCAT–CR and a clinical interview.

Socio-demographic and clinical and decisional capacity characteristics of participants patients with and without mental capacity are shown in Table 3.

The relationships between participants patients characteristics and lack of capacity are the following: using male gender as a reference, the Odds Ratio [OR] of lack of capacity was 4.43 (IC95%: 1.27-8.52; p= 0.044) for the women of our study. Thus, in our sample, men seemed to be more likely to lack capacity than female patients. SUD diagnosis had a slightly non-significant impact on the probability of consenting OR= 2.55 (IC95%: 0.98-6.61; p=0.054). Each one-point increase in the MMSE score increased the odds of a subject consenting the chance of being capable by approximately 6%: OR = 0.60 (IC95%: 0.39-0.93; p= 0.02).

The stepwise logistic regression model included relevant variables that were significantly associated with lack of capacity on univariate analysis. We choose MMSE scores and SUD diagnoses by its clinical importance and gender by its apparent high OR. Only one of the three two variables included in the univariate analysis was retained in the multivariate model: the MMSE scores: OR= 0.602 (IC95%: 0.38– 0.95; p= 0.029) although gender had a slightly non-significant impact on the probability of consenting being capable: OR= 3.03 (IC95%: 0.98- 9.36; p=0.054).
When the other variables associated with lack of capacity on our univariate analysis are considered, SUD diagnosis no longer has an impact on the probability of consenting OR=1.13 (IC95%: 0.37-3.41; p=0.83).

When other variables associated with lack of capacity on our univariate analysis are considered, gender no longer has an impact on the probability of being capable OR=4.36 (IC95%: 0.81-8.06; p=0.86).