Author’s response to reviews

Title: Anthropometric, Biochemical and Clinical Assessment of Malnutrition among Egyptian Children with Chronic Liver Diseases: A Single Institutional Cross-sectional Study

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Dear Editor,

I am pleased to resubmit for publication of the revised version of BMGE-D-18-00788, entitled “Anthropometric, Biochemical and Clinical Assessment of Malnutrition among Egyptian Children with Chronic Liver Diseases: A Single Institutional Cross-sectional Study”. I would like to express our gratitude to you.

I have addressed each of their concerns as outlined below.

1. Consent to participate – clarify if written or verbal

In your “ethical approval and consent to participate” section, please confirm whether informed consent, obtained from all appropriate parents/guardians of the patients, was written or verbal and clearly state this in your manuscript. If verbal, please state the reason and whether the ethics committee approved this.

Despite the progress made on medical research in Egypt [1], there are a lot of challenges concerning ethical aspects of research [2, 3]. In this context, we used to face difficult circumstances in which it is inappropriate to ask the study participants to sign the consent forms.
One obvious example is when conducting the research in an illiterate population, it is not consistent to request such participants to "sign" a written consent form that they are unable to read. According to the Central Agency for Public Mobilization and Statistics (CAMPS) [4] report in 2013, 25.9% of the Egyptian population above 10 years of age are illiterate (17.2 million), especially in rural areas. Moreover, in many settings, literate participants refused to sign the written consent based mainly on security issues; as there were many political and social problems following the Egyptian Revolution in January, 2011. A lot of participants, especially the rural – background participants, believed that "they could sign their marriage papers, newborn and death of parents certificates, but not to sign anything else", a belief aggravated by current unstable political and security situations in the country. Also, in terms of signing, different social groups in Egypt have concepts that signing documents means greater risk of getting into troubles. Such concept raises fear of participations among the potential respondents, making them unwilling to participate. Consequently, we had to find solutions which were optimal or near-optimal with respect to Egyptian community beliefs and attitudes. In a quiet recent Egyptian study [5], members of different Research Ethics Committees (REC) in Egypt, believed that RECs should propose different ways to indicate consent other than signing an informed consent forms, such as verbal consent or voice recording [6, 7]. In our study, obtaining verbal consent instead of written consent was the only feasible way to obtain consent from subjects.

Two professional social workers were assigned to verbally inform the potential subjects about their rights and explain the study purpose, procedures and the potential risks and benefits of participation [8].

A verbal consent script was designed to include the same eight elements of the written consent, but in a more conversational style. All verbal consents were fully documented and witnessed [9]. When appropriate, a written statement, including the basic elements of the informed consent, about the research was given to the study participants. Furthermore, they were given sufficient time to consider whether or not to participate in the research.

This was clearly written in the declaration section, Page 15, line 8.

References


2. Clean manuscript

At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.

Thank you. A clear single, final, clean version of the manuscript was submitted. The same for the tables and figure.