Reviewer’s report

Title: Sepsis Survivors Monitoring and Coordination in Outpatient Health Care (SMOOTH) - Study Protocol for a randomized controlled trial

Version: 1
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Reviewer: Jacques Lacroix

Reviewer’s report:

Manuscript entitled “Sepsis survivors monitoring and coordination in outpatient health care (SMOOTH) — study protocol for a randomized controlled trial” by Konrad Schmidt et al.

Submitted to the journal “TRIALS”
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SUMMARY. – In this research protocol, Schmidt et al describe a randomized controlled trial (RCT) with 2 arms. The aim of the RCT is to estimate the efficacy in sepsis survivors of “a primary care-based long-term program on their health-related quality of life”. The RCT is performed in 20 intensive care units (ICU) in nine institutions of Germany. All critically ill adults with severe sepsis or septic shock are considered for recruitment if their cognitive capacity is “sufficient”. The intervention in the experimental group includes three points: 1) discharge management; 2) training of general practitioners and patients in evidence-based care for sepsis sequelae; 3) telephone monitoring of patients 6, 12 and 24 months post-randomization. In the control group, only telephone monitoring will be implemented. The primary outcome measure of the RCT is quality of life at 6-month, as measured with the questionnaire SF-36. Secondary outcome measures include costs, mortality, clinical, psycho-social and process-of-care measures.

MAJOR COMPULSARY REVISIONS

METHODOLOGY

• Patients. – In the section entitled “Recruitment of patients and randomization”, the authors must provided more details on how patients are screened. Are they screened on a daily basis? Is the screening done by research assistants?

• It is written in the manuscript that all critically ill adults are considered for recruitment if their cognitive capacity is “sufficient”; please, define what is meant by “sufficient”.

• Most of the text presently imbedded in the section entitled “Recruitment of patients and randomization” must be moved to a section on “Data collection and data management” or to a section on “Outcomes monitoring”.

• Randomization. – A section devoted to the randomization process must be added. In this section, the authors must describe how randomization
concealment is done.

- Intervention and co-interventions. – The standardized procedures are well described. However, compliance and how will be checked compliance are not described.
- Cross-overs are not defined.
- Statistical analysis. – What will be time zero?
- How will be handled lost to follow-up in the statistical analysis?

DISCUSSION

- What this study can add to the available literature can be better discussed.
- The greatest risk of the trial is contamination: patients and/or practitioners could talk to each other about the maneuver in the two arms of the study and might start to change their standard care in ICU survivors. This can hurt very much the study. A cluster randomized clinical trial would have prevented such problem. Please, comment this point in the discussion.
- It is said in the manuscript that the control group will receive standard care. This is not exactly the case: phone calls to participants will be done in the control arm, which is not usually done. The trial cannot be done without such phone calls since it is indeed the only way to get data on the primary outcome measure (quality of life). Please, comment in the discussion.

MINOR ESSENTIAL REVISIONS (not for publication).

General suggestions.
- The authors use two times for the verb in their manuscript: present and future. Since the trial is on going, I suggest using the present all over the manuscript.

Background.
- Last paragraph: I suggest deleting “to our knowledge for the first time”.

Methods.
- Section “Aim of the study”. 3rd line: “… survivors will be improved by…” rather than “… survivors will improve by…”.
- Section “Control treatment”: I do not understand the 2nd paragraph (According to…”).
- Section “Data analysis”, 2nd paragraph, 1st line: “we will analyze” rather than “we analyze”.
- Section “Description of risks”, last line: “Thus, there is no stopping rules” rather than “Thus, there is no definition of stop criteria”.

List of abbreviations.
- A list of abbreviations and acronyms must be added after the discussion.

Authors’ contributions.
A section on authors' contributions is missing.

References.

Please, embed the references in the main document of the manuscript. The references must be formatted according to the editorial standards of the journal TRIALS.

• Reference 16. – Please, update this reference.

Tables and captions.

• Legends of all tables must be typewritten below the table.
• The legend of each table must include the definitions of all acronyms used (ICD, SF, NSS, KFM, DeMOL, etc).

DISCRETIONARY REVISIONS.

None.

DECLARATION OF CONFLICT OF INTEREST

I declare that I have no competing interests.

REVIEWER

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Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.