Appendix 5

Core Outcome Measurement Set for Research and Clinical Practice in Post COVID-19 Condition (Long COVID) in Children and Young People: An International Delphi Consensus Study 'PC-COS Children'

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Additional methodological details

1. First phase (COS development)

1.1. Study group and participants

The International Study Group, which represented the International Paediatric Post-COVID Condition in Children Collaboration (IP4C) and consisted of healthcare professionals, researchers, methodologists, WHO representatives, and affected CYP, played a crucial role in designing and executing the project. The "core group" consisting of DM, NS, AC, DB, CB and SV was responsible for the study's methodology and management. DM, TN, DMN, and PRW discussed methodology for design and conduct of the study following a similar process for an adult-based study [10,11].

In the Delphi process, potential participants were selected from authors of published research, global institutions (e.g. WHO, IP4C, ISARIC), and patient organisations (e.g. Long Covid Kids). They received invitations to participate in the online Delphi process through direct emails from the research team or relevant patient/professional organisations. Additionally, Long COVID social media groups (primarily via Facebook and Twitter) were approached for recruitment, with eligibility criteria and contact information provided on the PC-COS study website (https://www.pc-cos.org/). Prospective participants underwent eligibility screening before registration as Delphi participants.

Only those participants who evaluated 50% or more of the outcomes in the first Delphi consensus round were invited to participate in the second round. Upon completion of both Delphi rounds, participants became eligible for the online consensus meeting and expressed interest in meeting participation as part of the online Delphi process. This approach aimed to ensure global representation and balanced stakeholder group distribution among attendees.

1.2. Delphi process and definitions

The order of outcomes presented in the Delphi process was randomised by domain categories (“mortality/survival”, “physiological/clinical”, “life impact” and “resource use”). A free-text option was available to suggest additional outcomes, which were assessed for inclusion in the second Delphi round (outcomes that formed ≥1% of the total number of suggested outcomes were included). All outcomes from the first round were included in the second round, regardless of the results.

2. Second phase (Outcome measurement instruments consensus)

2.1. Literature review of outcome measurement instruments

Instruments were systematically mapped to the core outcomes defined in the first phase of the project. This process was also instrumental in identifying and removing any duplicates and ensuring accurate mapping to outcomes. Any instruments that did not map to any of the COS domains were excluded from consideration. Additional instruments not used in published research and clinical trial protocols were considered based on expert suggestions and experience of adult project 11. For instance, PROMIS instruments were screened for eligibility and added to the list.