Core Outcome Set for Post Covid Condition in Children

Reaching consensus

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‘Core Outcome Set’ (COS)

Necessary minimum

Outcomes
Core Outcome Measures in Effectiveness Trials

“A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care.”
Our team

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We are an international team of health professionals, researchers and people with lived experience of Post COVID Condition. Our goal is to improve research and clinical care by identifying the most important outcomes of long COVID through collecting the views of different people from around the world.
COS = Critical outcomes

This does not mean that other outcomes are not important!
Post-COVID-19 condition in children: a COS is urgently needed

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PC-COS Children

Identification of studies via databases and registers

- Records identified from PubMed (n = 7,445)
- Records screened (n = 8,573)
- Full text assessed for eligibility (n = 68)

Excluded studies (n = 47)
- Protocol, review, commentary (n = 11)
- Less than 30 patients/case reports (n = 11)
- No long-COVID (acute or MISC) (n = 10)
- No denominator (n = 5)
- Data combined with adults (n = 2)
- Abstract (n = 1)

Included studies (n = 21)

Neuropsychiatric (%) (25.24%)
- Mood (16.93%): sad, tearful, angry, anxiety, depression
- Fatigue (5.26%)
- Sleep disorder (5.42%): insomnia, hypersomnia, poor sleep quality
- Headache (7.84%)
- Cognition (6.57%): concentration, impaired memory, learning difficulties
- Dizziness (4.10%)
- Neurological abnormalities (9.35%): seizures, ataxia, numbness
- Balance problems (5.54%)

Gastrointestinal (%) (1.59%)
- Abdominal pain (2.91%)
- Constipation (2.99%)
- Diarrhea (1.68%)
- Vomiting/nausea (1.59%)

Respiratory symptoms (7.62%)
- Pharynx/nasal congestion (7.53%)
- Orthostatic intolerance (6.92%)
- Exercise intolerance (5.73%)

Chest pain (4.62%)
- Throat pain (3.80%)
- Sore throat (2.47%)
- Chest tightness (2.45%)
- Changes in heart rate (2.29%)
- Palpitations (1.27%)

Hyperhidrosis (4.66%)
- Dermatologic (2.59%): dry skin, rash, hives
- Hair loss (1.17%)

Others (%) (1.33%)
- Loss of appetite (6.67%)
- Altered smell (3.40%): phantom smell, hyposmia, anosmia, hyperosmia
- Body weight changes (3.99%)
- Myalgia/myalgia (3.76%)
- Altered taste (3.55%)
- Otalgia (3.14%): ear pain, earache or vertigo
- Ophthalmologic (3.06%): conjunctivitis, dry eyes, problems seeing/double vision, photophobia, pain
- Swollen lymph nodes (2.58%)
- Dysphoria (1.89%)
- Fever (1.60%)
- Musculoskeletal other (1.17%)
- Changes in menstruation (1.27%)
- Urinary symptoms (0.65%)
- Dysphagia (0.46%)
- Speech disturbances (0.44%)

Lopez-León, S. et al. Sci Rep 12, 9950 (2022)
**Core Outcome Set**

"What to measure?"

**Next phase**

"How to measure?"

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**Outcome**

"Fatigue or Exhaustion"

**Description**

New onset or worsening of feeling exhausted, having too little energy, or needing more rest, including fatigue not relieved by rest

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**Preparation of the outcome list and descriptives** by Core Group

**Invitation of stakeholders to participate in the Survey** IP4C, Long Covid Kids, WHO, Professional Networks

**Final list of outcomes approval preparation for Delphi** by study’s International Steering Committee

**2-round Delphi** Scoring of outcomes from the final list

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**Preliminary list of outcomes for the Delphi**

1. Survival
2. Cardiovascular
3. Endocrine and metabolic
4. Hearing-related
5. Gastrointestinal
6. Pain
7. Fatigue or Exhaustion
8. Sleep
9. Muscle and joint
10. Taste/smell
11. Neuro-cognitive
12. Mental
13. Kidney and urinary
14. Respiratory
15. Skin, hair, dental
16. Post-exertion
17. Vision
18. Fever/body temperature
19. Satisfaction with life/personal enjoyment
20. Physical
21. Social
22. Work/occupational and study
23. Stigma
24. Healthcare resource utilisation
25. Family/carer burden
26. Recovery added a priori

**Stakeholders to be classified into:**
- 'CYP with post COVID-19 condition and their family members/caregivers'
- 'Healthcare professionals working with CYP with post COVID-19 condition'
- 'Researchers working with CYP with post COVID-19 condition'

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**Outcome classification using COMET taxonomy**

**Outcome**

"Fatigue or Exhaustion" Description

New onset or worsening of feeling exhausted, having too little energy, or needing more rest, including fatigue not relieved by rest

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**Scoping Systematic review of published data and clinical trial protocols**

**Long list of outcomes developed based on scoping systematic review results**

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Core Outcome Set (COS)

**Can**
- Help to reach consensus between all relevant stakeholders regarding “critical outcomes”
- Make voices of people with lived experience and their families heard
- Assist with research harmonisation
- Help to identify important research gaps

**Cannot**
- Develop/provide new instruments
- Meet everyone needs (e.g. some researchers may be interested in outcomes which did not end in COS and/or instruments may be unavailable in particular languages)
- Be perfect, like any other research
Stay ready for the Delphi!

- Healthcare professionals
- Researchers
- Children and Young people with lived experience of post-covid-19 condition and their carers

*We need your help!*

[https://www.pc-cos.org/](https://www.pc-cos.org/)

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Thank you!

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