

Use of Patient Reported Outcomes in Registered Drug Studies for Long COVID

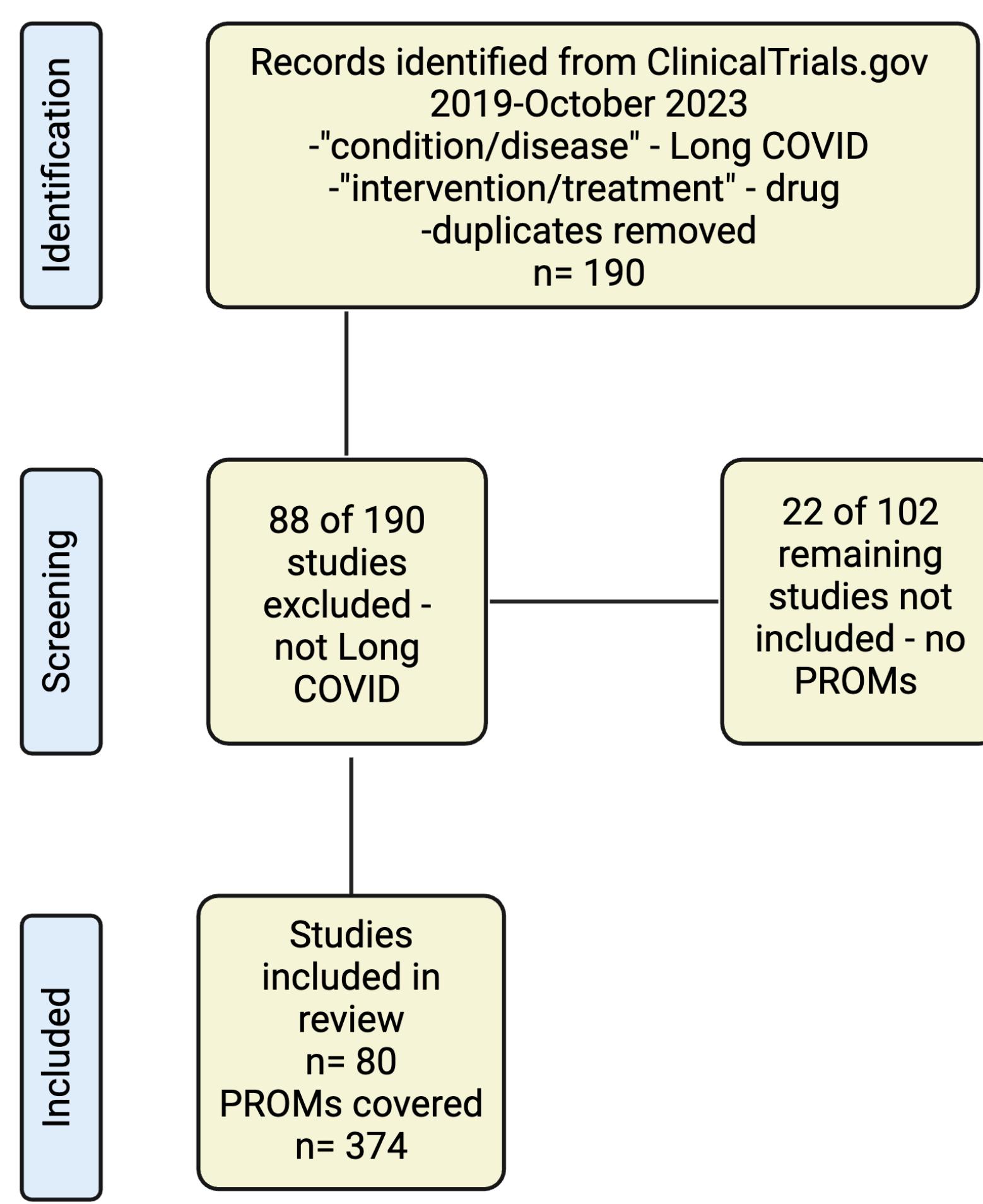
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Introduction

- The World Health Organization defines Long COVID as "the continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection".
- Around 10-20% of people infected by SARS-CoV-2 develop Long COVID.
- The most common Long COVID symptoms include fatigue (15-87%), dyspnea (10-71%), anxiety/depression (22-23%), and impaired cognition (16%).
- Long COVID diagnosis is based on patient reported symptoms, thus patient reported outcome measures (PROMs) are required to diagnose and monitor Long COVID.
- Objective:** Conduct a scoping review to identify which PROMs are utilized in registered drug studies for Long COVID to understand the variability in which Long COVID is being studied.

Methodology



Results – Table 1 PROMs Identified Per Domain

Domain	Total # Instances	% Instances
Global	67	18
Fatigue	64	17
Pulmonary	34	9
Depression	32	9
Smell/Olfaction	28	7
Anxiety	23	6
Cognition	22	6
Physical Activity	20	5
Pain	12	3
COVID-specific	11	3
Headache	7	2
QOL not health related	7	2
ADLs/IADLs	6	2
Other	41	11
TOTAL	374	100

Results – Table 2 Global Health-Related PROMs

PRO	Total # Instances	% Instances
Short Form or RAND or VA 12 or 36 EuroQol 5-dimension (EQ5D)	17	25
Patient Global Impressions Scale - Change (PGI-C)	13	19
Patient Global Impressions Scale - Severity (PGI-S)	7	10
EuroQol Visual Analogue Scale (EQ-VAS)	4	6
COVID-19 Yorkshire Rehabilitation Scale (C19-YRS)	3	4
Patient-Reported Outcomes Measurement Information System-29 (PROMIS 29)	3	4
Measure Yourself Medical Outcomes Profile (MYMOP)	2	3
Patient-Reported Outcomes Measurement Information System-Global/10 (PROMIS-Global/PROMIS-10)	2	3
Other	13	19

Results – Table 5 Anxiety/Depression-Related PROMs

ANXIETY	PRO	Total # Instances	% Instances
General Anxiety Disorder-7 (GAD7)	7	30	
Unspecified	4	17	
Hospital Anxiety and Depression Scale (HADS)	3	13	
Beck Anxiety Inventory (BAI)	2	9	
State-Trait Anxiety Inventory (STAI)	2	9	
Depression Anxiety Stress Scale-21 (DASS-21)	2	9	
Other	3	13	

Results – Table 3 Fatigue-Related PROMs

PRO	Total # Instances	% Instances
Fatigue Severity Scale (FSS)	9	14
Chalder Fatigue Scale (CFS)	7	11
Patient-Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form	6	9
Unspecified fatigue	5	8
Functional Assessment of Chronic Illness Therapy-Fatigue (FACT-F)	4	6
Multidimensional Fatigue Inventory (MFI)	4	6
Patient-Reported Outcomes Measurement Information System (PROMIS) sleep disturbance	3	5
Fatigue Assessment Scale (FAS)	3	5
Pittsburgh Sleep Quality Index (PSQI)	3	5
Brief Fatigue Inventory (BFI)	2	3
Insomnia Severity Index (ISI)	2	3
Unspecified trouble sleeping	2	3
Other	14	22

DEPRESSION	PRO	Total # Instances	% Instances
Patient Health Questionnaire (PHQ)	10	31	
Beck's Depression Inventory (BDI)	9	28	
Unspecified	5	16	
Hospital Anxiety and Depression Scale (HADS)	3	9	
Depression Anxiety Stress Scale-21 (DASS-21)	2	6	
Other	3	9	

Results – Table 6 Cognition-Related PROMs

COGNITION	PRO	Total # Instances	% Instances
Unspecified	7	32	
Patient-Reported Outcomes Measurement Information (PROMIS) Cognition	6	27	
Multifactorial Memory Questionnaire (MMQ)	2	9	
Other	7	32	

Conclusion

- 11% of studies were excluded for not including PROMs, demonstrating a gap among registered drug studies in understanding how therapies improve Long COVID outcomes.
- Long COVID drug studies utilize highly variable validated and non-specific patient reported outcome measures.
- This variability will hinder future efforts in accurately comparing study outcomes and performing meta-analyses.
- Next steps include comparing PROMs utilized in different disease populations and demographics to better illustrate the necessity for a standardized Long COVID PROM.

References

- World Health Organization. (2022). Post COVID-19 Condition (Long COVID). <https://www.who.int/europe/news-room/fact-sheets/item/post-covid-19-condition>
- Sneller MC, Liang CJ, Marques AR, Chung JY, Shanbhag SM, Fontana JR, Raza H, Okeke O, Dewar RL, Higgins BP, Tolstenko K, Kwan RW, Gittens KR, Seaman CA, McCormick G, Shaw JS, Okpali GM, Law M, Trihemisava K, Kennedy BD, Shi V, Justement JS, Buckner CM, Blazkova J, Moir S, Chun TW, Lane HC. A Longitudinal Study of COVID-19 Sequelae and Immunity: Baseline Findings. Ann Intern Med. 2022 Jul;175(7):969-979. doi: 10.7326/M21-4905. Epub 2022 May 24. PMID: 35605238; PMCID: PMC9128805.
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DEPRESSION		
PRO	Total # Instances	% Instances
PHQ	10	31.25
BDI	9	28.13
unspecified	5	15.63
HADS	3	9.38
DASS-21	2	6.25
POMS	1	3.13
Likert Scale	1	3.13
PROMIS depression	1	3.13

