

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

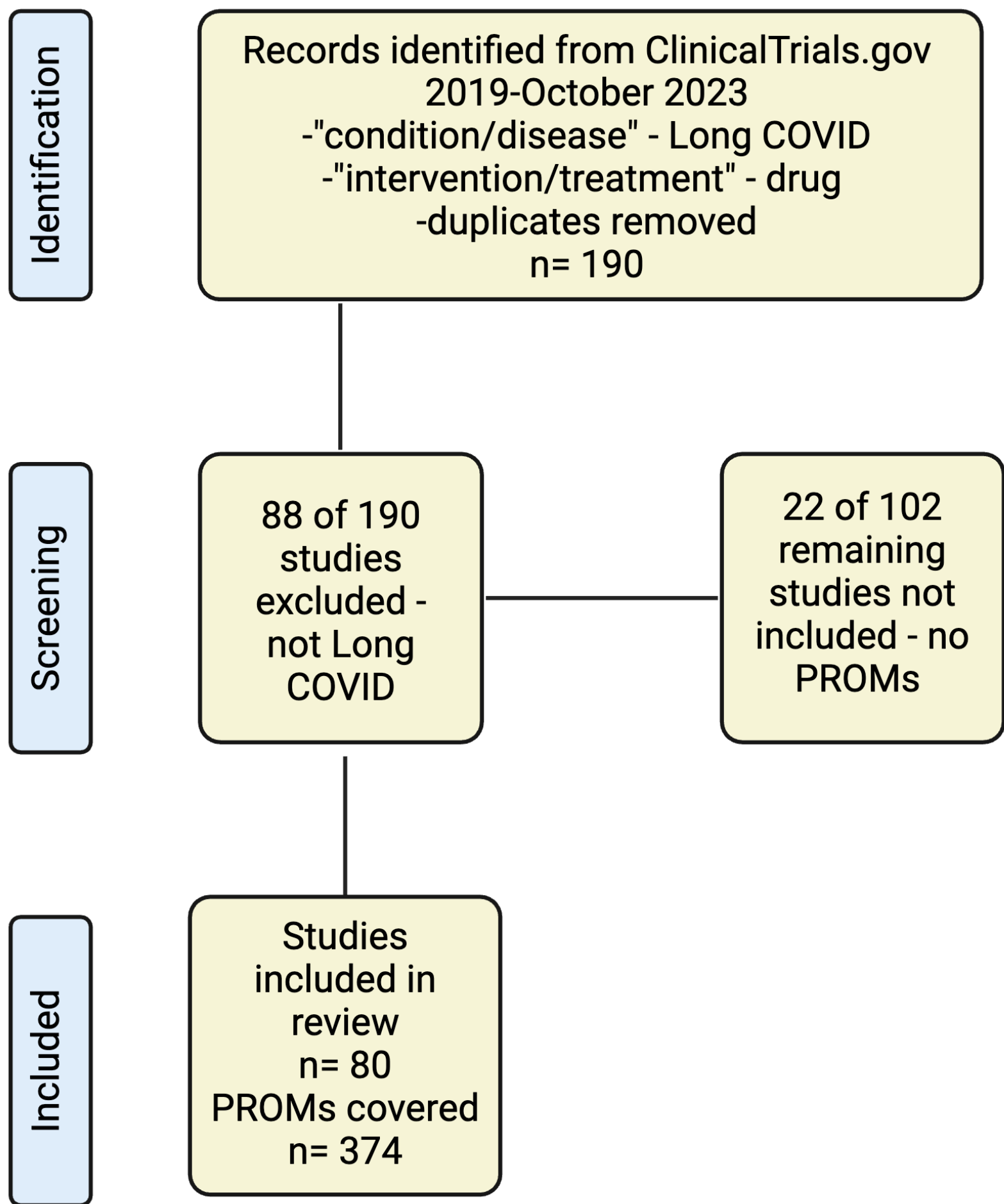
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Introduction

- 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	17	25
EuroQol 5-dimension (EQ5D)	13	19
Patient Global Impressions Scale - Change (PGI-C)	7	10
Patient Global Impressions Scale - Severity (PGI-S)	4	6
EuroQol Visual Analogue Scale (EQ-VAS)	3	4
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 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 (FACIT-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

Results – Table 4 Pulmonary Related-PROMs

PRO	Total # Instances	% Instances
Modified Medical Research Council Scale (mMRC)	11	32
Unspecified shortness of breath	6	18
Unspecified cough	4	12
The King's Brief Interstitial Lung Disease (KBILD)	3	9
The COPD Assessment Test (CAT)	2	6
Borg Dyspnea Scale	2	6
Functional Assessment of Chronic Illness Therapy- Dyspnea (FACIT-Dyspnea)	2	6
Other	4	12

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

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

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>
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PRO	DEPRESSION	
	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

