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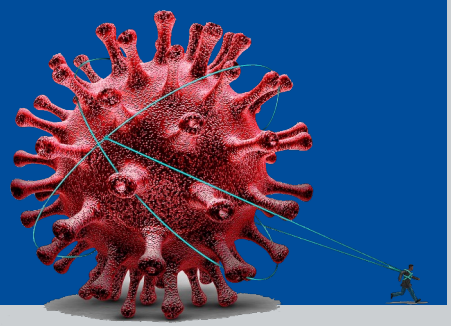
UNIVERSITÄTSMEDIZIN BERLIN

Bundesministerium
für Bildung
und Forschung

Methylprednisolone in PCS

Preliminary results of the PoCoVIT Study

Lucas Adam | 08. Mai 2026 | International ME/CFS Conference 2026



Klinik für Neurologie

Campus Benjamin Franklin (CBF)

Purpose

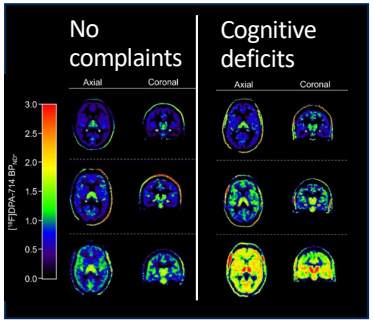
- **Cardinal features of Post-COVID19 Condition (PCC)[1]:**
  - Fatigue
  - Dysautonomia (or POTS)
  - Postexertional malaise (PEM)
  - Cognitive deficits ("brain fog")
- **~30%** of PCC patients report cognitive symptoms in a neurological outpatient clinic[2]
- **28.7%** of PCC patients complain about persisting memory deficits at at least 6 months follow-up[3]
- **Therapy:** cognitive training, vortioxetine[4] (Federal Joint Committee decision 04/2026)

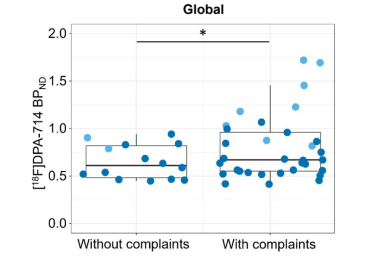
→ Beside no established causal therapy available

1 Al-Aly, Z., & Rosen, C. J. (2025). *NEJM.*
2 Boesl et al. (2021). *Front. Neurol.*
3 Elboraay, T., et al. (2025*). BMC neurology,*
4 McIntyre, R. S. et al. (2024). *Brain.*

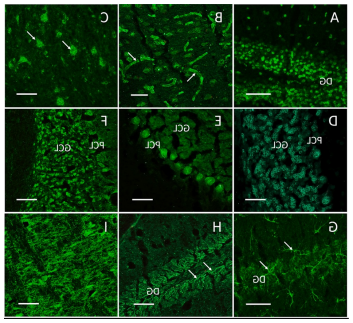
From pathophysiology to therapy?

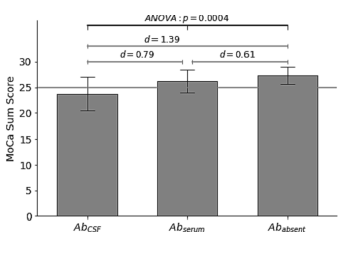
Neuroinflammation

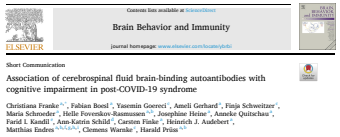




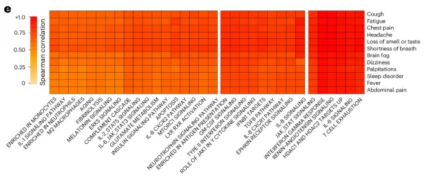
Autoimmunity

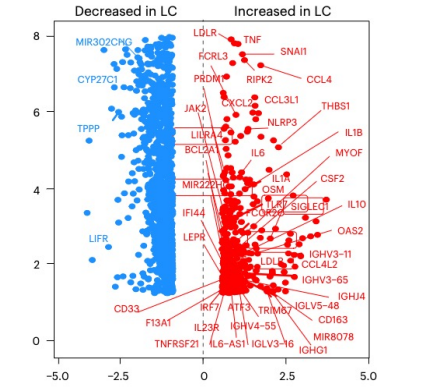


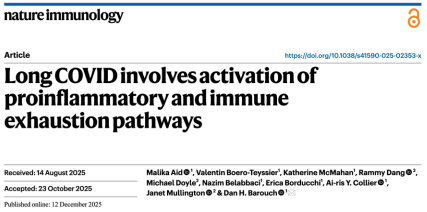




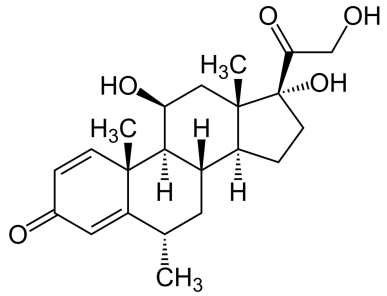
Persistent immune activation







Methylprednisolone



FDA Approval 1957

Cost 20 € / month

cross blood-brain barrier

„If inflammation drives symptoms steroids might help“

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The post-corona-virus immune treatment (PoCoVIT) Trial[1]

Study Design

- Population 418 adults PCC patients with self-reported cognitive deficitis
- Phase 2a monocentric RCT
- methylprednisolone vs. placebo
- 2 Phase design including extention open-label

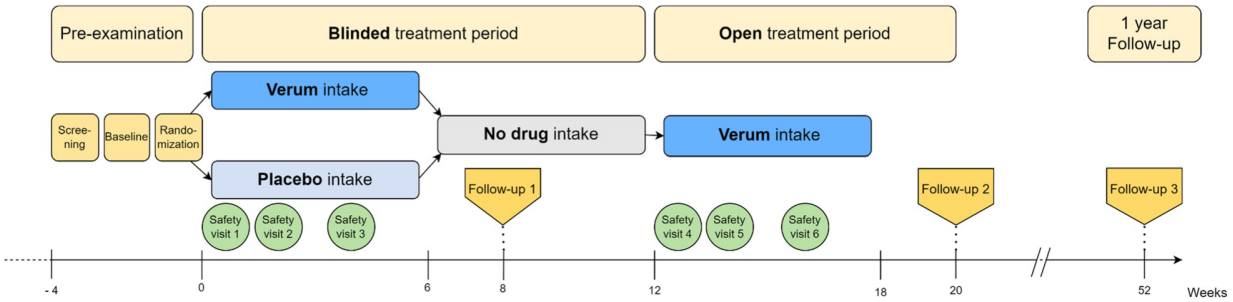


Fig. 1 Flowchart of the post-corona-virus immune treatment (PoCoVIT) trial

Primary Endpoint:
Change Memory satisfaction (MMQ) from baseline to follow-up (8 weeks): **+ 15 Points**

Secondary Endpoints:

- MMQ subscales:
- Neuropsychological Tests
- Fatigue
- Mood
- Quality of life

Exploratory outcomes:

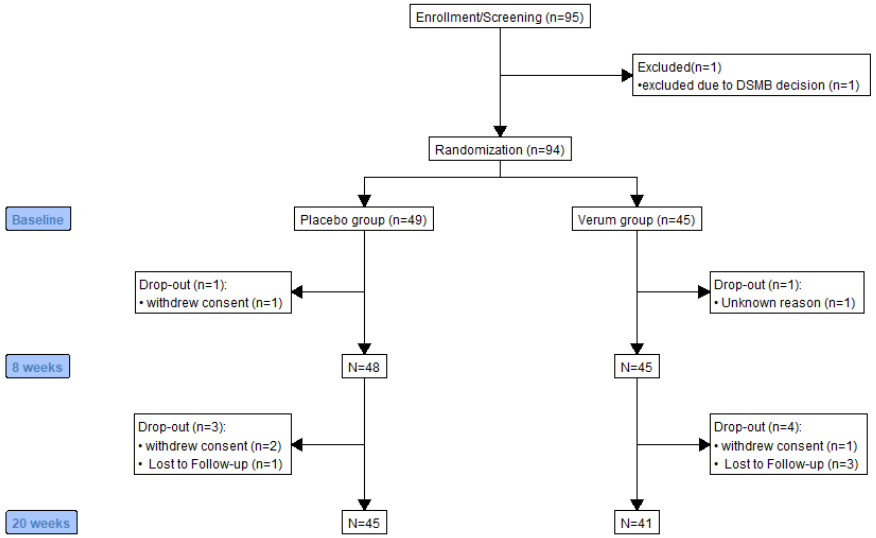
- Serum/CSF biomarkers
- Structural MRI

1 Franke et al., (2024). Neurol Res Pract. ClinicalTrials.gov Identifier: NCT05986422

Results

Randomization Flowchart

DSMB recommendations (03/2025):
Study termination early after enrolling **96 patients**:
5 serious adverse events (SAEs) in verum group:



Baseline Demographics

Characteristic	N	Placebo N = 49[1]	Verum N = 46[1]	p
Age	95			
Mean (SD)		45.24 (11.02)	45.98 (10.19)	
Median [Min; Max]		46.00 [22.00; 61.00]	48.00 [25.00; 66.00]	n.s.
Age Group	95			
<=50 Jahre		29 (59%)	28 (61%)	n.s.
>50 Jahre		20 (41%)	18 (39%)	
Sex	95			
Male		16 (33%)	12 (26%)	n.s.
Female		33 (67%)	34 (74%)	
Diverse		0 (0%)	0 (0%)	
Time since Covid (Months)				
Mean (SD)		24.22 (11.80)	22.79 (9.11)	n.s.

Baseline Cognitive Measures

Cognitive Assessment	Placebo	Verum	p
MMQ Satisfaction			
Mean (SD)	30.35 (12.81)	27.24 (11.51)	n.s.
MoCA Total Score			
Mean (SD)	26.04 (2.11)	25.67 (2.73)	n.s.

Key Safety data

Adverse Events (AEs)

	Placebo (n=49)	Verum (n=46)	p
Total patients report AEs	43 (87.8%)	44 (95.7%)	n.s.
Total Number of AEs	254	332	<0.001

Serious Adverse Events (SAEs) !!!

during the active intervention phase

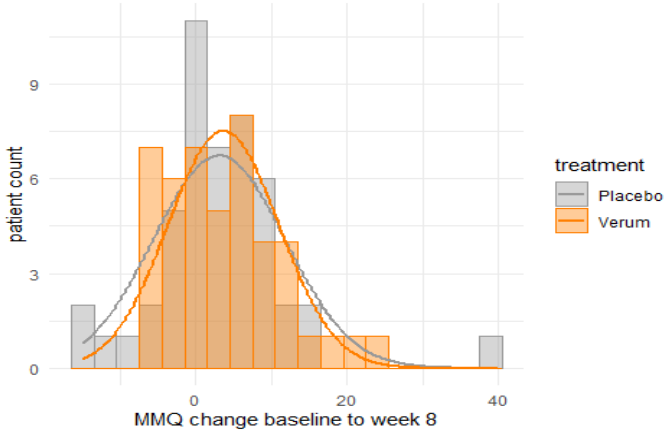
	Placebo (n=49)	Verum (n=46)
Total patients reported SAEs	0	5 (11%)
Total Number of SAEs	0	5

Reported SAE Category	Count
1. Deep vein thrombosis	1
2. Pulmonary Embolism	1
3. Atypical Pneumonia	1
4. Pyelonephritis	1
5. Headache	1

→ DSMB Decision 03/2025: Study termination

Results

Main Effect



Characteristic	Placebo	Verum	p
MMQ Satisfaction Absolute BL			
Mean (SD)	30.35 (12.81)	27.24 (11.51)	
MMQ Satisfaction Absolute FU			
Mean (SD)	33.12 (13.52)	31.29 (12.54)	
MMQ Satisfaction Change 8 weeks			
Mean (SD)	**3.04 (8.72)**	**3.62 (7.33)**	**n.s.**

Characteristic	Placebo	Verum
Reached Primary Endpoint	**2 (4.2%)**	**3 (6.7%)**

Secondary endpoints

Characteristic	Placebo	Verum	p
MMQ Satisfaction Change 20 weeks			
Mean (SD)	5.12 (8.72)	5.31 (7.33)	**n.s.**
MMQ Strategy Change 8 weeks			
Mean (SD)	2.04 (5.85)	-0.09 (6.68)	**n.s.**
MMQ Strategy Change 8 weeks			
Mean (SD)	2.06 (8.44)	2.09 (8.93)	**n.s.**
Trail-Making-Test A Change			
Mean (SD)	-1.96 (9.90)	-3.80 (16.47)	**n.s.**
Trail-Making-Test B Change			
Mean (SD)	-3.60 (35.72)	-3.64 (41.38)	**n.s.**
MoCa Change			
Mean (SD)	0.50 (1.79)	0.70 (2.45)	**n.s.**
Chalder Fatigue Scale (CFS) Change			
Mean (SD)	-1.88 (3.30)	-1.29 (4.15)	**n.s.**
Fatigue Severity Scale (FSS) Change			
Mean (SD)	-0.77 (6.58)	0.22 (6.52)	**n.s.**
Cognitive Deficit Global Self-report			
Still Persisting	47 (98%)	44 (98%)	**n.s.**
Not anymore	1 (2.1%)	1 (2.2%)	
Concentration Deficit Self-report			
Still Persisting	0 (0%)	1 (2.3%)	**n.s.**
Not anymore	47 (100%)	43 (98%)	
Attention Deficit Self-report			
Still Persisting	42 (89%)	38 (86%)	**n.s.**
Not anymore	2 (4.3%)	3 (6.8%)	
Memory Deficit Self-report			
Still Persisting	39 (83%)	39 (89%)	**n.s.**
Not anymore	4 (8.5%)	2 (4.5%)	

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Discussion & Conclusions

Strengths

- RCT design (high evidence level)
- Mechanism-driven (not purely symptomatic)
- Focus on defined phenotype (cognitive PCS)

Limitations

- Narrow phenotype → limited generalizability
- DSMB Decision to Terminate → Underpowered
- Subgroup and biomarker analysis still missing

Conclusions

- Endpoint (MMQ satisfaction + 15 Poiint) too strict or not optimally suited?
- Inflammation hypothesis warrants a more careful patient stratification
- Are steroids the right target or too unspecific?
- Safety concerns: Risk of side effects in immune therapies

1 McKenzie et al. (1992). *JAMA.*
2 Cleare et al. (1999). *Lancet.*

Thank you!

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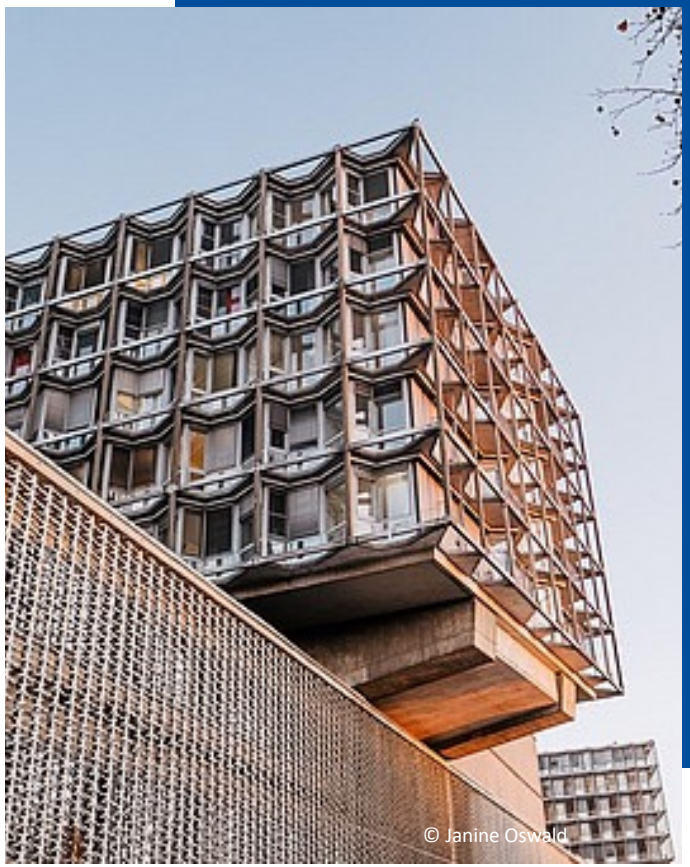

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Methylprednisolone in PCS

Summary

Background

- ~30% of PCC patients report cognitive symptoms
- Methylprednisolone promising in individual treatment attempts as causal therapy

PoCoVIT Study[1]

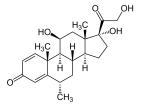
- PoCoVIT Study Phase 2a RCT design
- Endpoint: Memory Satisfaction (MMQ) + 15 Point
- Study termination (DSMB Decision) due to SAEs
- Primary and secondary endpoint not reached

Discussion

- Limited conclusions by underpowered sample size
- Immune hypothesis requires precise stratification
- Risk of side effects in immune therapies

Hypothesis

- Immune hypothesis of cognitive Post-COVID-19
- Clinical improve by methylprednisolone



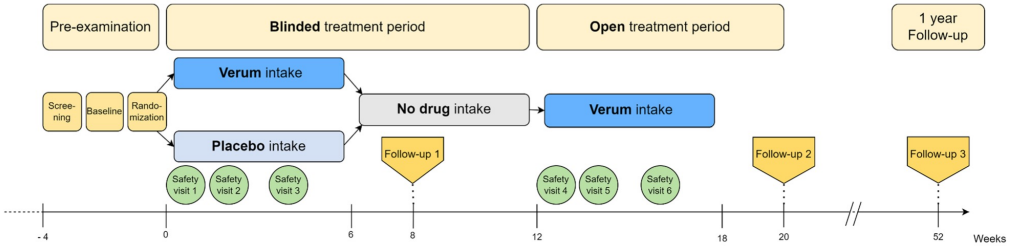
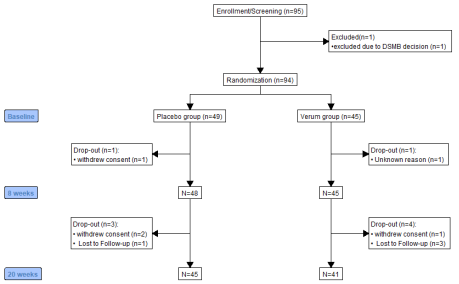
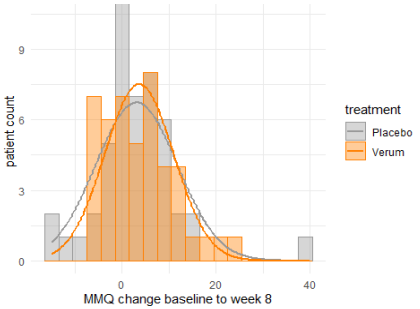


Fig. 1 Flowchart of the post-corona-virus immune treatment (PoCoVIT) trial





1 Franke et al., (2024). Neurol Res Pract. ClinicalTrials.gov Identifier: NCT05986422