Vivantes

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UNIVERSITÄTSMEDIZIN BERLIN

KLINIK BAVARIA
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Bundesministerium
für Bildung
und Forschung

NKSG Nationale Klinische Studiengruppe MECFS PCS

Efficacy of Hyperbaric Oxygen Therapy (HBOT) in ME/CFS

Phase II observational two cohort trial –
20 vs 40 sessions -

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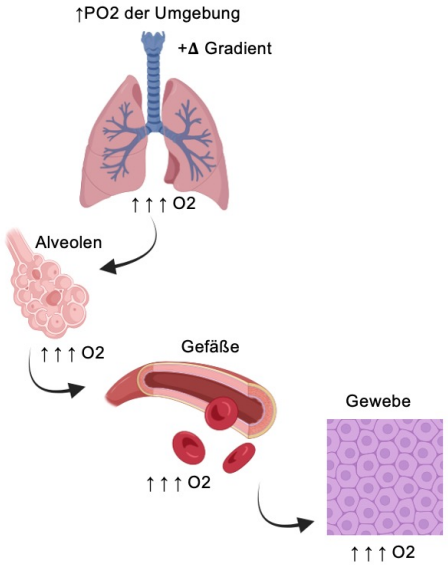
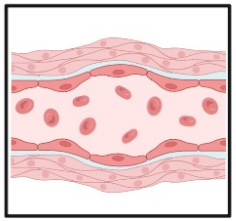
Effects of HBOT

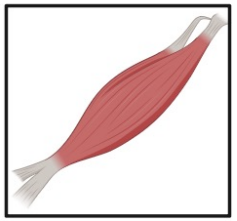
Improved tissue oxygenation independent of erythrocytes



Oxygention modulates disease-relevant pathomechanisms

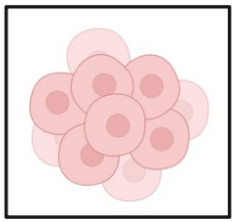


Verbesserung **endothelialer Dysfunktion, Angiogenese**

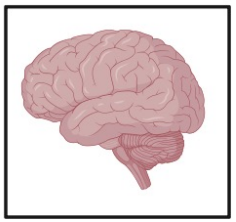


Regeneration von **Muskel-zellen**

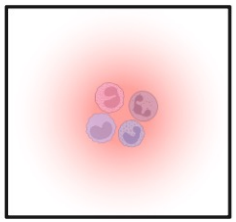
Reduktion von **oxidativem Stress**, Verbesserung der **Mitochondrienfunktion**



Stammzellproliferation und **-mobilisation**



Neurogenese, Verbesserung der **zerebralen Durchblutung**



Reduktion von **chronischer Inflammation**

HBOT trials in Post-COVID Syndrome

Several studies have reported improvements in fatigue, pain, and cognitive symptoms in post-COVID patients.

- Different HBOT protocols
- Positive RCT, Tel Aviv: 40 HBOT sessions
- Negative RCT, Karolinska: 10 HBOT sessions

Research question

- Is this transferable and feasible in patients with ME/CFS?
- What is the impact of treatment duration: 40 vs 20 sessions?

Zilberman-Itskovich S et al. Scientific Reports. 2022

Kjellberg A et al. BMJ Open. 2025.

Wu et al. : Effects of Hyperbaric Oxygen Therapy on Long COVID: A Systematic Review, 2024

Study design of Charité HBOT trial

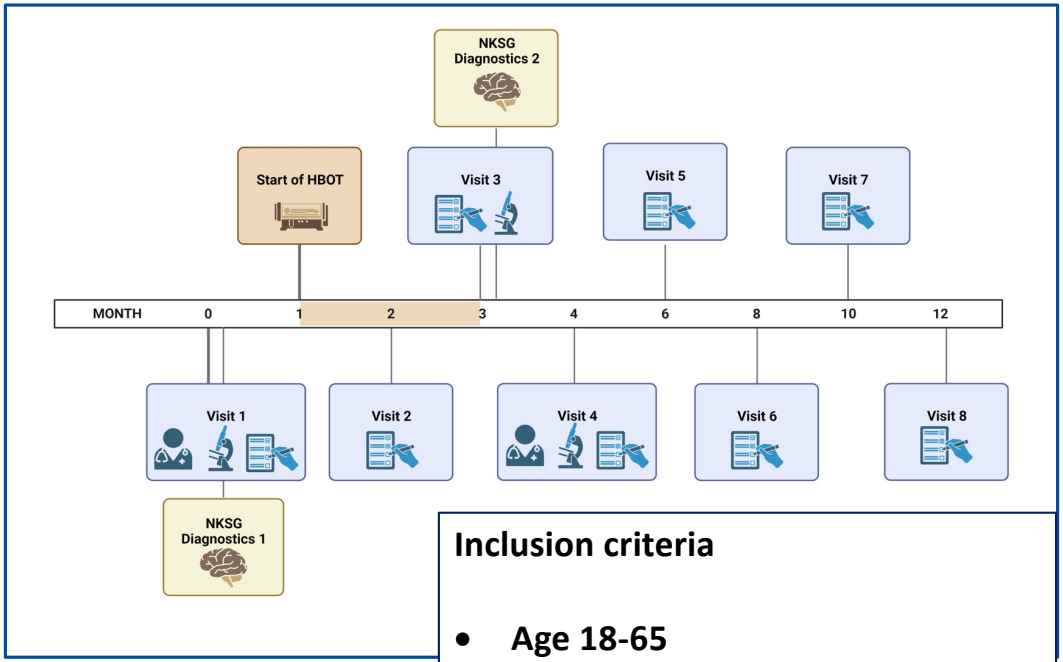
40 vs. 20 HBOT sessions 3-5x/ week each 90 Minutes, 2 ATA, 100% oxygen

Outpatient Appointment
- Medical Consultation
- Hand Grip Strength Test
- 1 Minute Sit-to-Stand Test
- NASA Lean Test
- Neurocognitive Testing

Online Survey
- SF-36
- Bell Score
- MBSQ
- Chalder Fatigue Scale
- HBOT Tolerability Questionnaire

NKSG Diagnostics Platform
- MRI
- Endopat
- OCT-A

Laboratory Markers
- GPCR Autoantibodies
- Microclots
- Spike Protein
- Endothelial Function Biomarkers
- Proteomics
- SCS
- Flow Cytometry
- Cytokines and further soluble markers



Inclusion criteria

- **Age 18-65**
- **postinf ME/CFS Canadian Consensus Criteria (CCC)**
- **Bell 30 – 60**

Patient Characteristics

No significant differences between cohorts except for disease duration

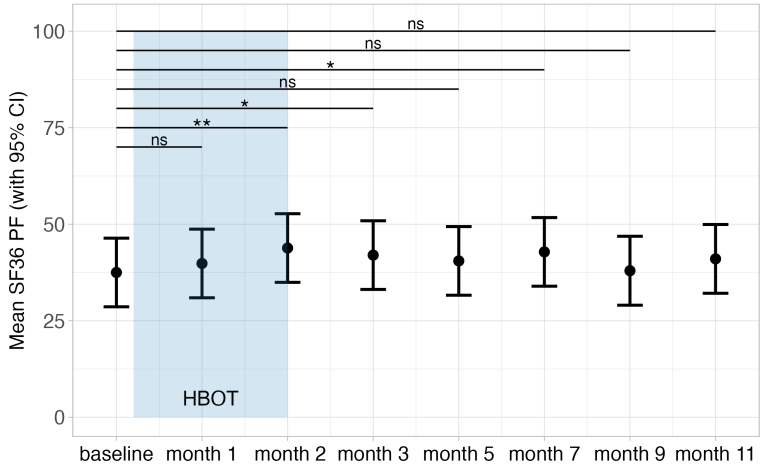
In the 2nd cohort, four patients withdrew from the study and could not be replaced due to end of study period.

Characteristics	all patients	40 sessions group	20 sessions group
Total patients (n)	56	30	26
Male (n, %)	14 (25%)	7 (23.33%)	7 (26.92%)
Female (n, %)	42 (75%)	23 (76.67%)	19 (72.08%)
Age, years (mean ± SD)	40.93 ± 10.96	42.33 ± 11.73	39.31 ± 9.98
BMI, kg/m² (mean ± SD)	25.15 ± 5.32	24.45 ± 4.04	25.96 ± 6.48
Education level (n, %)			
No degree	0 (0%)	0 (0%)	0 (0%)
High School	6 (10.71%)	4 (13.33%)	2 (7.69%)
Vocational Training	17 (30.36%)	10 (33.33%)	7 (26.92%)
University degree	33 (58.93%)	16 (53.33%)	17 (65.38%)
Disease duration, months (mean ± SD)	28.89 ±8.52	27.03 ± 11.21	31.04 ± 2.22 ***
Infectious trigger (n, %)	56 (100%)	30 (100%)	26 (100%)
COVID-19	47 (83.93%)	27 (90%)	20 (76.93%)
EBV	3 (5.36%)	1 (3.33%)	2 (7.69%)
Upper respiratory tract infection	6 (10.71%)	2 (6.67%)	4 (15.38%)
SF-36 PF score (mean ± SD)	41.60 ± 21.19	37.50 ± 20.63	46.35 ± 21.24
Bell Score (mean ± SD)	38.04 ± 10.17	38.00 ± 10.95	38.08 ± 9.39
Handgrip strength, kg (mean ± SD)			
Mean handgrip strength (Fmean)	15.04 ± 9.63	15.82 ± 11.03	14.14 ± 7.84
Maximum handgrip strength (Fmax)	18.12 ± 10.59	19.02 ± 12.02	17.08 ± 8.77

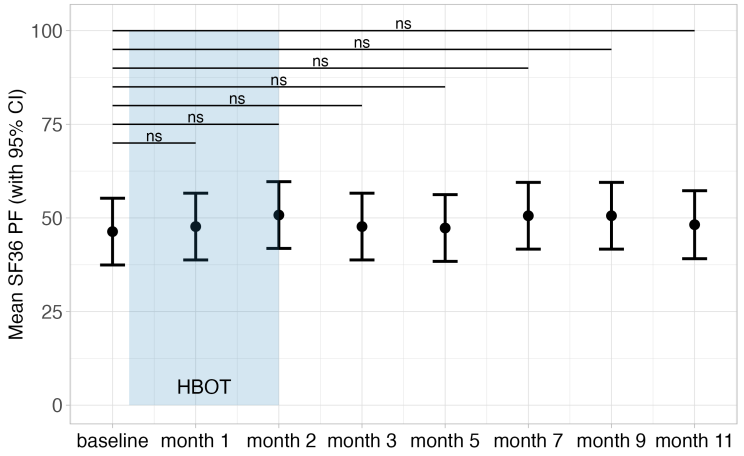
Results: SF-36 physical function

- **HBOT40 but not HBOT20 cohort showed significant improved physical function at month 3, not lasting until month 11**

40 sessions (n=30)



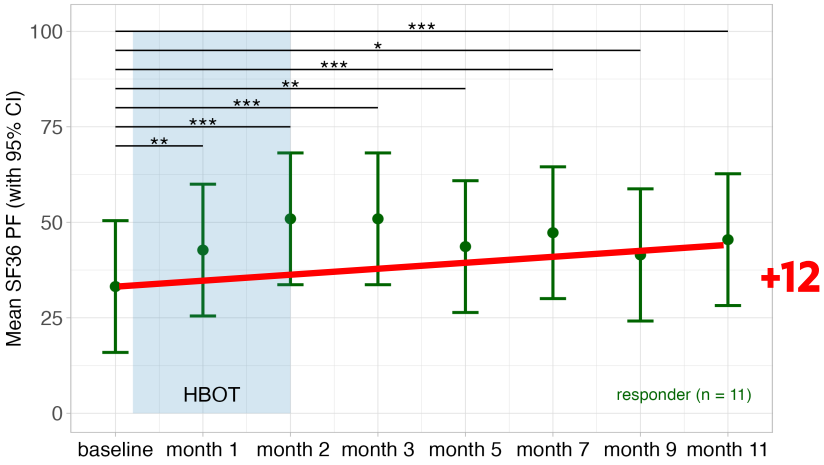
20 sessions (n=26)



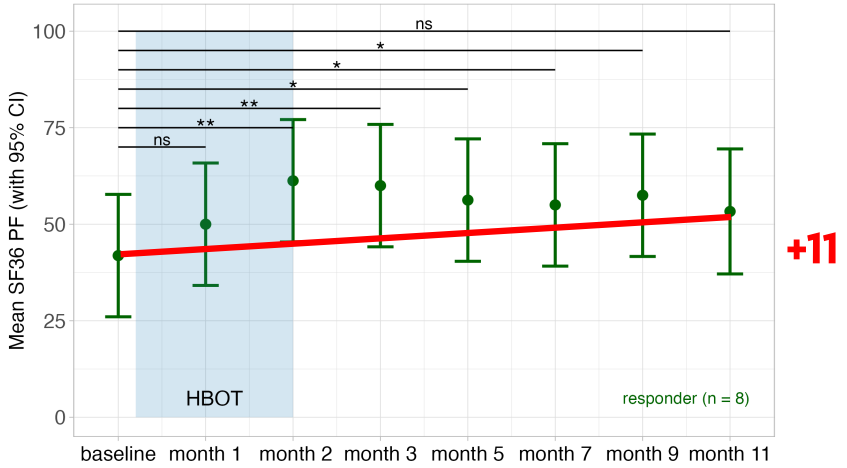
SF-36 physical function in responder defined = SF-36 PF>10 month 3

- **Primary aim: Increase of SF36 PF > 10 points at month 3:**
  Responder: 11/30 HBOT40 vs 8/26 HBOT20 patients
- **Responder in both cohorts showed improvement in physical function at month 3 and 11 (only significant for HBOT 40)**

40 sessions (n=11/30)



20 sessions (n=8/26)

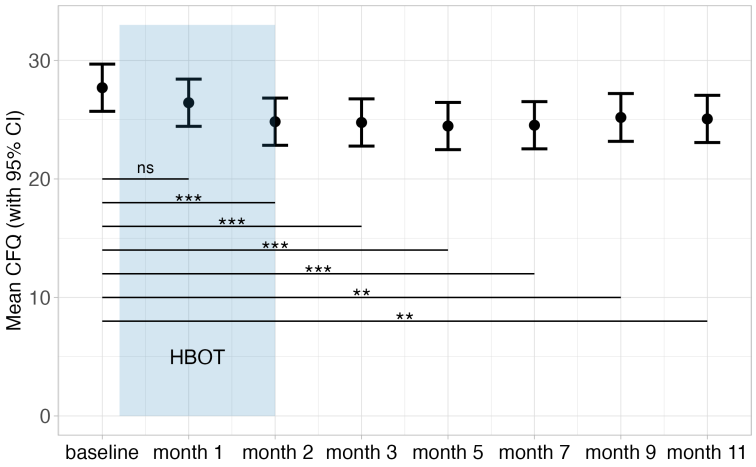


>10 points = clinical meaningful improvement

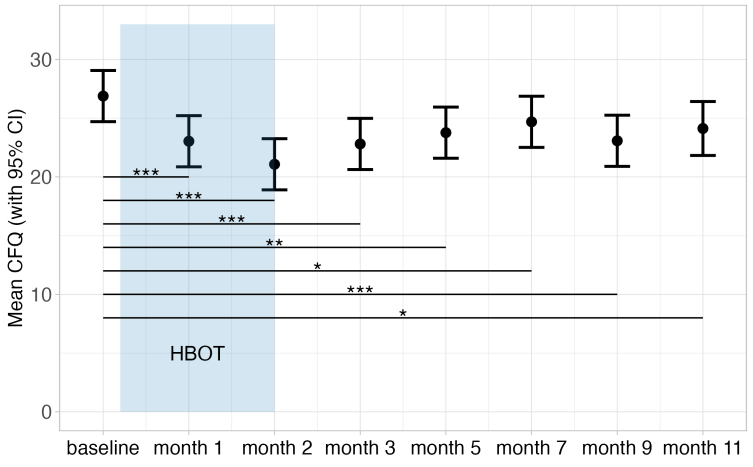
Chalder Fatigue Scale

- **Both cohorts showed a significant improvement in fatigue from months 2 - 11**

40 sessions (n=30)



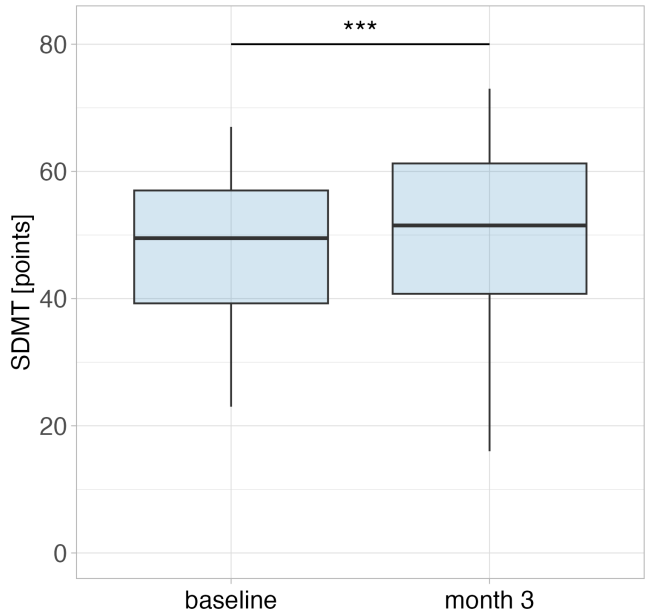
20 sessions (n=26)



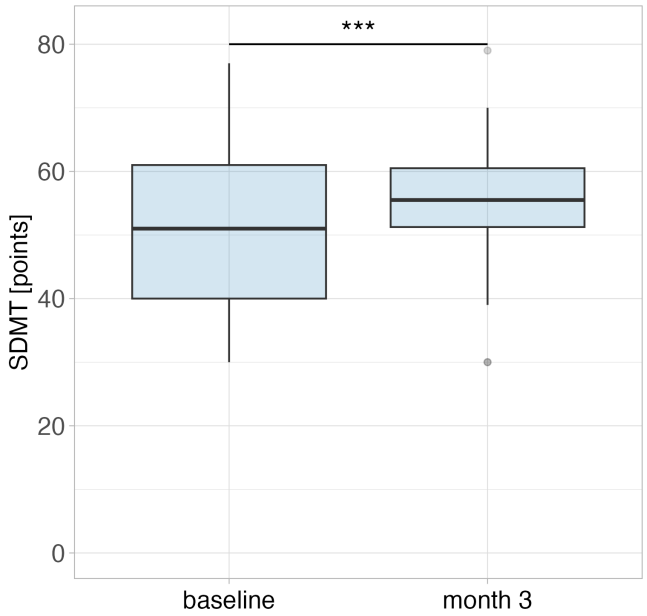
SDMT (Information processing speed)

- **Both cohorts showed a significant improvement in SDMT at month 3**

40 sessions (n=30)



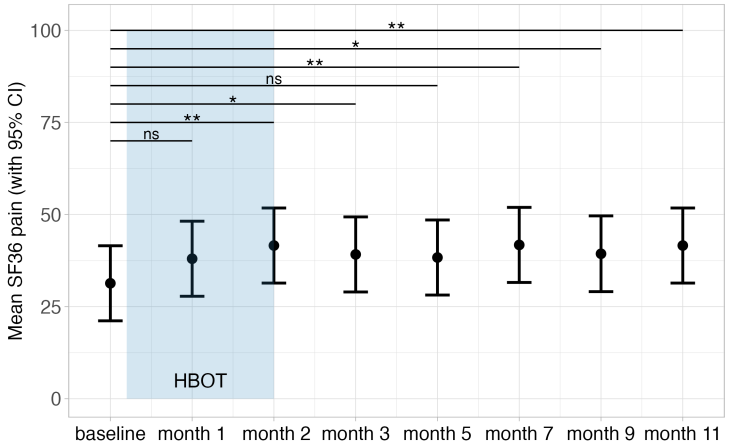
20 sessions (n=26)



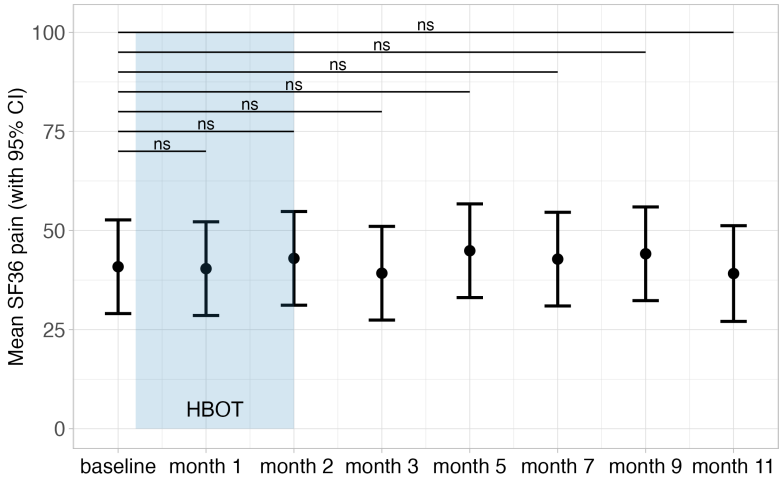
SF36 pain

- **Only the HBOT40 cohort showed a significant improvement in pain from months 2 to 11**

40 sessions (n=30)



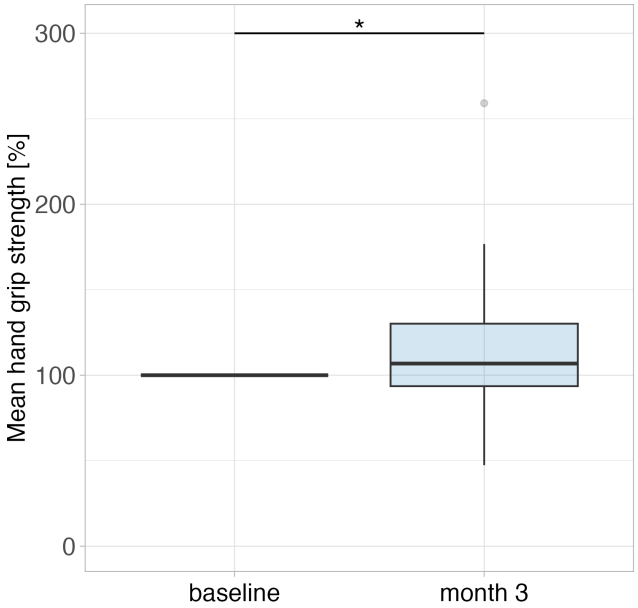
20 sessions (n=26)



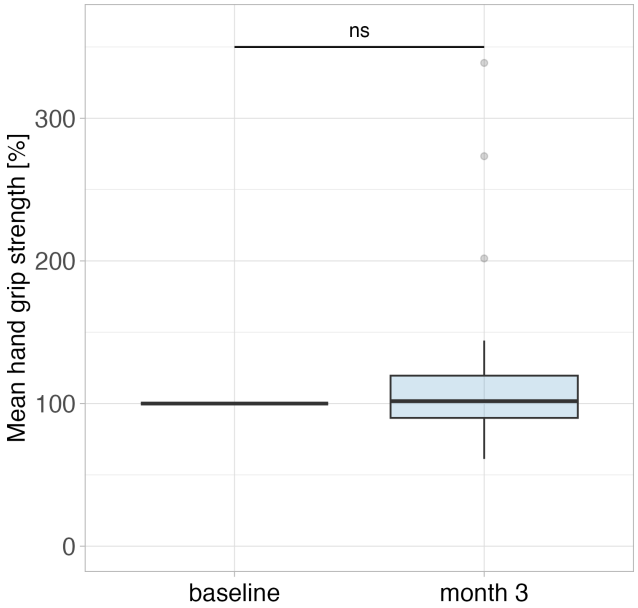
Hand grip strength (mean, n= 10 pulls)

- **Only the HBOT 40 cohort showed a significant improvement in HGS at month 3**

40 sessions (n=30)



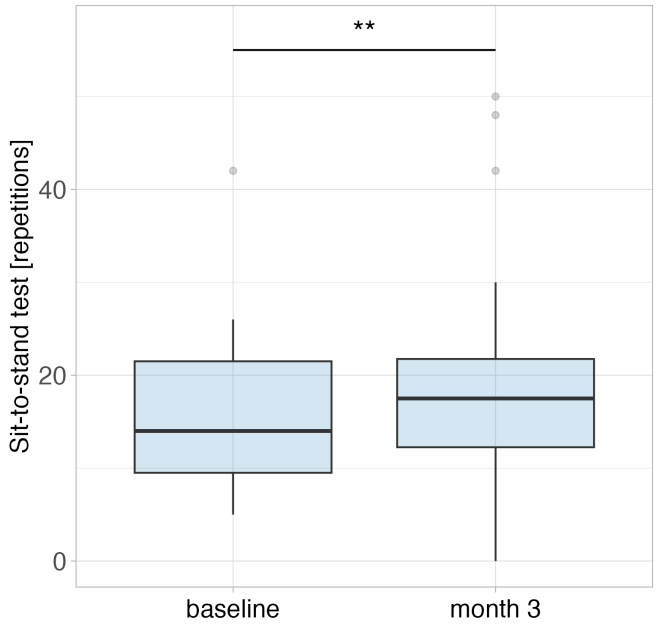
20 sessions (n=26)



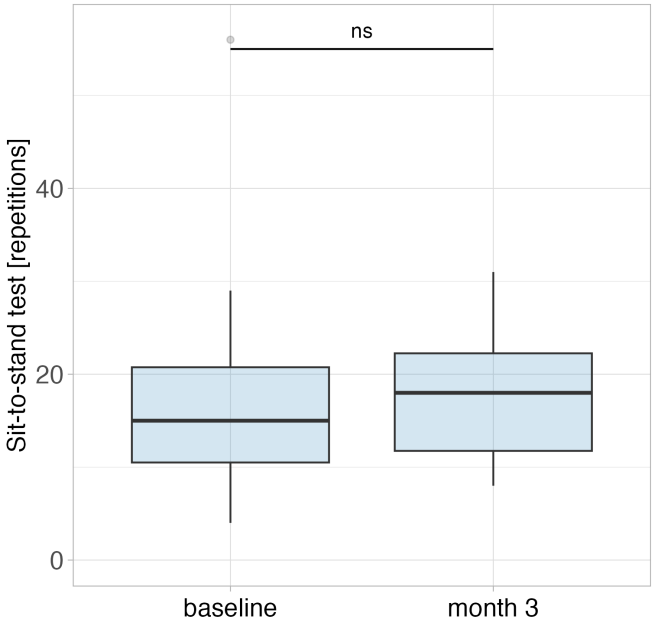
One Minute Sit-to-stand test

- **Only the HBOT 40 cohort showed a significant improvement in Sit to stand test at month 3**

40 sessions (n=30)



20 sessions (n=26)



Summary

HBOT in ME/CFS	HBOT 40 m3 - m11	HBOT 20 m3 - m11
	significant	improvement:
SF-36 physical function	✅ ✅only* 11/19 responders*	✅❌only* 8/26 responders
Fatigue	✅ ✅	✅ ✅
Pain	✅ ✅	❌ ❌
Cognitive performance	✅	✅
Hand grip strength	✅	❌
Sit to stand	✅	❌

Conclusion

- HBOT is feasible and well tolerated in most patients with ME/CFS
- Only a subgroup showed clinical response and sustained improvement after a year
- Treatment duration is relevant: 40 sessions more benefit than 20
- Improvements in SF36PF are paralleled by normalization of functional connectivity in MRI
- Biomarker analyses suggest pre-treament differences between responders and non-responders (work in progress)

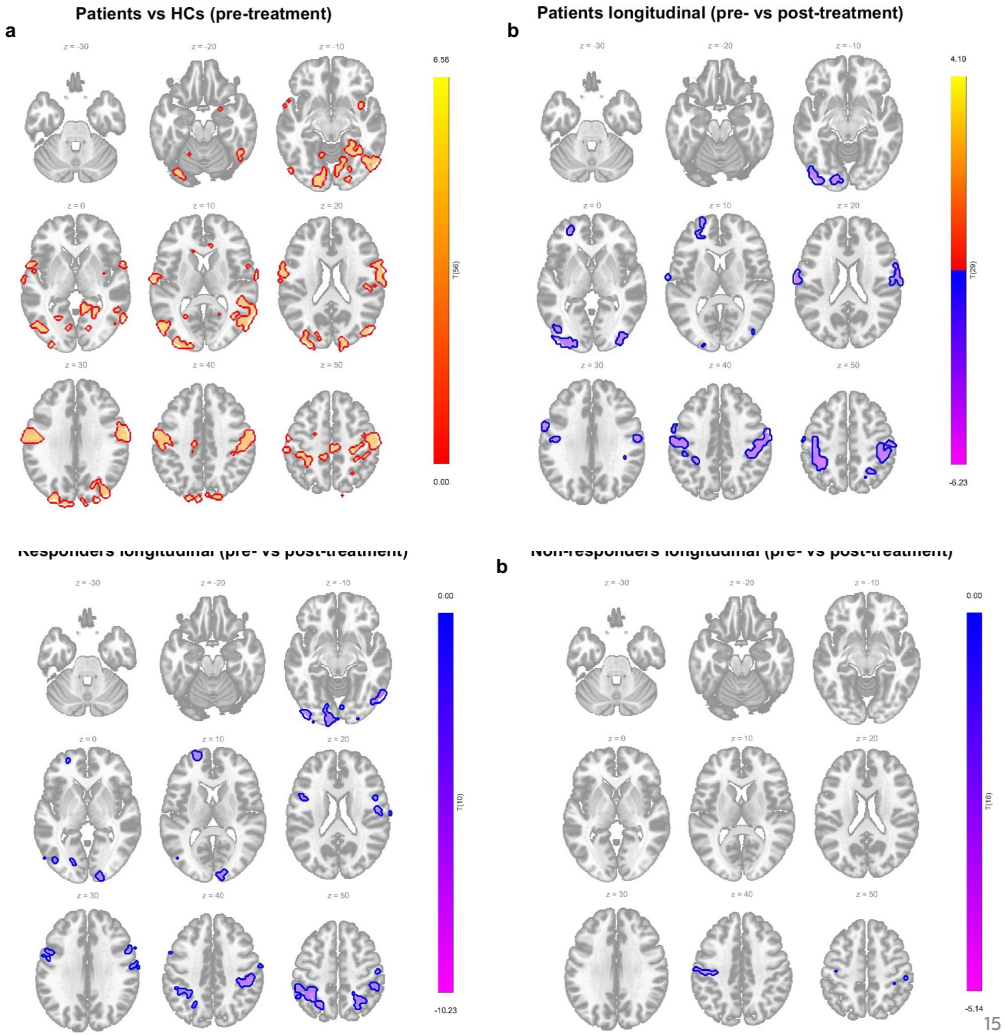
→ HBOT may represent a mechanism-based therapy for a ME/CFS subgroup

Preprint, MedRxiv

Article

Hyperbaric oxygen therapy improves clinical symptoms and functional capacity and restores thalamic connectivity in ME/CFS

Dr. Laura Kim [1*,#], Guido Cammà [4,#], Dr. Claudia Kedor Peters [1], Maron Mantwill [4], Oliver Müller [2], Nadège Leprêtre[1], Cornelia Heindrich [1], Dr. Rebekka Rust [1,3], Dr. Moritz Krill [4], Dr. Tim J. Hartung [4], Lukas G. Reeß [5,6], Dr. Stephan Krohn [4], Prof. Christian von Heymann [2], Dr. Kirsten Wittke [1], Prof. Carsten Finke [4,#] and Prof. Carmen Scheibenbogen [1,#]



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ME/CFS Research Foundation

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