CHARITÉ
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CFS_CARE: Results of an Integrated Care Study for ME/CFS

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Disclosure

- I have nothing to disclose

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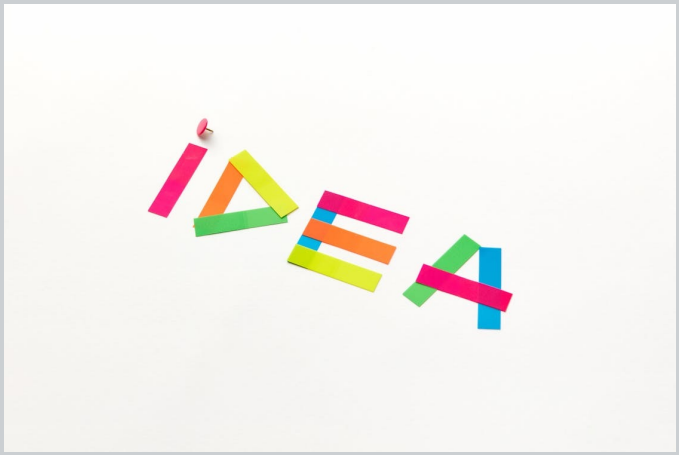
Study Concept



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New Form of Care for ME/ CFS 2021-2025

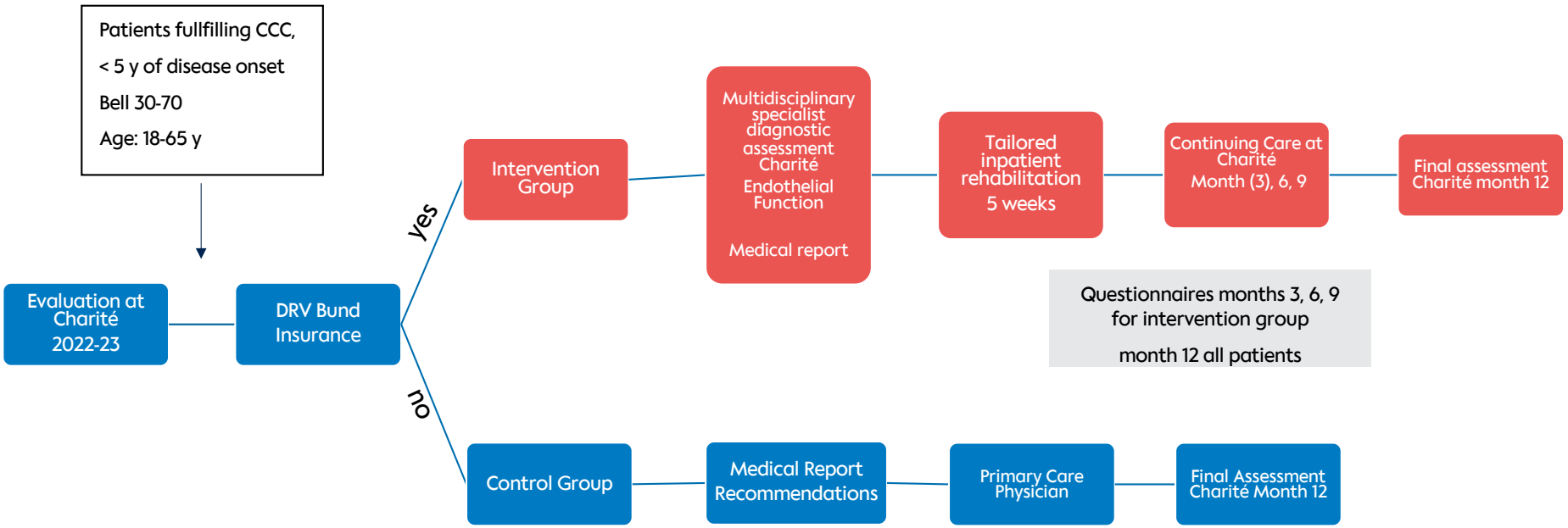
CFS Care Study Design

- **Objective:** To evaluate the effectiveness of specialized care and rehabilitation for ME/CFS compared to standard care

- **Design**: Prospective two-arm intervention study:
  - Intervention: Specialized ME/CFS outpatient clinic + specialized inpatient rehabilitation
  - Control: Initial visit ME/CFS outpatient clinic, follow-up care by general practitioner

- **Endpoints (12 months)**
  - Primary: Physical function (SF-36)
  - Secondary: Symptoms, fatigue, quality of life, mental health, routine data: costs, sickdays

CFS Care Study Design II



2 Study Results – Primary and Secondary Endpoints

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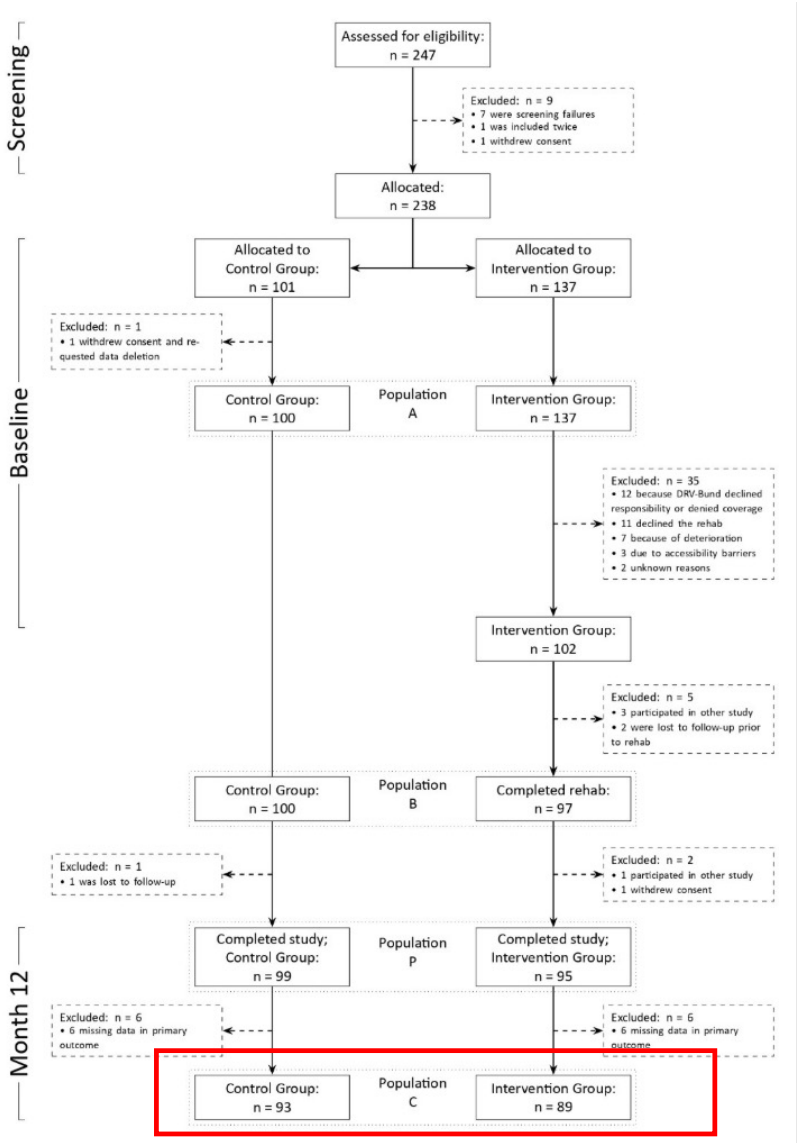
CFS-Care

Flow diagram



Population C: Per Protocol

CFS_CARE – Patient characteristics

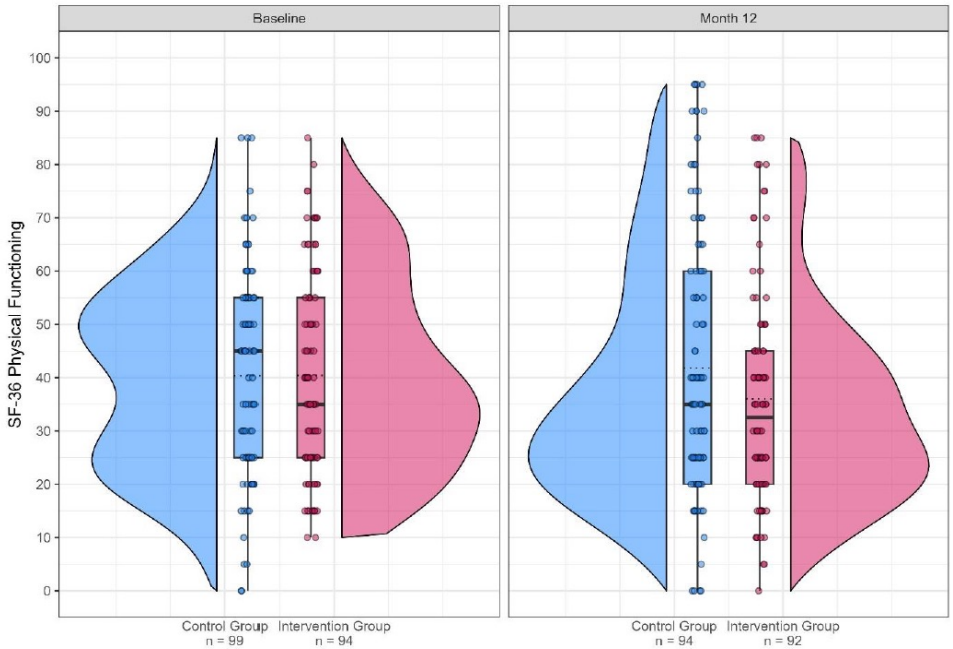
	Control	Intervention
Patients (female)	93 (84%)	89 (90%)
Disease Duration (months)	21,1	16,9
Age (years)	39,3	44,4
Infectious trigger (COVID) %	95.6 (78)	94.4 (78.7)
SF36 (PF) at baseline	41.6	40.0
Bell at baseline, (range 30 - 60)	38	38

- Per protocol analysis

CFS_CARE – Primary Endpoint SF36 Physical Function at month 12

There was **no significant difference** in the **SF-36 physical functioning** subscale between the control group and the intervention group, nor between months 0 and 12.

month 0 month 12



Population B: ITT

CFS_CARE - Endpoints

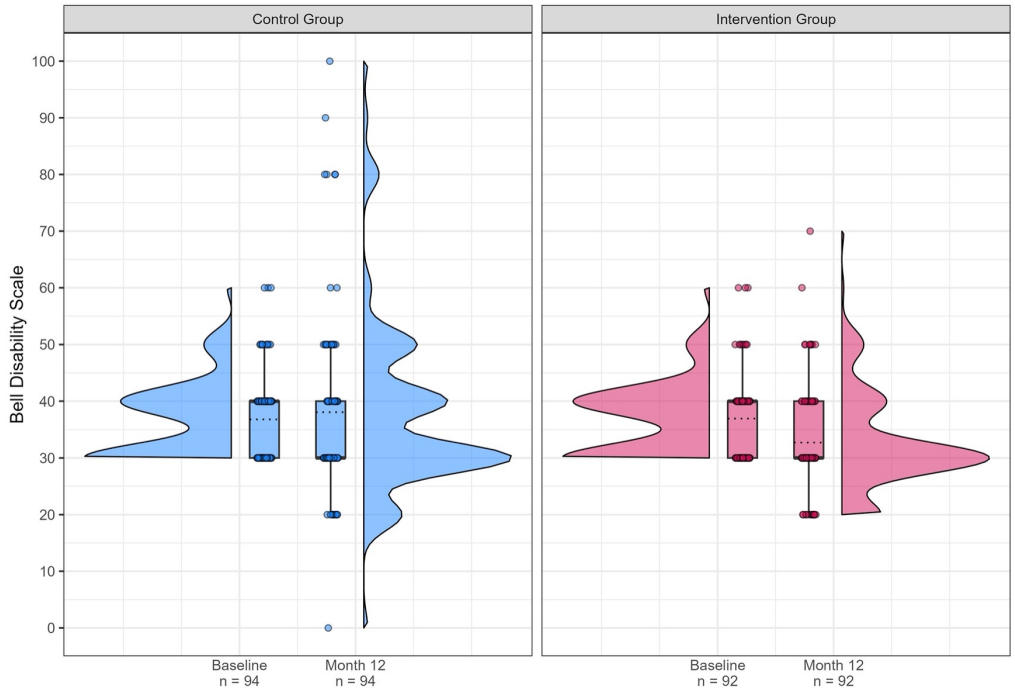
Secondary Endpoints (I)

There was also **no significant difference** in the secondary endpoints between the control group and the intervention group, or between months 0 and 12.

- **Disability:** (Bell scale)
- **Fatigue:** (Chalder Scale)
- **Symptom Severity**
- **Autonomic Function:** (COMPASS31)
- **Health Perception:** (SF-36 scale)
- **Hand Grip Strength**
- **POTS:** NASA-Lean Test
- **Step Count**
- **Physical Activity:** (Physical Activity Questionnaire (IPAQ) scale)

CFS_CARE – Endpoint: Bell disability scale

Secondary Endpoints (I)



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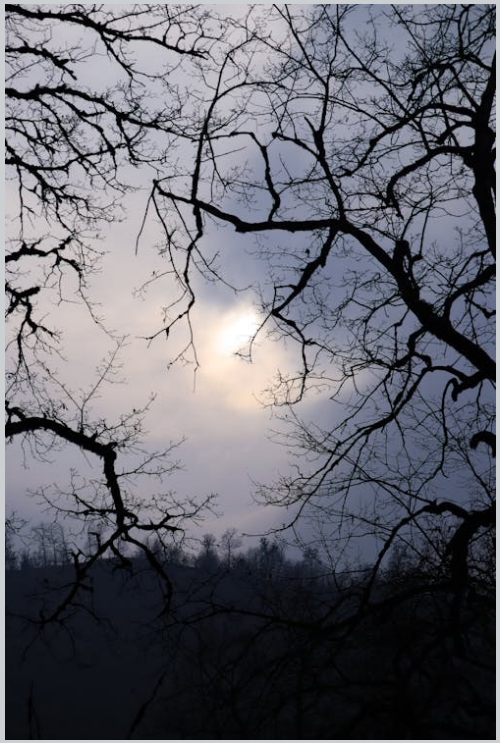
Study Results – Rehabilitation Experience



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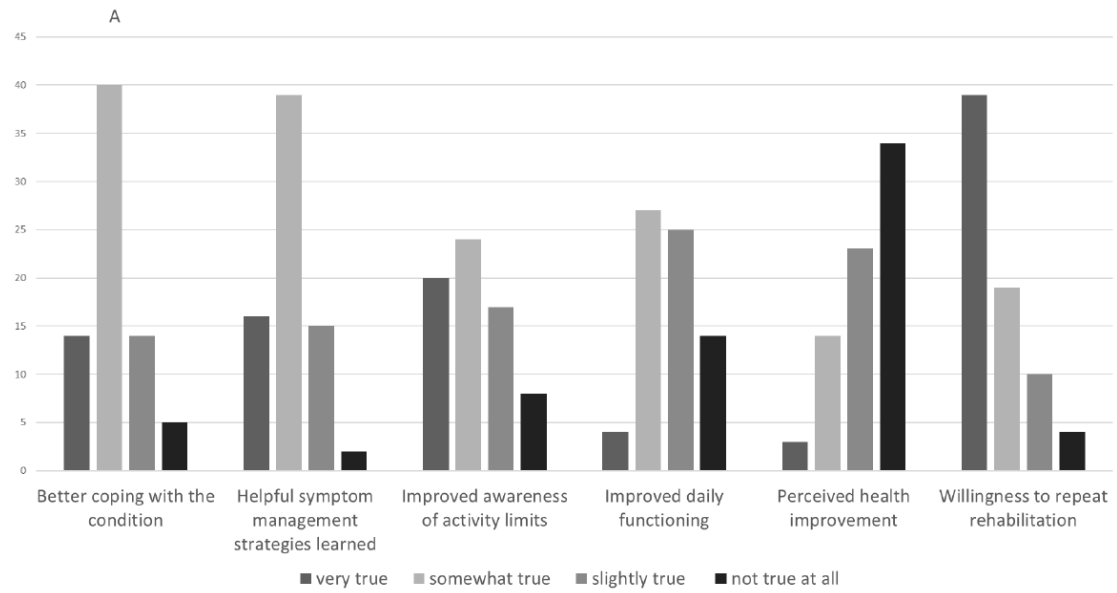
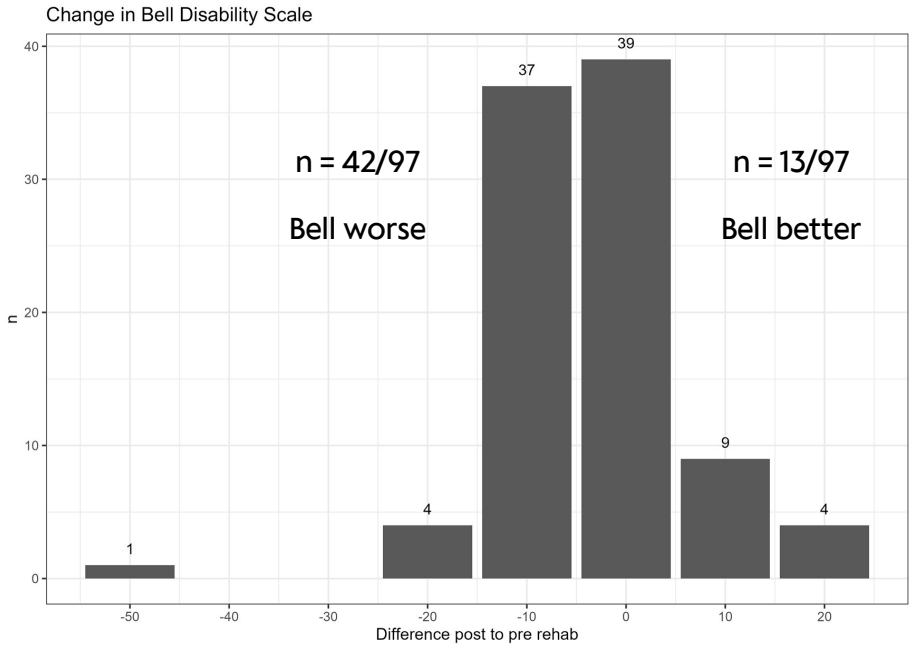
CFS_CARE – Rehabilitation: Self Assessment (n=74)



- n = 54: The Rehabilitation enabled me to cope better with the condition
- n = 17: My condition related to the disease has improved due to rehabilitation
- n = 39: I would participate in another inpatient rehabilitation program

CFS_CARE – Rehabilitation Change of Bell pre- and post-Rehabilitation Visit (n = 97)



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CFS-Care: Summary

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CFS_CARE Summary

Results at 12 months

- No differences in SF-36 PF, Bell score, fatigue, pain, cognition, etc.
- No differences in subgroups (Bell ⩽ 30 vs. ⩾ 40)
- Emotional health slightly improved in the intervention group

Inpatient rehabilitation Self Assessment:

- better understanding of the condition, improved daily life management, higher perceived appreciation
- But Bell score at the post-rehab visit: **43% deterioration in Bell ;** 13% improvement in Bell – 23% say they feel better, 53% would undergo rehab again

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CFS-Care: Lessons Learned

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„Primum non nocere“

- An integrated multidisciplinary care model did not approve physical functioning even under tailored conditions
- The linkage of participation in rehabilitation and social benefits must be reconsidered in patients with ME/ CFS
- Supportive management strategies may contribute to disease stabilization but are insufficient to achieve improvement
- The results underscore the urgent need for mechanism-based therapeutical approaches
- Structured approaches for patient education, self management abilities, social support are needed

Thank you!

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