CogEval project: tackling unmet multiple sclerosis-related cognitive challenges

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Introduction

-Processing Speed Test (PST) stands out as a self-administered iPad®-based tool to measure MS-related deficits in processing speed that has been shown to have significant advantages over conventional Symbol Digit Modalities Test (SDMT)[1]

The rational of a cognitive-based therapeutic approach remains speculative and largely unknown This poster presents the **design and conduct** of an innovative multicenter, Open-Label, randomized trial aimed to answer one crucial unmet Multiple Sclerosis-related cognitive issue question: **Should we move towards earlier initiation of highly effective treatment based on cognitive function?**
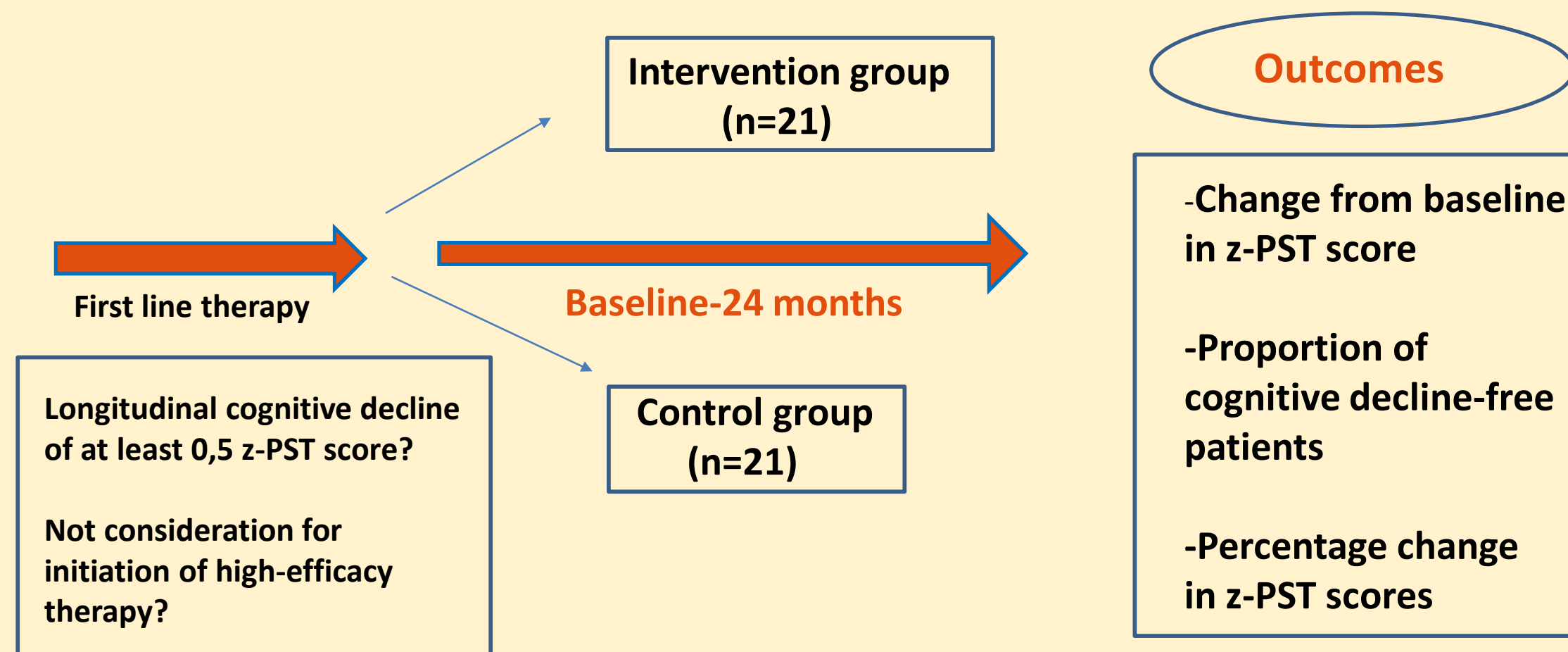
Objectives

To determine whether early **initiation of high-efficacy** disease-modifying therapy (DMT) in MS patients who have cognitive dysfunction as measured on the PST but without any traditional suboptimal response criteria to first-line treatment **is associated with a decreased rate of longitudinal cognitive decline when compared to usual treatment approach** with first-line therapies.

Methodology

Patients **not under consideration** (imaging- and/or relapse-based) **for** initiation of **high-efficacy therapy** but whose results on PST demonstrates **longitudinal cognitive decline from baseline of at least 0.5 standard deviations[2]** on standarized PST (z-PST) will be selected

The primary outcome is processing speed function, measured by the PST. Data analysis will use the standardized score (z-scores)

After eligible patients have provided informed written consent, they will be randomly assigned to one of two groups (experimental or intervention group with initiation of highly effective treatment (natalizumab, ocrelizumab or alemtuzumab) or control group without intervention which will continue with conventional first-line treatment , via a computer-generated permuted-block randomization in a 1:1 ratio by an independent study-blinded statistician

Intervention group (n=21)

Outcomes

First line therapy

Baseline-24 months

Longitudinal cognitive decline of at least 0,5 z-PST score?

Not consideration for initiation of high-efficacy therapy?

Control group (n=21)

-**Change from baseline in z-PST score**

-**Proportion of cognitive decline-free patients**

-**Percentage change in z-PST scores**

Inclusion and exclusion criteria

Inclusion criteria
• Any MS patient who show impaired longitudinal cognitive performance, defined by aa change in at least 0.5 standard deviations on PST[2]
• Confirmed diagnosis of MS in accordance with the 2017 revised McDonald criteria
• Be male or female between 18 and 45 years of age
•Disease duration of not more than 10 years

Exclusion criteria
•On-treatment disease activity defined by MAGNIMS score[3]
• EDSS score of at least 4
• Presence of relapse or treatment with corticosteroids at least 1 month before recruitment (or both)
• Anxiety and/or major depressive disorder in accordance with the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM V).

References

1. Rao SM, Losinski G, Mourany L. Processing speed test: Validation of a self-administered, iPad®-based tool for screening cognitive dysfunction in a clinic setting. Multiple Sclerosis Journal 2017, 23(14) 1929– 1937

2. Kalb R, Beier M, Benedict R, et al., Recommendations for cognitive screening and management in multiple sclerosis care. Multiple Sclerosis Journal 2018, . 24(13) 1665– 1680

3. Prosperini L et al. Minimal evidence of disease activity (MEDA) in relapsing-remitting multiple sclerosis. J Neurol Neurosurg Psychiatry 202091(3):271-277.

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