



DIMMI SI - Integrated Imaginative Distention: a self-managed tool to cope with fatigue. A randomized controlled trial in Multiple Sclerosis.

Preliminary data.

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The diagnosis and the unpredictable nature of Multiple sclerosis (MS) have a profound psychosocial impact on persons with (pw) MS (pw MS). Fatigue, depression and disability are independent determinants of quality of life (QoL) and stress may differently impact on disease activity. The Imaginative Distention (ID) is a mind-body technique that combines physical and psychological relaxation. ID can be easily practised, also in pw physical disability, promoting self awareness and body well-being. Integrated Imaginative Distention in Multiple Sclerosis and Insomnia (DIMMI SI) trial aims to verify ID efficacy on MS, investigating fatigue, disease specific QoL, stress, insomnia. It's an independent single centre trial carried out at Niguarda Ca' Granda Hospital Milan (Italy). Final results are expected in early 2016.

Enrollment

The trial was approved by the local Ethics Committee Registered on ClinicalTrials.gov NCT02290990. Enrollment started on September 2014.

Inclusion criteria: 18-75 years of age, definite MS, psychophysiologic insomnia. Health personnel working at Niguarda Ca' Granda Hospital

Exclusion criteria: inability to understand Italian language and to provide informed consent, presence of severe psychiatric comorbidities.

To preserve privacy, participants selected a secret code to identify the questionnaires.

Randomization

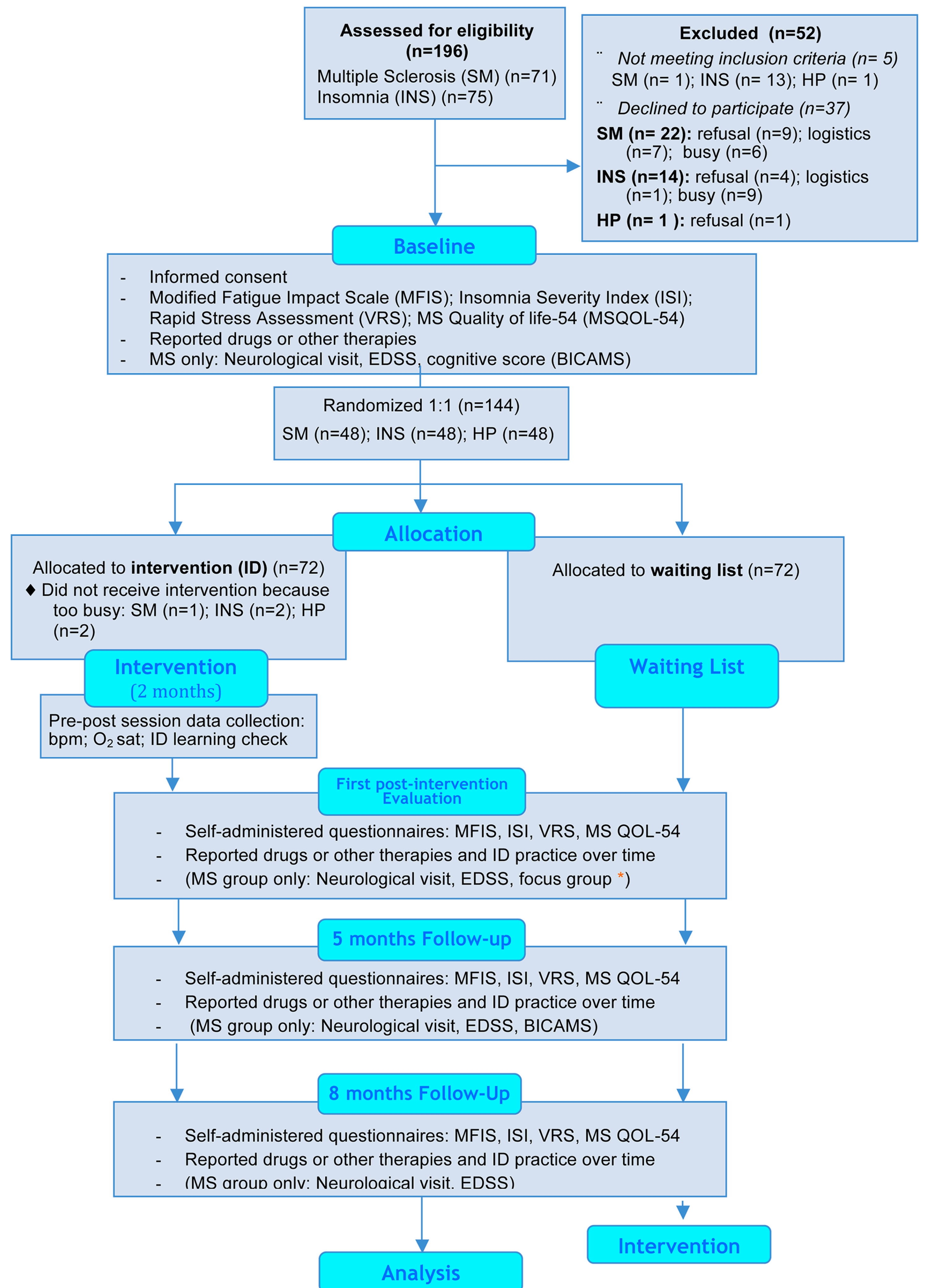
Randomization was performed centrally using a computer-generated central randomization list (1:1 ratio) stratified by sex and condition.

Intervention

Imaginative Distention (ID) is a mind-body technique combining relaxation (based on Jacobson technique¹), motor imagery and imagination. Eight ID weekly training sessions were practiced by intervention group, from October 2014 (2 months). Each session lasted 40 minutes and involved 8 persons, homogeneous for condition. ID was delivered by a skilled psychotherapist. The muscle contraction/relaxation movements were explained and trained. The conductor encouraged to obtain the motor imagery of the same exercises and to imagine the body parts or other scenes. ID learning was checked and recalled to reach good performance. In control group ID was planned 8 months later to assure the same care.

Design and Analysis

The design is RCT open label with two parallel, control groups: insomnia pw (mild stress) and health professionals (at risk of stress). According to the Moss Morris² study, primary endpoint is the measure of the post intervention effect of ID on fatigue in pw MS. The fatigue score change will be analyzed by ANCOVA, using intervention and condition as main effects. Assuming a baseline score of approximately 13±4 and anticipating a change after intervention of approximately 4 units with correlation among repeated measures ≤ 0.6 , a total sample of 144 subjects (24 subjects for intervention/condition group) has a power $\geq 90\%$ to detect with an alpha error ≤ 0.025 an effect of the intervention explaining at least 12.5% of the total variance. In case of violation of the ANOVA assumptions, a Wilcoxon test for repeated measures will have a power of 85%.



Baseline data		Age	Time from disease/job onset	Fatigue
group	N	Years, median (range)	Years, median (range)	mFIS, median (range)
multiple sclerosis	48	45 (24-76)	13 (0-43)	41 (5-73)
insomnia	48	49 (25-73)	10 (0-55)	38 (12-73)
health profession	48	50 (24-61)	20 (2-38)	30 (5-70)

* Focus groups were performed to understand pw MS needs and emotions 1 month after training conclusion. Any item derived from the focus groups will be analyzed using qualitative and quantitative text analysis.

CONCLUSION: If efficacy will be showed ID could become a tool of empowerment to cope with MS, to reduce its negative impact on daily life and, possibly, to improve therapy compliance.

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¹ Jacobson E: The technic of progressive relaxation. The Journal of Nervous and Mental Disease 1924;60(6):568-578.

² Moss-Morris R, McCrone P, Yardley L, van Kessel K, Wills G, Dennison L: A pilot randomised controlled trial of an Internet-based cognitive behavioural therapy self-management programme (MS Invigor8) for multiple sclerosis fatigue. Behav Research and Therapy 2012;50:415-421.