

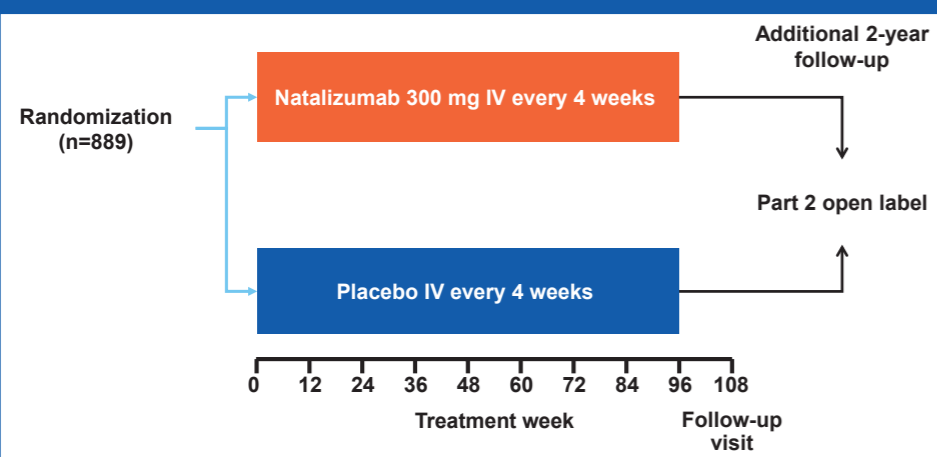
INTRODUCTION

- Disability in multiple sclerosis (MS) has been shown to impact multiple aspects of patients' lives.¹
- Persons with MS have lower employment rates than those for the general population.²⁻⁴
- ASCEND is an ongoing international (United States, Canada, Europe, Russia, Israel), Phase 3b, randomized, double-blind, placebo-controlled study to evaluate whether natalizumab reduces disability progression unrelated to relapses in patients with secondary progressive MS (SPMS; NCT01416181).
- The objective of this study is to investigate differences in clinical and patient-reported outcomes stratified by baseline employment status in patients with SPMS randomized into the ASCEND trial.

METHODS

- Natalizumab-naïve patients (18–58 years of age) with SPMS onset ≥ 2 years before enrollment, with an Expanded Disability Status Score (EDSS) score between 3 and 6.5 and confirmed disease progression, were eligible for the ASCEND study.
- Patients were randomized 1:1 to treatment with either natalizumab 300 mg or placebo intravenous (IV) every 4 weeks for 2 years (Figure 1).
- Neurological and patient-reported assessments include measures of walking ability (Timed 25-Foot Walk [T25FW], 12-item Multiple Sclerosis Walking Scale [MSWS-12], 6-Minute Walk Test [6MWT]), hand dexterity (ABILHAND, 9-Hole Peg Test [9HPT]), physical disability (EDSS), and cognitive impairment (Symbol Digit Modalities Test [SDMT]; every 4 weeks) for all patients and a novel composite endpoint (MS-COG; based on SDMT, Selective Reminding Test [SRT], Brief Visuospatial Memory Test-Revised [BVMTR], and Paced Auditory Serial Addition Test [PASAT]) for a subgroup of patients.
- At enrollment, detailed information on employment was obtained from all patients.
- Associations between employment status (full-time/part-time or unemployed) and baseline disability outcome measures were evaluated using pooled blinded patient data. Association between employment status and standard demographic variables (age, sex, level of education) also were investigated.
- Employed (full-time/part-time) category encompasses employed at home, employed outside home, homemaker, and student.
- Statistical analyses included Wilcoxon rank-sum tests (most variables) and chi-square test (sex and marital status).
- A sensitivity analysis was performed to compare only those individuals employed outside the home with those unemployed.

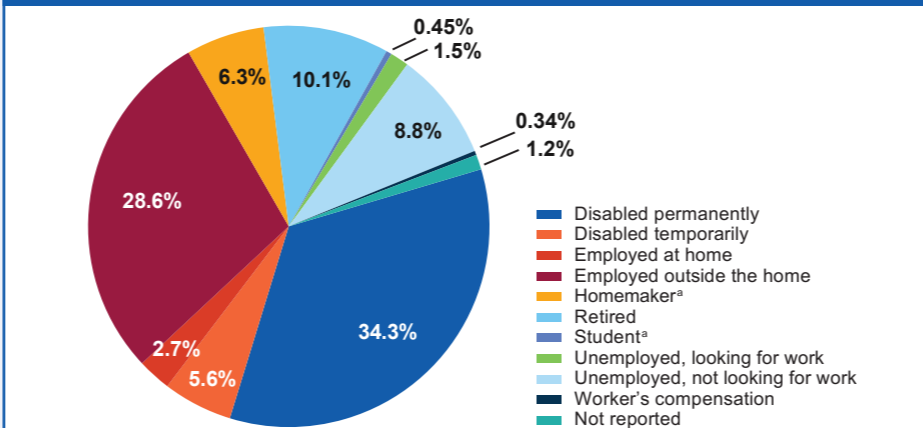
Figure 1. ASCEND study design



RESULTS

- At Baseline, 339 of 889 (38%) patients with SPMS enrolled in ASCEND were employed (29% outside the home, 3% employed at home, 6% homemakers, < 0.5% students) while most (550; 62%) were unemployed (Figure 2).

Figure 2. Baseline employment status in ASCEND



Percentages may add to > 100 because of rounding. *Employed (full-time/part-time) category encompasses employed at home, employed outside home, homemaker, and student.

- There was no significant difference in age or sex between unemployed and employed patients (Table 1).
- Employed patients were more likely than unemployed patients to be married and had a greater number of years of education (Table 1).

Table 1. Baseline demographics by employment status

Characteristic	Employed n=339	Unemployed n=550	Total N=889
Mean (SD) age, y	46.7 (7.53)	47.5 (7.62)	47.2 (7.59)
Female, n (%)	200 (59.0)	349 (63.5)	549 (61.8)
Marital status, n (%) ^{a,b}			
Single	45 (13.3)	85 (15.8)	130 (14.8)
Live with partner	32 (9.5)	43 (8.0)	75 (8.6)
Married	237 (70.1)	327 (60.7)	564 (64.3)
Separated	3 (0.9)	13 (2.4)	16 (1.8)
Divorced	19 (5.6)	58 (10.8)	77 (8.8)
Widowed	2 (0.6)	13 (2.4)	15 (1.7)
Mean (SD) years of education ^b	13.8 (3.41)	12.9 (3.20)	13.2 (3.31)

^an= 338 (employed); 539 (unemployed); 877 (total). ^bP<.05 (chi-square test [marital status] or Wilcoxon rank-sum [education]; employed vs. unemployed).

- At Baseline, unemployed patients performed worse on walking measures with significantly longer T25FW times, shorter 6MWT distances, and higher MSWS-12 scores than employed patients (all P<.0001; Table 2).
- Unemployed patients also had worse information processing (lower SDMT scores and PASAT scores) than employed patients (all P<.05; Table 2).
- Median EDSS scores were worse in unemployed vs. employed patients (Table 2).
- Unemployed patients also had worse upper extremity function (e.g., lower median ABILHAND scores and slower median 9HPT times).
- In the MS-COG substudy, unemployed patients had worse cognitive function reflected by lower mean MS-COG z score (Table 2).

Table 2. Baseline assessments by employment status

Characteristic	Employed n=339		Unemployed n=550		Total N=889	
	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
T25FW, s ^a	11.6 (6.76)	339	14.6 (8.41)	549	13.5 (7.96)	888
MSWS-12 total score ^a	64.5 (23.76)	338	71.1 (21.67)	545	68.6 (22.71)	883
6MWT, m ^a	246.3 (129.09)	326	197.4 (193.73)	535	215.9 (173.68)	861
EDSS score ^{a,b}	5.5 (3.0–6.5)	339	6.0 (3.0–6.5)	550	6.0 (3.0–6.5)	889
ABILHAND total score ^a	87.6 (14.15)	339	81.1 (16.91)	546	83.6 (16.21)	885
9HPT, s ^{a,c}	31.8 (22.74)	338	36.8 (26.96)	543	34.9 (25.53)	881
SDMT score ^a	43.2 (12.93)	320	36.0 (13.38)	524	38.8 (13.66)	844
PASAT-2 score ^d	31.8 (11.17)	42	25.6 (10.11)	56	28.3 (10.96)	98
PASAT-3 score ^e	41.0 (12.76)	47	35.4 (13.47)	60	37.9 (13.39)	107
MS-COG z score ^d	-0.9 (0.85)	41	-1.4 (0.97)	53	-1.2 (0.95)	94

^aP<.0001. ^bData presented as median (range). ^cDominant hand. ^dP<.01; ^eP<.05; MS cognitive composite score based on SDMT, SRT, BVMTR, and PASAT-2 and PASAT-3 for a subgroup of patients.

- A sensitivity analysis that compared only those patients employed outside the home with those unemployed indicated similar significant differences.

CONCLUSIONS

- This analysis demonstrates a significant association between unemployment status and physical and cognitive impairment in the SPMS population at enrollment in the ASCEND study.
- While significant differences were observed in all measures, greater differences between the employed and unemployed groups were noted in objective measures of physical function (manual dexterity and ambulation) and cognition.
- The extent of effect of physical vs. cognitive impairment on unemployment remains to be determined.
- These results suggest that differences in disability measures translate to real-world changes, such as employment. This study expands prior research on the impact of SPMS on employment by including both cognitive and physical impairment.

References

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Disclosures

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