Supplementary Online Content

Writing Group for the NINDS Exploratory Trials in Parkinson Disease (NET-PD) Investigators. Effect of creatine monohydrate on clinical progression in patients with Parkinson disease: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2015.120

This supplementary material was provided by the authors to give readers additional information about their work.

eTable 1. Baseline Characteristics of LS-1 Participants by Cohort

	Cohort 1[a]						Cohort 2[b]					
	Total		Placebo		Creatine		Total		Placebo		Creatine	
Demographics	**N**		**N**		**N**		**N**		**N**		**N**	
Age[c] Mean Years (SD)	955	62.5 (9.7)	478	62.3 (9.6)	477	62.8 (9.9)	786	60.9 (9.5)	389	60.6 (9.5)	397	61.2 (9.5)
Male Frequency (%)	955	621 (65%)	478	314 (66%)	477	307 (64%)	786	502 (64%)	389	240 (62%)	397	262 (66%)
Non-Hispanic whites Frequency (%)	955	856 (90%)	478	428 (90%)	477	428 (90%)	786	715 (91%)	389	355 (91%)	397	360 (91%)
PD Characteristics[d]												
Time since PD Diagnosis[c] Mean Years (SD)	955	1.7 (1.1)	478	1.7 (1.1)	477	1.6 (1.1)	786	1.4 (1.0)	389	1.4 (1.0)	397	1.4 (1.0)
Duration of PD Symptoms Mean Years (SD)	955	3.3 (2.2)	478	3.4 (2.4)	477	3.2 (1.9)	786	3.2 (2.2)	389	3.2 (2.0)	397	3.3 (2.4)
Duration of Symptomatic Therapy Mean Years (SD)	953	0.9 (0.7)	477	0.9 (0.7)	476	0.9 (0.7)	786	0.8 (0.6)	389	0.8 (0.6)	397	0.7 (0.6)
Total daily LEDD Mean mg (SD)	952	382 (238)	477	373 (230)	475	391 (246)	786	386 (251)	389	380 (266)	397	391 (246)
UPDRS Total Mean (SD)	949	26.3 (11.3)	475	26.1 (10.9)	474	26.5 (11.6)	783	26.1 (11.5)	389	25.7 (11.2)	394	26.6 (11.8)
UPDRS Mental Mean (SD)	955	1.2 (1.3)	478	1.2 (1.2)	477	1.2 (1.3)	786	1.5 (1.5)	389	1.5 (1.5)	397	1.4 (1.5)
UPDRS ADL Mean (SD)	955	7.2 (3.9)	478	7.1 (3.8)	477	7.4 (4.1)	785	7.1 (4.0)	389	6.9 (3.8)	396	7.3 (4.1)
UPDRS Motor Mean (SD)	949	17.9 (8.2)	475	17.9 (7.9)	474	17.9 (8.5)	784	17.6 (8.5)	389	17.3 (8.4)	395	17.8 (8.7)

Ambulatory Capacity (UPDRS items) Mean (SD)	954	1.8 (1.6)		477	1.8 (1.6)		477	1.8 (1.6)		785	1.6 (1.5)		389	1.5 (1.4)		396	1.7 (1.5)
Modified Rankin Score [e] Mean (SD)	955	1.2 (0.5)		478	1.2 (0.5)		477	1.2 (0.5)		786	1.2 (0.5)		389	1.2 (0.4)		397	1.2 (0.5)
0 Frequency (%)		9 (1%)			6 (1%)			3 (0.6%)			14 (1.8%)			6 (1.5%)			8 (2.0%)
1 Frequency (%)		729 (76%)			362 (76%)			367 (77%)			615 (78.2%)			318 (81.8%)			297 (74.8%)
2 Frequency (%)		197 (21%)			99 (21%)			98 (21%)			148 (18.8%)			64 (16.5%)			84 (21.2%)
3 Frequency (%)		20 (2%)			11 (2%)			9 (2%)			9 (1.2%)			1 (0.3%)			8 (2.0%)
PDQ-39 Summary Index[c] **Mean (SD)**	955	12.8 (10.2)		478	12.6 (10.4)		477	12.9 (9.9)		783	13.8 (11.2)		387	13.4 (11.0)		396	14.2 (11.3)
Schwab & England Activities of Daily Living Mean (SD)	954	90.9 (6.6)		478	91.0 (6.6)		476	90.9 (6.6)		786	91.3 (6.3)		389	91.8 (6.0)		397	90.8 (6.6)
Symbol Digit Modalities Test[c] **Mean (SD)**	952	42.8 (11.8)		475	43.0 (11.7)		477	42.6 (12.0)		784	46.4 (11.3)		388	46.3 (11.2)		396	46.5 (11.3)
Total Functional Capacity (TFC) Mean (SD)	955	12 (1.4)		478	12.0 (1.4)		477	12.1 (1.4)		784	12.0 (1.4)		389	12.2 (1.3)		395	11.9 (1.5)
Scales for Outcomes in Parkinson's disease-Cognition (SCOPA-COG) Mean (SD)	950	30 (5.6)		475	30.4 (5.4)		475	29.6 (5.7)		781	30.6 (5.1)		388	30.7 (5.1)		393	30.6 (5.1)

EuroQOL EQ-5D Mean (SD)	955	0.8 (0.2)		478	0.8 (0.2)		477	0.8 (0.2)		786	0.8 (0.2)		389	0.8 (0.2)		397	0.8 (0.2)
BDI Score Mean (SD)	951	6.7 (5.5)		478	6.8 (5.6)		473	6.5 (5.4)		785	7.1 (5.6)		389	7.0 (5.4)		396	7.3 (5.9)
BDI Score >17, Frequency (%)	951	39 (4%)		478	19 (4%)		473	20 (4%)		785	44 (6%)		389	18 (5%)		396	26 (7%)
Body Mass Index (kg/m^2) Mean (SD)	949	28 (6.9)		477	28.3 (5.8)		472	27.7 (7.8)		782	27.8 (7.0)		386	27.4 (4.9)		396	28.3 (8.5)

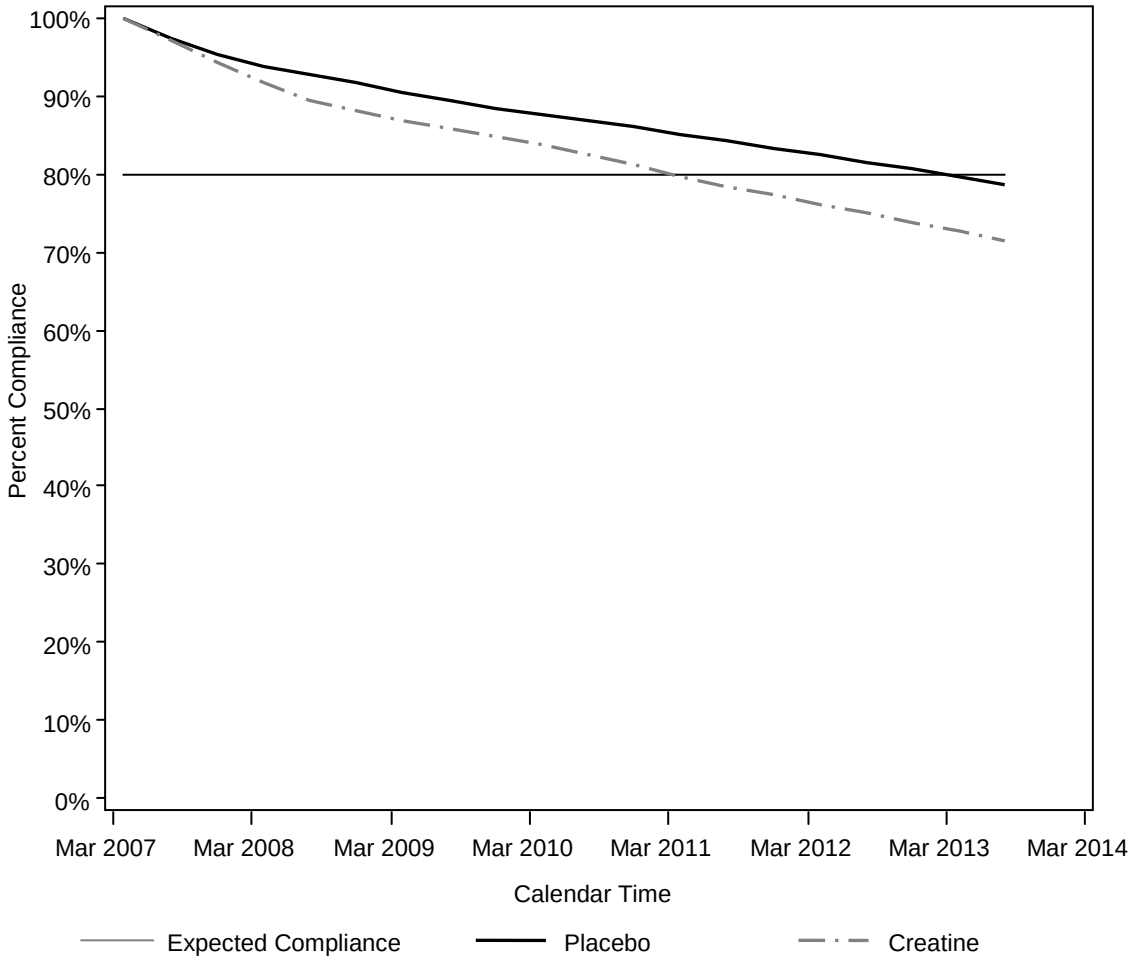
[a] Cohort 1 includes 55% of LS-1 participants who were eligible for a 5-year follow-up visit prior to interim analysis on July 17, 2013
[b] Cohort 2 includes 45% of LS-1 participants who were ineligible for a 5-year follow-up visit (i.e.: randomized <5 years) prior to interim analysis on July 17, 2013
[c] Age, time since diagnosis, Symbol Digit Modalities, and PDQ-39 Summary Index are significantly (t-test, two-sided $p<0.05$) different between the two Cohorts
[d] A higher score indicates a better outcome for Schwab and England, Symbol Digit Modalities, TFC, SCOPA-Cog, and EQ-5D. For all other measures, a higher score indicates a worse outcome. Range of possible scores for each measure: UPDRS Total: 0-176; UPDRS Mental: 0-16; UPDRS ADL: 0-52; UPDRS Motor: 0-108; Ambulatory Capacity: 0-20; Schwab & England Activities of Daily Living: 0-100%; PDQ-39 Summary Index: 0-100; Symbol Digit Modalities Test: 0-110; TFC: 0-13; SCOPA-COG: 0-43; EQ-5D: 0-1; BDI: 0-63; Modified Rankin: 0-6.
[e] 0, No significant symptoms; 1, no significant disability despite symptoms; 2, slight disability; 3, moderate disability
SD, standard deviation; LEDD, levodopa equivalent daily dose; UPDRS, United Parkinson Disease Rating Scale

eTable 2. Frequency of Deaths by Body System Prior to Interim Analysis and Study Termination

Body System	Treatment Arm		
	Placebo (n=867)	**Creatine (n=874)**	**Total (n=1,741)**
Cardiac	10 (1.2%)	15 (1.7%)	25 (1.4%)
General/Unknown[a]	7 (0.8%)	10 (1.1%)	17 (1.0%)
Neoplasm	6 (0.7%)	5 (0.6%)	11 (0.6%)
Infections	4 (0.5%)	5 (0.6%)	9 (0.5%)
Respiratory	5 (0.6%)	2 (0.2%)	7 (0.4%)
Nervous	3 (0.3%)	3 (0.3%)	6 (0.3%)
Gastrointestinal	0 (0%)	2 (0.2%)	2 (0.1%)
Injury & Procedures	0 (0%)	1 (0.1%)	1 (0.1%)
Metabolism	0 (0%)	1 (0.1%)	1 (0.1%)
Psychiatric disorders	1 (0.1%)	0 (0%)	1 (0.1%)
Total Deaths	36 (4.2%)	44 (5.0%)	80 (4.6%)

[a] 9 participants having an unknown cause of death were grouped with General. This table includes 2 additional deaths that occurred prior to July 17, 2013, but were not discovered until after the data freeze on that date.

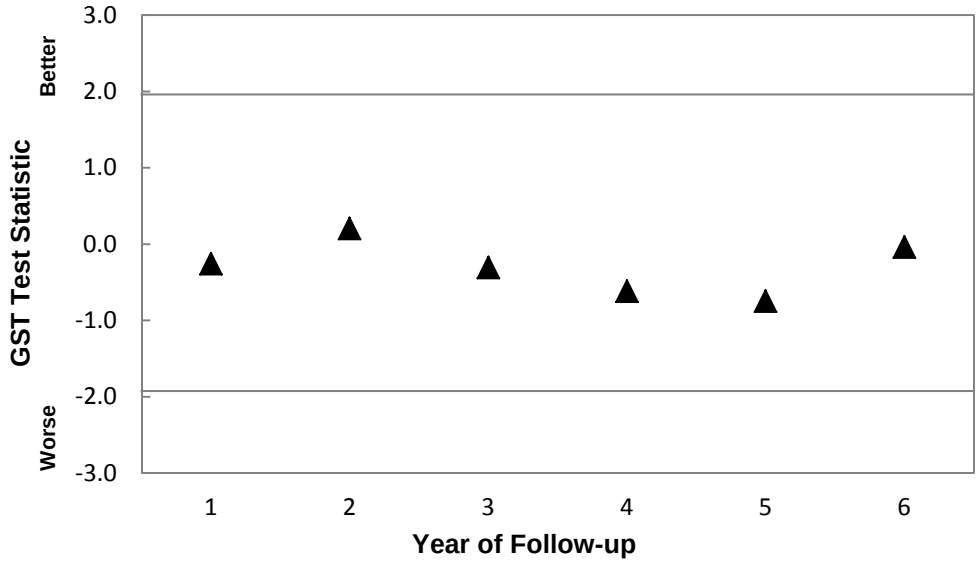
e**Figure 1.** Percent Compliance Observed Over Study Calendar Time: (Cumulative Days on Study Drug / Expected Days of Follow-up) x 100



The study design assumed the expected compliance would be 80%. The observed compliance is shown for each treatment group by calendar time. At the end of the study (July 2013), the observed compliance was 78.7% for the placebo and 71.5% for the creatine group. For a given calendar date, the cumulative days on study drug is the total number of days that participants, who enrolled prior to that date, were taking study drug.

If a participant was temporarily or permanently suspended from study drug or had withdrawn from the study prior to that date, then the days on study drug was the actual number of days the participant had received study drug (e.g. the number of days between enrollment and date of permanent suspension). The expected days of follow-up for a given calendar date is the total number of days of follow-up expected for all participants enrolled prior to that date (i.e. the number of days between enrollment and calendar date). If a participant died prior to that calendar date, then the expected days of follow-up for that participant was the number of days between enrollment and date of death.

eFigure 2. Global Statistical Test (GST) by Year of Follow-up

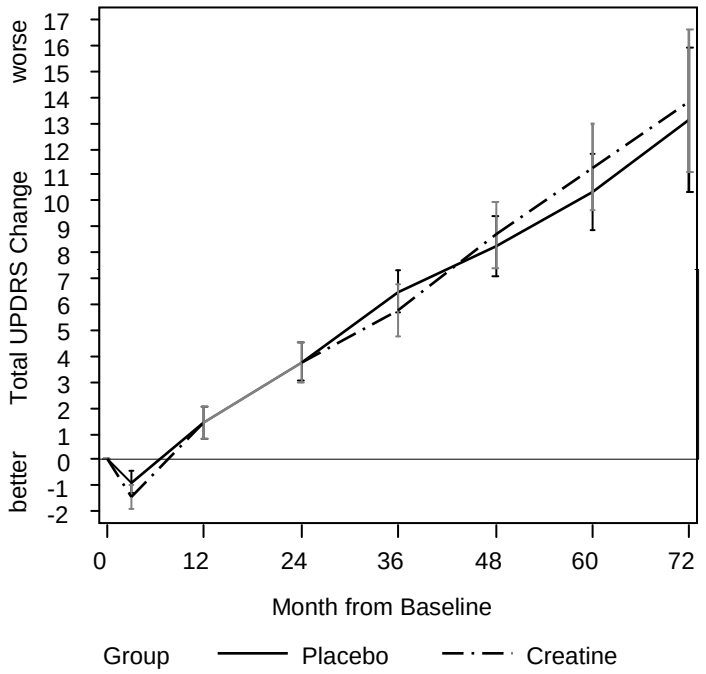


	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
N[a]	1,741	1,741	1,741	1,365	955	369
GST test statistic	-0.26	0.2	-0.31	-0.62	-0.75	-0.04

[a] Missing data were imputed.

The horizontal lines are located at ± 1.96 represent the approximate boundaries of statistical significance when alpha is 0.05, two-sided (uncorrected for multiple tests).

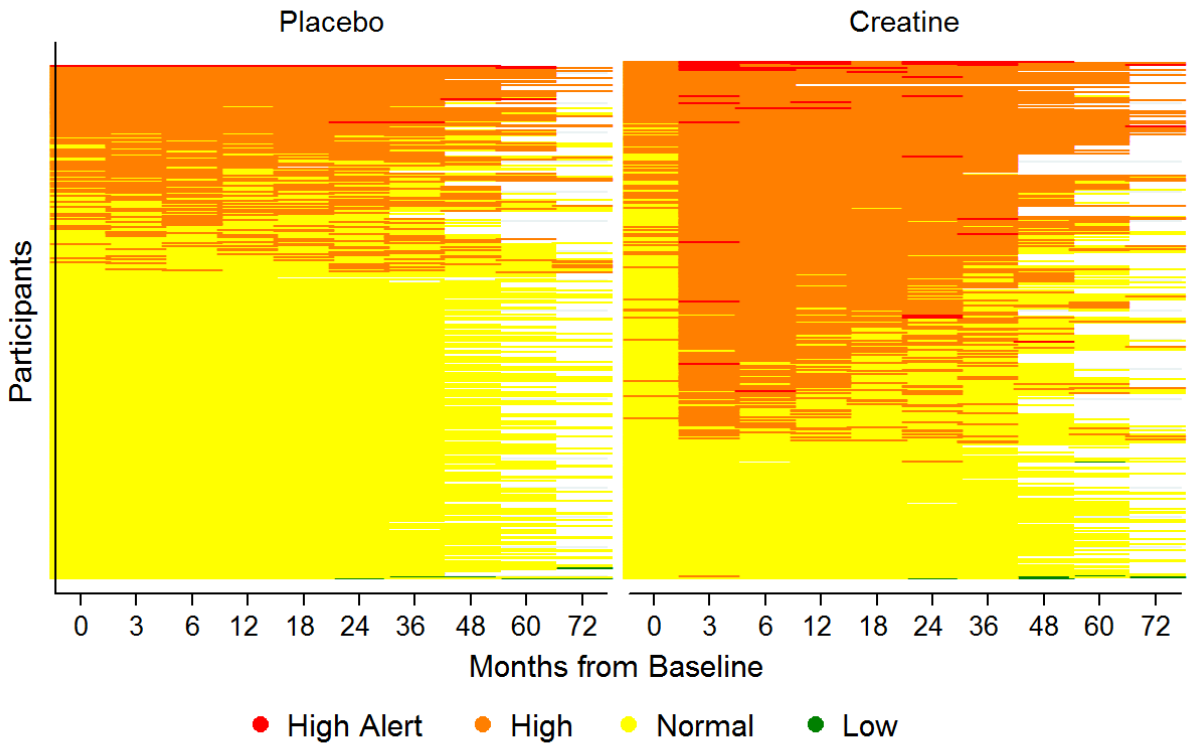
eFigure 3. Mean Total UPDRS Change From Baseline by Year for all Available Trial Participants (N=1,741)



	Baseline	Month 3	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Placebo	864	834	795	757	709	513	336	130
Creatine	868	843	807	753	698	509	330	119

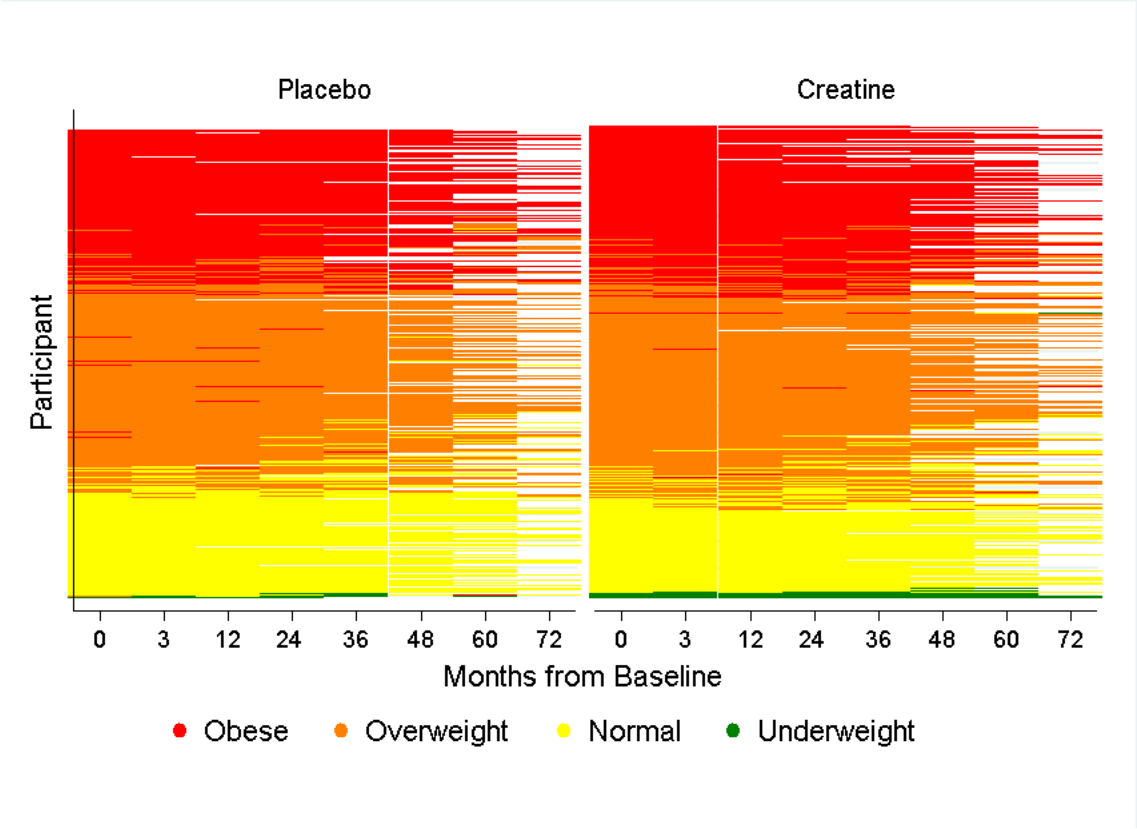
This figure includes all available data from Cohort 1 and Cohort 2. Error Bars are 95% Confidence Intervals of the Group Means. Missing data were not imputed.

e**Figure 4.** Heat Map of Creatinine Laboratory Values by Treatment Group and Visit



Each horizontal line represents a single participant over calendar time (months). Participants with the highest average creatinine values (averaged across visits) are sorted on top. Values associated with each category: High Alert (males and females: ≥2.0 mg/dL), High (males: 1.17 – <2.0 mg/dL; females: 0.95 – <2.0 mg/dL), Normal (males: 0.67 – <1.17 mg/dL; females: 0.51 – <0.95), Low (males: <0.67 mg/dL; females: <0.51 mg/dL).

e**Figure 5.** Heat Map of Body Mass Index (BMI) Categories by Treatment Group and Visit



Each horizontal line represents a single participant over calendar time (months). Participants with the highest average BMI (averaged across visits) are sorted on top. Values associated with each category: Obese: ≥30 kg/m^2; Overweight: 25 – 29.9 kg/m^2; Normal: 18.5 – 24.9 kg/m^2; Underweight: <18.5 kg/m^2.

eAppendix. Participating Investigators and Coordinators and Associated Grants

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