Dataset Integrity Check (DSIC) for the Chronic Prostatitis Collaborative Research Network 2 - Pregabalin (CPCRN2-Pregabalin) Study

Prepared by

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Revision History

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1 Introduction

As a partial check of the integrity of the CPCRN2-Pregabalin dataset archived in the NIDDK data repository, a set of tabulations was performed to verify that published results can be reproduced using the archived dataset. Analyses were performed to duplicate selected results for the data published by Pontari et al. [1] in the *Archives of Internal Medicine* in September 2010. The results of this dataset integrity check (DSIC) are described below. The Stata code for our tabulations is included in Attachment 1 and full text of the article can be found in Attachment 2.

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository are a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected on a first (or second) exercise in secondary analysis. This occurs for a number of reasons, including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, and software coding used to define complex variables, among others. Experience suggests that most discrepancies can ordinarily be resolved by consulting with the study data coordinating center (DCC); however, this process is labor-intensive for both DCC and Repository staff. Therefore, it is not our policy to resolve every discrepancy that is observed in an integrity check.

Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, *unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff*. However, we document in footnotes to the integrity check those instances in which our secondary analyses produced results not fully consistent with those reported in the target publication.

2 Background

The Chronic Prostatitis Collaborative Research Network 2 - Pregabalin Study was a multicenter randomized double-blind placebo-controlled clinical trial to evaluate the efficacy of pregabalin in reducing symptoms associated with chronic prostatitis-chronic pelvic pain syndrome (CP/CPSS) in men. Men were randomly assigned (2:1) to treatment with pregabalin or placebo for 6 weeks. Pregabalin dosage was increased from 150 to 600 mg/d during the first 4 weeks. The primary outcome was a reduction of at least 6 points on the NIH Chronic Prostatitis Symptom Index (NIH-CPSI, range 0-43 with higher scores indicating more severe symptoms) from baseline to 6 weeks. Additional secondary outcomes were assessed.

In this DSIC, we compare our results to the results published in the Pontari et al. (2010) manuscript: specifically in Table 1 (Baseline characteristics of the participants by treatment arm), Table 2 (Dose titration by treatment arm) and Table 4 (Primary and secondary outcome measures at baseline and 6 weeks and differences in change across time by treatment arm).

The tabulations from this DSIC reproduce closely the results presented in Tables 1, 2, and 4. Numbers highlighted and in italics indicate differences between the DSIC and published results. In most instances, these differences were minor (one to two tenths of one percent).

3 DSIC Analysis

Table A lists the data variables that we used in our replication for Tables 1, 2, and 4 found in Pontari et al. The variables were derived from an analysis dataset provided by the DCC -- “cp02_long.sas7bdat ”. This SAS dataset was converted to Stata format using Stat/Transfer and output as Stata data file cp02_long.dta. We did not use the original form-based data – rather we used the variables as contained in cp02_long, the analysis file. The analysis dataset variable name, variable algorithms, and the table number in which the variables appeared in the published manuscript (indicated in brackets) are listed below.

Table A: Variables and Analysis Variable Algorithms for Pontari et al. (2010), Tables 1, 2, and 4.

	Analysis dataset variable	**Variable algorithm [by published Table number.]**
Randomized participants	arm	egen treatment=group(arm) [1-3]
Evaluable participants		**agebase=nonmissing [1]**
Age, mean/median/range	age base	[1]
Race — no. (%)†	race	recode (5=1) (3=2) (2=3) (else=4) [1]
Educational level	education	[1]
Employment	employment	[1]
Annual family income	income	[1]
Ever diagnosis of IC,CP, or CPPS	hxdiag	[1]
Years since first diagnosis	med1a	[1]
Years since first symptoms began	med2a	[1]
Family diagnosis of IC/PBS	fmdiagic	[1]
Family ever diagnosis of CP/CPSS	fmdiagcp	[1]
Participants with baseline CPSI	cpsibase, cpsiv1, cpsiv2	[1]
NIH-CPSI total score		
Mean, median	cpsibase, cpsiv5	[1,3]
NIH-CPSI pain score		
Mean, median	painbase, painv5	[1,3]
NIH-CPSI urinary score		
Mean, median	uribase, uriv5	[1,3]
NIH-CPSI Quality-of-life score		
Mean, median	qolbase, qolv5	[1,3]
SF-12 PCS		
Mean, median	pcs12_v2	[1,3]
SF-12 MCS		
Mean, median	mcs12_v2	[1,3]
Maximum dosage, mg/d	maxdosep1	[2]
Dosage at primary end point, mg/d	maxdosepe	[2]

	Analysis dataset variable	Variable algorithm [Table no.]
NIH-CPSI responder rate	cpsi6ptdrop6wk	[3]
GRA responder rate	grarespv5	[3]
HADS score	had15_v2, had15_v5	[3]
IIEF-SHIM score	iief_shim_v2, iief_shim_v5	[3]
McGill Pain q'aire score	mcgill_total_v2, mcgill_total_v5	[3]
MOS SF-12 score, PCS	pcs12_v2, pcs12_v5	[3]
MOS SF-12 score, MCS	mcs12_v2, mcs12_v5	[3]

Note: Evaluable subjects did not appear to be associated with a variable in the dataset; for this DSIC it was calculated based on valid responses to the *agebase* variable, i.e., *age=nonmissing*.

3.1 Baseline Characteristics of Participants by Treatment Arm

The published and DSIC results for Table 1 of the publication are shown in Table B. The base Ns, means, medians, and *p* values for differences in baseline characteristics across study treatment arms as calculated by the DSIC closely match the published values. Slight differences between the DSIC and published values are highlighted in the text and noted by italics.

Baseline characteristics of study participants by treatment arm were similar. *P* values were calculated using Fisher exact tests and Kruskal-Wallis tests (ordinal data).

Table B: Baseline Characteristics of the Participants by Treatment Arm.

	Pontari et al. (2010)				DSIC calculations			
Characteristic	**Pregabalin Arm**	**Placebo Arm**	**Total**	***p***	**Pregabalin Arm**	**Placebo Arm**	**Total**	***p***
Randomized participants, no.	218	106	324		218	106	324	
Evaluable participants, no.	216	103	319		216	103	319	
Age, y				0.09				0.09
Mean (SD)	48 (13)	45.2 (12.2)	47 (13.1)		48 (13)	45.2 (12.2)	*47.1 (12.8)*	
Median (range	47 (21-78)	46 (19-76)	47 (19-78)		47 (21-78)	46 (19-76)	47 (19-78)	
Race, No (%)				0.17[a]				*0.08*[a]
North Amer. Indian/ North Native	1 (0.5)	3 (2.9)	4 (1.3)		1 (0.5)	3 (2.9)	4 (1.3)	
Asian/Asian Amer.	0	4 (3.9)	4 (1.3)		0	4 (3.9)	4 (1.3)	
Black	24 (11.1)	14 (13.6)	38 (11.9)		24 (11.1)	14 (13.6)	38 (11.9)	
Native Hawaiian/ other PI	0	1 (1.0)	1 (0.3)		0	1 (1.0)	1 (0.3)	
White	178 (82.4)	75 (72.8)	253 (79.3)		178 (82.4)	75 (72.8)	253 (79.3)	
Other	11 (5.1)	1 (1.0)	12 (3.8)		11 (5.1)	1 (1.0)	12 (3.8)	
Multirace	2 (1.0)	4 (3.9)	6 (1.9)		2 (1.0)	4 (3.9)	6 (1.9)	
Missing, No.	0	1 (1.0)	1 (0.3)		0	1 (1.0)	1 (0.3)	
Education level, No.				0.97				0.97
Less than high school	5 (2.3)	2 (1.9)	7 (2.2)		5 (2.3)	2 (1.9)	7 (2.2)	
HS/GED	30 (13.9)	17 (16.5)	47 (14.7)		30 (13.9)	17 (16.5)	47 (14.7)	
Some college	58 (26.9)	26 (25.2)	84 (26.3)		58 (26.9)	26 (25.2)	84 (26.3)	
Graduated college	78 (36.1)	35 (34)	113 (35.4)		78 (36.1)	35 (34)	113 (35.4)	
Graduate school	45 (20.8)	23 (22.3)	68 (21.3)		45 (20.8)	23 (22.3)	68 (21.3)	
Employment, No. (%)				0.25				0.25
Employed	166 (76.9)	74 (71.8)	240 (75.2)		166 (76.9)	74 (71.8)	240 (75.2)	
Unemployed	12 (5.6)	13 (12.6)	25 (7.8)		12 (5.6)	13 (12.6)	25 (7.8)	
Retired	27 (12.5)	11 (10.7)	38 (11.9)		27 (12.5)	11 (10.7)	38 (11.9)	

	Pontari et al. (2010)				DSIC calculations			
Full-time homemak	1 (0.5)	0	1 (0.3)		1 (0.5)	0	1 (0.3)	
Disabled	10 (4.6)	5 (4.9)	15 (4.7)		10 (4.6)	5 (4.9)	15 (4.7)	
Annual family income, No. (%)				0.70				0.70
<$10,000	12 (7.1)	7 (8.4)	19 (7.5)		12 (7.1)	7 (8.4)	19 (7.5)	
$10,000;$25,000	16 (9.4)	7 (8.4)	23 (9.1)		16 (9,4)	7 (8.4)	23 (9.1)	
$25,000-$50,000	29 (17.1)	19 (22.9)	48 (19)		29 (17.1)	19 (22.9)	48 (19)	
$50,001-$100,000	64 (37.6)	25 (30.1)	89 (35.2)		64 (37.6)	25 (30.1)	89 (35.2)	
>$100,000	49 (28.8)	25 (30.1)	74 (29.2)		49 (28.8)	25 (30.1)	74 (29.2)	
Missing	46	20	66		46	20	66	
Ever diagnosis of IC, CP, or CPPS, no. (%)				0.99				1
Yes	139 (64.4)	67 (64.4)	206 (64.4)		139 (64.4)	67 (64.4)	206 (64.4)	
No	77 (35.6)	37 (35.6)	114 (35.6)		77 (35.6)	37 (35.6)	114 (35.6)	
Years since first diagnosis				0.62				0.62
Mean (SD)	8.7 (9.5)	9.2 (9.2)	8.8 (9.4)		8.7 (9.5)	9.2 (9.2)	8.8 (9.4)	
Median (range)	5.2 (0.2-47.7)	6 (0-36.2)	5.3 (0-47.7)		5.2 (0.2-47.7)	6 (0-36.2)	5.3 (0-47.7)	
Missing, No.	78	37	115		78	37	115	
Years since first symptom began				0.87				0.87
Mean (SD)	10.3 (10.6)	9.9 (9.8)	10.2 (10.3)		10.3 (10.6)	9.9 (9.8)	10.2 (10.3)	
Median (range)	6.5 (0.5-48.7)	6.3 (0-40.8)	6.5 (0-48.7)		6.5 (0.5-48.7)	6.3 (0-40.8)	6.5 (0-48.7)	
Missing, No.	49	22	71		49	22	71	
Family ever diagnosis of IC/PBS				0.59				0.59
Yes	13 (7.8)	4 (4.9)	17 (6.8)		13 (7.8)	4 (4.9)	17 (6.8)	
No	154 (92.2)	78 (95.1)	232 (93.2)		154 (92.2)	78 (95.1)	232 (93.2)	
Missing, No.	49	21	70		49	21	70	
Family ever diagnosis of CP/CPPS				0.81				0.81

	Pontari et al. (2010)				DSIC calculations			
Yes	14 (8.3)	7 (9.3)	21 (8.6)		14 (8.3)	7 (9.3)	21 (8.6)	
No	155 (91.7)	68 (90.7)	233 (91.4)		155 (91.7)	68 (90.7)	233 (91.4)	
Missing, No.	47	28	75		47	28	75	
Participants with a baseline CPSI score, No	217	104	321		*216*	*103*	*319*	
NIH-CPSI total score				0.64				0.64
Mean (SD)	26.2 (5.6)	26 (6.1)	26.1 (5.7)		26.2 (5.6)	26 (6.1)	*26.1 (5.8)*	
Median (range)	25.5 (15-42.5)	25.5 (15-43)	25.5 (15-43)		*25.7 (15-42.5)*	25.5 (15-43)	25.5 (15 43)	
NIH-CPSI pain subscore				0.96				0.96
Mean (SD)	12.3 (3)	12.4 (3.1)	12.4 (3)		12.3 (3)	12.4 (3.2)	12.4 (3)	
Median (range)	12.5 (4-20.5)	12 (6-21)	12 (4-21)		12.5 (4-20.5)	12 (6-21)	12 (4-21)	
NIH-CPSI urinary symptom sub score				0.35				0.41
Mean (SD)	4.9 (2.7)	4.7 (2.7)	4.8 (2.7)		4.9 (2.7)	4.7 (2.7)	4.8 (2.7)	
Median (range)	5 (0-10)	4.5 (0-10)	5 (0-10)		5 (0-10)	4.5 (0-10)	5 (0-10)	
NIH-CPSI QOL subscore				0.64				0.69
Mean (SD)	8.9 (2)	8.9 (2)	8.9 (2)		8.9 (2)	8.9 (2)	8.9 (2)	
Median (range)	9 (4-12)	9 (5-12)	9 (4-12)		9 (4-12)	9 (5-12)	9 (4-12)	
SF-12 PCS score				0.51				0.5
Mean (SD)	44.9 (10.1)	43.9 (10.3)	44.6 (10.2)		44.9 (10.1)	43.9 (10.3)	*44.5 (10.2)*	
Median (range)	46.9 (17.9-64.3)	44.4 (20-60.1)	46.1 (17.9-64.3)		46.9 (17.9-64.3)	*44.1 (20-60.1)*	*45.8 (17.9-64.3)*	
Missing, No.	3	1	4		3	1	4	
SF-12 MCS score				0.43				0.45
Mean (SD)	41.8 (10.6)	42.8 (10.6)	42.1 (10.6)		41.8 (10.6)	*42.7 (10.6)*	42.1 (10.6)	
Median (range)	41.3(12.2-61.2)	44.1(18-62)	42.2(12.2-62)		*41.2 (12.2-61.2)*	44.1(18-62)	42.2 (12.2-62)	
Missing, No.	3	1	4		3	1	4	

CP/CPPS = chronic prostatitis/chronic pelvic pain syndrome
GED = General Educational Development
IC = Interstitial cystitis

MCS = Mental Component Summary
NIH-CPSI = National Institutes of Health Chronic Prostatitis Symptom Index
PBS = painful bladder syndrome
PCS = Physical Component Summary
QOL = Quality of Life
SF-12 = 12-item Short Form Health Survey
[a] Based on a comparison of the proportion of white versus nonwhite participants.
Note: Published results from Pontari et al. (2010) Arch Intern Med 170(17):1587-88.

3.2 Dose Titration by Treatment Arm

All participants were included in the intent-to-treat analysis. Table C contains the published and DSIC results for Table 2, Medication adherence by treatment group.

Capsule count adherence rates were similar between the two treatment arms. Our DSIC estimates matched exactly the published results for Table 2.

Table C: Dose Titration by Treatment Arm.

Variable	Pontari et al. (2010) Participants, No. (%) Pregabalin Arm (n=218)	Pontari et al. (2010) Participants, No. (%) Placebo Arm (n=106)	Pontari et al. (2010) Participants, No. (%) Total (n=324)	DSIC Calculations Participants, No. (%) Pregabalin Arm (n=218)	DSIC Calculations Participants, No. (%) Placebo Arm (n=106)	DSIC Calculations Participants, No. (%) Total (n=324)
Maximum dosage, mg/d						
150	14 (6.4)	6 (5.7)	20 (6.2)	14 (6.4)	6 (5.7)	20 (6.2)
300	39 (17.9)	12 (11.3)	51 (15.7)	39 (17.9)	12 (11.3)	51 (15.7)
600	154 (70.6)	82 (77.4)	236 (72.8)	154 (70.6)	82 (77.4)	236 (72.8)
Never took study drug	11 (5)	6 (5.7)	17 (5.2)	11 (5)	6 (5.7)	17 (5.2)
Dosage at primary end point, mg/d						
150	36 (17.1)	14 (13.6)	50 (16)	36 (17.1)	14 (13.6)	50 (16)
300	32 (15.2)	12 (11.7)	44 (14.1)	32 (15.2)	12 (11.7)	44 (14.1)
600	122 (58.1)	68 (66)	190 (60.7)	122 (58.1)	68 (66)	190 (60.7)
Not taking study drug	20 (9.5)	9 (8.7)	29 (9.3)	20 (9.5)	9 (8.7)	29 (9.3)
Missing/unknown	8	3	11	8	3	11

Note: Published results from Pontari et al. (2010) Arch Intern Med 170(17):1590.

3.3 Primary Outcome

The study's primary outcome was a response rate for the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) and was based on a decline in the total index score of $\geq$6 points at 6 weeks; a high score indicates more severe symptoms (total possible score of 0 to 43). The NIH-CPSI measures three key domains of chronic prostatitis: pain (total possible score of 0 to 21), urinary symptoms (possible score, 0 to 10), and quality of life (possible score, 0 to 12).

3.4 Secondary Outcomes

Secondary measures that were assessed included the Global Response Assessment (GRA), a 7-point self-reported assessment of change in symptoms. Men who reported a moderate or markedly improved change in symptoms at the end of the study were identified as treatment responders (the final count includes 3 men in the placebo group and 8 in the pregabalin group who withdrew early from the study). Other measures included the NIH-CPSI subscores (pain, urinary symptoms, quality of life); the McGill Pain Questionnaire scores (higher scores indicate greater pain); the Medical Outcomes Study 12-item Short Form Health Survey (SF-12, higher scores indicate better quality of life. Score ranges for both the physical and mental component summaries is 0 to 100); the Hospital Anxiety and Depression Scale (range 0 to 42 with higher scores indicating greater anxiety and depression); and the Sexual Health Inventory for Men (SHIM, range 1 to 25 with higher scores indicating better sexual function).

3.5 Primary and Secondary Outcome Measures at Baseline and 6 weeks and Differences in Change Across Time by Treatment Arm

Table D contains the published and DSIC results for Table 4. Tabulations provide estimates of change at 6 weeks in each primary and secondary outcome measure by treatment arm, the pooled rate difference by treatment arm, and the 95% CI for the rate difference. The DSIC Ns and percentages for each outcome by treatment match exactly the published results.

Note: P values for the differences in change between the pregabalin and placebo groups were not presented in the DSIC. The manuscript calculated the pooled rate differences and the 95% CI for the rate difference using the 'metan' routine in Stata to adjust for differences across clinical centers. The metan routine was not available for this DSIC analysis; however, a t-test procedure in Stata was used to test for mean differences across treatment groups. The p values estimated by the t-test procedure were similar to the published results.

Table D: **Primary and Secondary Outcome Measures at Baseline and 6 weeks and Differences in Change Across Time by Treatment Arm.**

Outcome Measure	Pontari et al. (2010)					DSIC Calculation	
Primary Outcome	Baseline		6 Wk				
NIH-CPSI responder rate (≥6-point decline)	Pregabalin Arm	Placebo Arm	Pregabalin Arm	Placebo Arm	Differences in Change, Pregabalin-Placebo, N (95% CI)		Differences in Change, Pregabalin-Placebo, N (95% CI)
No./total No. (%)							
Secondary Outcom□s							
GRA responder rate, No/total (%)	NA	NA	103/218 (47.2)	38/106 (35.8)	10.9 (-0 to 21.8)	*Note: □SIC*	10.9 (-□ t□ 21.8)
NIH-CPSI score, mean(SD)					□	*baseline*	
Total	NA	NA	8/218 (31.2)	20/□06 (18.9)	12 (2.6 to 21.5)	*and 6 week*	12 (2.6 to 21.5)
Pain domain						*Calculations*	
Urin.symp.domain	26.2 (5.6)	25.9 (6.1)	19.7 (8.5)	21.6 (8.9)	-2.4 (-4.1 to -0.6)	*match*	-2.4 (-4.1 to -0.6)
QOL domain	12.3 (3)	12.4 (3.1)	9.1 (4.6)	10.1 (4.7)	-1 (-2 to -0.04)	*published*	-1 (-2 to -0.04)
HADS score, mean (SD)	4.9 (2.7)	4.7 (2.7)	3.7 (2.6)	4 (2.7)	-0.7 (-1.2 to -0.2)	*tabulations*	-0.7 (-1.2 to -0.2)
IIEF-SHIM score, mean (SD)	8.9 (2)	8.9 (2)	6.9 (2.9)	7.4 (3.1)	-0.7 (-2 to -0.1)	*exactly*	-0.7 (-2 to -0.1)
McGill Pain score, mean (SD)	14.8 (7.5)	14.1 (7.3)	12.4 (7.8)	12.2 (7.8)	).7 (-2 to 0.7)		*6 (-2 to 0.7)*
MOS SF-12 score, mean (SD)	16.9 (7.9)	17.4 (7.1)	16.4 (8.4)	17.2 (7.8)	-0.6 (-2.1 to 0.9)		*-0.5 (-2.0 to 1.0)*
PCS	13.8 (8.7)	14.1 (8.5)	9.6 (8.8)	12.4 (9.1)	-2.3 (-4 to -0.7)		*-2.3 (-4 to -0.6)*
MCS							
	44.9 (10.1)	43.9 (10.3)	46.9 (10.1)	44.3 (10.6)	1.3 (-0.5 to 3.2)		1.3 (-0.5 to 3.2)

Note: Published results from Pontari et al. (2010) Arch Intern Med 170(17):1591.

3.6 Summary.

Our DSIC analyses using archived data for the baseline measurements and the primary and secondary outcomes as presented in Tables 1, 2, and 4 of Pontari et al. (2010) closely agree with the published values.

In Tables B and C, we compare the results calculated from the archived data file to the results published in Dixon et al.'s Table 1, Baseline Characteristics of the Patients, According to Study Group. As the tables show, the results of the replication are similar to published results.

Attachment 1: Stata code for DSIC analysis of Tables 1, 2, and 4 from (Pontari et al., 2010)

```
*****CPCRN2-Pregabalin
**Reproduce tabulations in Pontari et al. (2010) Pregabalin for the treatment of men with
*chronic prostatitis-chronic pelvic pain syndrome
*use cp02_long.dta

***Table 1. Baseline characteristics of the participants by treatment arm
tab arm
codebook age
tabstat age, by (arm) stat (mean sd min max median)
**select 'evaluable participants' (based on non-missing age?)
recode age (.=0)
keep if age >0
tabstat age, by (arm) stat (mean sd min max median)
label define race 1"indian" 2"asian" 3"black" 4"pi" 5"white" 6"other" 7"multi"
label values race race
tab race arm, col chi2 missing
recode race (1/4=1) (5=2) (6/7=1), gen recrace
tab recrace arm, col exact
label define educ 1"<hs" 2"hs" 3"some coll" 4"coll grad" 5"grad+"
label values educ educ
tab educ arm, col exact
label define employ 1"emp" 2"unemp" 3"ret" 4"FT home" 5"disabled"
label values employ employ
tab employ arm, col exact
label define income 1"<10" 2"10-25" 3"25-50" 4"50-100" 5">100"
label values income income
tab income arm, col exact
codebook income
tab hxdiag arm, col exact
tabstat diagdur, by (arm) stat (mean sd min max median)
tabstat sympdur, by (arm) stat (mean sd min max median)
kwallis diagdur, by(arm)
kwallis sympdur, by(arm)
tab fmdiagic arm, col exact
codebook diagdur sympdur fmdiagic if arm=="A"
codebook diagdur sympdur fmdiagic if arm=="B"
tab fmdiagcp arm, col exact
codebook fmdiagcp cpsibase if arm=="A"
codebook fmdiagcp cpsibase if arm=="B"
tabstat cpsibase, by (arm) stat (mean sd min max median)
kwallis cpsibase, by(arm)
tabstat painbase, by (arm) stat (mean sd min max median)
kwallis painbase, by(arm)
tabstat uribase, by (arm) stat (mean sd min max median)
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kwallis uribase, by(arm)
tabstat qolbase, by (arm) stat (mean sd min max median)
kwallis qolbase, by(arm)
tabstat pcs12_v2, by (arm) stat (mean sd min max median)
tabstat mcs12_v2, by (arm) stat (mean sd min max median)
codebook pcs12_v2 mcs12_v2 if arm=="A"
codebook pcs12_v2 mcs12_v2 if arm=="B"
kwallis pcs12_v2, by(arm)
kwallis mcs12_v2, by(arm)

clear
use "C:\Documents and Settings\smr\My
Documents\CPCRN\CPCRN2_Pregabalin_FinalPacket\data\cp02_long.dta", clear
**Table 2. Dose titration by treatment arm
tab maxdosep1 arm, col
tab maxdosepe arm, col
tab maxdosepe arm, missing

***Table 4. Primary and secondary outcome measures at baseline
**and 6 weeks and differences in change across time by arm
tab graresp5 arm, col
tab cpsi6ptdrop6wk arm, col

***tabulate baseline measures not included in Table 1
tab arm summarize (had15_v2) mean standard
tab arm summarize (iief_shim_v2) mean standard
tab arm summarize (mcgill_total_v2) mean standard

***tabulate 6 wk measures by arm
tabulate arm, summarize (cpsiv5) mean standard
tabulate arm, summarize (painv5) mean standard
tabulate arm, summarize (uriv5) mean standard
tabulate arm, summarize (qolv5) mean standard
tabulate arm, summarize(had15_v5) mean standard
tabulate arm, summarize(iief_shim_v5) mean standard
tabulate arm, summarize(mcgill_total_v5) mean standard
tabulate arm, summarize(mcs12_v5) mean standard
tabulate arm, summarize(pcs12_v5) mean standard

**calculate difference in mean change by arm
ttest cpsicgv5, by(arm)
ttest paincgv5, by(arm)
ttest uricgv5, by(arm)
ttest qolcgv5, by(arm)
ttest had15_6wkcng, by(arm)
ttest iief_shim_6wkcng, by(arm)
ttest mcs12_6wkcng, by(arm)
ttest pcs12_6wkcng, by(arm)
ttest mcgill_total_6wkcng, by(arm)
```

Attachment 2: Article Text

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