Dataset Integrity Check for the FDTT Data Files

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Contents

1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is 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 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, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus 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. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

Antidepressants are frequently prescribed to treat functional dyspepsia (FD), a common disorder characterized by upper abdominal symptoms, including discomfort or postprandial fullness. However, there is little evidence of the efficacy of these drugs in patients with FD. This study performed a randomized, double-blind, placebo-controlled trial to evaluate the effects of antidepressant therapy on symptoms, gastric emptying (GE), and meal-induced satiety in patients with FD.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the “Data” folder in the data package. For this replication, variables were taken from those datasets only.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by The FDTT Research Group in Gastroenterology, August 2015. To verify the integrity of the datasets, tables from the paper were checked (Tables 2)

5 Results

Table 2 in the publication [1], Subject Characteristics (n=292). Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data files to the results published in Table 2. The results of the replication are very similar to published results.

Table 3 in the publication [1], Daily Diary Scores and Nepean Dyspepsia Index Functional Dyspepsia-Specific Quality of Life. Table C lists the variables that were used in the replication and Table D compares the results calculated from the archived data files to the results published in Table 2. The results of the replication are similar to published results, with some typos in quality of life figures.

6 Conclusions

The NIDDK repository are confident that the FDTT data files to be distributed are a copy of the manuscript data with only small discrepancies.

7 References

[1] Effect of Amitriptyline and Escitalopram on Functional Dyspepsia: A Multicenter, Randomized Controlled Study Talley Nicholas J, Locke G. Richard, Saito Yuri A, Almazar Ann E, Bouras Ernest P, Howden Colin W, Lacy Brian E, DiBaise John K, Prather Charlene M, Abraham Bincy P, El-Serag Hashem B, Moayyedi Paul, Herrick Linda M, Szarka Lawrence A, Camilleri Michael, Hamilton Frank A, Schleck Cathy D, Tilkes Katherine E, Zinsmeister Alan R; Gastoenterology. 2015 Augl;149(2):340-349. doi: /10.1053/j.gastro.2015.04.020. Epub 2015 Apr 25.

Table A: Variables used to replicate Table 2. Subject Characteristics (n=292)

Characteristic	File.Variable(s)
Age, y, mean (SD)	Primary_outcome.age_rand
Female, n (%)	Primary_outcome.Gender
Caucasian, n (%)	Primary_outcome.raceCNC
Body mass index, mean (SD)	Primary_outcome.bmi
HADS score, mean (SD)	
HADS depression	Card13.v13_21, v13_23, v13_24, v13_26, v13_29, v13_31, v13_33 For card13.visit = 1
HADS anxiety	Card13.v13_20, v13_22, v13_25, v13_27, v13_28, v13_30, v13_32 For card13.visit = 1
Dyspepsia subtype, n (%)	Primary_outcome. Dyspepsia_Subtype
Delayed GE, n (%)	Primary_outcome.Gastric_emptying
Abnormal satiety, n (%)	Primary_outcome.Satiety
Helicobacter pylori antibody positive, n (%)	Primary_outcome.HPpositive
Baseline PPI use, n (%)	Card3.visit=1, 1.01 <= Card3.v3_20 <=1.07

Table B: Comparison of values computed in integrity check to reference article Table 2 values

Characteristic	Manuscript Placebo (N = 97)	DSIC Placebo (N = 97)	Manuscript Amitriptyline (N=97)	DSIC Amitriptyline (N=97)	Manuscript Escitalopram (N=98)	DSIC Escitalopram (N=98)
Age, y, mean (SD)	45 (16)	45 (16)	43 (15)	43 (15)	45 (15)	45 (15)
Female, n (%)	73 (75)	73 (75)	72 (74)	72 (74)	74 (76)	74 (76)
Caucasian, n (%)	83 (86)	81 (84)	82 (85)	82 (85)	85 (87)	82 (84)
Body mass index, mean (SD)	26.4 (5.2)	26.4	25.7 (6.0)	25.7 (6.0)	26.1 (5.6)	26.1 (5.6)
HADS score, mean (SD)						
HADS depression	3.1 (2.9)	3.1 (2.9)	3.1 (2.7)	3.1 (2.7)	3.1 (2.7)	3.1 (2.7)
HADS anxiety	5.0 (3.8)	5.0 (3.8)	5.2 (3.2)	5.2 (3.2)	5.4 (3.8)	5.4 (3.8)
Dyspepsia subtype, n (%)						
Dysmotility-like	69 (71)	69 (71)	67 (69)	67 (69)	68 (69)	68 (69)
Ulcer-like	28 (29)	28 (29)	30 (31)	30 (31)	30 (31)	30 (31)
Delayed GE, n (%)	20 (21)	20 (21)	20 (21)	20 (21)	21 (21)	21 (21)
Abnormal satiety, n (%)	55 (57)	55 (57)	55 (57)	55 (57)	55 (56)	55 (56)
Helicobacter pylori antibody positive, n (%)	9/92 (10)	9/92 (10)	14/96 (15)	14/96 (15)	17/94 (18)	17/94 (18)
Baseline PPI use, n (%)	18 (19)	18 (19)	27 (28)	27 (28)	23 (23)	23(23)

Table C: Variables used to replicate Table 3. Daily Diary Scores and Nepean Dyspepsia Index Functional Dyspepsia – Specific Quality of Life

Characteristic	File.Variable(s)		
	Baseline	**Post treatment**	**Delta**
Placebo/ Amitriptyline/ Escitalopram	PO.treatment	PO.treatment	PO.treatment
Diary			
Upper abdominal pain	PO.mnv2820base	PO.mnv2820post	mnv2820post-mnv2820base
Nausea	PO.mnv2821base	PO.mnv2821post	mnv2821post-mnv2821base
Bloating	PO.mnv2822base	PO.mnv2822post	mnv2822post-mnv2822base
Fullness	PO.mnv2823base	PO.mnv2823post	mnv2823post-mnv2823base
Early Satiety	PO.mnv2824base	PO.mnv2824post	mnv2824post-mnv2824base
NDI overall quality of life	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Interference	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Knowledge/control	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Eat/drink	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Sleep disturbance	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Work/study	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
NDI mean symptom score	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Abdominal pain	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6
Postprandial distress	Card15, visit=1 Calculated field with details in SAS code in Attachment A.	Card15, visit=6 Calculated field with details in SAS code in Attachment A.	Card15 Visit=1-Card 15 Visit=6

PO = primary_outcome

*For the NDI variables, there are multiple calculations to get to the final number. Details can be seen in the SAS code in Attachment A, or in the separate document NDI scoring code.docx from the DCC

Table D: Comparison of values computed in integrity check to reference article Table 3 values

Characteristic	Baseline Manuscript	Baseline DSIC	Baseline Diff
Placebo (PO.treatment=1)			
Diary			
Upper abdominal pain	1.6 (1.4 to 1.8)	1.6 (1.4 to 1.8)	0 (0 to 0)
Nausea	1.2 (1.0 to 1.4)	1.2 (0.9 to 1.4)	0 (0.1 to 0)
Bloating	1.4 (1.2 to 1.6)	1.4 (1.2 to 1.6)	0 (0 to 0)
Fullness	1.5 (1.3 to 1.7)	1.5 (1.3 to 1.7)	0 (0 to 0)
Early Satiety	1.4 (1.2 to 1.6)	1.4 (1.2 to 1.6)	0 (0 to 0)
NDI overall quality of life	63.6 (58.9 to 68.2)	63.3 (59.1 to 67.5)	0.3 (-0.2 to 0.7)
Interference	68.0 (62.8 to 73.1)	68.3 (63.6 to 72.9)	-0.3 (-0.8 to 0.2)
Knowledge/control	62.9 (58.1 to 67.8)	63.2 (58.7 to 67.6)	-0.3 (-0.6 to 0.2)
Eat/drink	52.2 (45.6 to 58.9)	52.2 (46.2 to 58.2)	0 (-0.6 to 0.7)
Sleep disturbance	67.3 (60.8 to 73.8)	65.9 (59.9 to 71.9)	1.4 (0.9 to 1.9)
Work/study	68.8 (63.0 to 74.6)	68.3 (63.0 to 73.6)	0.5 (0 to 1)
NDI mean symptom score	8.5 (8.1 to 9.0)	8.6 (8.2 to 9.0)	-0.1 (-0.1 to 0)
Abdominal pain	32.2 (29.9 to 34.4)	31.9 (29.9 to 33.9)	0.3 (0 to 0.5)
Postprandial distress	13.6 (12.0 to 15.3)	14.0 (12.5 to 15.5)	-0.4 (-0.5 to -0.2)
Amitriptyline (PO.treatment=2)			
Diary			
Upper abdominal pain	1.6 (1.4 to 1.8)	1.6 (1.4 to 1.8)	0 (0 to 0)
Nausea	1.1 (0.9 to 1.3)	1.1 (0.9 to 1.3)	0 (0 to 0)
Bloating	1.7 (1.5 to 1.9)	1.7 (1.5 to 1.9)	0 (0 to 0)
Fullness	1.5 (1.3 to 1.7)	1.5 (1.3 to 1.7)	0 (0 to 0)
Early Satiety	1.4 (1.2 to 1.7)	1.4 (1.2 to 1.7)	0 (0 to 0)
NDI overall quality of life	63.7 (59.0 to 68.3)	62.5 (58.1 to 66.8)	1.2 (0.9 to 1.5)
Interference	69.5 (64.5 to 74.5)	68.0 (63.3 to 72.7)	1.5 (1.2 to 1.8)
Knowledge/control	62.4 (57.4 to 67.4)	61.5 (56.8 to 66.2)	0.9 (0.6 to 1.2)
Eat/drink	49.1 (43.0 to 55.2)	48.5 (43.0 to 54.1)	0.6 (0 to 1.1)
Sleep disturbance	67.6 (61.2 to 74.1)	65.8 (59.8 to 71.7)	1.8 (1.4 to 2.4)
Work/study	70.1 (64.6 to 75.5)	68.7 (63.4 to 73.9)	1.4 (1.2 to 1.6)
NDI mean symptom score	8.0 (7.6 to 8.5)	8.0 (7.6 to 8.4)	0 (0 to 0.1)
Abdominal pain	29.4 (27.3 to 31.6)	29.4 (27.4 to 31.4)	0 (-0.1 to 0.2)
Postprandial distress	12.8 (11.3 to 14.4)	13.1 (11.7 to 14.5)	-0.3 (-0.4 to -0.1)
Escitalopram (PO.treatment=3)			
Diary			
Upper abdominal pain	1.7 (1.6 to 1.9)	1.7 (1.6 to 1.9)	0 (0 to 0)
Nausea	1.1 (0.8 to 1.3)	1.1 (0.8 to 1.3)	0 (0 to 0)
Bloating	1.8 (1.6 to 2.0)	1.8 (1.6 to 2.0)	0 (0 to 0)
Fullness	1.7 (1.4 to 1.9)	1.7 (1.4 to 1.9)	0 (0 to 0)
Early Satiety	1.4 (1.2 to 1.7)	1.4 (1.2 to 1.7)	0 (0 to 0)
NDI overall quality of life	72.2 (67.1 to 77.3)	65.0 (60.5 to 69.4)	7.2 (6.6 to 7.9)
Interference	72.2 (67.1 to 77.3)	69.9 (64.9 to 74.9)	2.3 (2.2 to 2.4)
Knowledge/control	63.4 (58.2 to 68.6)	62.3 (57.5 to 67.1)	1.1 (0.7 to 1.5)
Eat/drink	53.3 (47.3 to 59.3)	50.9 (45.1 to 56.6)	2.4 (2.2 to 2.7)
Sleep disturbance	73.6 (67.9 to 79.2)	69.8 (64.4 to 75.3)	3.8 (3.5 to 3.9)

Characteristic	Baseline Manuscript	Baseline DSIC	Baseline Diff
Work/study	75.3 (69.9 to 80.8)	72.6 (67.3 to 77.9)	2.7 (2.6 to 2.9)
NDI mean symptom score	8.4 (7.9 to 8.9)	8.2 (7.8 to 8.7)	0.2 (0.1 to 0.2)
Abdominal pain	31.6 (29.2 to 34.1)	31.0 (28.7 to 33.3)	0.6 (0.5 to 0.8)
Postprandial distress	13.1 (11.6 to 14.6)	12.8 (11.4 to 14.2)	0.3 (0.2 to 0.4)

Characteristic	Post treatment Manuscript	Post treatment DSIC	Post treatment Diff
Placebo (PO.treatment=1)			
Diary			
Upper abdominal pain	1.2 (1.0 to 1.4)	1.2 (1.0 to 1.4)	0 (0 to 0)
Nausea	0.8 (0.6 to 1.0)	0.8 (0.6 to 1.0)	0 (0 to 0)
Bloating	1.2 (1.0 to 1.4)	1.2 (1.0 to 1.4)	0 (0 to 0)
Fullness	1.2 (1.0 to 1.4)	1.2 (0.9 to 1.3)	0 (0.1 to 0.1)
Early Satiety	1.1 (0.9 to 1.3)	1.0 (0.8 to 1.2)	0.1 (0.1 to 0.1)
NDI overall quality of life	73.5 (69.1 to 77.8)	73.5 (69.1 to 77.8)	0 (0 to 0)
Interference	76.2 (70.9 to 81.5)	76.2 (71.0 to 81.4)	0 (-0.1 to 0.1)
Knowledge/control	72.9 (68.2 to77.6)	72.8 (68.1 to 77.4)	0.1 (0.1 to 0.2)
Eat/drink	64.8 (59.6 to 70.1)	64.8 (59.6 to 70.1)	0 (0 to 0)
Sleep disturbance	76.4 (70.9 to 81.8)	76.4 (70.9 to 81.8)	0 (0 to 0)
Work/study	79.7 (74.5 to 84.9)	79.7 (74.5 to 84.9)	0 (0 to 0)
NDI mean symptom score	9.6 (9.2 to 10.0)	9.6 (9.2 to 10.0)	0 (0 to 0)
Abdominal pain	36.3 (34.0 to 38.6)	36.3 (34.0 to 38.6)	0 (0 to 0)
Postprandial distress	15.8 (14.2 to 17.4)	15.8 (14.2 to 17.4)	0 (0 to 0)
Amitriptyline (PO.treatment=2)			
Diary			
Upper abdominal pain	1.6 (1.4 to 1.8)	1.1 (0.9 to 1.3)	0.5 (0.5 to 0.5)
Nausea	1.1 (0.9 to 1.3)	0.7 (0.5 to 0.9)	0.4 (0.4 to 0.4)
Bloating	1.7 (1.5 to 1.9)	1.2 (1.0 to 1.5)	0.5 (0.5 to 0.4)
Fullness	1.5 (1.3 to 1.7)	0.9 (0.7 to 1.1)	0.6 (0.6 to 0.6)
Early Satiety	1.4 (1.2 to 1.7)	0.8 (0.6 to 1.0)	0.6 (0.6 to 0.7)
NDI overall quality of life	80.6 (76.2 to 85.0)	80.1 (75.7 to 84.6)	0.5 (0.5 to 0.4)
Interference	83.2 (78.3 to 88.2)	82.8 (77.8 to 87.7)	0.4 (0.5 to 0.5)
Knowledge/control	78.2 (73.2 to 83.2)	77.8 (72.8 to 82.8)	0.4 (0.4 to 0.4)
Eat/drink	72.4 (66.7 to 78.0)	71.4 (65.6 to 77.2)	1 (1.1 to 0.8)
Sleep disturbance	86.3 (81.6 to 91.0)	85.9 (81.1 to 90.6)	0.4 (0.5 to 0.4)
Work/study	86.9 (82.6 to 91.1)	86.6 (82.3 to 90.9)	0.3 (0.3 to 0.2)
NDI mean symptom score	9.8 (9.3 to 10.2)	9.7 (9.3 to 10.2)	0.1 (0 to 0)
Abdominal pain	38.0 (35.6 to 40.4)	37.8 (35.4 to 40.2)	0.2 (0.2 to 0.2)
Postprandial distress	17.5 (16.0 to 18.9)	17.6 (16.1 to 19.0)	-0.1 (-0.1 to -0.1)
Escitalopram (PO.treatment=3)			
Diary			
Upper abdominal pain	1.7 (1.6 to 1.9)	1.4 (1.2 to 1.6)	0.3 (0.4 to 0.3)
Nausea	1.1 (0.8 to 1.3)	0.8 (0.6 to 1.1)	0.3 (0.2 to 0.2)
Bloating	1.8 (1.6 to 2.0)	1.3 (1.1 to 1.6)	0.5 (0.5 to 0.4)
Fullness	1.7 (1.4 to 1.9)	1.2 (1.0 to 1.5)	0.5 (0.4 to 0.4)
Early Satiety	1.4 (1.2 to 1.7)	1.1 (0.9 to 1.3)	0.3 (0.3 to 0.4)

Characteristic	Post treatment Manuscript	Post treatment DSIC	Post treatment Diff
NDI overall quality of life	82.8 (78.4 to 87.1)	78.9 (74.6 to 83.1)	3.9 (3.8 to 4)
Interference	82.8 (78.4 to 87.1)	82.8 (78.4 to 87.1)	0 (0 to 0)
Knowledge/control	76.2 (71.3 to 81.1)	76.2 (71.3 to 81.1)	0 (0 to 0)
Eat/drink	70.6 (65.4 to 75.6)	70.6 (65.4 to 75.8)	0 (0 to -0.2)
Sleep disturbance	80.8 (75.2 to 86.3)	80.8 (75.2 to 86.3)	0 (0 to 0)
Work/study	87.2 (83.5 to 90.9)	87.2 (83.4 to 90.9)	0 (0.1 to 0)
NDI mean symptom score	9.7 (9.3 to 10.2)	9.7 (9.3 to 10.2)	0 (0 to 0)
Abdominal pain	37.1 (34.8 to 39.4)	37.3 (35.0 to 39.5)	-0.2 (-0.2 to -0.1)
Postprandial distress	16.7 (15.1 to 18.4)	16.7 (15.1 to 18.4)	0 (0 to 0)

Characteristic	Delta Manuscript	Delta DSIC	Delta Diff
Placebo (PO.treatment=1)			
Diary			
Upper abdominal pain	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.2)	0 (0 to 0)
Nausea	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.2)	0 (0 to 0)
Bloating	-0.3 (-0.5 to -0.2)	-0.3 (-0.5 to -0.2)	0 (0 to 0)
Fullness	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.3)	0 (0 to 0.1)
Early Satiety	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.3)	0 (0 to 0.1)
NDI overall quality of life	9.9 (5.7 to 14.1)	9.9 (5.7 to 14.1)	0 (0 to 0)
Interference	8.2 (3.6 to 12.9)	8.2 (3.6 to 12.9)	0 (0 to 0)
Knowledge/control	10.0 (5.8 to 14.2)	10.0 (5.8 to 14.2)	0 (0 to 0)
Eat/drink	12.6 (6.8 to 18.4)	12.6 (6.8 to 18.4)	0 (0 to 0)
Sleep disturbance	9.0 (3.5 to 14.6)	9.0 (3.5 to 14.6)	0 (0 to 0)
Work/study	10.9 (5.3 to 16.6)	10.9 (5.3 to 16.6)	0 (0 to 0)
NDI mean symptom score	1.1 (0.7 to 1.4)	1.1 (0.7 to 1.4)	0 (0 to 0)
Abdominal pain	4.2 (2.2 to 6.2)	4.2 (2.2 to 6.2)	0 (0 to 0)
Postprandial distress	2.2 (1.0 to 3.3)	2.2 (1.0 to 3.3)	0 (0 to 0)
Amitriptyline (PO.treatment=2)			
Diary			
Upper abdominal pain	-0.6 (-0.8 to -0.4)	-0.6 (-0.8 to -0.4)	0 (0 to 0)
Nausea	-0.5 (-0.7 to -0.3)	-0.5 (-0.7 to -0.3)	0 (0 to 0)
Bloating	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.2)	0 (0 to 0)
Fullness	-0.7 (-0.8 to -0.5)	-0.7 (-0.8 to -0.5)	0 (0 to 0)
Early Satiety	-0.6 (-0.8 to -0.4)	-0.6 (-0.8 to -0.4)	0 (0 to 0)
NDI overall quality of life	16.9 (12.3 to 21.6)	16.1 (11.2 to 21.0)	0.8 (1.1 to 0.6)
Interference	13.7 (8.8 to 18.6)	12.9 (7.8 to 18.0)	0.8 (1 to 0.6)
Knowledge/control	15.8 (10.9 to 20.8)	15.1 (10.1 to 20.2)	0.7 (0.8 to 0.6)
Eat/drink	23.3 (16.9 to 29.70	22.6 (15.9 to 29.3)	0.7 (1 to 0.4)
Sleep disturbance	18.7 (12.2 to 25.2)	17.9 (11.2 to 24.5)	0.8 (1 to 0.7)
Work/study	16.7 (11.9 to 21.7)	16.2 (11.1 to 21.2)	0.5 (0.8 to 0.5)
NDI mean symptom score	1.7 (1.3 to 2.1)	1.7 (1.2 to 2.1)	0 (0.1 to 0)
Abdominal pain	8.6 (5.9 to 11.3)	8.2 (5.4 to 10.9)	0.4 (0.5 to 0.4)
Postprandial distress	4.7 (3.1 to 6.2)	4.7 (3.2 to 6.3)	0 (-0.1 to -0.1)
Escitalopram (PO.treatment=3)			
Diary			

Characteristic	Delta Manuscript	Delta DSIC	Delta Diff
Upper abdominal pain	-0.4 (-0.5 to -0.2)	-0.4 (-0.5 to -0.2)	0 (0 to 0)
Nausea	-0.2 (-0.4 to -0.0)	-0.2 (-0.4 to -0.0)	0 (0 to 0)
Bloating	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.2)	0 (0 to 0)
Fullness	-0.4 (-0.6 to -0.2)	-0.4 (-0.6 to -0.2)	0 (0 to 0)
Early Satiety	-0.3 (-0.5 to -0.1)	-0.3 (-0.5 to -0.1)	0 (0 to 0)
NDI overall quality of life	10.6 (5.5 to 15.6)	11.4 (6.9 to 15.9)	-0.8 (-1.4 to -0.3)
Interference	10.6 (5.5 to 15.6)	10.6 (5.5 to 15.6)	0 (0 to 0)
Knowledge/control	12.8 (7.6 to 18.0)	12.8 (7.6 to 18.0)	0 (0 to 0)
Eat/drink	17.3 (11.3 to 23.3)	17.3 (11.3 to 23.3)	0 (0 to 0)
Sleep disturbance	7.2 (1.6 to 12.8)	7.2 (1.6 to 12.8)	0 (0 to 0)
Work/study	11.9 (6.4 to 17.3)	11.9 (6.4 to 17.3)	0 (0 to 0)
NDI mean symptom score	1.3 (0.8 to 1.8)	1.3 (0.8 to 1.8)	0 (0 to 0)
Abdominal pain	5.5 (3.0 to 8.0)	5.5 (3.0 to 8.0)	0 (0 to 0)
Postprandial distress	3.6 (2.1 to 5.1)	3.6 (2.1 to 5.1)	0 (0 to 0)

Attachment A: SAS Code

```
%let fdtt = %sysfunc(getoption(sysin));
title "Program saved as: &FDTT.";
title2 "DSIC for FDTT files";

/*****************************************************************************************************************************
Programmer: Patty Griffin
Date: September 2015
Function/Notes: Check FDTT input files for DSIC (Tables 2 and 3)

Revised: Michael Spriggs
Date: December 2015
*****************************************************************************************************************************/

*** File containing macro for examining each dataset ***;
%include '/prj/niddk/ims_analysis/sas_macros/redaction_data_summary.edit.sas';
%include 'borrowed_macro.sas';

libname fdtt "/prj/niddk/ims_analysis/FDTT/private_orig_data/";

options nofmterr;

%global caser;
%let caser=TREATMENT_GRP;

*************;
*  Formats  *;
*************;
proc format;
  value treatment_fmt
    1 = "(1) Placebo"
    2 = "(2) Amitriptyline"
    3 = "(3) Escitalopram"
    ;


data primary_outcome ;
  set fdtt.primary_outcome ;
run;

proc contents data = primary_outcome varnum;
run;

proc sort data = primary_outcome;
  by site ptnum;
run;

proc freq data = primary_outcome;
  table treatment;
run;


data card13 ;
  set fdtt.card13;
```

```
  if visit = 1;         *screening;

  v13_21 = v13_21-1;    *adjust depression related questions/answers to 'points';
  v13_23 = v13_23-1;
  v13_24 = 4 - v13_24;
  v13_26 = 4 - v13_26;
  v13_29 = 4 - v13_29;
  v13_31 = v13_31-1;
  v13_33 = v13_33-1;

  v13_20 = 4 - v13_20;
  v13_22 = 4 - v13_22;
  v13_25 = v13_25-1;
  v13_27 = 4 - v13_27;
  v13_28 = 4 - v13_28;
  v13_30 = v13_30-1;
  v13_32 = 4 - v13_32;

  hads_depression = sum(v13_21, v13_23, v13_24, v13_26, v13_29, v13_31, v13_33);
  hads_anxiety = sum(v13_20, v13_22, v13_25, v13_27, v13_28, v13_30, v13_32);

  keep site ptnum visit hads_depression hads_anxiety;
run;

/*
proc contents data = card13 varnum;
run;

proc freq data = card13;
  table hads_depression hads_anxiety / list missing;
run;
*/

proc sort data = card13;
  by site ptnum;
run;

** Begin DCC Code: **;
data primary; set fdtt.primary_outcome;
   keep ptnum site treatment randomization_date;

data card__3; set fdtt.card3;
proc sort data=card__3; by site ptnum visitdt;
proc sort data=primary; by site ptnum;
data use; merge card__3(in=in1) primary(in=in2); by site ptnum;
   if in1 and in2;
run;

data ppi; set use;
   if 1.01 <= v3_20 <= 1.07;      ** PPI meds **;
   if visit=1;                              ** baseline visit **;
   tm_visit = visitdt - randomization_date;                        ** days from randomization date to first visit date **;
   if tm_visit < 0;                              ** since randomization occurs after the first visit, use those who are <= 0 days **;
   ppi=1;

proc sort data=ppi nodupkey; by site ptnum;
```

```
proc freq data=ppi; tables treatment*ppi / list missprint;
run;

**Confirm Numbers: ***;
data ppi; set ppi;
   keep site ptnum treatment ppi;
data check; merge primary(in=in1) ppi; by site ptnum;
   if in1;
   if ppi=. then ppi=0;
proc freq data=check; tables treatment * ppi / missprint;
run;
** End DCC Code: **;

data card3;       *medications - look for PPI use at baseline;
  set fdtt.card3;
  if visit in (1);   *screening ;

  if (v3_20 > 1 and v3_20 < 2 )  ;
  *keep site ptnum v3_20 visit ;
run;


proc sort data = card3 nodupkey;
  by site ptnum ;
run;

proc freq data = card3;
  table v3_20*visit;
run;

*proc print data =card3;
run;

data table2;
  merge primary_outcome(in=inprime) card13(in=in13) card3(in=in3) check;
  by site ptnum;
  if inprime;

  length treatment_grp $20.;

  treatment_grp = put(treatment, treatment_fmt.);

  if (1 < v3_20 < 2) then baseline_ppi_use = 1;
  else baseline_ppi_use = 0;

  keep site ptnum treatment treatment_grp age_rand Gender raceCNC bmi Dyspepsia_Subtype Gastric_Emptying
       Satiety  HPpositive hads_depression hads_anxiety baseline_ppi_use ppi;
run;

proc freq data = table2;
  table  treatment treatment_grp*(Gender raceCNC Dyspepsia_Subtype Gastric_Emptying Satiety ppi ) / missing;
run;

proc freq data = table2(where=(HPpositive ne .));
  table treatment_grp*HPpositive / missing;
run;
```

```
proc means data = table2  mean stddev;
        var age_rand bmi hads_depression hads_anxiety;
        class treatment_grp;
run;

**********************************************************************;

data table3;
  set primary_outcome;
  length treatment_grp $20.;

  treatment_grp = put(treatment, treatment_fmt.);

  delta2820 = mnv2820post-mnv2820base;
  delta2821 = mnv2821post-mnv2821base;
  delta2822 = mnv2822post-mnv2822base;
  delta2823 = mnv2823post-mnv2823base;
  delta2824 = mnv2824post-mnv2824base;


  keep site ptnum treatment treatment_grp mnv2820base mnv2821base mnv2822base mnv2823base mnv2824base
       mnv2820post mnv2821post mnv2822post mnv2823post mnv2824post delta2820 delta2821 delta2822
       delta2823 delta2824 ;
run;

proc means data=table3 mean clm ;
        var mnv2820base mnv2821base mnv2822base mnv2823base mnv2824base
            mnv2820post mnv2821post mnv2822post mnv2823post mnv2824post
            delta2820 delta2821 delta2822 delta2823 delta2824 ;
        class &caser;
run;

proc sort data = table3(keep=site ptnum treatment_grp);
  by site ptnum;
run;

*****Nepean Dyspepsia Index (NDI);

data card15 ;
  set fdtt.card15;
  if visit in (1,6);

  /* code provided by Dr. Zinsmeister for calculating fields related to the NDI */
  pnup=mean(of v15_20 v15_35 v15_50)*3.0;
  dscf=mean(of v15_21 v15_36 v15_51)*3.0;
  brnu=mean(of v15_22 v15_37 v15_52)*3.0;
  brnc=mean(of v15_23 v15_38 v15_53)*3.0;
  crmp=mean(of v15_24 v15_39 v15_54)*3.0;
  pnch=mean(of v15_25 v15_40 v15_55)*3.0;
  inab=mean(of v15_26 v15_41 v15_56)*3.0;
  bitr=mean(of v15_27 v15_42 v15_57)*3.0;
  fuln=mean(of v15_28 v15_43 v15_58)*3.0;
  prup=mean(of v15_29 v15_44 v15_59)*3.0;
  bltu=mean(of v15_30 v15_45 v15_60)*3.0;
  naus=mean(of v15_31 v15_46 v15_61)*3.0;
```

```
  burp=mean(of v15_32 v15_47 v15_62)*3.0;
  vomt=mean(of v15_33 v15_48 v15_63)*3.0;
  badb=mean(of v15_34 v15_49 v15_64)*3.0;

  if nmiss(of v15_65 v15_73 v15_74 v15_75 v15_76 v15_77 v15_78 v15_79 v15_80 v15_83 v15_84 v15_85 v15_89)>0 then interf=.;
  else interf=sum(of v15_65 v15_73 v15_74 v15_75 v15_76 v15_77 v15_78 v15_79 v15_80 v15_83 v15_84 v15_85 v15_89);

  if nmiss(of v15_66 v15_67 v15_81 v15_82 v15_86 v15_87 v15_88)>0 then know_c=.;
  else know_c=sum(of v15_66 v15_67 v15_81 v15_82 v15_86 v15_87 v15_88);

  if nmiss(of v15_68 v15_69 v15_70)>0 then eat_dk=.;
  else eat_dk=sum(of v15_68 v15_69 v15_70);

  if nmiss (of v15_71 v15_72)>0 then sleepd=.;
  else sleepd=sum(of v15_71 v15_72);

  if nmiss (of v15_73 v15_74 v15_85) >0 then wrkstdy=.;
  else wrkstdy=sum(of v15_73 v15_74 v15_85);

  abdp=sum(of pnup dscf brnu crmp);
  ppds=sum(of fuln inab);

  keep site ptnum visit pnup dscf brnu brnc crmp pnch inab bitr fuln prup bltu naus burp vomt badb interf know_c eat_dk sleepd
       wrkstdy abdp ppds;

run;

proc freq data = card15;
  table visit;
run;

proc sort data = card15;
  by site ptnum;
run;

data card15;
  merge card15(in=in1) table3(in=in3);
  by site ptnum;
  if in1 and in3;
run;

proc sort data = card15;
  by visit;
run;

proc means data = card15 noprint;
  by visit;
  var interf know_c eat_dk sleepd wrkstdy;
  output out=temp min=min1-min5 max=max1-max5;
run;

data card15;
  merge card15 temp;
  by visit;
   /* code provided by Dr. Zinsmeister for calculating fields related to the NDI */
```

```
  interf=100*(interf-min1)/(max1-min1);
  know_c=100*(know_c-min2)/(max2-min2);
  eat_dk=100*(eat_dk-min3)/(max3-min3);
  sleepd=100*(sleepd-min4)/(max4-min4);
  wrkstdy=100*(wrkstdy-min5)/(max5-min5);
  symptoms=mean(of pnup--badb);
  *Reverse scales;
  if interf ne . then interf=100-interf;
  if know_c ne . then know_c=100-know_c;
  if eat_dk ne . then eat_dk=100-eat_dk;
  if sleepd ne . then sleepd=100-sleepd;
  if wrkstdy ne . then wrkstdy=100-wrkstdy;
  if abdp ne . then abdp=52-abdp;
  if ppds ne . then ppds=26-ppds;
  ovrall_qol=sum(of interf know_c eat_dk sleepd wrkstdy)/5;
  symptoms=13-symptoms;

run;

proc sort data = card15;
  by visit &caser;
run;

proc means data = card15 mean  clm maxdec=1;
  by visit &caser;
  var ovrall_qol interf know_c eat_dk sleepd wrkstdy symptoms abdp ppds;
run;

proc sort data =card15;
  by site ptnum visit;
run;

data ndi (drop=visit);
  set card15;
  by site ptnum visit;
  retain ovrall_qol_pre interf_pre know_c_pre eat_dk_pre sleepd_pre wrkstdy_pre symptoms_pre abdp_pre ppds_pre;

  if visit = 1 then do;
    ovrall_qol_pre = ovrall_qol;
    interf_pre = interf;
    know_c_pre = know_c;
    eat_dk_pre = eat_dk;
    sleepd_pre = sleepd;
    wrkstdy_pre = wrkstdy;
    symptoms_pre = symptoms;
    abdp_pre = abdp;
    ppds_pre = ppds ;
    end;
  else if visit = 6 then do;
    ovrall_qol_d= ovrall_qol - ovrall_qol_pre;
    interf_d= interf - interf_pre;
    know_c_d= know_c - know_c_pre ;
    eat_dk_d= eat_dk - eat_dk_pre ;
    sleepd_d= sleepd - sleepd_pre ;
    wrkstdy_d= wrkstdy - wrkstdy_pre;
    symptoms_d= symptoms - symptoms_pre ;
```

```
    abdp_d= abdp - abdp_pre ;
    ppds_d= ppds - ppds_pre ;
    end;

  if last.ptnum then output;

run;

*proc print data = ndi;

proc sort data = ndi;
  by &caser;
run;

proc means data = ndi mean  clm maxdec=1;
  by  &caser;
  var ovrall_qol_d interf_d know_c_d eat_dk_d sleepd_d wrkstdy_d symptoms_d abdp_d ppds_d;
  title3 'Table 3 Deltas';
run;
```