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Dataset Integrity Check (DSIC)
for the PRIDE Study Data Files

Reference paper:
Subak L, et al., NEJM 360(5) [2009 Jan 29]: 481-90.

The Program to Reduce Incontinence by Diet and Exercise (PRIDE) Study is a randomized controlled clinical trial designed to compare incontinence improvement between groups randomized to a weight reduction program versus control, among obese or overweight women with urinary incontinence. As a partial check of the integrity of the PRIDE baseline survey dataset archived in the NIDDK data repository, a dataset integrity check (DSIC) was performed to verify that selected published results from the PRIDE study can be reproduced using the archived dataset. The DSIC consists of a small number of analyses performed to duplicate published results reported by the PRIDE Study Group [1] in *NEJM* in January 2009. Results of the DSIC are described below.

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 on a first 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, 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. We do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, *unless staff of the NIDDK Repository 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 the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

Archived Datasets Contents. The DCC submitted a dataset called “full0_18nih.sas7bdat” which represents data collected from the raw intake forms. The dataset “sae0_18.sas7bdat” represents data collected on severe adverse events. The dataset “willpay.sas7bdat” represents income data collected from participants.

DSIC Analysis Methods. A portion of published results was replicated to ensure integrity of archived datasets.

Baseline demographic and clinical characteristics were compared between randomization groups, adjusting for “wave” of randomization into the study (one control group and two weight-loss groups). Means, standard deviations, and frequencies calculated from archived data were compared to published results.

Mean levels of outcomes (body weight, number of urinary-incontinence episodes of any type, number of stress episodes, number of urge episodes) were calculated at baseline and at 6-mo by treatment group, and compared to published results.

Percent change in body weight and percent change in incontinence measures were also calculated by treatment group and compared to published results. If a percent change measure calculated using archived data was highly skewed, the corresponding median was also calculated and reported. Medians, however, were not reported in the publication. Also, it was not clear how published confidence intervals for percent change were calculated, so these were not generated using archived data.

The effects of treatment on the percentage change in weight from baseline to 6 months were assessed using linear mixed models, adjusted for site, as indicated in the publication methods.

Generalized estimating equations with negative binomial models were used to assess the effects of treatment on the frequency of incontinence, adjusting for clinical site and considering baseline and 6-month outcomes as repeated measures. Treatment effects were assessed by fitting an interaction term between treatment and time into the model. *P*-values from interaction terms were compared to reported *P*-values on treatment effects.

The publication states that multiple imputation methods were used to impute missing weight data at 6 months, as well as incontinence frequency at 6 months, and pad weight for participants in both groups. No multiple imputations were performed for the purposes of this DSIC, so results of archived analyses using 6-month data are expected to differ slightly from published results.

All statistical analyses were conducted using *SAS version 9.2 (Cary, NC)*.

DSIC Results: Demographics. Total counts and counts by treatment group in the archived dataset matched published counts (338 women overall, 226 in the weight-loss group and 112 in the control group). Distributions of baseline demographic and clinical characteristics closely matched published breakdowns; any difference could be attributable to rounding. [Table 1].

Table 1. Baseline Characteristics of the Participants according to Treatment Group*: Archived vs. Published Results
(published results extracted from Table 1 in Subak L, et al., NEJM 360(5) [2009 Jan 29]: 481-90*)*

	Total (N=338)			Weight-Loss Group (N=226)			Control Group (N=112)		
	Archived	Published	Difference	Archived	Published	Difference	Archived	Published	Difference
Age - yr	53 (10)	53 (11)	0 (1)	53 (11)	53 (11)	0 (0.0)	53 (10)	53 (10)	0 (0.0)
Race -- n (%)									
White	262 (77.5)	262 (77.5)	0 (0.0)	171 (75.7)	171 (75.7)	0 (0.0)	91 (81.2)	91 (81.2)	0 (0.0)
Black	64 (18.9)	64 (18.9)	0 (0.0)	47 (20.8)	47 (20.8)	0 (0.0)	17 (15.2)	17 (15.2)	0 (0.0)
Other	12 (3.6)	12 (3.6)	0 (0.0)	8 (3.5)	8 (3.5)	0 (0.0)	4 (3.5)	4 (3.6)	0 (0.1)
Education beyond H.S. -- n (%)	293 (86.7)	293 (86.7)	0 (0.0)	200 (88.5)	200 (88.5)	0 (0.0)	93 (83.0)	93 (83.0)	0 (0.0)
Relationship status -- n (%)									
Married or living with a partner	256 (75.7)	256 (75.7)	0 (0.0)	166 (73.5)	166 (73.5)	0 (0.0)	90 (80.4)	90 (80.4)	0 (0.0)
Single, widowed, or divorced	82 (24.3)	82 (24.3)	0 (0.0)	60 (26.5)	60 (26.5)	0 (0.0)	22 (19.6)	22 (19.6)	0 (0.0)
Body-mass index	36 (6)	36 (6)	0 (0)	36 (6)	36 (6)	0 (0)	36 (5)	36 (5)	0 (0)
Diabetes -- n (%)	10 (3.0)	10 (3.0)	0 (0.0)	9 (4.0)	9 (4.0)	0 (0.0)	1 (0.9)	1 (0.9)	0 (0.0)
Current smoker -- n (%)	18 (5.3)	18 (5.3)	0 (0.0)	14 (6.2)	14 (6.2)	0 (0.0)	4 (3.6)	4 (3.6)	0 (0.0)
Current alcohol use -- n (%)	228 (67.5)	228 (67.5)	0 (0.0)	154 (68.1)	154 (68.1)	0 (0.0)	74 (66.1)	74 (66.1)	0 (0.0)
Postmenopausal -- n/N (%)	177/316 (56.0)	177/316 (56.0)	0/0 (0.0)	115/209 (55.0)	115/209 (56.0)	0/0 (1.0)	62/107 (57.9)	62/107 (57.9)	0/0 (0.0)
Self-reported health status -- n (%)									
Excellent or very good	151 (44.7)	151 (44.7)	0 (0.0)	107 (47.3)	107 (47.3)	0 (0.0)	44 (39.3)	44 (39.3)	0 (0.0)
Good	150 (44.4)	150 (44.4)	0 (0.0)	99 (43.8)	99 (43.8)	0 (0.0)	51 (45.5)	51 (45.5)	0 (0.0)
Fair or poor	37 (10.9)	37 (10.9)	0 (0.0)	20 (8.8)	20 (8.8)	0 (0.0)	17 (15.2)	17 (15.2)	0 (0.0)
Hysterectomy -- n/N (%)	99/337 (29.4)	99/337 (29.4)	0/0 (0.0)	70/225 (31.1)	70/225 (31.1)	0/0 (0.0)	29/112 (25.9)	29/112 (25.9)	0/0 (0.0)
Parity	2 (1)	2 (1)	0 (0)	2 (1)	2 (1)	0 (0)	2 (1)	2 (1)	0 (0)

Type of urinary incontinence -- n (%)																
stress only	18	(5.3)	18	(5.3)	0	(0.0)	8	(3.5)	8	(3.5)	0	(0.0)	10	(8.9)	10	(8.9)	0	(0.0)
urge only	41	(12.1)	41	(12.1)	0	(0.0)	33	(14.6)	33	(14.6)	0	(0.0)	8	(7.1)	8	(7.1)	0	(0.0)
stress predominant	57	(16.9)	57	(16.9)	0	(0.0)	36	(15.9)	36	(15.9)	0	(0.0)	21	(18.8)	21	(18.8)	0	(0.0)
urge predominant	108	(32.0)	108	(32.0)	0	(0.0)	71	(31.4)	71	(31.4)	0	(0.0)	37	(33.0)	37	(33.0)	0	(0.0)
mixed incontinence with no predominant type	114	(33.7)	114	(33.7)	0	(0.0)	78	(34.5)	78	(34.5)	0	(0.0)	36	(32.1)	36	(32.1)	0	(0.0)
24-Hr involuntary urine loss** – g	33	(55)	33	(55)	0	(0)	33	(58)	32	(55)	-1	(-3)	34	(48)	33	(48)	-1	(0)

***** For both archived and published data: *P*-value>0.05 for the comparison between the weight-loss and control groups, for all variables listed in the table. Values are means(SD) unless otherwise indicated.

** As described in the publication, involuntary urine loss was measured by the 24-hour increase in pad weight.

DSIC Results: Analysis of Outcomes. Mean levels of outcomes (body weight, number of urinary-incontinence episodes of any type, number of stress episodes, number of urge episodes), calculated at baseline and at 6-mo by treatment group, were similar between archived and published data. Differences may be attributable to rounding error, and/or to the use of multiply-imputed datasets in published results. Mean percent change in body weight was similar in archive versus published data. However, differences in calculated mean percent change differed were more pronounced for measures of incontinence. For example, the mean percent change in stress incontinence episodes in the weight-loss group was -39% in archived data, -58% in published data. We suspect that a data transformation may have been applied to the measures of percent change in incontinence, as it is highly skewed. (Mean percent change was largely different from median percent change in incontinence episodes, as calculated in archived data.) [Table 2]

P-values of treatment effects on change in body weight and/or change in numbers of urinary-incontinence episodes were the same in archived versus published results, with the exception of the number of urge incontinence, where the p-value was 0.09 in archived data versus 0.14 in published data. This difference could be attributable to the use of multiply-imputed data for published results [Table 2].

Conclusion. With the replication of selected results, the analysis of archived data closely matches published results, allowing for rounding error and variations expected from analysis of multiply imputed data for published data. We are confident there were no errors in the transmission of archived datasets from the DCC to the Repository.

Table 2. Body Weight and Frequency of Urinary-Incontinence Episodes at Baseline and at 6 Months According to Treatment Group: Archived vs. Published Results

(published results extracted from Table 2 in Subak L, et al., NEJM 360(5) [2009 Jan 29]: 481-90*)*

	Weight-Loss Group (N=226)			Control Group (N=112)			*P*-value**	
	Archived	Published	Difference	Archived	Published	Difference	Archived	Published
Body weight							<.001	<.001
Baseline* -- kg	98 (17)	98 (17)	0 (0)	95 (16)	95 (16)	0 (0)		
6 Mo* -- kg	89 (17)	90 (17)	1 (0)	93 (16)	94 (17)	1 (1)		
Mean % Change	**-8.2**	**-8.0**	**0.2**	**-1.8**	**-1.6**	**0.2**		
Median† % Change	-8.4			-1.1				
Any incontinence							0.01	0.01
Baseline* – no./wk	24 (18)	24 (18)	0 (0)	24 (18)	24 (16)	0 (-2)		
6 Mo* – no./wk	13 (13)	13 (13)	0 (0)	16 (15)	17 (19)	1 (4)		
Mean % Change	**-42**	**-47**	**-5**	**-28**	**-28**	**0**		
Median† % Change	-60			-33				
Stress incontinence							0.01	0.01
Baseline* – no./wk	9 (11)	9 (11)	0 (0)	10 (10)	10 (10)	0 (0)		
6 Mo* – no./wk	4 (7)	4 (7)	0 (0)	7 (8)	7 (9)	0 (1)		
Mean % Change	**-39**	**-58**	**-19**	**-17**	**-33**	**-16**		
Median† % Change	-71			-45				
Urge incontinence							0.09	0.14
Baseline* – no./wk	14 (14)	14 (14)	0 (0)	13 (15)	13 (15)	0 (0)		
6 Mo* – no./wk	8 (9)	8 (11)	0 (2)	9 (12)	10 (15)	1 (3)		
Mean % Change	**-36**	**-42**	**-6**	**-13**	**-26**	**-13**		
Median† % Change	-53			-32				

* Mean (standard deviation)

† Medians were calculated for archived data only, to indicate the distribution of change values

** Details on how *P*-values were generated are described in the Methods, page 2.

References

[1] Subak L, Wing R, West DS, Franklin F, Vittinghoff E, Creasman J, Richter H, Myers D, Burgio K, Gorin A, Macer J, Kusek J, and Grady D, for the PRIDE Investigators. Weight Loss to Treat Urinary Incontinence in Overweight and Obese Women. *N Engl J Med.* 360(5) [2009 Jan 29]: 481-90.

Appendices

[1] Full Text of *Subak L, et al., NEJM* 360(5), provided to approved data requestors.

[2] SAS version 9.2 Log for programming code submitted for the replication of results in *Subak L, et al., NEJM* 360(5)

[3] SAS version 9.2 Output for programming code submitted for the replication of results in *Subak L, et al., NEJM* 360(5)

Attachment 1

Full Text of Publication

Subak L, Wing R, West DS, Franklin F, Vittinghoff E, Creasman J, Richter H, Myers D, Burgio K, Gorin A, Macer J, Kusek J, and Grady D, for the PRIDE Investigators. Weight Loss to Treat Urinary Incontinence in Overweight and Obese Women. *N Engl J Med.* 360(5) [2009 Jan 29]: 481-90.

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Weight Loss to Treat Urinary Incontinence in Overweight and Obese Women

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Abstract

BACKGROUND—Obesity is an established and modifiable risk factor for urinary incontinence, but conclusive evidence for a beneficial effect of weight loss on urinary incontinence is lacking.

METHODS—We randomly assigned 338 overweight and obese women with at least 10 urinary-incontinence episodes per week to an intensive 6-month weight-loss program that included diet, exercise, and behavior modification (226 patients) or to a structured education program (112 patients).

RESULTS—The mean (±SD) age of the participants was 53±11 years. The body-mass index (BMI) (the weight in kilograms divided by the square of the height in meters) and the weekly number of incontinence episodes as recorded in a 7-day diary of voiding were similar in the intervention group and the control group at baseline (BMI, 36±6 and 36±5, respectively; incontinence episodes, 24±18 and 24±16, respectively). The women in the intervention group had a mean weight loss of 8.0% (7.8 kg), as compared with 1.6% (1.5 kg) in the control group (P<0.001). After 6 months, the mean weekly number of incontinence episodes decreased by 47% in the intervention group, as compared with 28% in the control group (P = 0.01). As compared with the control group, the intervention group had a greater decrease in the frequency of stress-incontinence episodes (P = 0.02), but not of urge-incontinence episodes (P = 0.14). A higher proportion of the intervention group than of the control group had a clinically relevant reduction of 70% or more in the frequency of all incontinence episodes (P<0.001), stress-incontinence episodes (P = 0.009), and urge-incontinence episodes (P = 0.04).

CONCLUSIONS—A 6-month behavioral intervention targeting weight loss reduced the frequency of self-reported urinary-incontinence episodes among overweight and obese women as

No other potential conflict of interest relevant to this article was reported.

compared with a control group. A decrease in urinary incontinence may be another benefit among the extensive health improvements associated with moderate weight reduction.

Urinary incontinence affects more than 13 million women in the United States and has been associated with profound adverse effects on quality of life[1,2]; an increased risk of falls, fractures,[3] and nursing-home admissions[4]; and more than $20 billion in estimated annual direct health care costs.[5]

Observational studies suggest that obesity is a strong risk factor for urinary incontinence,[6–9] and preliminary studies suggest that weight loss may have a beneficial effect on urinary incontinence in obese patients.10−14 Reductions in urinary incontinence have been observed in morbidly obese women who have had dramatic weight loss after bariatric surgery.11−13 In a small cohort study of overweight and obese women with incontinence, those who had a weight loss of more than 5% had a reduction of at least 50% in the frequency of incontinence (P = 0.03).[14] A 3-month study reported that overweight and obese women randomly assigned to a very-low-calorie liquid diet had a significantly greater decrease in the weekly number of urinary-incontinence episodes than those assigned to no intervention. 10

We conducted a randomized, clinical trial, the Program to Reduce Incontinence by Diet and Exercise (PRIDE), to determine whether a behavioral weight-reduction intervention for overweight and obese women with incontinence would result in greater reductions in the frequency of incontinence episodes at 6 months as compared with a control group.

METHODS

PARTICIPANTS

We recruited 338 women between July 2004 and April 2006 in Providence, Rhode Island, and Birmingham, Alabama. Women were eligible for the study if they were at least 30 years of age, had a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) of 25 to 50, and at baseline reported 10 or more urinary-incontinence episodes in a 7-day diary of voiding. The participants were required to monitor their food intake and physical activity for 1 week, to be able to walk unassisted for two blocks (approximately 270 m) without stopping, and to agree not to initiate new treatments for incontinence or weight reduction for the duration of the study. Previous medical therapy for incontinence or obesity did not affect eligibility. Exclusion criteria included use of medical therapy for incontinence or weight loss within the previous month, current urinary tract infection or four or more urinary tract infections in the previous year, a history of incontinence of neurologic or functional origin (due to factors not involving the lower urinary tract, such as chronic impairment of physical or cognitive functioning), previous surgery for incontinence or urethral surgery, major medical or genitourinary tract conditions, pregnancy or parturition in the previous 6 months, type 1 or type 2 diabetes mellitus requiring medical therapy that increased the risk of hypoglycemia, and uncontrolled hypertension.

The study was approved by the institutional review board at each site, and written informed consent was obtained from all participants before enrollment. Slim-Fast, a meal-replacement product, was donated by the manufacturer, Unilever, which had no role in trial design, data accrual, data analysis, or preparation of the manuscript. The biostatistician authors at the University of California, San Francisco, vouch for the completeness and accuracy of the data.

STUDY DESIGN

Eligible participants were randomly assigned at a 2:1 ratio to an intensive 6-month behavioral weight-loss program or to a structured four-session education program (the control group). Randomization was performed with the use of randomly permuted blocks of three or six, stratified according to clinical center, with random assignment concealed in tamper-proof envelopes. The participants were aware of their treatment assignment, but the staff members who collected the outcome data were not.

The participants completed questionnaires concerning their demographic characteristics, medical and behavioral history, and history of incontinence that were routinely used by the investigators. The participants were weighed to the nearest 0.5 kg on a calibrated digital scale (Tanita BWB 800) while wearing street clothes and without shoes. Height was measured at baseline to the nearest centimeter with the use of a calibrated, wall-mounted stadiometer and a horizontal measuring block.

The participants were trained to complete a 7-day diary of voiding (see the Supplementary Appendix, available with the full text of this article at NEJM.org), and interviewers reviewed the diaries with the participants to answer questions and reconcile inconsistencies.[15,16] The participants recorded the time of each void and each incontinence episode. According to the instructions provided, the participants identified each episode as stress incontinence (involuntary loss of urine with coughing, sneezing, straining, or exercise), urge incontinence (loss of urine associated with a strong need or urge to void), or other. For the purposes of analysis, each woman was then classified as having stress-only incontinence, stress-predominant incontinence (i.e., at least two thirds of the total number of episodes were stress episodes), urge-only incontinence, urge-predominant continence (i.e., at least two thirds of the total number of episodes were urge episodes), or mixed incontinence (i.e., at least two types were reported, but no type constituted two thirds of the total number of episodes).

STUDY GROUPS

At randomization, all participants were given a self-help behavioral-treatment booklet with instructions for improving bladder control.[17] The booklet provided basic information about incontinence, how to locate pelvic-floor muscles and how to perform daily exercises with them, how to use pelvic-floor muscles to avoid stress incontinence, and how to control urinary urgency, as well as instructions on completing voiding diaries. Incontinence was not discussed further in either the control group or the weight-loss group.

Women assigned to the control group were scheduled to participate in four education sessions at months 1, 2, 3, and 4. During these 1-hour group sessions, which included 10 to 15 women, general information was presented about weight loss, physical activity, and healthful eating habits, according to a structured protocol.

The weight-loss program was designed to produce an average loss of 7 to 9% of initial body weight within the first 6 months of the program and was modeled after that used in the following two large clinical trials: Look AHEAD (Action for Health in Diabetes),[18,19] a lifestyle intervention trial intended to achieve and maintain weight loss in patients with diabetes, and the Diabetes Prevention Program.[20] The participants in the weight-loss program met weekly for 6 months in groups of 10 to 15 for 1-hour sessions that were led by experts in nutrition, exercise, and behavior change and were based on a structured protocol. The participants were given a standard reduced-calorie diet (1200 to 1500 kcal per day), with a goal of providing no more than 30% of the calories from fat. To improve adherence, the participants were provided with sample meal plans and were given vouchers for a meal-

replacement product (Slim-Fast) to be used for two meals a day during months 1 to 4 and for one meal a day thereafter.

The participants were encouraged to gradually increase physical activity (brisk walking or activities of similar intensity) until they were active for at least 200 minutes each week. Behavioral skills, including self-monitoring, stimulus control, and problem-solving, were emphasized.

OUTCOMES

The primary outcome measure was the percentage change in the number of incontinence episodes reported in the 7-day voiding diary at 6 months after randomization.[15,16] Secondary outcome measures included the percentage change in the number of episodes of urge and stress incontinence; the proportion of women in whom the frequency of incontinence decreased by at least 50%, 70%, or 100%; and change in a validated measure of participant satisfaction with incontinence treatment (assessed with the use of Likert scales of perceived change in frequency of incontinence, volume of urine loss, the degree to which incontinence is a problem, and satisfaction with the change in incontinence at 6 months).[21] In addition, 24-hour involuntary urine loss at baseline and 6 months was determined by a pad test standardized by the International Continence Society. 22 Preweighed urinary-incontinence pads were used for 24 hours and returned by the participants in sealed plastic bags, and the amount of urine lost was measured by weighing the pads.

STATISTICAL ANALYSIS

We estimated that 330 women would need to be enrolled to detect a net reduction in incontinence frequency of six episodes per week after 6 months; this reduction was half the effect seen in a pilot study[10] but was large enough to be clinically meaningful. This estimate allowed for a 10% rate of attrition at 6 months and assumed imputation of missing data for 6-month outcomes. In addition, we assumed that correlation of outcomes within the small intervention groups would result in a 25% increase in the required sample size.

We compared the two groups in terms of baseline demographic and clinical characteristics, accounting for potential correlation among the women in each new “wave” (a wave consisted of one control group and two weight-loss groups) who were beginning treatment. Chi-square tests were used to compare the proportion of missing 6-month data according to treatment group.

To assess the effects of treatment on the frequency of incontinence, we used generalized estimating equations with negative binomial models, with adjustment for clinical site and the baseline and 6-month outcomes treated as repeated measures. In a sensitivity analysis, we also used the nonparametric Wilcoxon rank-sum test to compare percentage changes in the frequency of incontinence. The effects of treatment on the percentage change in weight from baseline to 6 months were assessed with the use of linear mixed models adjusted for site.

Attrition in weight-loss studies commonly masks regained weight. To address this potential source of bias, we used multiple-imputation methods to impute missing weight data at 6 months, on the assumption of no change from baseline on average among dropouts. In addition, we imputed missing data on incontinence frequency at 6 months and pad weight for participants in both groups as if they had been assigned to the control group, in which the average weight loss was minimal but some reduction in incontinence frequency was observed. We also performed a complete-case analysis without imputation of missing outcomes.

The proportions of women with reductions of 50%, 70%, and 100% in the frequency of incontinence were compared by generalized estimating equations, with the use of logistic models with robust standard errors. We focused on a 70% reduction in incontinence frequency, because this figure has been reported as a threshold for improvement in patient satisfaction.[21]

RESULTS

BASELINE CHARACTERISTICS

Of the 2116 participants screened by telephone, 1778 were excluded during screening and 338 underwent randomization (Fig. 1). The characteristics of the participants in the weight-loss and control groups were similar at baseline (Table 1).

The mean (±SD) age was 53±11 years; 19% were black. The mean BMI (36±6) and the total number of incontinence episodes per week (24±18) (Table 2) were similar in the two groups. At baseline, 297 women had at least one episode of stress incontinence and 320 women had at least one episode of urge incontinence per week. In both groups, urge-related incontinence was more common than stress-related incontinence.

FOLLOW-UP

At the 6-month follow-up assessment, 318 women (94.1%) provided weight data (97.8% of the women in the weight-loss group and 86.6% of those in the control group, P<0.001) (Fig. 1), and 304 women (89.9%) completed the 7-day voiding diary (94.7% of those in the weight-loss group and 80.4% of those in the control group, P<0.001). Baseline variables, including age, race, parity, BMI, type of incontinence, frequency of incontinence episodes, and pad weight were not significantly associated with the retention of participants at 6 months.

WEIGHT LOSS

At the 6-month visit, the women in the weight-loss group had a mean loss of 8.0% of body weight from baseline (95% confidence interval [CI], −9.0 to −7.0; mean loss, 7.8 kg), as compared with 1.6% (95% CI, −2.7 to −0.4; mean loss, 1.5 kg) among women in the control group (P<0.001) (Table 2). The results were similar in analyses adjusted for baseline weight and in sensitivity analyses performed with the use of complete-case methods (the mean loss was 8.2% in the weight-loss group and 1.8% in the control group, P<0.001).

URINARY INCONTINENCE

After 6 months, women in the weight-loss group had a mean decrease in the total number of incontinence episodes per week of 47.4% (95% CI, −54.0 to −39.9), as compared with 28.1% in the control group (95% CI, −40.9 to −12.6; P = 0.01) (Table 2). The results were similar in analyses performed with the use of complete-case methods (the mean decrease in the total number of incontinence episodes per week was 49.1% in the intervention group and 34.0% in the control group, P = 0.01) and nonparametric tests (P = 0.003 by the Wilcoxon rank-sum test). The reduction in the number of urinary-incontinence episodes from baseline was attributable primarily to a reduction in episodes of stress incontinence (a decrease of 57.6% in the intervention group as compared with 32.7% in the control group, P = 0.02; P<0.001 by the Wilcoxon rank-sum test). Although the average decrease in the frequency of episodes of urge incontinence was larger in the weight-loss group than in the control group (42.4% vs. 26.0%), this difference was not statistically significant (P = 0.14; P = 0.16 by the Wilcoxon rank-sum test). The effect of treatment on the total number of incontinence episodes per week was similar among subgroups classified at baseline as having stress or

stress-predominant incontinence, urge or urge-predominant incontinence, or the mixed type of incontinence (P = 0.75 by a test for heterogeneity).

A higher proportion of women in the weight-loss group than in the control group had a reduction of at least 70% in the total number of incontinence episodes per week (P<0.001) (Fig. 2). This pattern was also observed for both stress incontinence and urge incontinence (P = 0.009 and P = 0.04, respectively) (Fig. 3). The results were similar after analysis by complete-case methods.

No differences were reported between the intervention and control groups in the use of behavioral techniques presented in the self-help incontinence booklet. About one third of the women in both groups reported using urge-suppression techniques or doing pelvic-floor exercises at least weekly, and three quarters of the women found the booklet helpful (P>0.20 for all comparisons). In exploratory analyses, we assessed potential correlates of a decrease in urinary incontinence in the control group. We found moderate associations with weight loss and physical exercise (P = 0.11 and P = 0.05, respectively) but no evidence for an effect of pelvic-floor exercises.

There was no significant change from baseline in either group and no difference between treatment groups in daytime or nighttime voiding frequency. Involuntary urine loss during a 24-hour period, as measured by an increase in pad weight, decreased significantly from baseline, by 45% in the weight-loss group and by 34% in the control group, but the difference between the groups was not statistically significant (P = 0.23).

SATISFACTION WITH AND PERCEPTION OF TREATMENT

As compared with women in the control group, women in the weight-loss group perceived a greater decrease in the frequency of urinary-incontinence episodes and a lower volume of urine loss. They also regarded incontinence as less of a problem and reported higher satisfaction with the change in their incontinence at 6 months (P<0.001 for all comparisons) (Table 3).

DISCUSSION

Among overweight and obese women with urinary incontinence, the comprehensive behavioral weight-loss program in this study resulted in a significantly greater reduction in the frequency of self-reported urinary-incontinence episodes at 6 months as compared with the structured education program. A higher proportion of women in the weight-loss group than in the control group reported a clinically meaningful reduction of at least 70% in the total weekly number of episodes of any incontinence, stress incontinence, and urge incontinence. In addition, the women in the weight-loss group perceived greater improvement in their incontinence and were more satisfied with their improvement.

The 8% reduction in weight achieved in this study slightly exceeded the 6-month weight loss among participants in the lifestyle-intervention subgroup of the Diabetes Prevention Program (7%)[18] and approximated the 1-year weight losses in the Look AHEAD trial,23 on which the current intervention was modeled. These trials suggest that behavioral weight-loss programs can consistently produce initial weight losses of this magnitude.

Both stress incontinence and urge incontinence were reduced more in the weight-loss group than in the control group, but the difference between the groups was significant only for stress incontinence. However, there was no interaction between treatment and type of incontinence, a result suggesting that the difference in treatment effects between the subgroup of women with urge incontinence and the subgroup with stress incontinence may

have been due to chance. In addition, the proportion of women reporting a clinically meaningful decrease in the number of incontinence episodes per week of 70% or more was greater in the intervention group than the control group for all incontinence episodes, urge-incontinence episodes, and stress-incontinence episodes. This result suggests that overweight or obese women with stress, urge, or mixed incontinence may benefit from weight loss.

Previous studies that have reported significant reductions in incontinence after weight reduction provide information on possible mechanisms by which reduction in incontinence occurs.[10,11,14] It has been hypothesized that obesity may contribute to urinary incontinence because of the increase in intraabdominal pressure due to central adiposity, which in turn increases bladder pressure and urethral mobility, exacerbating stress incontinence and possibly urge incontinence.[10,11,24,25] Weight reduction may reduce forces on the bladder and pelvic floor, thus reducing incontinence. Positive effects of the weight-loss intervention on incontinence may also have resulted from changes in dietary intake and physical activity.

The frequency of incontinence episodes decreased by about 28% in the control group. This reduction is consistent with reports from trials of other interventions for incontinence and is probably due to regression to the mean and heightened awareness of bladder habits among participants, which may result from completing voiding diaries and questionnaires. The booklet describing behavioral approaches to the control of incontinence has been shown to be effective[26,27] and, in combination with four group-education sessions about diet and exercise, may have contributed to improvement in the control group.

The primary outcome measure in our study was change in self-reported incontinence episodes as recorded in the 7-day voiding diary. This is the most common outcome measure in non-surgical intervention trials for urinary incontinence. The participants were trained in diary recording, and each diary was reviewed for completeness by trained research staff. We did not find a parallel difference between treatment groups in 24-hour changes in pad weight. Other trials conducted after our study have also reported a lack of correlation between changes in pad weight and diary-recorded frequency of incontinence, subjective measures of the severity of incontinence, and incontinence-specific quality of life, possibly because these techniques measure different domains of incontinence.[28,29] The generalizability of our findings might be limited by the facts that the participants were selected for their potential to adhere to the behavioral weight-loss intervention and that participants with certain medical conditions were excluded. Since the participants were not blinded to their treatment assignment, differential reporting between the randomized groups cannot be excluded. The reductions in the frequency of incontinence in the control group were partially explained by a moderate effect of weight loss and physical activity, but we observed no evidence for a benefit from pelvic-floor exercises. Future studies might examine specifically whether weight loss combined with other incontinence interventions, such as pelvic-floor exercises, would be beneficial.

Previous studies have indicated that behavioral weight-loss interventions can decrease the risk of type 2 diabetes[18,30] and hypertension,[31] improve control of hypertension[31,32] and hyperlipidemia, [32] and improve mood and quality of life.[33–35] Our results suggest that a decrease in urinary incontinence may be another benefit among the health improvements associated with moderate weight loss and support consideration of weight reduction as a first-line treatment for overweight and obese women with incontinence.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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The views expressed are those of the authors and do not necessarily represent the official views of the NIDDK or the National Institutes of Health.

APPENDIX

The investigators in the Program to Reduce Incontinence by Diet and Exercise (PRIDE) are as follows: **University of Alabama at Birmingham** — F. Franklin (principal investigator), H.E. Richter (coinvestigator), K.L. Burgio (coinvestigator), L. Abdo, C. Bragg, K. Carter, J. Dunlap, S. Gilbert, S. Hannum, A. Hubbell, K. Marshall, L. Pair, P. Pierce, C. Smith, S. Thompson, J. Turman, A. Wrenn; **Miriam Hospital** — R. Wing (principal investigator), A. Gorin (coinvestigator), D. Myers (coinvestigator), T. Monk, R. Ata, M. Butryn, P. Coward, L. Gay, J. Hecht, A. Lepore-Ally, H. Niemeier, Y. Nillni, A. Pinto, D. Ranslow-Robles, N. Robinson, D. Sepinwall, M.E. Hahn, V.W. Sung, V. Winn, N. Zobel; **University of Arkansas for Medical Sciences** — D. West (investigator); **University of Pennsylvania** — G. Foster (consultant); **University of California, San Francisco** (coordinating center) — D. Grady (principal investigator), L. Subak (co-principal investigator), J. Macer, A. Chang, J. Creasman, J. Quan, E. Vittinghoff, J. Yang; **NIDDK** — J.W. Kusek, L.M. Nyberg (project officers); **Data and Safety Monitoring Board: University of Utah Health Sciences Center** — I. Nygaard (chair); **Children's Hospital, Boston** — L. Kalish; **University of California, San Diego** — C. Nager; **Medical University of South Carolina** — P.M. O'Neil; **Johns Hopkins School of Medicine** — C.S. Rand; **University of Virginia Health Systems** — W.D. Steers.

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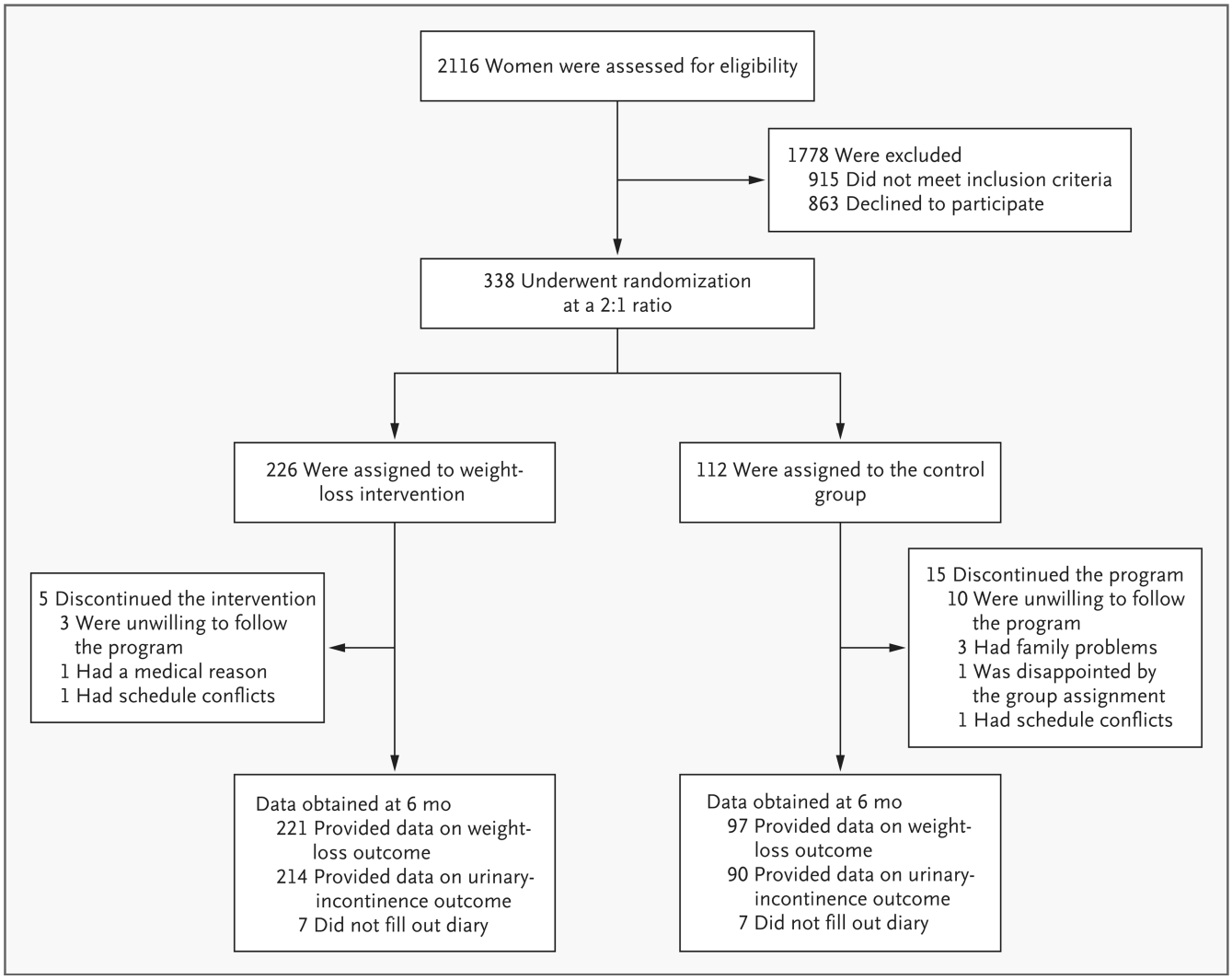

Figure 1.
Study Participants.

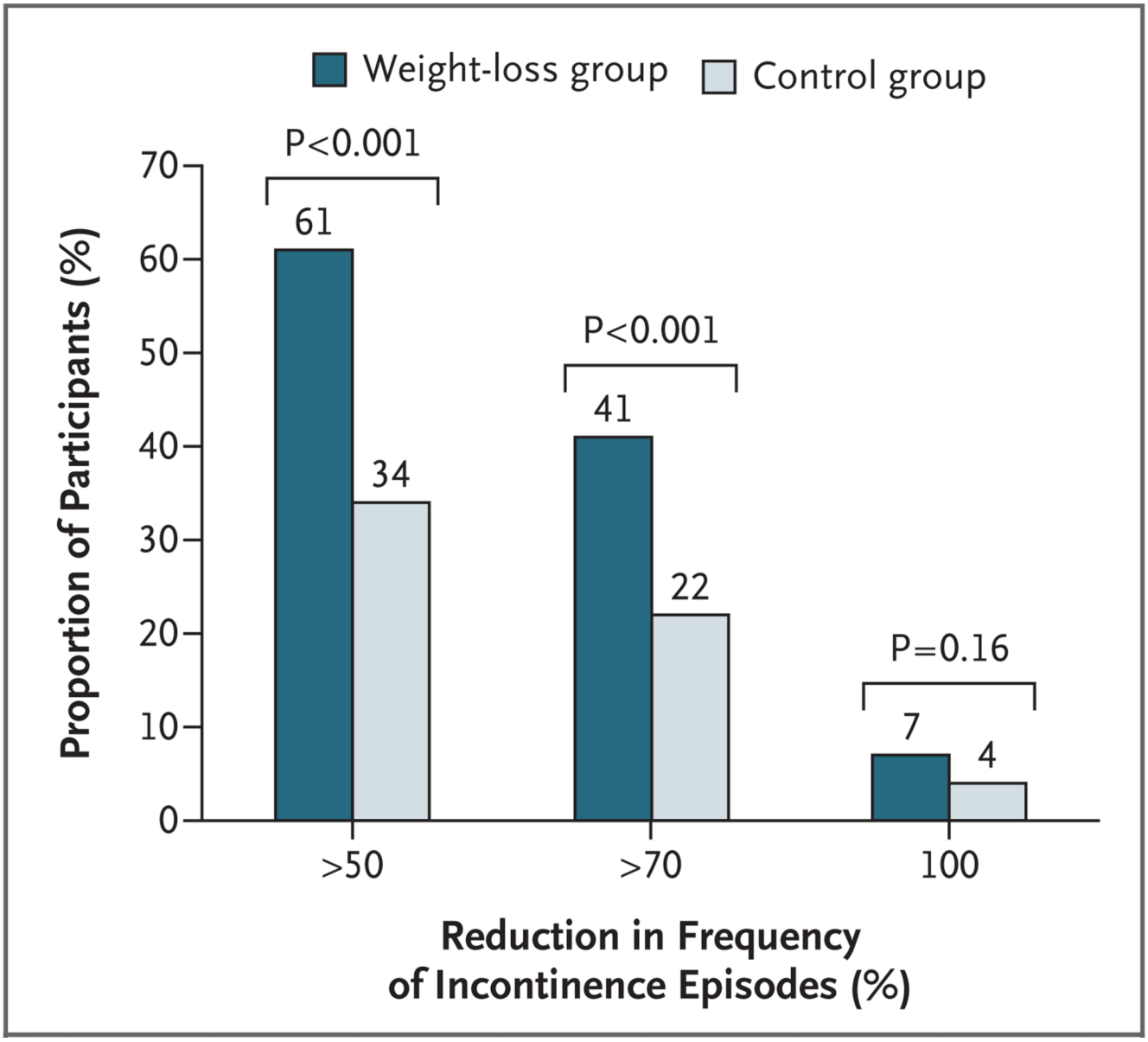

Figure 2.
Proportion of Participants with Reductions in the Frequency of Any Incontinence Episode at 6 Months.

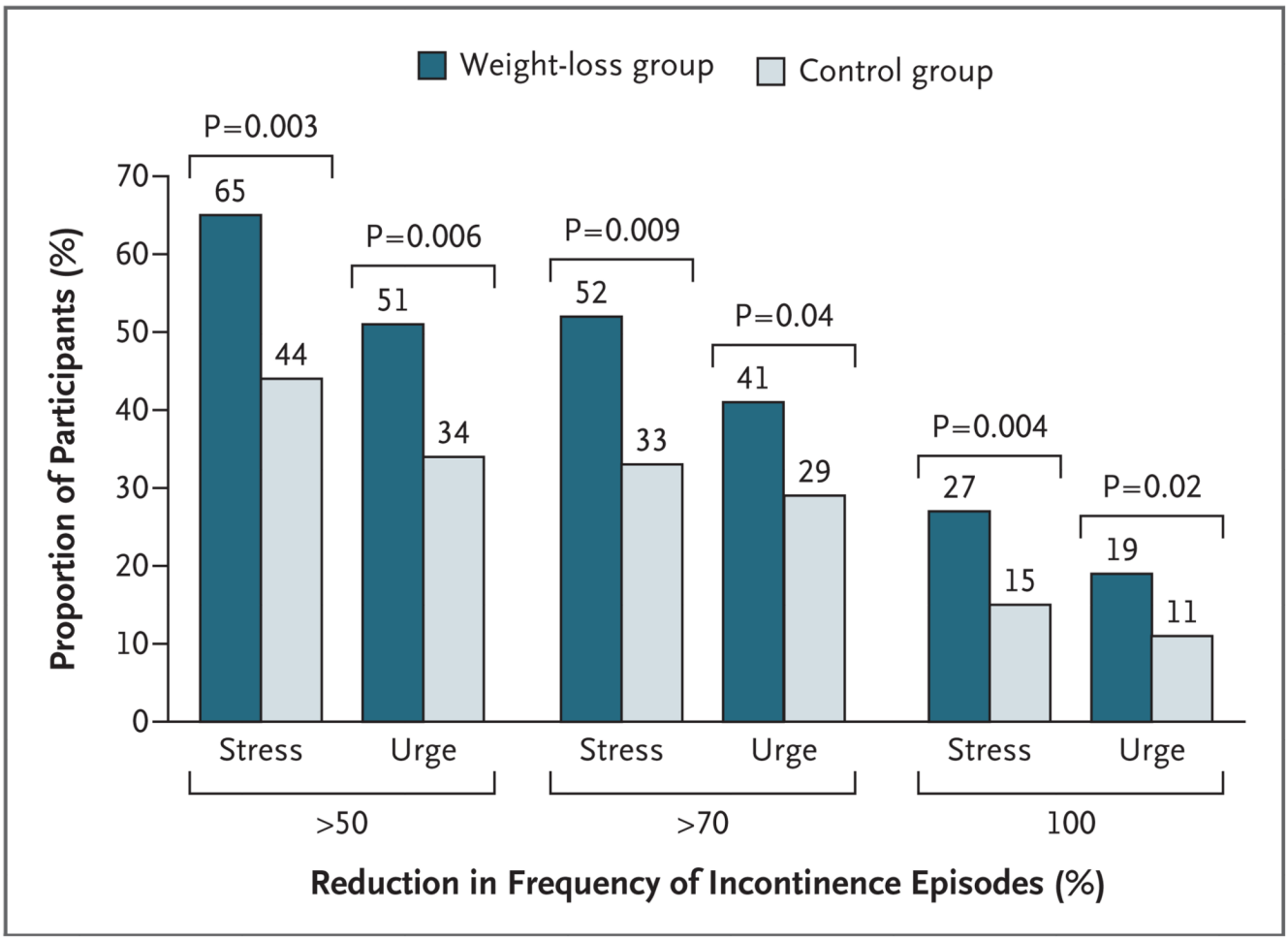

Figure 3.
Proportion of Participants with Reductions in the Frequency of Episodes of Stress Incontinence and of Urge Incontinence at 6 Months.

Table 1

Characteristics of the Participants According to Treatment Group.*

Characteristic	Total (N = 338)	Weight-Loss Group (N = 226)	Control Group (N = 112)
Age — yr	53±11	53±11	53±10
Race — no. (%)†			
White	262 (77.5)	171 (75.7)	91 (81.2)
Black	64 (18.9)	47 (20.8)	17 (15.2)
Other	12 (3.6)	8 (3.5)	4 (3.5)
Education beyond high school — no. (%)	293 (86.7)	200 (88.5)	93 (83.0)
Relationship status — no. (%)			
Married or living with a partner	256 (75.7)	166 (73.5)	90 (80.4)
Single, widowed, or divorced	82 (24.3)	60 (26.5)	22 (19.6)
Body-mass index‡	36±6	36±6	36±5
Diabetes — no. (%)	10 (3.0)	9 (4.0)	1 (0.9)
Current smoker — no. (%)	18 (5.3)	14 (6.2)	4 (3.6)
Current alcohol use — no. (%)	228 (67.5)	154 (68.1)	74 (66.1)
Postmenopausal — no./total no. (%)	177/316 (56.0)	115/209 (55.0)	62/107 (57.9)
Self-reported health status — no. (%)			
Excellent or very good	151 (44.7)	107 (47.3)	44 (39.3)
Good	150 (44.4)	99 (43.8)	51 (45.5)
Fair or poor	37 (10.9)	20 (8.8)	17 (15.2)
Hysterectomy — no./total no. (%)	99/337 (29.4)	70/225 (31.1)	29/112 (25.9)
Parity	2±1	2±1	2±1
Type of urinary incontinence — no. (%)§			
stress only	18 (5.3)	8 (3.5)	10 (8.9)
Urge only	41 (12.1)	33 (14.6)	8 (7.1)
Stress predominant	57 (16.9)	36 (15.9)	21 (18.8)
Urge predominant	108 (32.0)	71 (31.4)	37 (33.0)
Mixed incontinence with no predominant type	114 (33.7)	78 (34.5)	36 (32.1)
24-Hr involuntary urine loss — g¶	33±55	32±55	33±48

*P>0.05 for the comparison between the weight-loss and control groups for all variables listed in the table. Plus–minus values are means ±SD.

†Race was self-assessed.

‡Body-mass index is the weight in kilograms divided by the square of the height in meters.

§Type of urinary incontinence was classified according to the participant's designation of each incontinence episode in a 7-day voiding diary.

¶Involuntary urine loss was measured by the 24-hour increase in pad weight.

Table 2

Body Weight and Frequency of Urinary-Incontinence Episodes at Baseline and at 6 Months According to Treatment Group.*

Outcome	Weight-Loss Group (N = 226)	Control Group (N = 112)	P Value
Body weight†			
Baseline — kg	98±17	95±16	
6 Mo — kg	90±17	94±17	
% Change (95% CI)	−8.0 (−9.0 to −7.0)	−1.6 (−2.7 to −0.4)	<0.001
Urinary-incontinence episodes‡			
Any incontinence			
Baseline — no./wk	24±18	24±16	
6 Mo — no./wk	13±15	17±19	
% Change (95% CI)	−47 (−54 to −40)	−28 (−41 to −13)	0.01
Stress incontinence			
Baseline — no./wk	9±11	10±10	
6 Mo — no./wk	4±7	7±9	
% Change (95% CI)	−58 (−67 to −46)	−33 (−50 to −9)	0.02
Urge incontinence			
Baseline — no./wk	14±14	13±15	
6 Mo — no./wk	8±11	10±15	
% Change (95% CI)	−42 (−51 to −32)	−26 (−44 to −3)	0.14

*Plus–minus values are means ±SD and were calculated with the use of multiply imputed data sets for body weight and frequency of urinary-incontinence episodes.

†Percentage changes and P values for the comparison between the weight-loss group and the control group were calculated with the use of multiply imputed data sets and mixed linear regression models, with control for clinical site and correlation of outcomes in the intervention groups. The data sets for body weight were based on 221 women in the weight-loss group and 97 in the control group for whom data were available at baseline and 6 months.

‡Percentage changes and P values for the comparison between the weight-loss and the control groups were calculated with the use of multiply imputed data sets and negative binomial models, with control for clinical site and correlation of outcomes in the intervention group. The data sets for urinary incontinence were based on 214 women in the weight-loss group and 90 in the control group for whom data were available at baseline and 6 months.

Table 3

Perceptions of Change in Urinary Incontinence at 6 Months as Compared with Baseline According to Treatment Group.*

Participants' Perception	Weight-Loss Group (N = 219)	Control Group (N = 94)
	no. (%)	
Less frequent incontinence episodes	160 (73.1)	50 (53.2)
Smaller volume of urine loss	125 (57.1)	35 (37.2)
Incontinence somewhat or much less of a problem	166 (75.8)	51 (54.3)
Moderately or very satisfied with change in incontinence	166 (75.8)	44 (46.8)

* P<0.001 for all comparisons between the weight-loss group and the control group.

Attachment 2

SAS version 9.2 Log
for programming code submitted
for the replication of results
in Tables 1 and 2 of
Subak L, et al., _N Engl J Med._ 360(5): 481-90.

```
1                                                          The SAS System
19:31 Tuesday, August 23, 2011

NOTE: Unable to open SASUSER.REGSTRY. WORK.REGSTRY will be opened instead.
NOTE: All registry changes will be lost at the end of the session.

WARNING: Unable to copy SASUSER registry to WORK registry. Because of this, you will
not see registry customizations during this
        session.
NOTE: Unable to open SASUSER.PROFILE. WORK.PROFILE will be opened instead.
NOTE: All profile changes will be lost at the end of the session.
NOTE: Copyright (c) 2002-2008 by SAS Institute Inc., Cary, NC, USA.
NOTE: SAS (r) Proprietary Software 9.2 (TS2M0)
      Licensed to RTI INTL MAIN, Site 70006746.
NOTE: This session is executing on the XP_PRO  platform.



NOTE: SAS initialization used:
      real time           4.78 seconds
      cpu time            0.56 seconds

1          options ps=55 ls=75 nonumber formchar='|----|+\---+=|-^<>*' mprint
orientation=portrait
1        ! ;
2
3          libname pride 'C:\Documents and Settings\stan\My
3        ! Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data';
NOTE: Libref PRIDE was successfully assigned as follows:
      Engine:        V9
      Physical Name: C:\Documents and Settings\stan\My
      Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data
4          libname codebook 'C:\Documents and Settings\stan\My
4        ! Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data\Codebooks';
NOTE: Libref CODEBOOK was successfully assigned as follows:
      Engine:        V9
      Physical Name: C:\Documents and Settings\stan\My
      Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data\Codebooks
5          libname library 'C:\Documents and Settings\stan\My
5        ! Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data\formats';
NOTE: Libref LIBRARY was successfully assigned as follows:
      Engine:        V9
      Physical Name: C:\Documents and Settings\stan\My
      Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data\formats
6
7          options fmtsearch=(pri_fmt.formats);
8
9          proc format library=library;
9        !                             * fmtlib; run;

NOTE: PROCEDURE FORMAT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


10
11           ** formats for table 1 variables **;
12         %include 'C:\Documents and Settings\stan\My
```

```
12       !
Documents\DATA\NIDDK\PRIDE\working_archive\PRIDE_data\formats\formats.sas';
NOTE: Format CATAGE has been output.
NOTE: Format CATWT has been output.
NOTE: Format CATABC has been output.
NOTE: Format ETHNB has been output.
NOTE: Format EDUC has been output.
NOTE: Format RSTAT has been output.
NOTE: Format BMIC has been output.
NOTE: Format LIVBIR has been output.
NOTE: Format UITYPE has been output.
NOTE: Format ALMANY has been output.
NOTE: Format NEWALCO has been output.
NOTE: Format GENH has been output.
NOTE: Format SITE has been output.
NOTE: Format STRATUM has been output.
NOTE: Format TX has been output.

NOTE: PROCEDURE FORMAT used (Total process time):
      real time           0.96 seconds
      cpu time            0.03 seconds


113
114        proc freq data=pride.full0_18nih noprint; tables id/out=a;

NOTE: There were 1298 observations read from the data set PRIDE.FULL0_18NIH.
NOTE: The data set WORK.A has 338 observations and 3 variables.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.23 seconds
      cpu time            0.00 seconds


115        proc freq data=a noprint; tables id; run;

NOTE: There are no valid requests for output data sets or printed output, so
processing will
      terminate.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


115      !                                          *n=338, as in Pub *;
116
117        data baseline; set pride.full0_18nih; where nvisit=0;
118          clustr=trim(left(clustr));
119          wave=substr(clustr,1,1); run;

NOTE: There were 338 observations read from the data set PRIDE.FULL0_18NIH.
      WHERE nvisit=0;
NOTE: The data set WORK.BASELINE has 338 observations and 1606 variables.
NOTE: DATA statement used (Total process time):
      real time           0.20 seconds
      cpu time            0.20 seconds
```

```
120
121
********************************************************************************;
122          * Table 1 *;
123          title PRIDE DSIC:  Table 1;
124        proc freq data=baseline; tables g2ethn deeduc destat g7diab h1smnow
h1aluse h2lmp
124      ! fagh01 h2hyst type;
125          format type uitype. deeduc educ. destat rstat.; run;

NOTE: There were 338 observations read from the data set WORK.BASELINE.
NOTE: The PROCEDURE FREQ printed pages 1-3.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.20 seconds
      cpu time            0.01 seconds


126        proc means maxdec=0; var rage bmi H2LIVBIR padwt; run;

NOTE: There were 338 observations read from the data set WORK.BASELINE.
NOTE: The PROCEDURE MEANS printed page 4.
NOTE: PROCEDURE MEANS used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


127
128        title2 baseline treatment comparisons , adjusting for potential
correlation among women
128      !  in each new wave
129           ( per pub methods ) *;
130        %macro gmodels0(out);
131        proc glimmix data = baseline ;
132         class wave &out;
133         model tx = &out wave/dist = binary;
134        run;
135        %mend;
136        %gmodels0(g2ethn);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave g2ethn;
MPRINT(GMODELS0):   model tx = g2ethn wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
```

```
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
```

```
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 5-6.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.10 seconds
      cpu time            0.04 seconds


137         %gmodels0(deeduc);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave deeduc;
MPRINT(GMODELS0):   model tx = deeduc wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (ABSGCONV=0.00001) satisfied.
```

```
NOTE: The PROCEDURE GLIMMIX printed pages 7-8.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.09 seconds
      cpu time            0.04 seconds


138        %gmodels0(destat);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave destat;
MPRINT(GMODELS0):   model tx = destat wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (ABSGCONV=0.00001) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 9-10.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


139        %gmodels0(g7diab);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave g7diab;
MPRINT(GMODELS0):   model tx = g7diab wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
```

```
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 11-12.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


140         %gmodels0(h1smnow);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave h1smnow;
MPRINT(GMODELS0):   model tx = h1smnow wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
```

```
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 13-14.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.09 seconds
      cpu time            0.04 seconds


141        %gmodels0(h1aluse);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave h1aluse;
MPRINT(GMODELS0):   model tx = h1aluse wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 15-16.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.07 seconds
      cpu time            0.03 seconds


142        %gmodels0(h2lmp);
```

```
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave h2lmp;
MPRINT(GMODELS0):   model tx = h2lmp wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 17-18.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.12 seconds
      cpu time            0.07 seconds


143         %gmodels0(fagh01);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave fagh01;
MPRINT(GMODELS0):   model tx = fagh01 wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
```

```
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (ABSGCONV=0.00001) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 19-20.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.03 seconds


144         %gmodels0(h2hyst);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave h2hyst;
MPRINT(GMODELS0):   model tx = h2hyst wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
```

```
NOTE: Convergence criterion (ABSGCONV=0.00001) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 21-22.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.07 seconds
      cpu time            0.06 seconds


145        %gmodels0(type);
MPRINT(GMODELS0):   proc glimmix data = baseline ;
MPRINT(GMODELS0):   class wave type;
MPRINT(GMODELS0):   model tx = type wave/dist = binary;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_CALCMU_) then do;
MPRINT(GMODELS0):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0):   run;

MPRINT(GMODELS0):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   __r__ = __Y__ ;
MPRINT(GMODELS0):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -1E20;
MPRINT(GMODELS0):   else do;
MPRINT(GMODELS0):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   end;
MPRINT(GMODELS0):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (ABSGCONV=0.00001) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 23-24.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.07 seconds
      cpu time            0.06 seconds


146        %macro gmodels0_b(out);
147        proc glimmix data = baseline ;
148         class wave;
149         model tx = &out wave/dist = binary;
150        run;
151        %mend;
152        %gmodels0_b(rage);
MPRINT(GMODELS0_B):   proc glimmix data = baseline ;
```

```
MPRINT(GMODELS0_B):   class wave;
MPRINT(GMODELS0_B):   model tx = rage wave/dist = binary;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_CALCMU_) then do;
MPRINT(GMODELS0_B):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0_B):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   __r__ = __Y__ ;
MPRINT(GMODELS0_B):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0_B):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -
1E20;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 25-26.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


153        %gmodels0_b(bmi);
MPRINT(GMODELS0_B):   proc glimmix data = baseline ;
MPRINT(GMODELS0_B):   class wave;
MPRINT(GMODELS0_B):   model tx = bmi wave/dist = binary;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_CALCMU_) then do;
MPRINT(GMODELS0_B):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0_B):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   _ETA_ = log(_MEAN_/(1-_MEAN_));
```

```
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   __r__ = __Y__ ;
MPRINT(GMODELS0_B):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0_B):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -
1E20;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 27-28.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


154        %gmodels0_b(h2livbir);
MPRINT(GMODELS0_B):   proc glimmix data = baseline ;
MPRINT(GMODELS0_B):   class wave;
MPRINT(GMODELS0_B):   model tx = h2livbir wave/dist = binary;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_CALCMU_) then do;
MPRINT(GMODELS0_B):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0_B):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   __r__ = __Y__ ;
MPRINT(GMODELS0_B):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0_B):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -
1E20;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;
```

```
NOTE: Some observations are not used in the analysis because of: missing fixed
effects (n=31).
NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
```

```
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 29-30.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


155        %gmodels0_b(padwt);
MPRINT(GMODELS0_B):   proc glimmix data = baseline ;
MPRINT(GMODELS0_B):   class wave;
MPRINT(GMODELS0_B):   model tx = padwt wave/dist = binary;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_ = .) then _VARIANCE_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _VARIANCE_ = _MU_ * (1-_MU_);
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_CALCMU_) then do;
MPRINT(GMODELS0_B):   if (_LINP_ > 0) then _MU_ = 1/(1+exp(-_LINP_));
MPRINT(GMODELS0_B):   else _MU_=exp(_LINP_)/(1+exp(_LINP_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   _ETA_ = log(_MEAN_/(1-_MEAN_));
MPRINT(GMODELS0_B):   run;

MPRINT(GMODELS0_B):   if (_MU_=.) or (_LINP_=.) then _LOGL_ = .;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   __r__ = __Y__ ;
MPRINT(GMODELS0_B):   if (__r__<0) or (__r__>1) then _LOGL_ = -1E20;
MPRINT(GMODELS0_B):   else if (_MU_ < 1E-13) or ((1-_MU_) < 1E-13) then _LOGL_ = -
1E20;
MPRINT(GMODELS0_B):   else do;
MPRINT(GMODELS0_B):   _LOGL_ = __F__ * __W__ * (__r__*log(_MU_) + (1-__r__)*log(1-
_MU_));
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   end;
MPRINT(GMODELS0_B):   run;

NOTE: The GLIMMIX procedure is modeling the probability that tx='Control'.
NOTE: Convergence criterion (GCONV=1E-8) satisfied.
NOTE: The PROCEDURE GLIMMIX printed pages 31-32.
NOTE: PROCEDURE GLIMMIX used (Total process time):
      real time           0.06 seconds
      cpu time            0.03 seconds


156
157
*************************************************************************;
158        data basemo6; set pride.full0_18nih; where nvisit in (0,6); run;

NOTE: There were 669 observations read from the data set PRIDE.FULL0_18NIH.
      WHERE nvisit in (0, 6);
NOTE: The data set WORK.BASEMO6 has 669 observations and 1605 variables.
```

```
NOTE: DATA statement used (Total process time):
```

```
      real time           0.18 seconds
      cpu time            0.18 seconds


159
160          title PRIDE DSIC:  Table 2;
161          title2;
162
163        proc means data=basemo6 n mean std maxdec=0; class tx nvisit; var weight
totleak
163      ! totstres toturge; run;

NOTE: There were 669 observations read from the data set WORK.BASEMO6.
NOTE: The PROCEDURE MEANS printed pages 33-34.
NOTE: PROCEDURE MEANS used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


164        proc freq; tables nvisit tx clinic; run;

NOTE: There were 669 observations read from the data set WORK.BASEMO6.
NOTE: The PROCEDURE FREQ printed page 35.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


165
166        proc sort data=basemo6; by id nvisit;
167
168        %macro gmodels(out);
169        proc genmod data=basemo6;
170          class id tx nvisit clinic; * take visit out of class statement to see
trend effect *;
171          model &out= tx nvisit clinic tx*nvisit/type3 wald link=log dist=negbin;
172          repeated subject=id/type=un sorted corrw;
173          lsmeans tx nvisit tx*nvisit/diff cl; * this only gives absolute
differences *;
174        run;
175        %mend;
176        %gmodels(totleak);

NOTE: There were 669 observations read from the data set WORK.BASEMO6.
NOTE: The data set WORK.BASEMO6 has 669 observations and 1605 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           1.00 seconds
      cpu time            0.03 seconds


MPRINT(GMODELS):   proc genmod data=basemo6;
MPRINT(GMODELS):   class id tx nvisit clinic;
MPRINT(GMODELS):   * take visit out of class statement to see trend effect *;
MPRINT(GMODELS):   model totleak= tx nvisit clinic tx*nvisit/type3 wald link=log
dist=negbin;
```

```
MPRINT(GMODELS):   repeated subject=id/type=un sorted corrw;
MPRINT(GMODELS):   lsmeans tx nvisit tx*nvisit/diff cl;
```

```
MPRINT(GMODELS):   * this only gives absolute differences *;
MPRINT(GMODELS):   run;

NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The empirical covariance matrix estimate is used in the LSMEANS statement.
NOTE: The PROCEDURE GENMOD printed pages 36-39.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


177        %gmodels(totstres);
MPRINT(GMODELS):   proc genmod data=basemo6;
MPRINT(GMODELS):   class id tx nvisit clinic;
MPRINT(GMODELS):   * take visit out of class statement to see trend effect *;
MPRINT(GMODELS):   model totstres= tx nvisit clinic tx*nvisit/type3 wald link=log
dist=negbin;
MPRINT(GMODELS):   repeated subject=id/type=un sorted corrw;
MPRINT(GMODELS):   lsmeans tx nvisit tx*nvisit/diff cl;
MPRINT(GMODELS):   * this only gives absolute differences *;
MPRINT(GMODELS):   run;

NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The empirical covariance matrix estimate is used in the LSMEANS statement.
NOTE: The PROCEDURE GENMOD printed pages 40-43.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds


178        %gmodels(toturge);
MPRINT(GMODELS):   proc genmod data=basemo6;
MPRINT(GMODELS):   class id tx nvisit clinic;
MPRINT(GMODELS):   * take visit out of class statement to see trend effect *;
MPRINT(GMODELS):   model toturge= tx nvisit clinic tx*nvisit/type3 wald link=log
dist=negbin;
MPRINT(GMODELS):   repeated subject=id/type=un sorted corrw;
MPRINT(GMODELS):   lsmeans tx nvisit tx*nvisit/diff cl;
MPRINT(GMODELS):   * this only gives absolute differences *;
MPRINT(GMODELS):   run;

NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The empirical covariance matrix estimate is used in the LSMEANS statement.
NOTE: The PROCEDURE GENMOD printed pages 44-47.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.06 seconds
      cpu time            0.04 seconds
```

```
179
180        data mo6; set pride.full0_18nih; where nvisit =6; run;

NOTE: There were 331 observations read from the data set PRIDE.FULL0_18NIH.
      WHERE nvisit=6;
NOTE: The data set WORK.MO6 has 331 observations and 1605 variables.
NOTE: DATA statement used (Total process time):
      real time           0.53 seconds
      cpu time            0.17 seconds


181        data diff; merge baseline( in=in1 keep=id tx clinic weight totleak
totstres toturge
182                                   rename=(weight=weight0 totleak=totleak0
totstres=totstres0
182      ! toturge=toturge0 ))
183          mo6( in=in2 keep=id weight totleak totstres toturge
184                rename=(weight=weight6 totleak=totleak6 totstres=totstres6
toturge=toturge6));
185          by id;
186          if in1 and in2;
187          perdiffwt=(weight6-weight0)*100/weight0;
188          perdifftot=.; perdiffstres=.; perdiffurge=.;
189          if totleak0>0 then perdifftot=(totleak6-totleak0)*100/totleak0;
190          if totstres0>0 then perdiffstres=(totstres6-totstres0)*100/totstres0;
191          if toturge0>0 then perdiffurge=(toturge6-toturge0)*100/toturge0;
192
193          array perdiffs perdifftot perdiffstres perdiffurge;
194          array chgdiff50s totgt50 stresgt50 urgegt50;
195          array chgdiff70s totgt70 stresgt70 urgegt70;
196          array chgdiff100s toteq100 streseq100 urgeeq100;
197          do over perdiffs;
198            if .<perdiffs<-50 then chgdiff50s=1; else if perdiffs>=-50 then
chgdiff50s=0;
199            if .<perdiffs<-70 then chgdiff70s=1; else if perdiffs>=-70 then
chgdiff70s=0;
200            if perdiffs=-100 then chgdiff100s=1; else if perdiffs>-100 then
chgdiff100s=0;
201          end;
202          run;

NOTE: Missing values were generated as a result of performing an operation on missing
values.
      Each place is given by: (Number of times) at (Line):(Column).
      13 at 187:21   27 at 189:42   23 at 190:46   24 at 191:43
NOTE: There were 338 observations read from the data set WORK.BASELINE.
NOTE: There were 331 observations read from the data set WORK.MO6.
NOTE: The data set WORK.DIFF has 331 observations and 24 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


203
```

```
204          title2 reporting medians as well as means, as percent different in
incontinence
204      ! episodes appears to be skewed;
205        proc means data=diff n mean median stderr; class tx; var perdiffwt
perdifftot
205      ! perdiffstres perdiffurge; run;

NOTE: There were 331 observations read from the data set WORK.DIFF.
```

```
NOTE: The PROCEDURE MEANS printed page 48.
NOTE: PROCEDURE MEANS used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


206
207          title2;
208        PROC MIXED DATA=DIFF;
209          CLASS TX CLINIC;
210          MODEL perdiffwt = TX CLINIC /solution;
211        run;

NOTE: 13 observations are not included because of missing values.
NOTE: The PROCEDURE MIXED printed pages 49-50.
NOTE: PROCEDURE MIXED used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


212
213        %macro gmodels2(out);
214        proc genmod data = diff descending;
215         class id clinic;
216         model &out = tx clinic / dist = binomial link = logit;
217         repeated subject = id/ type = unstr; * to get estimate of robust standard
error,
218           even if only one record per id *;
219        run;
220        %mend;
221        %gmodels2(totgt50);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model totgt50 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that totgt50='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 51-52.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


222        %gmodels2(totgt70);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model totgt70 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
```

```
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that totgt70='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 53-54.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


223        %gmodels2(toteq100);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model toteq100 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that toteq100='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 55-56.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


224        %gmodels2(stresgt50);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model stresgt50 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that stresgt50='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 57-58.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds
```

```
225         %gmodels2(stresgt70);
```

```
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model stresgt70 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that stresgt70='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 59-60.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


226        %gmodels2(streseq100);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model streseq100 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that streseq100='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 61-62.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


227        %gmodels2(urgegt50);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model urgegt50 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that urgegt50='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 63-64.
NOTE: PROCEDURE GENMOD used (Total process time):
```

```
real time            0.03 seconds
```

```
      cpu time            0.03 seconds


228        %gmodels2(urgegt70);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model urgegt70 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that urgegt70='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 65-66.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


229        %gmodels2(urgeeq100);
MPRINT(GMODELS2):   proc genmod data = diff descending;
MPRINT(GMODELS2):   class id clinic;
MPRINT(GMODELS2):   model urgeeq100 = tx clinic / dist = binomial link = logit;
MPRINT(GMODELS2):   repeated subject = id/ type = unstr;
MPRINT(GMODELS2):   * to get estimate of robust standard error, even if only one
record per id *;
MPRINT(GMODELS2):   run;


NOTE: Class levels for some variables were not printed due to excessive size.
NOTE: PROC GENMOD is modeling the probability that urgeeq100='1'.
NOTE: Algorithm converged.
NOTE: Algorithm converged.
NOTE: The PROCEDURE GENMOD printed pages 67-68.
NOTE: PROCEDURE GENMOD used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


230
231

NOTE: SAS Institute Inc., SAS Campus Drive, Cary, NC USA 27513-2414
NOTE: The SAS System used:
      real time           12.35 seconds
      cpu time            2.46 seconds
```

Attachment 3

SAS version 9.2 Output
for programming code submitted
for the replication of results
in Tables 1 and 2 of
Subak L, et al., *N Engl J Med.* 360(5): 481-90.

The FREQ Procedure

6. Ethnicity

G2ETHN	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:American Indian/Alaska Native	4	1.18	4	1.18
3:Black or African American	64	18.93	68	20.12
4:White	262	77.51	330	97.63
8:Don t know/Other	8	2.37	338	100.00

2. Highest level of education

DEEDUC	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:<=High School	45	13.31	45	13.31
2:Some College/Vacational	147	43.49	192	56.80
3:College Degree or more	146	43.20	338	100.00

3. Describes relationship?

DESTAT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1:Married	228	67.46	228	67.46
2:Other/Partner	28	8.28	256	75.74
4:Single/Widowed/Divorced	82	24.26	338	100.00

21. Have or had diabetes?

G7DIAB	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:No	328	97.04	328	97.04
1:Yes	10	2.96	338	100.00

2. Smoke now?

H1SMNOW	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:No	320	94.67	320	94.67
1:Yes	18	5.33	338	100.00

The FREQ Procedure

3. Drink alcoholic beverages?

H1ALUSE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:No	110	32.54	110	32.54
1:Yes	228	67.46	338	100.00

8. Last menstrual period?

H2LMP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0: Less than 1 year ago	139	41.12	139	41.12
1: More than 1 year ago	177	52.37	316	93.49
8: Dont know	22	6.51	338	100.00

1. General Health

FAGH01	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1: Excellent	27	7.99	27	7.99
2: Very Good	124	36.69	151	44.67
3: Good	150	44.38	301	89.05
4: Fair	36	10.65	337	99.70
5: Poor	1	0.30	338	100.00

9a. Had hysterectomy?

H2HYST	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0:No	238	70.41	238	70.41
1:Yes	99	29.29	337	99.70
8:Don t Know	1	0.30	338	100.00

INCONTINENCE TYPE

TYPE	Frequency	Percent
Stress Only	18	5.33
Mixed Incontinence with Stress Predominant*	57	16.86
Urge Only	41	12.13
Mixed Incontinence with Urge Predominant*	108	31.95
Mixed Incontinence with No Predominant Type or Other type*	114	33.73

The FREQ Procedure

INCONTINENCE TYPE

TYPE	Cumulative Frequency	Cumulative Percent
Stress Only	18	5.33
Mixed Incontinence with Stress Predominant*	75	22.19
Urge Only	116	34.32
Mixed Incontinence with Urge Predominant*	224	66.27
Mixed Incontinence with No Predominant Type or Other type*	338	100.00

The MEANS Procedure

Variable	Label	N	Mean	Std Dev	Minimum
RAGE	CALC AGE@RAND:(X2RDATE-DEBDATE)/365.25	338	53	10	30
BMI	BODY MASS INDEX(KG/M**2)	338	36	6	25
H2LIVBIR	7b. Number of births	307	2	1	0
PADWT	Total pad weight, grams	338	33	55	0

Variable	Label	Maximum
RAGE	CALC AGE@RAND:(X2RDATE-DEBDATE)/365.25	81
BMI	BODY MASS INDEX(KG/M**2)	50
H2LIVBIR	7b. Number of births	9
PADWT	Total pad weight, grams	639

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
G2ETHN	4	0:American Indian/Alaska Native 3:Black or African American 4:White 8:Don t know/Other

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	10
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	8
Lower Boundaries	0
Upper Boundaries	0

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Optimization Information

Fixed Effects	Not Profiled

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	213.52202394	.	7.995743
1	0	3	213.07174189	0.45028205	0.174837
2	0	3	213.07150704	0.00023484	0.000092
3	0	3	213.07150704	0.00000000	5.09E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	426.14
AIC (smaller is better)	442.14
AICC (smaller is better)	442.58
BIC (smaller is better)	472.73
CAIC (smaller is better)	480.73
HQIC (smaller is better)	454.33
Pearson Chi-Square	338.09
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
G2ETHN	3	330	0.75	0.5207
wave	4	330	0.22	0.9286

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
DEEDUC	5	2:6th - 11th grage 3:High school grad 4:Some college, JV or voc.sch 5:College degree 6:Graduate or Prof. Degree

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	11
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	9
Lower Boundaries	0

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Optimization Information

Upper Boundaries	0
Fixed Effects	Not Profiled

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	211.01024271	.	8.436464
1	0	3	210.36718441	0.64305829	0.10595
2	0	3	210.31072339	0.05646102	0.031376
3	0	3	210.29062836	0.02009503	0.011538
4	0	3	210.28330948	0.00731888	0.004238
5	0	3	210.28062681	0.00268266	0.001558
6	0	3	210.27964124	0.00098558	0.000573
7	0	3	210.27927884	0.00036240	0.000211
8	0	3	210.27914555	0.00013329	0.000078
9	0	3	210.27909651	0.00004903	0.000029
10	0	3	210.27907847	0.00001804	0.00001
11	0	3	210.27907184	0.00000664	3.862E-6

Convergence criterion (ABSGCONV=0.00001) satisfied.

Fit Statistics

-2 Log Likelihood	420.56
AIC (smaller is better)	438.56
AICC (smaller is better)	439.11
BIC (smaller is better)	472.97
CAIC (smaller is better)	481.97
HQIC (smaller is better)	452.27
Pearson Chi-Square	335.16
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DEEDUC	4	329	0.24	0.9155
wave	4	329	0.29	0.8840

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
DESTAT	5	0:Married 1:Living with sig other/partner 2:Living with a friend 3:Sig invloved; but not living together 4:Single, not invloved

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	11
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	9
Lower Boundaries	0

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Optimization Information

Upper Boundaries	0
Fixed Effects	Not Profiled

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	213.18737413	.	7.86372
1	0	3	212.68904854	0.49832559	0.20105
2	0	3	212.67015598	0.01889256	0.010556
3	0	3	212.66347954	0.00667644	0.003834
4	0	3	212.66104758	0.00243196	0.001408
5	0	3	212.66015613	0.00089145	0.000518
6	0	3	212.65982862	0.00032751	0.00019
7	0	3	212.65970819	0.00012043	0.00007
8	0	3	212.65966389	0.00004429	0.000026
9	0	3	212.6596476	0.00001629	9.482E-6

Convergence criterion (ABSGCONV=0.00001) satisfied.

Fit Statistics

-2 Log Likelihood	425.32
AIC (smaller is better)	443.32
AICC (smaller is better)	443.87
BIC (smaller is better)	477.73
CAIC (smaller is better)	486.73
HQIC (smaller is better)	457.03
Pearson Chi-Square	336.88
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
DESTAT	4	329	0.57	0.6835
wave	4	329	0.19	0.9424

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
G7DIAB	2	0:No 1:Yes

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	8
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	213.27651508	.	7.908647
1	0	3	212.77734982	0.49916525	0.19404
2	0	3	212.77688464	0.00046518	0.000271
3	0	3	212.77688462	0.00000002	1.748E-8

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	425.55
AIC (smaller is better)	437.55
AICC (smaller is better)	437.81
BIC (smaller is better)	460.49
CAIC (smaller is better)	466.49
HQIC (smaller is better)	446.70
Pearson Chi-Square	337.63
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
G7DIAB	1	332	2.01	0.1567
wave	4	332	0.19	0.9431

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
H1SMNOW	2	0:No 1:Yes

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	8
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	214.21488287	.	8.26327
1	0	3	213.74255554	0.47232733	0.178709
2	0	3	213.74232955	0.00022599	0.00008
3	0	3	213.74232955	0.00000000	2.49E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	427.48
AIC (smaller is better)	439.48
AICC (smaller is better)	439.74
BIC (smaller is better)	462.42
CAIC (smaller is better)	468.42
HQIC (smaller is better)	448.63
Pearson Chi-Square	337.65
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
H1SMNOW	1	332	0.90	0.3430
wave	4	332	0.19	0.9425

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
H1ALUSE	2	0:No 1:Yes

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	8
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	214.58135068	.	8.415963
1	0	3	214.09142451	0.48992617	0.189705
2	0	3	214.09116304	0.00026147	0.000095
3	0	3	214.09116304	0.00000000	3.73E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	428.18
AIC (smaller is better)	440.18
AICC (smaller is better)	440.44
BIC (smaller is better)	463.12
CAIC (smaller is better)	469.12
HQIC (smaller is better)	449.32
Pearson Chi-Square	337.96
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
H1ALUSE	1	332	0.29	0.5935
wave	4	332	0.25	0.9077

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
H2LMP	3	0: Less than 1 year ago 1: More than 1 year ago 8: Dont know

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	9
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	7
Lower Boundaries	0
Upper Boundaries	0

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Optimization Information

Fixed Effects	Not Profiled

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	213.77794093	.	8.084256
1	0	3	213.32342815	0.45451278	0.173812
2	0	3	213.3232004	0.00022774	0.000086
3	0	3	213.3232004	0.00000000	3.65E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	426.65
AIC (smaller is better)	440.65
AICC (smaller is better)	440.99
BIC (smaller is better)	467.41
CAIC (smaller is better)	474.41
HQIC (smaller is better)	451.31
Pearson Chi-Square	337.94
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
H2LMP	2	331	0.86	0.4261
wave	4	331	0.30	0.8748

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
FAGH01	5	1: Excellent 2: Very Good 3: Good 4: Fair 5: Poor

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	11
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	9
Lower Boundaries	0
Upper Boundaries	0

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Optimization Information

Fixed Effects	Not Profiled

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	211.90374128	.	7.423427
1	0	3	211.41956255	0.48417873	0.203546
2	0	3	211.40065521	0.01890734	0.010559
3	0	3	211.39397878	0.00667644	0.003834
4	0	3	211.39154681	0.00243196	0.001408
5	0	3	211.39065536	0.00089145	0.000518
6	0	3	211.39032785	0.00032751	0.00019
7	0	3	211.39020742	0.00012043	0.00007
8	0	3	211.39016312	0.00004429	0.000026
9	0	3	211.39014683	0.00001629	9.482E-6

Convergence criterion (ABSGCONV=0.00001) satisfied.

Fit Statistics

-2 Log Likelihood	422.78
AIC (smaller is better)	440.78
AICC (smaller is better)	441.33
BIC (smaller is better)	475.19
CAIC (smaller is better)	484.19
HQIC (smaller is better)	454.49
Pearson Chi-Square	337.25
Pearson Chi-Square / DF	1.03

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
FAGH01	4	329	1.20	0.3105
wave	4	329	0.19	0.9456

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
H2HYST	3	0:No 1:Yes 8:Don t Know

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	9
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	7
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	213.96227758	.	8.17536
1	0	3	213.43429368	0.52798389	0.211124
2	0	3	213.41538642	0.01890727	0.010557
3	0	3	213.40870998	0.00667644	0.003834
4	0	3	213.40627802	0.00243196	0.001408
5	0	3	213.40538657	0.00089145	0.000518
6	0	3	213.40505905	0.00032751	0.00019
7	0	3	213.40493862	0.00012043	0.00007
8	0	3	213.40489433	0.00004429	0.000026
9	0	3	213.40487803	0.00001629	9.482E-6

Convergence criterion (ABSGCONV=0.00001) satisfied.

Fit Statistics

-2 Log Likelihood	426.81
AIC (smaller is better)	440.81
AICC (smaller is better)	441.15
BIC (smaller is better)	467.57
CAIC (smaller is better)	474.57
HQIC (smaller is better)	451.48
Pearson Chi-Square	336.94
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
H2HYST	2	331	0.41	0.6612
wave	4	331	0.18	0.9472

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5
TYPE	6	1 2 3 4 5 6

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	12
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	10
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	210.16549138	.	6.867317
1	0	3	209.71141868	0.45407270	0.178686
2	0	3	209.69257264	0.01884604	0.010532
3	0	3	209.6858962	0.00667644	0.003834
4	0	3	209.68346424	0.00243196	0.001408
5	0	3	209.68257279	0.00089145	0.000518
6	0	3	209.68224527	0.00032751	0.00019
7	0	3	209.68212485	0.00012043	0.00007
8	0	3	209.68208055	0.00004429	0.000026
9	0	3	209.68206426	0.00001629	9.482E-6

Convergence criterion (ABSGCONV=0.00001) satisfied.

Fit Statistics

-2 Log Likelihood	419.36
AIC (smaller is better)	439.36
AICC (smaller is better)	440.04
BIC (smaller is better)	477.59
CAIC (smaller is better)	487.59
HQIC (smaller is better)	454.60
Pearson Chi-Square	336.45
Pearson Chi-Square / DF	1.03

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TYPE	5	328	1.55	0.1735
wave	4	328	0.28	0.8919

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	7
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	214.72149868	.	8.473208
1	0	3	214.22595307	0.49554561	0.191203
2	0	3	214.22569276	0.00026031	0.000093
3	0	3	214.22569276	0.00000000	3.36E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	428.45
AIC (smaller is better)	440.45
AICC (smaller is better)	440.71
BIC (smaller is better)	463.39
CAIC (smaller is better)	469.39
HQIC (smaller is better)	449.59
Pearson Chi-Square	337.98
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
RAGE	1	332	0.02	0.9016
wave	4	332	0.22	0.9298

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	7
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	214.6845482	.	8.458068
1	0	3	214.19050706	0.49404113	0.19079
2	0	3	214.1902465	0.00026057	0.000094
3	0	3	214.1902465	0.00000000	3.46E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	428.38
AIC (smaller is better)	440.38
AICC (smaller is better)	440.63
BIC (smaller is better)	463.32
CAIC (smaller is better)	469.32
HQIC (smaller is better)	449.52
Pearson Chi-Square	337.98
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
BMI	1	332	0.09	0.7694
wave	4	332	0.21	0.9309

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5

Number of Observations Read	338
Number of Observations Used	307

Response Profile

Ordered Value	tx	Total Frequency
1	Control	103
2	Intervention	204

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	7
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	307

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	195.49043227	.	7.484742
1	0	3	195.06419723	0.42623505	0.162837
2	0	3	195.06397503	0.00022219	0.000082
3	0	3	195.06397503	0.00000000	3.58E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	390.13
AIC (smaller is better)	402.13
AICC (smaller is better)	402.41
BIC (smaller is better)	424.49
CAIC (smaller is better)	430.49
HQIC (smaller is better)	411.07
Pearson Chi-Square	307.12
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
H2LIVBIR	1	301	0.44	0.5078
wave	4	301	0.26	0.9015

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Model Information

Data Set	WORK.BASELINE
Response Variable	tx
Response Distribution	Binary
Link Function	Logit
Variance Function	Default
Variance Matrix	Diagonal
Estimation Technique	Maximum Likelihood
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
wave	5	1 2 3 4 5

Number of Observations Read	338
Number of Observations Used	338

Response Profile

Ordered Value	tx	Total Frequency
1	Control	112
2	Intervention	226

The GLIMMIX procedure is modeling the probability that tx='Control'.

Dimensions

Columns in X	7
Columns in Z	0
Subjects (Blocks in V)	1
Max Obs per Subject	338

Optimization Information

Optimization Technique	Newton-Raphson
Parameters in Optimization	6
Lower Boundaries	0
Upper Boundaries	0
Fixed Effects	Not Profiled

baseline treatment comparisons , adjusting for potential correlation among women in each new wave

The GLIMMIX Procedure

Iteration History

Iteration	Restarts	Evaluations	Objective Function	Change	Max Gradient
0	0	4	214.71098327	.	8.469137
1	0	3	214.21570501	0.49527825	0.191231
2	0	3	214.21544413	0.00026089	0.000094
3	0	3	214.21544413	0.00000000	3.37E-11

Convergence criterion (GCONV=1E-8) satisfied.

Fit Statistics

-2 Log Likelihood	428.43
AIC (smaller is better)	440.43
AICC (smaller is better)	440.68
BIC (smaller is better)	463.37
CAIC (smaller is better)	469.37
HQIC (smaller is better)	449.57
Pearson Chi-Square	337.97
Pearson Chi-Square / DF	1.02

Type III Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
PADWT	1	332	0.04	0.8493
wave	4	332	0.22	0.9298

The MEANS Procedure

NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL	Visit recoded: Baseline or before=0, Regular or UDS Month 6=6	N Obs	Variable	Label	N
Intervention	0	226	WEIGHT	MEAN WEIGHT IN KG	226
			TOTLEAK	Number of all incontinence episodes	226
			TOTSTRES	Number of stress episodes	226
			TOTURGE	Number of urge episodes	226
	6	224	WEIGHT	MEAN WEIGHT IN KG	221
			TOTLEAK	Number of all incontinence episodes	214
			TOTSTRES	Number of stress episodes	214
			TOTURGE	Number of urge episodes	214
Control	0	112	WEIGHT	MEAN WEIGHT IN KG	112
			TOTLEAK	Number of all incontinence episodes	112
			TOTSTRES	Number of stress episodes	112
			TOTURGE	Number of urge episodes	112
	6	107	WEIGHT	MEAN WEIGHT IN KG	97
			TOTLEAK	Number of all incontinence episodes	90
			TOTSTRES	Number of stress episodes	90
			TOTURGE	Number of urge episodes	90

NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL	Visit recoded: Baseline or before=0, Regular or UDS Month 6=6	N Obs	Variable	Label	Mean
Intervention	0	226	WEIGHT	MEAN WEIGHT IN KG	98
			TOTLEAK	Number of all incontinence episodes	24
			TOTSTRES	Number of stress episodes	9
			TOTURGE	Number of urge episodes	14
	6	224	WEIGHT	MEAN WEIGHT IN KG	89
			TOTLEAK	Number of all incontinence episodes	13

```
                                    TOTSTRES  Number of stress episodes
4
                                    TOTURGE   Number of urge episodes
8

  Control                    0  112  WEIGHT    MEAN WEIGHT IN KG
95
                                    TOTLEAK   Number of all incontinence episodes
24
                                    TOTSTRES  Number of stress episodes
10
  ------------------------------------------------------------------------------------------
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```

The MEANS Procedure

NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL	Visit recoded: Baseline or before=0, Regular or UDS Month 6=6	N Obs	Variable	Label	Mean
Control	0	112	TOTURGE	Number of urge episodes	13
	6	107	WEIGHT	MEAN WEIGHT IN KG	93
			TOTLEAK	Number of all incontinence episodes	16
			TOTSTRES	Number of stress episodes	7
			TOTURGE	Number of urge episodes	9

NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL	Visit recoded: Baseline or before=0, Regular or UDS Month 6=6	N Obs	Variable	Label	Std Dev
Intervention	0	226	WEIGHT	MEAN WEIGHT IN KG	17
			TOTLEAK	Number of all incontinence episodes	18
			TOTSTRES	Number of stress episodes	11
			TOTURGE	Number of urge episodes	14
	6	224	WEIGHT	MEAN WEIGHT IN KG	17
			TOTLEAK	Number of all incontinence episodes	15
			TOTSTRES	Number of stress episodes	7
			TOTURGE	Number of urge episodes	11

Control	0	112	WEIGHT	MEAN WEIGHT IN KG
16				
			TOTLEAK	Number of all incontinence episodes
18				
			TOTSTRES	Number of stress episodes
10				
			TOTURGE	Number of urge episodes
15				
	6	107	WEIGHT	MEAN WEIGHT IN KG
16				
			TOTLEAK	Number of all incontinence episodes
15				
			TOTSTRES	Number of stress episodes
8				
			TOTURGE	Number of urge episodes
12				

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The FREQ Procedure

Visit recoded: Baseline or before=0, Regular or UDS Month 6=6

NVISIT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	338	50.52	338	50.52
6	331	49.48	669	100.00

NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL

tx	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Intervention	450	67.26	450	67.26
Control	219	32.74	669	100.00

PRIDE CLINIC

CLINIC	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	344	51.42	344	51.42
2	325	48.58	669	100.00

The GENMOD Procedure

Model Information

Data Set	WORK.BASEMO6	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	TOTLEAK	Number of all incontinence episodes

Number of Observations Read	669
Number of Observations Used	642
Missing Values	27

Class Level Information

Class	Levels	Values
ID	338	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
tx	2	Control Intervention
NVISIT	2	0 6
CLINIC	2	1 2

Parameter Information

Parameter	Effect	tx	NVISIT	CLINIC
Prm1	Intercept			
Prm2	tx	Control		
Prm3	tx	Intervention		
Prm4	NVISIT		0	
Prm5	NVISIT		6	
Prm6	CLINIC			1
Prm7	CLINIC			2
Prm8	tx*NVISIT	Control	0	
Prm9	tx*NVISIT	Control	6	
Prm10	tx*NVISIT	Intervention	0	
Prm11	tx*NVISIT	Intervention	6	

Algorithm converged.

The GENMOD Procedure

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (338 levels)
Number of Clusters	338
Clusters With Missing Values	27
Correlation Matrix Dimension	2
Maximum Cluster Size	2
Minimum Cluster Size	1

Algorithm converged.

Working Correlation Matrix

	Col1	Col2
Row1	1.0000	0.5603
Row2	0.5603	1.0000

GEE Fit Criteria

QIC	-45132.0722
QICu	-45132.4589

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter			Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept			2.5577	0.0880	2.3852	2.7301	29.06	<.0001
tx	Control		0.2655	0.1224	0.0255	0.5054	2.17	0.0301
tx	Intervention		0.0000	0.0000	0.0000	0.0000	.	.
NVISIT	0		0.6571	0.0653	0.5292	0.7850	10.07	<.0001
NVISIT	6		0.0000	0.0000	0.0000	0.0000	.	.
CLINIC	1		-0.0437	0.0881	-0.2164	0.1291	-0.50	0.6202
CLINIC	2		0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Control	0	-0.2696	0.0994	-0.4645	-0.0748	-2.71	0.0067
tx*NVISIT	Control	6	0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Intervention	0	0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Intervention	6	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Wald Statistics For Type 3 GEE Analysis

Source	DF	Chi-Square	Pr > ChiSq
tx	1	1.98	0.1595
NVISIT	1	109.99	<.0001
CLINIC	1	0.25	0.6202
tx*NVISIT	1	7.36	0.0067

Least Squares Means

Effect	tx	NVISIT	Estimate Mean	L'Beta	Standard Error	DF	Chi-Square	Pr > ChiSq	Alpha
tx	Control		19.9864	2.9951	0.0735	1	1662.2	<.0001	0.05
tx	Intervention		17.5381	2.8644	0.0571	1	2513.4	<.0001	0.05
NVISIT		0	24.3095	3.1909	0.0426	1	5619.8	<.0001	0.05
NVISIT		6	14.4192	2.6686	0.0614	1	1885.9	<.0001	0.05
tx*NVISIT	Control	0	24.2592	3.1888	0.0685	1	2164.5	<.0001	0.05
tx*NVISIT	Control	6	16.4661	2.8013	0.0944	1	880.12	<.0001	0.05
tx*NVISIT	Intervention	0	24.3599	3.1929	0.0503	1	4032.1	<.0001	0.05
tx*NVISIT	Intervention	6	12.6267	2.5358	0.0783	1	1049.0	<.0001	0.05

Least Squares Means

Effect	tx	NVISIT	Confidence Limits	
tx	Control		2.8511	3.1390
tx	Intervention		2.7524	2.9764
NVISIT		0	3.1074	3.2743
NVISIT		6	2.5481	2.7890
tx*NVISIT	Control	0	3.0545	3.3231
tx*NVISIT	Control	6	2.6162	2.9864
tx*NVISIT	Intervention	0	3.0944	3.2915
tx*NVISIT	Intervention	6	2.3824	2.6893

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Estimate	Standard Error	DF	Chi-Square

tx	Control		Intervention		0.1307	0.0929	1	1.98
NVISIT		0		6	0.5223	0.0498	1	109.99
tx*NVISIT	Control	0	Control	6	0.3875	0.0751	1	26.61
tx*NVISIT	Control	0	Intervention	0	-0.0041	0.0849	1	0.00
tx*NVISIT	Control	0	Intervention	6	0.6530	0.1039	1	39.47
tx*NVISIT	Control	6	Intervention	0	-0.3916	0.1068	1	13.44
tx*NVISIT	Control	6	Intervention	6	0.2655	0.1224	1	4.70

The GENMOD Procedure

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Estimate	Standard Error	DF	Chi-Square
tx*NVISIT	Intervention	0	Intervention	6	0.6571	0.0653	1	101.37

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Pr > ChiSq	Alpha	Confidence Limits	
tx	Control		Intervention		0.1595	0.05	-0.0514	0.3127
NVISIT		0		6	<.0001	0.05	0.4247	0.6199
tx*NVISIT	Control	0	Control	6	<.0001	0.05	0.2403	0.5347
tx*NVISIT	Control	0	Intervention	0	0.9611	0.05	-0.1705	0.1622
tx*NVISIT	Control	0	Intervention	6	<.0001	0.05	0.4493	0.8567
tx*NVISIT	Control	6	Intervention	0	0.0002	0.05	-0.6010	-0.1823
tx*NVISIT	Control	6	Intervention	6	0.0301	0.05	0.0255	0.5054
tx*NVISIT	Intervention	0	Intervention	6	<.0001	0.05	0.5292	0.7850

The GENMOD Procedure

Model Information

Data Set	WORK.BASEMO6	
Distribution	Negative Binomial	
Link Function	Log	
Dependent Variable	TOTSTRES	Number of stress episodes

Number of Observations Read	669
Number of Observations Used	642
Missing Values	27

Class Level Information

Class	Levels	Values
ID	338	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
tx	2	Control Intervention
NVISIT	2	0 6
CLINIC	2	1 2

Parameter Information

Parameter	Effect	tx	NVISIT	CLINIC
Prm1	Intercept			
Prm2	tx	Control		
Prm3	tx	Intervention		
Prm4	NVISIT		0	
Prm5	NVISIT		6	
Prm6	CLINIC			1
Prm7	CLINIC			2
Prm8	tx*NVISIT	Control	0	
Prm9	tx*NVISIT	Control	6	
Prm10	tx*NVISIT	Intervention	0	
Prm11	tx*NVISIT	Intervention	6	

Algorithm converged.

The GENMOD Procedure

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (338 levels)
Number of Clusters	338
Clusters With Missing Values	27
Correlation Matrix Dimension	2
Maximum Cluster Size	2
Minimum Cluster Size	1

Algorithm converged.

Working Correlation Matrix

	Col1	Col2
Row1	1.0000	0.4574
Row2	0.4574	1.0000

GEE Fit Criteria

QIC	-10798.4603
QICu	-10798.2052

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter			Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept			1.2864	0.1578	0.9770	1.5958	8.15	<.0001
tx	Control		0.5645	0.1823	0.2072	0.9218	3.10	0.0020
tx	Intervention		0.0000	0.0000	0.0000	0.0000	.	.
NVISIT	0		0.8796	0.1177	0.6490	1.1102	7.48	<.0001
NVISIT	6		0.0000	0.0000	0.0000	0.0000	.	.
CLINIC	1		0.0917	0.1332	-0.1693	0.3528	0.69	0.4910
CLINIC	2		0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Control	0	-0.4613	0.1666	-0.7877	-0.1348	-2.77	0.0056
tx*NVISIT	Control	6	0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Intervention	0	0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Intervention	6	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Wald Statistics For Type 3 GEE Analysis

Source	DF	Chi-Square	Pr > ChiSq
tx	1	6.57	0.0104
NVISIT	1	60.91	<.0001
CLINIC	1	0.47	0.4910
tx*NVISIT	1	7.67	0.0056

Least Squares Means

Effect	tx	NVISIT	Estimate Mean	L'Beta	Standard Error	DF	Chi-Square	Pr > ChiSq	Alpha
tx	Control		8.2147	2.1059	0.0927	1	516.15	<.0001	0.05
tx	Intervention		5.8830	1.7721	0.0919	1	371.83	<.0001	0.05
NVISIT		0	9.6165	2.2635	0.0604	1	1403.9	<.0001	0.05
NVISIT		6	5.0254	1.6145	0.0915	1	311.62	<.0001	0.05
tx*NVISIT	Control	0	10.1258	2.3151	0.0889	1	677.91	<.0001	0.05
tx*NVISIT	Control	6	6.6642	1.8968	0.1273	1	221.98	<.0001	0.05
tx*NVISIT	Intervention	0	9.1328	2.2119	0.0817	1	733.61	<.0001	0.05
tx*NVISIT	Intervention	6	3.7896	1.3323	0.1309	1	103.54	<.0001	0.05

Least Squares Means

Effect	tx	NVISIT	Confidence Limits	
tx	Control		1.9242	2.2876
tx	Intervention		1.5919	1.9522
NVISIT		0	2.1451	2.3819
NVISIT		6	1.4353	1.7938
tx*NVISIT	Control	0	2.1408	2.4894
tx*NVISIT	Control	6	1.6472	2.1463
tx*NVISIT	Intervention	0	2.0518	2.3719
tx*NVISIT	Intervention	6	1.0756	1.5889

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Estimate	Standard Error	DF	Chi-Square

tx	Control		Intervention		0.3339	0.1302	1	6.57
NVISIT		0		6	0.6490	0.0832	1	60.91
tx*NVISIT	Control	0	Control	6	0.4183	0.1177	1	12.63
tx*NVISIT	Control	0	Intervention	0	0.1032	0.1206	1	0.73
tx*NVISIT	Control	0	Intervention	6	0.9828	0.1578	1	38.79
tx*NVISIT	Control	6	Intervention	0	-0.3151	0.1512	1	4.35
tx*NVISIT	Control	6	Intervention	6	0.5645	0.1823	1	9.59

The GENMOD Procedure

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Estimate	Standard Error	DF	Chi-Square
tx*NVISIT	Intervention	0	Intervention	6	0.8796	0.1177	1	55.90

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Pr > ChiSq	Alpha	Confidence Limits	
tx	Control		Intervention		0.0104	0.05	0.0786	0.5891
NVISIT		0		6	<.0001	0.05	0.4860	0.8119
tx*NVISIT	Control	0	Control	6	0.0004	0.05	0.1876	0.6491
tx*NVISIT	Control	0	Intervention	0	0.3922	0.05	-0.1332	0.3397
tx*NVISIT	Control	0	Intervention	6	<.0001	0.05	0.6735	1.2921
tx*NVISIT	Control	6	Intervention	0	0.0371	0.05	-0.6114	-0.0189
tx*NVISIT	Control	6	Intervention	6	0.0020	0.05	0.2072	0.9218
tx*NVISIT	Intervention	0	Intervention	6	<.0001	0.05	0.6490	1.1102

The GENMOD Procedure

Model Information

Data Set	WORK.BASEMO6
Distribution	Negative Binomial
Link Function	Log
Dependent Variable	TOTURGE Number of urge episodes

Number of Observations Read	669
Number of Observations Used	642
Missing Values	27

Class Level Information

Class	Levels	Values
ID	338	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
tx	2	Control Intervention
NVISIT	2	0 6
CLINIC	2	1 2

Parameter Information

Parameter	Effect	tx	NVISIT	CLINIC
Prm1	Intercept			
Prm2	tx	Control		
Prm3	tx	Intervention		
Prm4	NVISIT		0	
Prm5	NVISIT		6	
Prm6	CLINIC			1
Prm7	CLINIC			2
Prm8	tx*NVISIT	Control	0	
Prm9	tx*NVISIT	Control	6	
Prm10	tx*NVISIT	Intervention	0	
Prm11	tx*NVISIT	Intervention	6	

Algorithm converged.

The GENMOD Procedure

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (338 levels)
Number of Clusters	338
Clusters With Missing Values	27
Correlation Matrix Dimension	2
Maximum Cluster Size	2
Minimum Cluster Size	1

Algorithm converged.

Working Correlation Matrix

	Col1	Col2
Row1	1.0000	0.6501
Row2	0.6501	1.0000

GEE Fit Criteria

QIC	-22810.8660
QICu	-22811.5476

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter			Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept			2.1697	0.1071	1.9598	2.3796	20.26	<.0001
tx	Control		0.1289	0.1530	-0.1709	0.4288	0.84	0.3994
tx	Intervention		0.0000	0.0000	0.0000	0.0000	.	.
NVISIT	0		0.5624	0.0768	0.4119	0.7129	7.33	<.0001
NVISIT	6		0.0000	0.0000	0.0000	0.0000	.	.
CLINIC	1		-0.1975	0.1175	-0.4277	0.0328	-1.68	0.0928
CLINIC	2		0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Control	0	-0.1786	0.1060	-0.3864	0.0292	-1.68	0.0921
tx*NVISIT	Control	6	0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Intervention	0	0.0000	0.0000	0.0000	0.0000	.	.
tx*NVISIT	Intervention	6	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Wald Statistics For Type 3 GEE Analysis

Source	DF	Chi-Square	Pr > ChiSq
tx	1	0.10	0.7559
NVISIT	1	79.26	<.0001
CLINIC	1	2.83	0.0928
tx*NVISIT	1	2.84	0.0921

Least Squares Means

Effect	tx	NVISIT	Estimate Mean	L'Beta	Standard Error	DF	Chi-Square	Pr > ChiSq	Alpha
tx	Control		10.9335	2.3918	0.1047	1	521.64	<.0001	0.05
tx	Intervention		10.5087	2.3522	0.0730	1	1038.0	<.0001	0.05
NVISIT		0	13.5798	2.6086	0.0608	1	1841.9	<.0001	0.05
NVISIT		6	8.4609	2.1355	0.0768	1	773.74	<.0001	0.05
tx*NVISIT	Control	0	13.2467	2.5837	0.1014	1	648.84	<.0001	0.05
tx*NVISIT	Control	6	9.0243	2.1999	0.1197	1	337.66	<.0001	0.05
tx*NVISIT	Intervention	0	13.9213	2.6334	0.0667	1	1558.6	<.0001	0.05
tx*NVISIT	Intervention	6	7.9327	2.0710	0.0957	1	468.30	<.0001	0.05

Least Squares Means

Effect	tx	NVISIT	Confidence Limits	
tx	Control		2.1866	2.5971
tx	Intervention		2.2091	2.4953
NVISIT		0	2.4895	2.7277
NVISIT		6	1.9850	2.2859
tx*NVISIT	Control	0	2.3849	2.7826
tx*NVISIT	Control	6	1.9653	2.4346
tx*NVISIT	Intervention	0	2.5027	2.7642
tx*NVISIT	Intervention	6	1.8834	2.2586

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Estimate	Standard Error	DF	Chi-Square

tx	Control		Intervention		0.0396	0.1274	1	0.10
NVISIT		0		6	0.4731	0.0531	1	79.26
tx*NVISIT	Control	0	Control	6	0.3838	0.0733	1	27.41
tx*NVISIT	Control	0	Intervention	0	-0.0497	0.1212	1	0.17
tx*NVISIT	Control	0	Intervention	6	0.5128	0.1393	1	13.55
tx*NVISIT	Control	6	Intervention	0	-0.4335	0.1369	1	10.03
tx*NVISIT	Control	6	Intervention	6	0.1289	0.1530	1	0.71

The GENMOD Procedure

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Estimate	Standard Error	DF	Chi-Square
tx*NVISIT	Intervention	0	Intervention	6	0.5624	0.0768	1	53.66

Differences of Least Squares Means

Effect	tx	NVISIT	_tx	_NVISIT	Pr > ChiSq	Alpha	Confidence Limits	
tx	Control		Intervention		0.7559	0.05	-0.2102	0.2894
NVISIT		0		6	<.0001	0.05	0.3690	0.5773
tx*NVISIT	Control	0	Control	6	<.0001	0.05	0.2401	0.5275
tx*NVISIT	Control	0	Intervention	0	0.6820	0.05	-0.2873	0.1879
tx*NVISIT	Control	0	Intervention	6	0.0002	0.05	0.2397	0.7858
tx*NVISIT	Control	6	Intervention	0	0.0015	0.05	-0.7017	-0.1653
tx*NVISIT	Control	6	Intervention	6	0.3994	0.05	-0.1709	0.4288
tx*NVISIT	Intervention	0	Intervention	6	<.0001	0.05	0.4119	0.7129

reporting medians as well as means, as percent different in incontinence episodes appears to be sk

The MEANS Procedure

NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL	N Obs	Variable	N	Mean	Median	Std Error
Intervention	224	perdiffwt	221	-8.2455434	-8.4280303	0.4098962
		perdifftot	214	-41.6339421	-60.0000000	4.9584001
		perdiffstres	179	-39.0851860	-71.4285714	10.0080345
		perdiffurge	205	-35.5748628	-53.3333333	5.1230407
Control	107	perdiffwt	97	-1.7940632	-1.0654490	0.4147467
		perdifftot	90	-27.3598749	-33.3333333	5.7237644
		perdiffstres	82	-17.4885821	-45.2991453	13.2849724
		perdiffurge	80	-13.0472910	-32.0512821	11.0154782

The Mixed Procedure

Model Information

Data Set	WORK.DIFF
Dependent Variable	perdiffwt
Covariance Structure	Diagonal
Estimation Method	REML
Residual Variance Method	Profile
Fixed Effects SE Method	Model-Based
Degrees of Freedom Method	Residual

Class Level Information

Class	Levels	Values
tx	2	Control Intervention
CLINIC	2	1 2

Dimensions

Covariance Parameters	1
Columns in X	5
Columns in Z	0
Subjects	1
Max Obs Per Subject	331

Number of Observations

Number of Observations Read	331
Number of Observations Used	318
Number of Observations Not Used	13

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	30.4790

Fit Statistics

-2 Res Log Likelihood	1984.6
AIC (smaller is better)	1986.6
AICC (smaller is better)	1986.7
BIC (smaller is better)	1990.4

The Mixed Procedure

Solution for Fixed Effects

Effect	PRIDE CLINIC	NUMERIC TX GROUP: 0=INTERVENTION 1=CONTROL	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept			-7.4914	0.4899	315	-15.29	<.0001
tx		Control	6.4208	0.6725	315	9.55	<.0001
tx		Intervention	0	.	.	.	.
CLINIC	1		-1.4619	0.6194	315	-2.36	0.0189
CLINIC	2		0	.	.	.	.

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
tx	1	315	91.15	<.0001
CLINIC	1	315	5.57	0.0189

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	totgt50

Number of Observations Read	331
Number of Observations Used	304
Number of Events	156
Number of Trials	304
Missing Values	27

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	totgt50	Total Frequency
1	1	156
2	0	148

PROC GENMOD is modeling the probability that totgt50='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	27
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	405.8491
QICu	405.8550

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		0.3556	0.1862	-0.0093	0.7205	1.91	0.0561
tx		-1.1908	0.2669	-1.7140	-0.6677	-4.46	<.0001
CLINIC	1	0.0800	0.2379	-0.3863	0.5463	0.34	0.7367
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	totgt70

Number of Observations Read	331
Number of Observations Used	304
Number of Events	105
Number of Trials	304
Missing Values	27

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	totgt70	Total Frequency
1	1	105
2	0	199

PROC GENMOD is modeling the probability that totgt70='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	27
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	387.0761
QICu	387.0752

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-0.4325	0.1905	-0.8059	-0.0591	-2.27	0.0232
tx		-0.9189	0.2936	-1.4943	-0.3435	-3.13	0.0017
CLINIC	1	0.0657	0.2458	-0.4160	0.5475	0.27	0.7891
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	toteq100

Number of Observations Read	331
Number of Observations Used	304
Number of Events	22
Number of Trials	304
Missing Values	27

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	toteq100	Total Frequency
1	1	22
2	0	282

PROC GENMOD is modeling the probability that toteq100='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	27
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	162.8838
QICu	162.9180

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-2.3053	0.3087	-2.9104	-1.7003	-7.47	<.0001
tx		-0.3919	0.5209	-1.4128	0.6290	-0.75	0.4519
CLINIC	1	-0.2907	0.4422	-1.1574	0.5759	-0.66	0.5109
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	stresgt50

Number of Observations Read	331
Number of Observations Used	261
Number of Events	148
Number of Trials	261
Missing Values	70

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	stresgt50	Total Frequency
1	1	148
2	0	113

PROC GENMOD is modeling the probability that stresgt50='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	70
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	351.7196
QICu	351.7233

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		0.5172	0.2037	0.1181	0.9164	2.54	0.0111
tx		-0.9070	0.2727	-1.4415	-0.3725	-3.33	0.0009
CLINIC	1	0.0853	0.2556	-0.4157	0.5864	0.33	0.7385
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	stresgt70

Number of Observations Read	331
Number of Observations Used	261
Number of Events	118
Number of Trials	261
Missing Values	70

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	stresgt70	Total Frequency
1	1	118
2	0	143

PROC GENMOD is modeling the probability that stresgt70='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	70
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	356.3724
QICu	356.3774

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		0.0204	0.2000	-0.3716	0.4124	0.10	0.9188
tx		-0.8233	0.2804	-1.3728	-0.2738	-2.94	0.0033
CLINIC	1	0.0676	0.2532	-0.4287	0.5639	0.27	0.7895
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	streseq100

Number of Observations Read	331
Number of Observations Used	261
Number of Events	61
Number of Trials	261
Missing Values	70

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	streseq100	Total Frequency
1	1	61
2	0	200

PROC GENMOD is modeling the probability that streseq100='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	70
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	285.7709
QICu	285.7707

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-1.0491	0.2311	-1.5020	-0.5962	-4.54	<.0001
tx		-0.6653	0.3463	-1.3440	0.0134	-1.92	0.0547
CLINIC	1	0.0851	0.2955	-0.4941	0.6642	0.29	0.7734
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	urgegt50

Number of Observations Read	331
Number of Observations Used	285
Number of Events	130
Number of Trials	285
Missing Values	46

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	urgegt50	Total Frequency
1	1	130
2	0	155

PROC GENMOD is modeling the probability that urgegt50='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	46
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	389.4277
QICu	389.4278

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		0.0335	0.1891	-0.3372	0.4042	0.18	0.8594
tx		-0.8361	0.2790	-1.3829	-0.2894	-3.00	0.0027
CLINIC	1	0.0290	0.2421	-0.4455	0.5036	0.12	0.9045
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	urgegt70

Number of Observations Read	331
Number of Observations Used	285
Number of Events	107
Number of Trials	285
Missing Values	46

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	urgegt70	Total Frequency
1	1	107
2	0	178

PROC GENMOD is modeling the probability that urgegt70='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	46
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	379.4427
QICu	379.4419

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-0.3821	0.1932	-0.7607	-0.0035	-1.98	0.0479
tx		-0.5413	0.2852	-1.1003	0.0176	-1.90	0.0577
CLINIC	1	0.0324	0.2466	-0.4510	0.5159	0.13	0.8953
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.

The GENMOD Procedure

Model Information

Data Set	WORK.DIFF
Distribution	Binomial
Link Function	Logit
Dependent Variable	urgeeq100

Number of Observations Read	331
Number of Observations Used	285
Number of Events	47
Number of Trials	285
Missing Values	46

Class Level Information

Class	Levels	Values
ID	331	10014 10029 10030 10040 10041 10043 10055 10077 10082 10083 10092 10097 10103 10109 10112 10113 10116 10121 10136 10142 10152 10157 10167 10175 10182 10198 10199 10206 10208 10210 10211 10213 10214 10226 10246 10247 10252 10260 10268 10281 10287 10290 ...
CLINIC	2	1 2

Response Profile

Ordered Value	urgeeq100	Total Frequency
1	1	47
2	0	238

PROC GENMOD is modeling the probability that urgeeq100='1'.

Parameter Information

Parameter	Effect	CLINIC
Prm1	Intercept	
Prm2	tx	
Prm3	CLINIC	1
Prm4	CLINIC	2

The GENMOD Procedure

Algorithm converged.

GEE Model Information

Correlation Structure	Unstructured
Subject Effect	ID (331 levels)
Number of Clusters	331
Clusters With Missing Values	46
Correlation Matrix Dimension	1
Maximum Cluster Size	1
Minimum Cluster Size	0

Algorithm converged.

GEE Fit Criteria

QIC	258.8009
QICu	258.8051

Analysis Of GEE Parameter Estimates
Empirical Standard Error Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		-1.5129	0.2465	-1.9960	-1.0298	-6.14	<.0001
tx		-0.5827	0.3966	-1.3600	0.1946	-1.47	0.1418
CLINIC	1	0.0611	0.3208	-0.5676	0.6898	0.19	0.8489
CLINIC	2	0.0000	0.0000	0.0000	0.0000	.	.