**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**HW**

**See Canvas for Due Date**

**Directions:**

You will be applying analyses and concepts learned this semester in order to complete the following report on a treatment’s efficacy. To help you get started and provide structure for the assignment, you have been provided with a partial write-up of the results of a clinical trial. Your goal is to complete the write-up provided below. Pay special attention to the highlighted portions, as these are the sections you are expected to fill in.

**Scenario:**

You will be working with a fictitious dataset modeled after a real RCT chosen by a previous class. The clinical trial chosen examined the effect of sertraline, a selective serotonin reuptake inhibitor, on language development, motor skills, visual perceptual abilities, and social participation in young children with Fragile X Syndrome. Please note that your findings may differ from the original study findings. This is an entirely new dataset after all; anything is possible.

**Measures:**

To help you get up to speed with this scenario, here is a brief summary of some of the measures employed

*Mullen Scales of Early Learning (MSEL)*

The Mullen Scales of Early Learning is an individually administered test intended to assess modality performance and to identify learning ability, learning disability, and mental retardation in children. It is comprised of 144 questions, which are then used to calculate 4 subscales. For this project I’ve already calculated the 4 subscales for you; you aren’t going to have to work with the original 144 individual questions.

The individual units of measurement aren’t important for the scope of this project, but you should know that higher scores reflect better performance, while lower scores reflect deficits in performance.

*MSEL: Visual Reception Subscale*

Questions for this subscale test children’s ability to perform visual localization, tracking, and scanning. Questions involve discriminating forms, matching letters, and demonstrating memory for form.

*MSEL: Fine Motor Subscale*

Questions for this subscale test fine-motor skill, eye-hand coordination, and motor planning and control. Questions involve copying a vertical line, stringing beads, and copying a square.

*MSEL: Receptive Language*

Questions for this subscale test auditory discrimination and auditory/motor ability. Questions involve comprehending action words, following three unrelated commands, and knowing left from right.

*MSEL: Expressive Language*

Questions for this subscale test overall verbal expressive abilities. Questions involve using two-word phrases, comprehending spoken questions, and orally repeating spoken sentences.

*Clinical Global Impression Scale (CGI)*

The Clinical Global Impression Scale is a well-established research rating tool that was developed for use in NIMH-sponsored clinical trials to provide a brief, stand-alone assessment of the clinician’s view of patients’ global functioning prior to and after initiating a study medication.

Only a single metric (CGI-Improvement) from the CGI tool was employed in this study, and it was only employed at posttest. This is a single question asking, “Compared to the patient’s condition at admission to the project [prior to medication initiation], this patient’s condition is…”

*Sensory Processing Measure - Preschool (SPM-P)*

The Sensory Processing Measure – Preschool is a validated tool used to identify sensory processing difficulties in children as young as 2 years of age. Only a single subscale, social participation, was utilized.

Scores are standardized based on population norms, resulting in a scale that has a mean score of 50 and standard deviation of 10 in the normal, healthy preschool population. Higher scores reflect greater social participation, while lower scores reflect less social participation.

**Materials and Methods**

**Study Design**

This was an exploratory first trial of sertraline in children with fragile X syndrome aged 2 to 6 years using a randomized, double-blind, placebo-controlled design. Inclusion criteria included molecular documentation of Fragile X syndrome (FXS), age between 2 to 6 years, English speaking, and willingness to travel and participate in the study. Volunteers were excluded if they had other central nervous system diseases. Patients both with and without autism spectrum disorders (ASD) were included in the study.

Subjects were randomly assigned to receive either sertraline liquid in age-appropriate dosages or a placebo liquid daily. Clinical assessments and data collection were conducted at baseline (prior to participation in the study) and again at a 6-month follow-up visit. Side effects were monitored via weekly phone calls to participants’ legal guardians.

**Results**

**Subject Characteristics**

A total of # subjects participated in the study, with # subjects providing complete data at both pretest and at the 6-month follow-up visit. All data included in the dataset were scrutinized for data entry errors or nonsensical responses. Data cleaning was accomplished by <*describe the techniques you used to clean your dataset here>*. A total of # errors were detected *<describe how you handled any errors you found>.*

In order to test the effectiveness of the random assignment procedure, the demographic characteristics and baseline characteristics of the intervention and control groups were compared (see Table 1). <*Briefly summarize the primary important findings from your analyses for Table 1 here. Make sure you address whether random assignment appeared to work as expected or not>*.

*Table 1*

*Demographic characteristics of intervention and control groups at baseline (n = # - #)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cases | |  | Controls | |  |
| Variable | M (SD) | ? (?) |  | M (SD) | ? (?) | *p\** |
| Age |  |  |  |  |  |  |
| Gender |  |  |  |  |  |  |
| Race |  |  |  |  |  |  |
| Autistic Spectrum Disorder |  |  |  |  |  |  |
| MESL |  |  |  |  |  |  |
| Visual Reception |  |  |  |  |  |  |
| Fine Motor |  |  |  |  |  |  |
| Receptive Language |  |  |  |  |  |  |
| Expressive Language |  |  |  |  |  |  |
| SPM-P |  |  |  |  |  |  |

\* Reported for <name the tests you ran>, where appropriate

**Survey Characteristics**

In order to assess the relationship between the measures collected in this study, a correlation matrix was generated (see Table 2 below).

As shown in Table 2, several correlations matched a priori expectations. For example <summarize the expected findings that emerged in this correlation matrix. Do not discuss each correlation coefficient one-by-one (your reader already has the correlation coefficients in Table 2, after all). Rather look for patterns, engage in critical thinking, and explain to your reader why these results make sense and were expected in advance. You goal is to walk your reader through the important patterns that you notice in Table 2>

However, several unanticipated findings also emerged in the correlation matrix. For example <summarize the unexpected findings that emerged in this correlation. As above, focus on the big picture, engage in critical thinking, and explain to your reader why these results were unexpected.>

*Note: Your summary for Table 2 should be less than 1-page total*

*Table 2*

*Correlation matrix of survey measures*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1. MESL – Visual Reception, Baseline |  |  |  |  |  |  |  |  |  |
| 2. MESL – Fine Motor, Baseline |  |  |  |  |  |  |  |  |  |
| 3. MESL – Receptive Language, Baseline |  |  |  |  |  |  |  |  |  |
| 4. MESL – Expressive Language, Baseline |  |  |  |  |  |  |  |  |  |
| 5. MESL – Visual Reception, 6-month |  |  |  |  |  |  |  |  |  |
| 6. MESL – Fine Motor, 6-month |  |  |  |  |  |  |  |  |  |
| 7. MESL – Receptive Language, 6-month |  |  |  |  |  |  |  |  |  |
| 8. MESL – Expressive Language, 6-month |  |  |  |  |  |  |  |  |  |
| 9. SPM-P – Baseline |  |  |  |  |  |  |  |  |  |
| 10. SPM-P – 6-month |  |  |  |  |  |  |  |  |  |

\* *p* ≤ .05, \*\* *p* ≤ .01, \*\*\* *p* ≤ .001

**Clinical Outcomes**

In order to assess the impact of sertraline of participant outcomes, difference scores were first calculated (6 month - baseline) for each of the MESL subscales and SPM-P. A series of *<name the statistical tests you would run>* were then conducted in order to determine whether changes in scores differed between the intervention and control groups (see Table 3). <*Briefly summarize the primary important findings from your analyses for Table 3 here>*

In addition, CGI-Improvement scores for the intervention and control groups were compared with *<name the statistical tests you need to run and provide an APA-formatted interpretation of your finding>.*

Table 3

*Changes in participant outcomes by condition*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Condition | |  |  |  |
|  | Sertraline | Control |  |  |  |
|  | ? (?) | ? (?) | <Test statistic> | df | *p* |
| MESL |  |  |  |  |  |
| Visual Reception | # (#) | # (#) | # | # | # |
| Fine Motor | # (#) | # (#) | # | # | # |
| Receptive Language | # (#) | # (#) | # | # | # |
| Expressive Language | # (#) | # (#) | # | # | # |
| SPM-P | # (#) | # (#) | # | # | # |

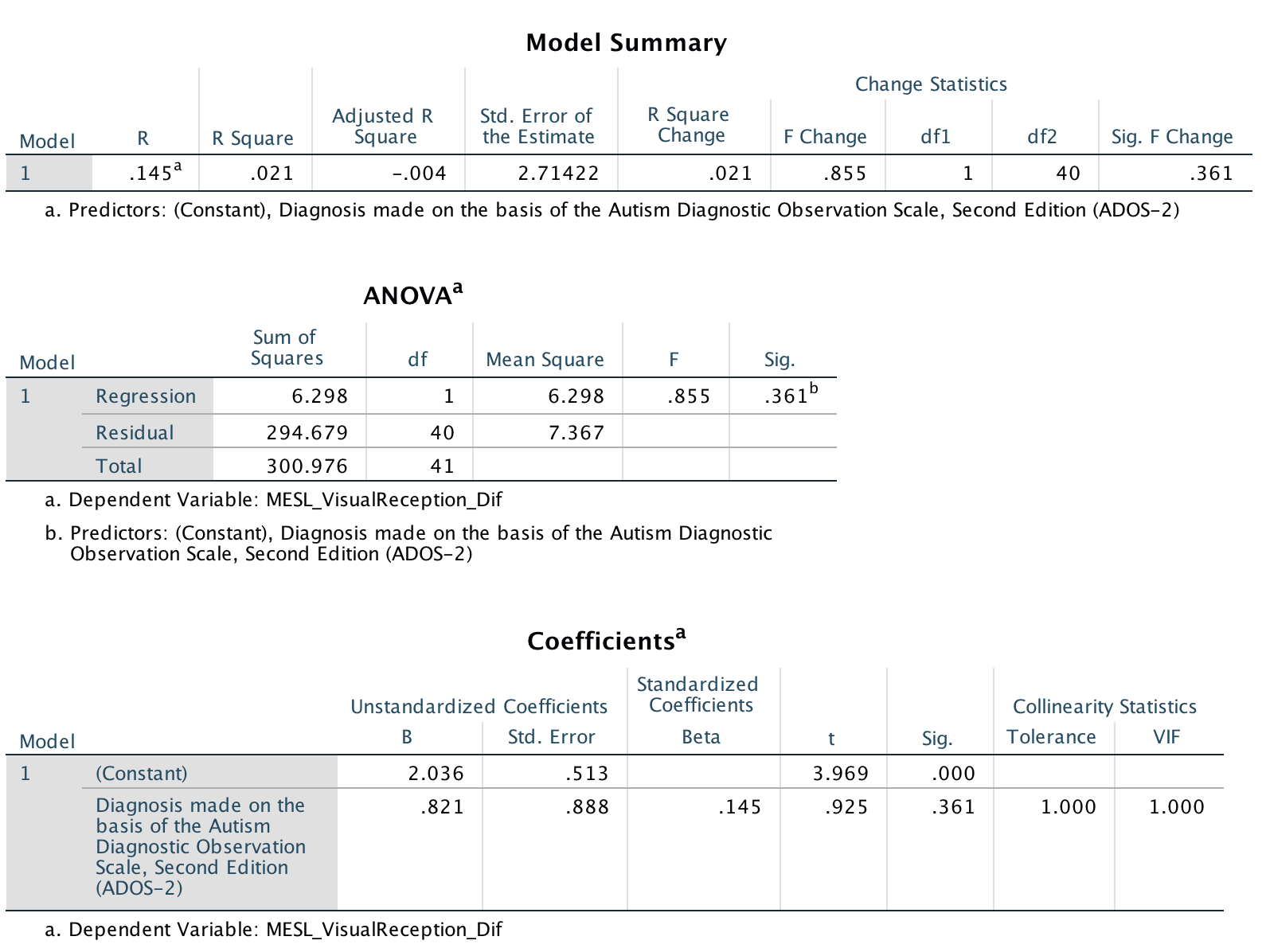
**Impact of Autism**

In order to examine the effect of autism, a common comorbidity encountered alongside FXS, predicts performance on language development, motor skills, visual perceptual abilities, and social participation (measured as the difference between 6 month – baseline scores for each of the MESL subscales and SPM-P) a series of analyses were run on the intervention group only.

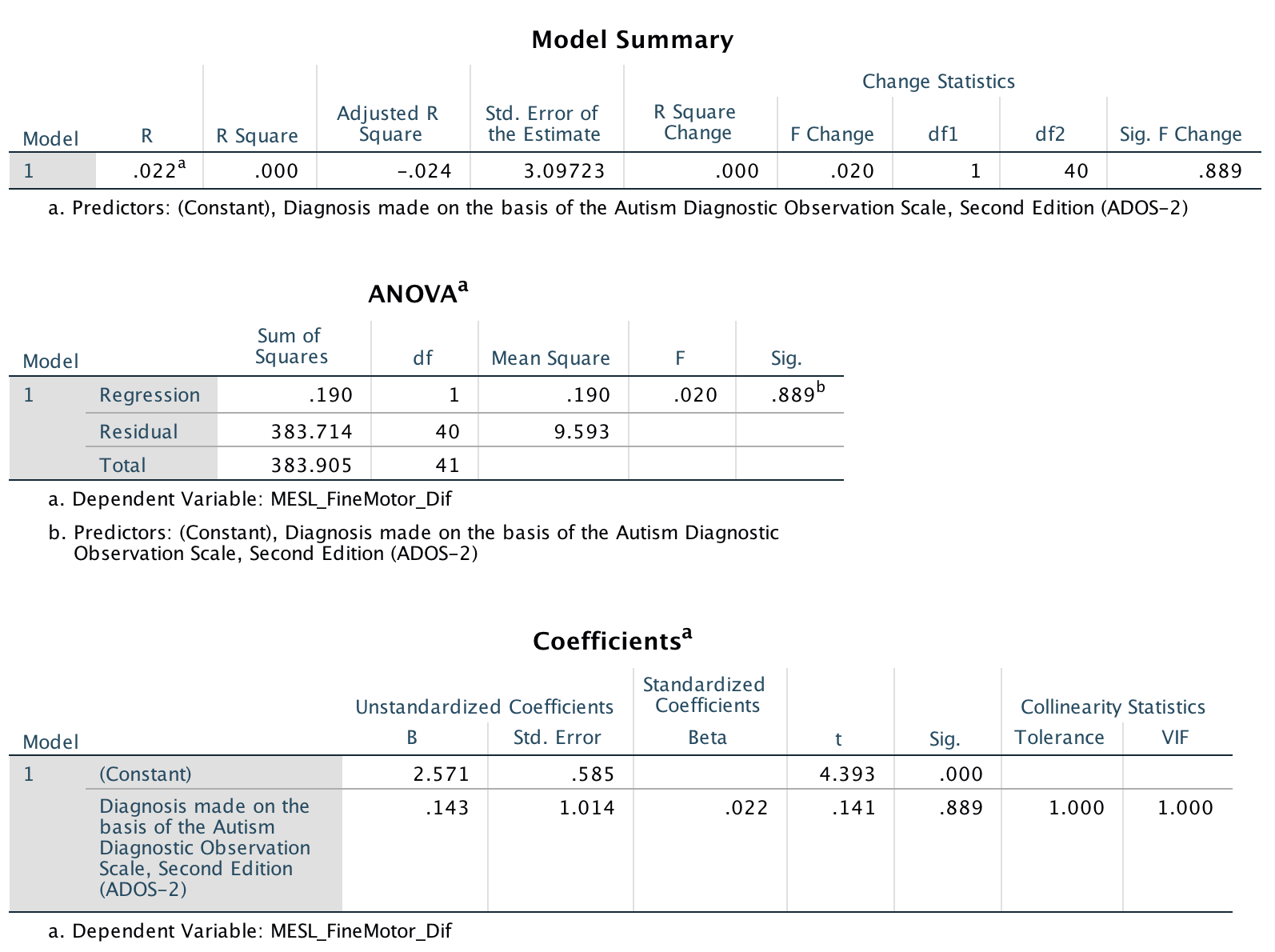
<I’ve run this analysis for you in SPSS - see the attached output for analyses 1-5 below. Use these output to write up an interpretation that summarizes all five analyses using:

* A **single** table (i.e. Table 4)
* A text-based interpretation to accompany your table
  + *Note: Your write up can be as short as two paragraphs, one summarizing statistically significant findings and the other summarizing the non-significant findings.*

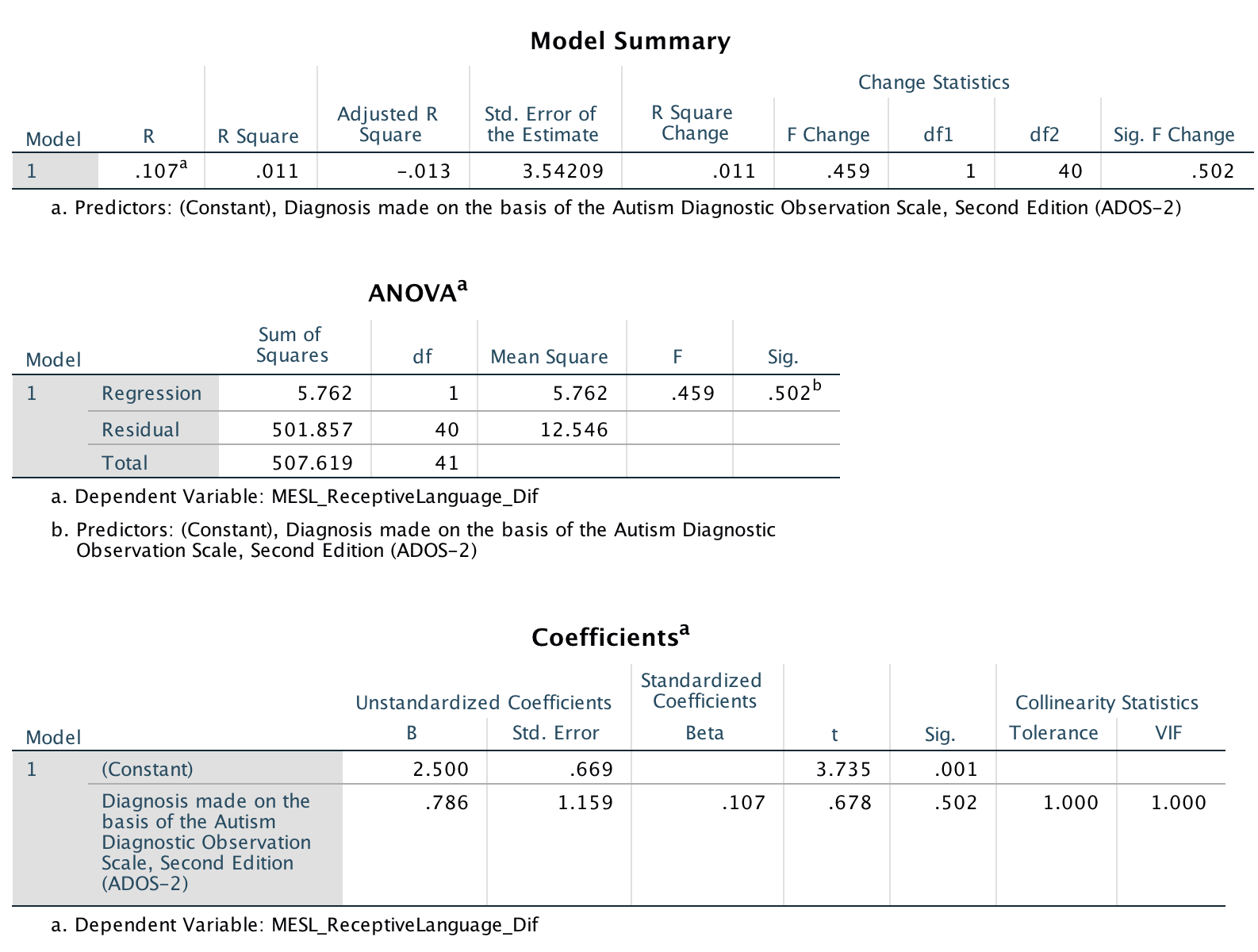
*Analysis #1:*

****

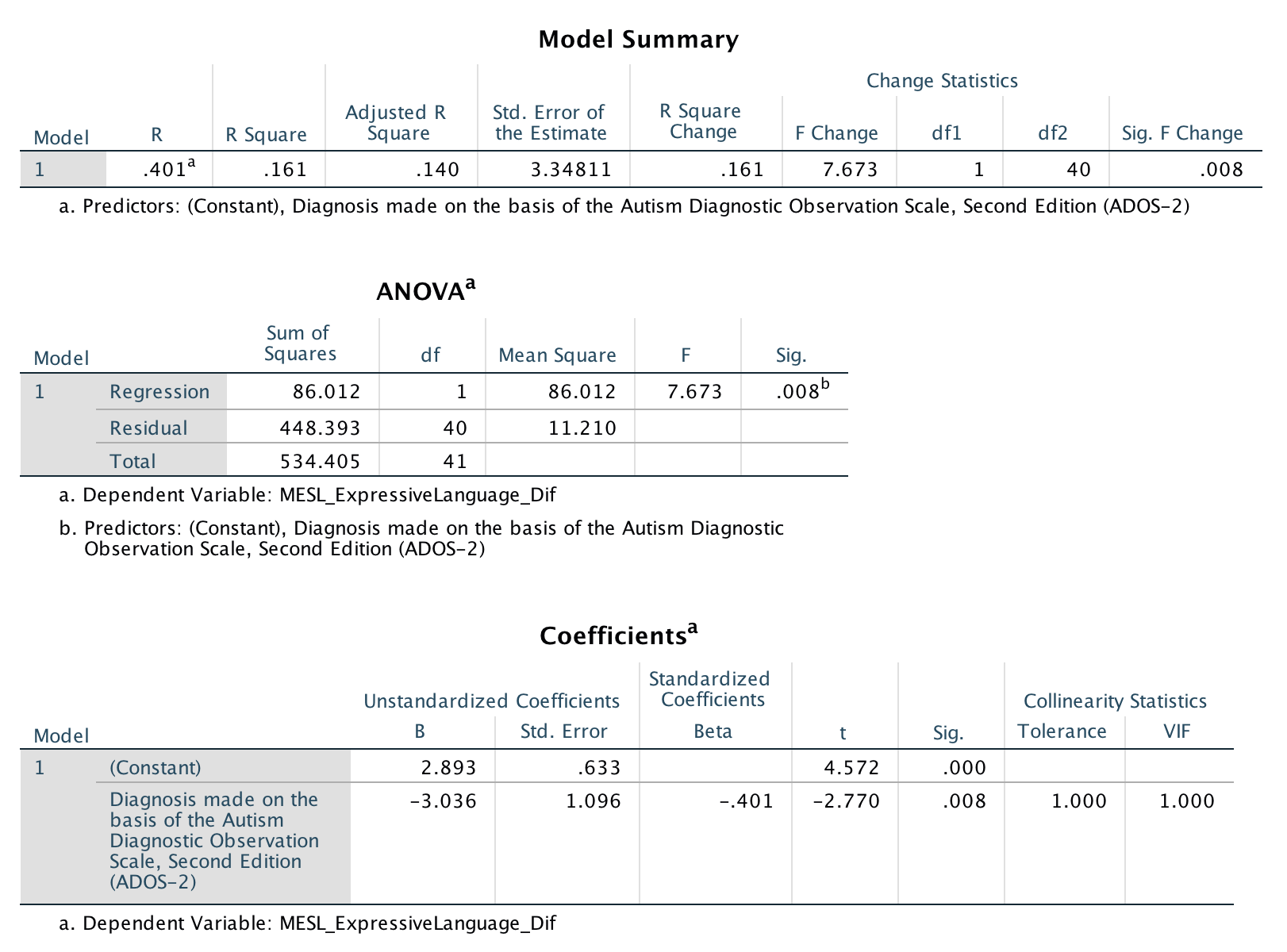
*Analysis #2:*

****

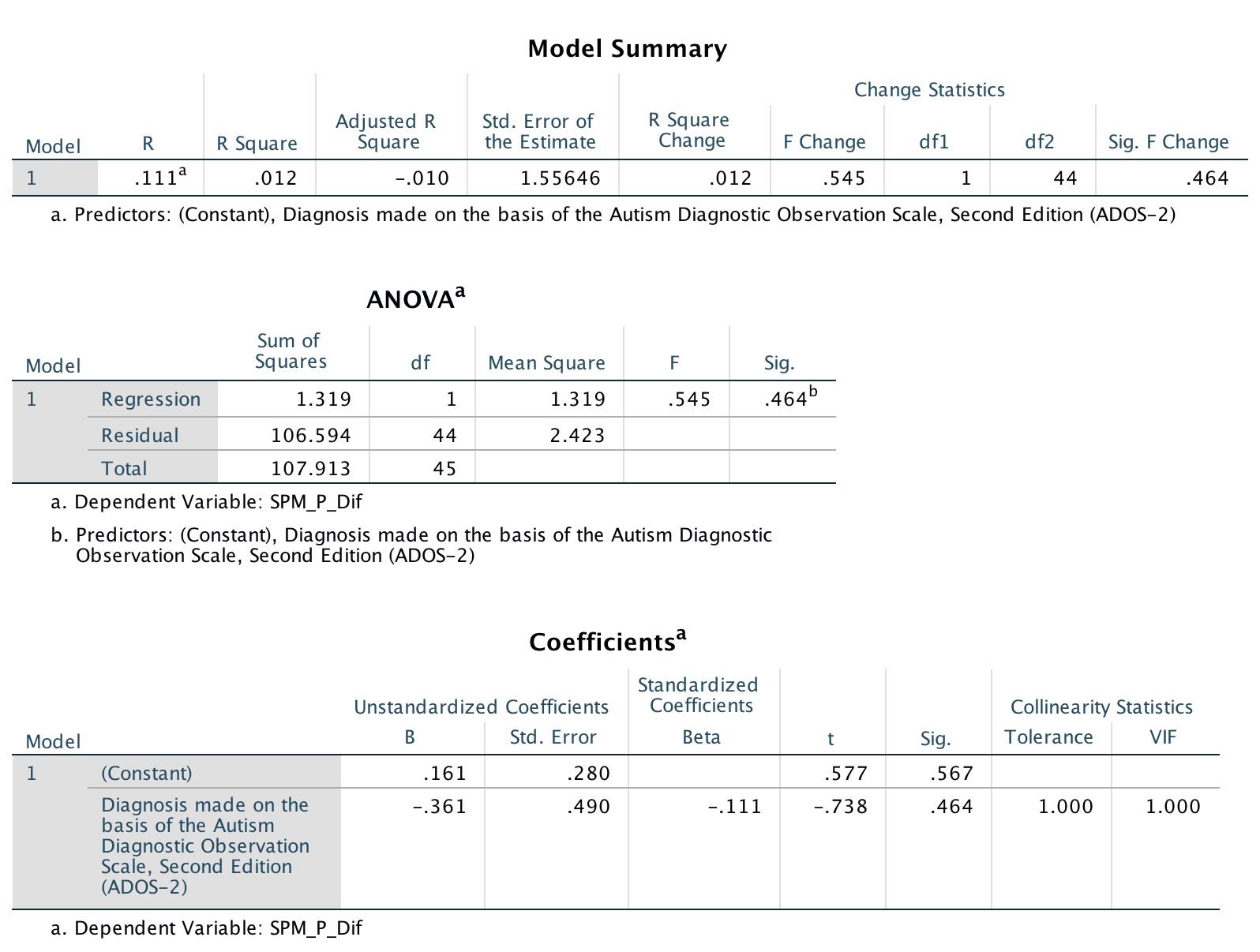
*Analysis #3:*

****

*Analysis #4:*

****

*Analysis #5:*

****

**Adverse Effects**

A total of # adverse events were reported, prompting further analysis into the possible impact of adverse effects on study outcomes. Table 5 reports on the proportion of Sertraline and Control group participants who experienced adverse events. < *Briefly summarize the primary important findings from your analyses for Table 5 here* >.

Table 5

*Adverse events reported by condition*

Create a new table (Table 5) summarizing these data. Be sure to:

1. Create a row for each of the adverse events in the dataset
2. Also create a row representing participants who either did or did not experience any of the adverse events
3. Run and include summaries of any relevant hypothesis tests