Cover Page

Title: Artificial Intelligence Screening for Body Dysmorphic Disorder in Aesthetic Surgery: Improving Patient Safety and Outcomes

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Study Protocol

Introduction: This study protocol outlines the procedures, objectives, and methodologies for the observational study titled "Artificial Intelligence Screening for Body Dysmorphic Disorder in Aesthetic Surgery: Improving Patient Safety and Outcomes." The primary aim is to evaluate the clinical utility of an AI-powered screening tool for Body Dysmorphic Disorder (BDD) in patients seeking elective aesthetic surgery.

Study Objectives

- To evaluate the effectiveness of the AI-based screening tool in identifying patients at risk for BDD.
- To determine the correlation between various demographic and psychological factors (such as age, gender, and stress levels) and positive BDD screening results.
- To assess the impact of early psychological intervention on surgical decision-making and outcomes.

Study Design

This is an observational study with a prospective time perspective. The study involves the collection of clinical and psychological data from patients seeking elective aesthetic surgery. The AI model analyzes this data to provide risk scores and identify patients who may benefit from psychological intervention.

Participant Eligibility

Inclusion Criteria:

- Individuals aged 18 and older.
- Completion of the Body Dysmorphic Disorder Questionnaire (BDDQ).

Exclusion Criteria:

- Individuals below 18 years of age.
- Patients who did not complete the Body Dysmorphic Disorder Questionnaire (BDDQ).

Study Population Description

Participants are individuals seeking elective aesthetic surgery. They will complete the BDDQ and provide demographic and psychological data, including age, gender, and recent stress levels. The AI model will analyze this information to screen for BDD.

Data Collection: The following data will be collected from each participant:

- Age
- Gender
- Stress levels
- BDDQ scores
- Surgical outcomes (where applicable)
- Patient satisfaction (as measured by the Visual Analog Scale, VAS)

Study Procedures

Participants will undergo a screening assessment using the AI model, which evaluates multiple factors based on their responses to the BDDQ and additional psychological data. The AI model will generate risk scores and recommendations for psychological referral if necessary.

Follow-Up

The follow-up period for this study ranges from 1 to 43 months post-surgery, with a mean follow-up of 22 months. Data on patient satisfaction and surgical outcomes will be collected and analyzed.

Outcome Measures

Primary Outcome Measure

- **Title:** Patient Satisfaction Post-Surgery
- **Description:** The primary outcome measure is the level of patient satisfaction with the cosmetic surgery results, measured using the Visual Analog Scale (VAS) within the follow-up period after surgery.

Secondary Outcome Measure

- **Title:** Correlation Between Positive BDD Screening and Risk Factors
- **Description:** This measure evaluates the correlation between a positive Body Dysmorphic Disorder (BDD) screening result and various risk factors, including demographic factors (age, gender), psychological stress levels, and previous psychiatric history. The study will utilize chi-square tests to analyze gender differences in the prevalence of BDD among the patient population.

The goal is to identify patterns that could inform better patient selection and management in cosmetic surgery.

Conclusion

This study protocol provides a comprehensive overview of the study design, objectives, data collection methods, and outcome measures for the observational study "Artificial Intelligence Screening for Body Dysmorphic Disorder in Aesthetic Surgery: Improving Patient Safety and Outcomes." The integration of AI-powered screening is expected to improve patient selection, surgical planning, and overall outcomes in aesthetic surgery.

Statistical Analysis Plan (SAP)

Introduction: This Statistical Analysis Plan (SAP) outlines the statistical methods and analyses to be performed for the study titled "Artificial Intelligence Screening for Body Dysmorphic Disorder in Aesthetic Surgery: Improving Patient Safety and Outcomes." The primary aim of the study is to assess the effectiveness of the AI-powered screening tool in identifying patients at risk for BDD and its impact on surgical decision-making.

Study Objectives:

- To evaluate the effectiveness of the AI-based screening tool in identifying patients at risk for BDD.
- To determine the correlation between various demographic and psychological factors (such as age, gender, and stress levels) and positive BDD screening results.
- To assess the impact of early psychological intervention on surgical decision-making and outcomes.

Study Design: This is an observational study with a prospective time perspective. The study involves the collection of psychological and demographic data from patients seeking elective aesthetic surgery. The AI model analyzes this data to identify at-risk patients and provide recommendations for psychological evaluation.

Data Collection: The following data will be collected from each participant:

- Age
- Gender
- Stress levels
- BDDQ scores
- Surgical outcomes (where applicable)
- Patient satisfaction (as measured by the Visual Analog Scale, VAS)

Statistical Methods:

- **Descriptive Statistics:**
    - Frequency and percentage of patients screening positive for BDD.
    - Analysis of demographic data and stress factors.

- **Pearson Correlation:**
    - Correlation between BDD and factors such as age, gender, and stress.

Python code

```
# Correlation calculations

stats.pearsonr(corr4['BDD'], corr4['Age'])

stats.pearsonr(corr4['BDD'], corr4['Stress in the last 3 months'])

stats.pearsonr(corr4['BDD'], corr4['Male'])

stats.pearsonr(corr4['BDD'], corr4['Female'])
```

- **Chi-Square Analysis:**
    - Chi-square tests will be conducted to evaluate the differences in the prevalence of BDD between genders, helping to identify any statistically significant associations between gender and BDD.

Python code

```
from scipy.stats import chi2_contingency

# Create a contingency table

contingency_table = pd.crosstab(tabla1['BDD'], tabla1['Female'])

# Calculate the chi-squared test

chi2, p, _, _ = chi2_contingency(contingency_table)

# Calculate the ratio of Male to Female in the positive BDD group

positive_BDD_female = tabla1[(tabla1['BDD'] == 1) & (tabla1['Female'] == 1)].shape[0]

positive_BDD_male = tabla1[(tabla1['BDD'] == 1) & (tabla1['Male'] == 1)].shape[0]
```

```
ratio_male_to_female_positive_BDD = positive_BDD_male / positive_BDD_female

# Calculate the ratio of Male to Female in the negative BDD group

negative_BDD_female = tabla1[(tabla1['BDD'] == 0) & (tabla1['Female'] == 1)].shape[0]

negative_BDD_male = tabla1[(tabla1['BDD'] == 0) & (tabla1['Male'] == 1)].shape[0]

ratio_male_to_female_negative_BDD = negative_BDD_male / negative_BDD_female

# Calculate the relative risk

relative_risk = (positive_BDD_male / positive_BDD_female) / (negative_BDD_male / negative_BDD_female)
```

- **Outcome Analysis:**
    - Patient satisfaction levels as measured by the Visual Analog Scale (VAS).
- **Data Analysis:**
    - Data analysis will be performed using Python in a Colab environment. The analysis will focus on correlations between BDD and identified risk factors, chi-square tests for gender differences, as well as the effectiveness of the AI model in screening for BDD.

Access Instructions: To request permission to access the individual participant data (IPD) and supporting information, please email drbukret@drbukret.com. Detailed instructions for requesting access can be found at IPD Sharing Instructions.

Conclusion: This SAP provides a detailed plan for the statistical analysis of the study "Artificial Intelligence Screening for Body Dysmorphic Disorder in Aesthetic Surgery: Improving Patient Safety and Outcomes." The analysis aims to provide insights into the effectiveness of the AI model in identifying and managing patients at risk for BDD, ultimately improving surgical outcomes and patient safety.