**Assessment of the Impact of Art-Based Pain Assessment Tool on Pain Communication, Joint Function, and Anxiety in Patients with Temporomandibular Disorders (TMD): A Randomized Controlled Trial**

**Study Protocol and Statistical Analysis Plan**

**ClinicalTrials.gov Identifier (NCT Number):** Pending Registration
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**Study Protocol**

**Background and Rationale:**
Temporomandibular Disorders (TMD) are commonly treated with pharmacological and conservative methods; however, these often neglect the psychosocial dimensions of chronic pain. The Artistic Pain Exploration (APE) method, an art-based diagnostic tool, offers a novel approach to enhancing pain communication and patient understanding.

**Objectives:**
**Primary:** To assess the effectiveness of the APE method in improving patient understanding and communication of pain.
**Secondary:** To evaluate the impact of the APE method on TMJ function, pain intensity, and anxiety levels over a 2-week period.

**Study Design:**
Single-blind, randomized controlled trial conducted at King Abdulaziz University Dental Hospital from April 2025 to November 2025.

**Participants:**
**Inclusion Criteria:** Adults ≥18 years old, diagnosed with Wilkes stage I or II TMD, able to provide informed consent.
**Exclusion Criteria:** Need for surgical intervention, diagnosed severe mental illness (e.g., psychosis, bipolar disorder), regular narcotic use.

**Sample Size Calculation:**
To determine the appropriate sample size, a calculation was performed using G*Power (Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). GPower 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences*. Behavior Research Methods, 39(2), 175–191. https://doi.org/10.3758/BF03193146). This analysis was based on repeated-measures ANOVA, as the study design includes two groups (intervention and control) and two measurement points (baseline and follow-up). We assumed a small to medium effect size (f = 0.2), an alpha of 0.05, and a statistical power of 0.80. A moderate correlation between repeated measures was also assumed. The analysis indicated that a total sample size of 52 would be required, with 26 participants per group. However, we will recruit 35 participants per group to account for potential loss to follow-up and missing data.

**Randomization and Blinding:**
Simple randomization with allocation concealment using sealed opaque envelopes. Outcome assessors and data analysts are blinded to group assignment.

**Intervention:**
**Control Group:** Receives standard care for TMD, including clinical examination, Visual Analogue Scale (VAS), Anxiety level (GAD-7), Screening for depression (PHQ-9), TMJ function, and conservative management.
**Intervention Group:** Receives standard care plus the Artistic Pain Exploration (APE) method.

Patients select a painting that resonates best with them and engage in a guided interview based on that selection to discuss pain characteristics and its effect of daily life.

**Data Collection:**
At baseline and 2-week follow-up:

- Demographics and medical history
- Pain level (VAS)
- Anxiety (GAD-7)
- Depression (PHQ-9, baseline only)
- TMJ function
- Pain Communication and Understanding Questionnaire (baseline only)

**Outcome Measures:**

- **Primary:** Pain communication and understanding
- **Secondary:** TMJ Pain, TMJ function, GAD-7 anxiety score, PHQ-9 depression score

**Statistical Analysis Plan**

Descriptive statistics will be calculated for all baseline characteristics. Continuous variables will be presented as means and standard deviations, while categorical variables will be presented as frequencies and percentages. The baseline characteristics of the two groups will be compared using the chi-square test for categorical variables and the two-sample t-test for continuous variables.

**Primary outcome:**
For the patient-reported outcomes on pain understanding and communication, the mean scores from the Pain Communication and Understanding Questionnaire will be compared between the intervention (APE method) and control groups. A two-sample t-test will be used to analyze differences between the two groups.

**Secondary outcomes:**
**Pain level** will be measured using the VAS and assessed at baseline and at the two-week follow-up. The two-week follow-up period was chosen to align with the expected initial response timeline for conservative TMD management, including NSAIDs, muscle relaxants, and behavioral modifications. A repeated-measures ANOVA will be conducted to evaluate changes in pain levels over time between the intervention and control groups.

**TMJ function** will be measured by maximum mouth opening (MMO). Mean MMO scores will be compared between groups at baseline and follow-up using repeated-measures ANOVA to assess changes over time.

**Anxiety level** will be measured using the General Anxiety Disorder-7 (GAD-7) questionnaire at baseline and the two-week follow-up. Mean GAD-7 scores will be compared between the intervention and control groups using repeated-measures ANOVA.

Normality will be assessed for all outcomes. If deviations from normality are present, non-parametric tests will be used.

All analyses will be conducted using an intent-to-treat approach, and missing data will be handled through multiple imputation if appropriate. Statistical analyses will be performed using Stata/IC 18.0 (StataCorp LLC, College Station, TX, USA), and p-values $\leq 0.05$ will be considered statistically significant.

**Handling of Missing Data:**
Multiple imputation used if missing data exceed 5%. All randomized participants will be included unless major protocol deviations occur.

**Ethical Considerations:**
Approved by the Research Ethics Committee of KAUFD (REC #02-01-25). Informed consent will be obtained from all participants. Confidentiality of participant data strictly maintained.