

Statistical Analysis Plan

Official Title:

Effects of Cold Spray and Stress Ball Methods on Pain in Intramuscular Injection: A Randomized Controlled Trial

NCT Number:

Pending (to be assigned by ClinicalTrials.gov)

Date of Document:

October 11, 2025

Principal Investigator(s):

- Ass. Prof. Handan Aydin Kahraman
- Ass. Prof. Esra Aydin
- Ass. Prof. Ibrahim Nas

Institution:

Erzincan Binali Yıldırım University

ANALYSIS OF DATA

The data of the study were analyzed with SPSS 26 statistical package program. Descriptive statistics were analyzed as sample size (n), percentage (%), mean and standard deviation ($\bar{x} \pm ss$), highest / lowest value (max./min.), mode and median and shown in tables (Güriş and Turanlı, 2018).

In the cross-tabulation comparison, the Pearson Chi-Square test statistic was used if the expected frequency for each cell was greater than 5, and the Fisher's Exact Test (ET) statistic was used if the expected frequency for each cell was 5 and less than 5 (Pallant, 2020).

For the normality test, the kurtosis and skewness values of the VAS according to the independent variables were taken as a basis, and if this value was between -1.5 and +1.5, it was accepted that it provided a normal distribution (Fein et al, 2008).

If the correlation coefficient is less than 0.30, it is assumed to be low, if it is 0.31 to 0.49, it is moderate, and if it is above 0.50, it is assumed to be highly correlated, and Spearman's rho correlation coefficients, which are nonparametric correlations, are taken as a basis (Tabachnick and Fidell, 2013).

In the comparisons between groups, one-way analysis of variance (One-Way ANOVA) was used if the analysis conditions were met, and Kruskal Wallis test statistics were used when it was not met (Tabachnick and Fidell, 2013). In case the assumption of homogeneity of variances was violated ($p < 0.05$) as a result of the Levene test performed before the analysis, the Welch ANOVA test, which does not require the assumption of homogeneity of variance, was preferred. The Welch test gives more reliable results when the variances are not equal (Field, 2013; Ruxton, 2006). Games-Howell test was used as post-hoc analysis for group comparisons. The Games-Howell test was preferred because the variances are not homogeneous and also gives more reliable results at small sample sizes (Howell, 2012; Field, 2013). The Games-Howell test is one of the recommended post-hoc tests, especially after the Welch ANOVA (Hayes, 2022).

The eta-squared (η^2) value was taken as the basis for the effect size. Eta square (η^2); If it takes a value between 0.01 and 0.06, it has a small effect, if it takes a value between 0.06 and 0.14, it has a medium effect, and if it takes a value greater than 0.14, it has a large effect size (George, 2002).

In order to determine the patterns between the variables, *Optimal Scaling Analysis, one of the Multiple Correspondence Analysis* techniques, was performed. Optimal scaling analysis provides visualization of relationships and understanding of patterns by digitizing qualitative or ordinal scale variables in multidimensional space. Optimal scaling is a multiple fit analysis technique that allows category-level variables to be quantified and modeled in multidimensional space. This method can be used in the analysis of data at the nominal or ordinal scale, making it easier to visually understand similarity or distance relationships between data (Gifi, 1990).

No test conditions such as sample size or normality are required for this analysis (Greenacre, 1993). In the optimal scaling process, categorical variables turn into quantitative data depending on a normalization. Thus, the homogeneity relationship of multiple *and different variables (categorical – continuous)* in the same space can be visualized (Roux and Rouanet, 2010).

The X and Y coordinates obtained in the analysis represent the positions of the variables in multidimensional space. Through these coordinates, similarities and distances between groups

and variables are determined (Meulman and Heiser, 2004). These positions indicate the relationship of the relevant variable to other variables. The factors obtained as a result of the analysis indicate how much of the variance in the data is explained, and the factor loads reveal the relationship of each variable to these factors (Takane, Young & De Leeuw, 1977).

The categories of the variables *form the dimensions by clustering in a certain place with the other categories they are related to, just like in factor analysis*. Thus, the relationships between the variables were visualized in two-dimensional space, and the reliability of the analysis was tried to be evaluated by calculating the eigenvalue of these dimensions, the amount of variance explained and the reliability coefficient (Funnell et al, 2004).

All statistical tests were performed at a 95% confidence level, so a threshold value of 0.05 was adopted as statistical significance (Büyüköztürk, 2012).

REFERENCES

Büyüköztürk, S. (2012). Handbook of data analysis for the social sciences. (19th Edition) Ankara: PegemA Publishing.

Fein, E. C., Gilmour, J., Machin, T., & Hendry, L. (2022). Statistics for research students. Darling Heights, Australia: University of Southern Queensland.

Field, A. (2013). Discovering Statistics Using IBM SPSS Statistics (4th ed.). Sage Publications.

Funnell, B., Bryer, F., Grimbeek, P., & Davies, M. (2004). Demographic profiling for educational researchers: Using SPSS optimal scaling to identify distinct groups of participants. *Educating: Weaving research into practice*, 2, 94-103.

George, D. M., P. (2020). IBM SPSS Statistics 26 Step by Step: A Simple Guide and Reference. Routledge

Gifi, A. (1990). Nonlinear Multivariate Analysis. New York: Wiley-Interscience

Greenacre M. (1993). Correspondence Analyses in Practice, 2nd Edition New York, Academic Press.

Guriş, S. and Turanlı, M. (2018), Basic Statistics, Istanbul: DER

Hayes, A. F. (2022). Introduction to Mediation, Moderation, and Conditional Process Analysis (3rd ed.). Guilford Press.

Howell, D. C. (2012). Statistical Methods for Psychology (8th ed.). Wadsworth.

Meulman, J. J., & Heiser, W. J. (2004). SPSS Categories 13.0. Chicago: SPSS Inc

Pallant, J. (2020). SPSS survival manual: A step by step guide to data analysis using IBM SPSS. Routledge.

Roux LB, Rouanet H. (2010) Multiple Correspondence Analysis, SAGE Publications.

Ruxton, G. D. (2006). The unequal variance t-test is an underused alternative to Student's t-test and the Mann-Whitney U test. *Behavioral Ecology*, 17(4), 688-690. <https://doi.org/10.1093/beheco/ark016>

Tabachnick, B. G., & Fidell, L.S. (2013). Using Multivariate Statistics. Pearson Education.

Takane, Y., Young, F. W., & De Leeuw, J. (1977). Nonmetric individual differences multidimensional scaling: An alternating least squares method with optimal scaling features. *Psychometrika*, 42(1), 7-67. <https://doi.org/10.1007/BF02293745>