The Effect of Nursing Counseling Perceived Stress, Coping and Birth Outcomes Among Pregnant Women

Study Protocol

Before commencing the study, approval from the ethics committee was obtained, from the Ondokuz Mayıs University Medical Practices Ethics Committee (see Appendix 1), and research permission was granted by OMUSUVAM (see Appendix 2). Pregnant women at risk of preterm birth were enrolled in the study after obtaining both written and verbal consent from them (see Appendix 3-4). It was emphasized that they were free to withdraw from the research at any time of their choosing.

Statistical Analysis Plan

Data analyses were performed via the SAS (Statistical Analysis System Institute, Cary, North Caroline) 9.4 Program. Scale data, including mean and standard deviations, were computed for both the experimental and control groups. Here, a focus was given to the dependent variables considered. A t-test was performed to examine the significance of the differences between the two groups in terms of the dependent variables held. A comparison of the pre-test, interim follow-up and post-test measurements for the participants in both the experimental and control groups, as based on the dimension of time, was carried out using repeated measures analysis of variance. Mean and standard deviation from descriptive statistics were used for the variables of the study determined by measurement, and number and percentage were used for the variables determined by counting. In pairwise comparisons between variables with two categories, t-test between independent groups was applied, and Analysis of Variance (F test) was applied to find differences between variables with three or more categories. In evaluating the pre-test, interim follow-up and post-test findings of the experimental and control groups; To compare the measurements taken from the same pregnant women at different follow-ups, interdependent groups or paired observation t-test was used, and Chi-Square analysis was used to reveal the relationship between the variables answered as open-ended questions in the findings determined by the measurement. One-way Repeated Measurement Variance Analysis was used in the analysis of more than one variable taken from the same pregnant women. Cronbach Alpha coefficient was used to calculate the reliability coefficients of the scale and its sub-dimensions. The value of 0.05 was accepted as the significance level throughout the study.

Appendix 1 Ethics Committee Approval

T.C.
ONDOKUZ MAYIS ÜNİVERSİTESİ
KLİNİK ARAŞTIRMALAR ETİK KURULU

Sayı: B.30.2.ODM.0.20.08/ 1076

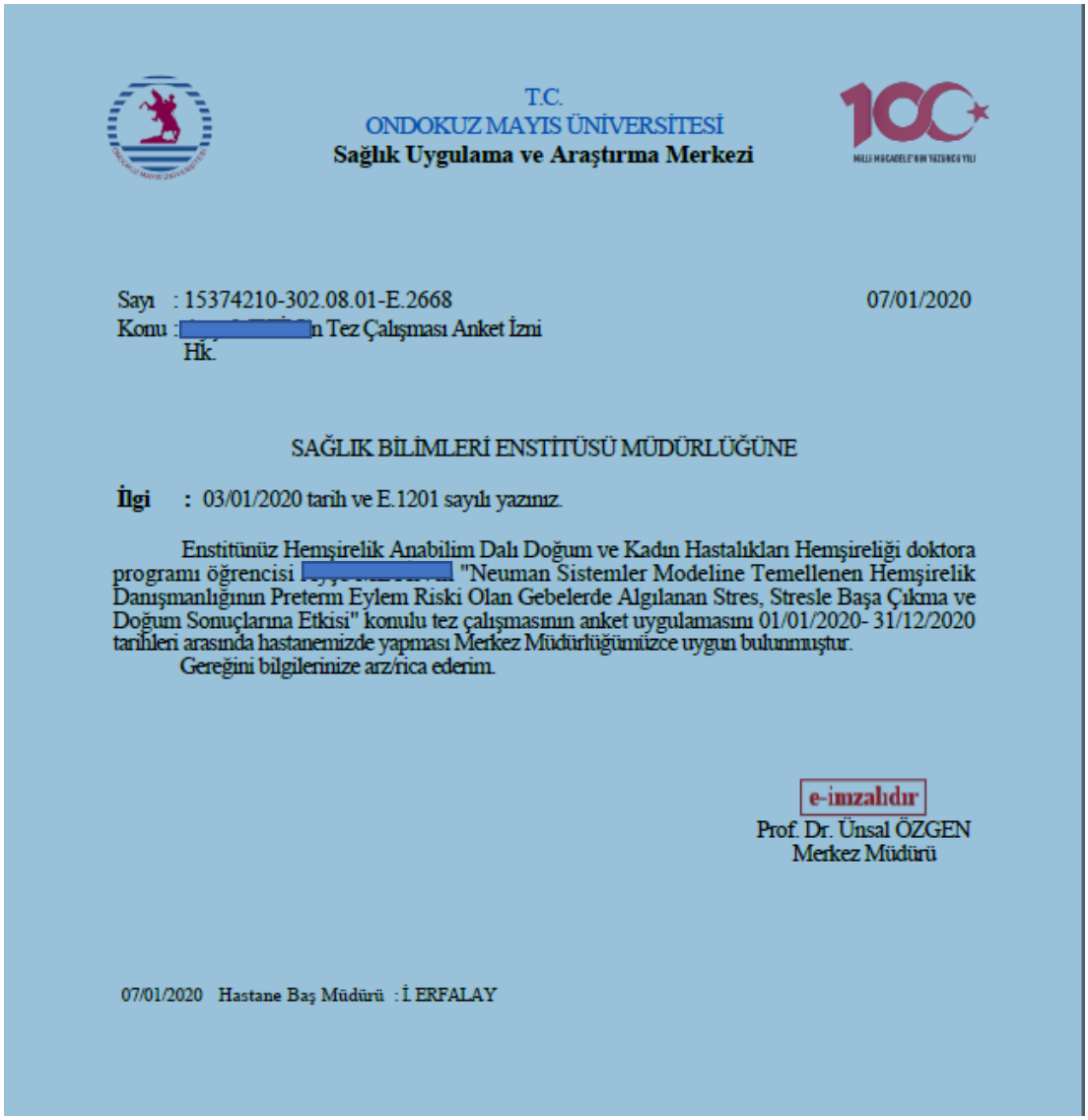
27 .12.2019

OMÜ **Sağlık Bilimleri Fakültesi**. tarafından kurulumuza sunulan **Neuman Sistemler Modeline Temellenen Hemşirelik Danışmanlığının Preterm Eylem Riski Olan Gebelerde Algılanan Stres, Stresle Başa Çıkma ve Doğum Sonuçlarına Etkisi** başlıklı Prof. Dr [redacted] Sorumluluğunda doktora öğrencisi [redacted] ait olan OMÜ KAEK 2019/981 Karar nolu **ANKET** nitelikli araştırma projesi, amaç, gerekçe, yaklaşım ve yöntemle ilgili açıklamaları, OMÜ-KAEK yönergesine göre 12.12.2019 tarihli Etik Komisyonumuzda incelenmiş etik açıdan uygun bulunmuştur. Ancak araştırma bütçesinin maddi desteği henüz sağlanamadığından projeye bütçe desteği sağlanıp, tarafımıza bildirilmesinden sonra *başlanmasına* oy birliği ile karar verilmiştir.

Prof.Dr.Ramis ÇOLAK
Klinik Araştırmalar Etik Kurulu Başkanı

Ondokuz mayıs Üniversitesi Klinik Araştırmalar Etik Kurulu Tel:(0362)3121919/2782 +4576007 Omutaek@gmail.com
Eski Diş Hekimliği Fakültesi 2.Kat Atakum/SAMSUN

Appendix 2 Hospital (OMU SUVAM) research permission certificate



T.C.
ONDOKUZ MAYIS ÜNİVERSİTESİ
Sağlık Uygulama ve Araştırma Merkezi

Sayı : 15374210-302.08.01-E.2668 07/01/2020
Konu : [redacted]n Tez Çalışması Anket İzni Hk.

SAĞLIK BİLİMLERİ ENSTİTÜSÜ MÜDÜRLÜĞÜNE

İlgi : 03/01/2020 tarih ve E.1201 sayılı yazınız.

Enstitünüz Hemşirelik Anabilim Dalı Doğum ve Kadın Hastalıkları Hemşireliği doktora programı öğrencisi [redacted] "Neuman Sistemler Modeline Temellenen Hemşirelik Danışmanlığının Preterm Eylem Riski Olan Gebelerde Algılanan Stres, Stresle Başa Çıkma ve Doğum Sonuçlarına Etkisi" konulu tez çalışmasının anket uygulamasını 01/01/2020- 31/12/2020 tarihleri arasında hastanemizde yapması Merkez Müdürlüğümüzce uygun bulunmuştur.
Gereğini bilgilerinize arz/rica ederim.

e-imzalıdır
Prof. Dr. Ünsal ÖZGEN
Merkez Müdürü

07/01/2020 Hastane Baş Müdürü : İ. ERFALAY

Appendix 3 Informed voluntary consent form (Experimental Group)

Hello, my name is XXX. I am a lecturer at Ondokuz Mayıs University, Faculty of Health Sciences, and a doctoral student in the Department of Nursing. Ondokuz Mayıs University, Faculty of Health Sciences, Department of Nursing, Lecturer Prof. Dr. I am conducting my thesis research titled "The Effect of Nursing Counseling Based on Neuman Systems Model on Perceived Stress, Coping with Stress and Birth Outcomes in Pregnant Women at Risk of Preterm Labor" under the supervision of YYY.

The aim of this study is to determine the effect of education and counseling offered to pregnant women at risk of premature birth on stress perception, coping with stress and pregnancy outcomes. In line with the results of this research, it aims to ensure continuity in providing education and counseling to pregnant women at risk of premature birth. Within the scope of the research, you will be provided with counseling through the phone number and counseling unit you can reach as long as you need until birth. Additionally, training will be provided under four headings, once a week for 40-60 minutes (simultaneously with your control day as much as possible). Some scales will be applied at the program's beginning, mid-term and end. Everything you say during the counseling process will remain confidential. Your name and personal information will be used solely for research purposes and will never be disclosed to others. The first interview and the last interview (including your opinions about the consultancy unit) will be recorded and with your permission. If you do not want to continue the research, you can leave at any time. Your data may be used for publication purposes without disclosing your name. Participation in the research is entirely voluntary. Reading and approving this form will mean that you agree to participate in the research.

Consent to Participate in the Study

I have read all the explanations in the Informed Volunteer Consent Form. Written and verbal explanations about the research whose subject and purpose are stated above were made to me by the researcher named below. I had the opportunity to ask questions and discuss and received satisfactory answers. I know that I can quit this study whenever I want, without having to give any reason, and that I will not face any negative consequences if I quit. I agree to participate in this research voluntarily, without any pressure or coercion.

History:
Participant:
Signature
Researcher:
XXX
Signature:

Appendix 4 Informed voluntary consent form (Control Group)

Hello, my name is XXX. I am a lecturer at Ondokuz Mayıs University, Faculty of Health Sciences, and also a doctoral student in the Department of Nursing. Ondokuz Mayıs University, Faculty of Health Sciences, Department of Nursing, Lecturer Prof. Dr. I am conducting my thesis research titled "The Effect of Nursing Counseling Based on Neuman Systems Model on Perceived Stress, Coping with Stress and Birth Outcomes in Pregnant Women at Risk of Preterm Labor" under the supervision of YYY.

This study aims to determine the effect of education and counseling offered to pregnant women at risk of premature birth on stress perception, coping with stress and pregnancy outcomes. In line with the results of this research, it is aimed to provide education and counseling to pregnant women at risk of premature birth. The research will be conducted through a survey of approximately 10-15 minutes. The surveys will be administered 3 times in total until birth. If you do not want to continue the research, you can leave at any time. Everything you say during the interview will remain confidential. Your name and personal information will be used solely for research purposes and will never be disclosed to others. Your data may be used for publication purposes without disclosing your name. Participation in the research is entirely voluntary. Reading and approving this form will mean that you agree to participate in the research.

Consent to Participate in the Study

I have read all the explanations in the Informed Volunteer Consent Form. Written and verbal explanations about the research whose subject and purpose are stated above were made to me by the researcher named below. I had the opportunity to ask questions and discuss and received satisfactory answers. I know that I can quit this study whenever I want, without having to give any reason, and that I will not face any negative consequences if I quit. The research in question is carried out on its own, without any pressure or coercion.

History:
Participant:
Signature
Researcher:
XXX
Signature: