TR Istanbul University-Cerrahpaşa ID: NYalcinbas

The Effectiveness of Motivational Interviewing in Reducing the Use of Household Chemicals and Personal Care Products During Pregnancy

Study Protocol: February 5, 2024

Clinical Trial Number: NCT ID not yet assigned

WORKING PROTOCOL	
Title / Date	The Effectiveness of Motivational Interviewing in Reducing the Use of Household Chemicals and Personal Care Products During Pregnancy
Approval of the education officer of the unit(s) where the study will be carried out.	Sile State Hospital Gynecology and Obstetrics Polyclinics
Name and surname of the responsible investigator, e-mail address, mobile phone, signature	Prof. Dr. Neslihan Özcan neslihan_keser@hotmail.com 05326341255
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Assistant researcher name and surname, e-mail address, mobile phone, signature	
Financial agreements between the sponsor, principal investigator or research site	

main purpose, Secondary purpose, if any hypothesis (es)	Purpose: The aim of the study is to raise awareness among women about the negative effects of household chemicals and personal care products that they frequently use in their daily lives, on themselves and their babies, through motivational interviewing, and to provide positive behavioral change in women through motivational interviewing. Hypotheses: H0: Motivational interviewing is not effective in reducing the use of domestic chemicals and personal care products by pregnant women. H1: Motivational interviewing is effective in reducing pregnant women's use of domestic chemicals and personal care products.
Medical condition/area of treatment investigated	In this study; The aim of the study is to examine the effect of motivational interviewing on reducing the use of household chemicals and personal care products during pregnancy. No treatment will be applied.

of the population to be examined (acceptance and exclusion criteria, age range by gender, termination criteria of the study when necessary) identification of subgroups, if any)	Inclusion Criteria: ● Being at least 18 years old ● Education level must be at least primary school ● Speaking Turkish ● Having a single pregnancy between the 8th and 40th weeks ● Using household chemicals and personal care products (any product at least once a week) Exclusion Criteria: ● Having a psychiatric illness that prevents communication, ● Having a chronic serious physical health problem ● Termination of pregnancy for any reason ● Having a risky pregnancy (preeclampsia, threat of premature birth) ● Intrauterine growth retardation, having a pregnancy with fetal anomalies ● Working in a job that requires heavy use of chemicals, such as hairdresser, dry cleaner, beautician.

	Independent variables: Demographic characteristics of women, obstetric characteristics, motivational interviewing Dependent variables: Household Chemicals and Personal Care Products Use Evaluation Form, Self-Efficacy Competence Scale, and Endocrine Disruptors Attitude Scale.
Design features (clinical trial / retrospective study / case) sample size, determination of the number of centers, study duration, *if any* randomization method and its importance Blindness method and its importance, *if any*	The research was conducted in a prospective pre-test, post-test based randomized controlled experimental research design.Using the G*Power (3.0.10) Program, the sample size was determined as at least 64 people for each of the experimental and control groups, with 80% power, 0.05 margin of error and 0.5 effect level. Considering the possibility of data loss later on, 70 pregnant women (140 in total) were included in each group. The groups were randomized into 2 groups using a web-based randomization program (http://www.randomizer.org). The researcher included pregnant women who met the inclusion criteria in the outpatient clinics on certain days of the week, in accordance with the randomization process.
Address of the clinic, laboratory, other medical units and institutions, if any, from cases , processing of data/keeping records, evaluation criteria, quality control and quality assurance	No samples will be taken from the pregnant women forming the sample group.
Statistical method to be applied	Analysis of the research data was done with SPSS version 23.0 package program. Descriptive statistics of continuous variables in the study were shown with mean, standard deviation, minimum and maximum values, and descriptive statistics of categorical variables were shown with frequency and percentage. Normality analysis was performed before making comparisons between variables. Since skewness and kurtisos values are between -2 and +2, it is assumed that the variables have a normal distribution (George and Mallery, 2010). Therefore, parametric tests were used in the analyses. While the score differences of the experimental and control groups between groups and time were examined with the t test, the change between groups according to time was examined using mixed pattern analysis of variance - ANOVA (generalized linear model). Cohen-d effect value was used for change over time and between groups, and eta squared (η2) value was used for change on the group*time axis. Eta

	squared is considered as low potency of 0.01, medium potency of 0.06, and high potency of 0.14 and above.

List of publications: at least 2 (copies will be on file)	Ashrap P, Watkins DJ, Calafat AM, Ye X, Rosario Z, Brown P, Velez-Vega CM, Alshawabkeh A, Cordero JF, Meeker JD. Elevated concentrations of urinary triclocarban, phenol and paraben among pregnant women in Northern Puerto Rico: Predictors and trends. Environ Int. 2018 Dec;121(Pt 1):990-1002. doi: 10.1016/j.envint.2018.08.020. Epub 2018 Oct 11. PubMed ID: 30316544 Deierlein AL, Grayon AR, Zhu X, Sun Y, Liu X, Kohlasch K, Stein CR. Personal Care and Household Cleaning Product Use among Pregnant Women and New Mothers during the COVID-19 Pandemic. Int J Environ Res Public Health. 2022 May 6;19(9):5645. doi: 10.3390/ijerph19095645. PubMed ID: 35565038

Summary of findings from studies conducted / supporting information for this study	in 2022, Deierlein et al. Women reported use of personal care and household cleaning products within the previous month, changes in antibacterial product use, receipt of healthcare provider advice, and opinions on environmental chemicals (n = 320). On average, women used 15 personal care products and 7 household cleaning products. Results from this study suggest that women may have increased their product use during the pandemic (Deierlein, L. et al, 2022). in 2018, Ashrap et al. 1003 pregnant women between years 2010 and 2016 from prenatal clinics and collected urine samples and questionnaire data on personal care product use at up to three separate visits, between 16 and 28 weeks gestation. A decreasing temporal trend was statistically significant for urine concentrations of BPA during the study period, while the BPA substitute BPS showed an increasing temporal trend. Significant and positive associations were found between biomarker concentrations with the products use in the past 48-h (soap, sunscreen, lotion, cosmetics). There was an increasing trend of triclocarban/triclosan urinary concentrations with increased concentrations of triclocarban/triclosan listed as the active ingredient in the bar soap/liquid soap products reported being used.Results suggest several potential exposure sources to triclocarban, phenols, and parabens in this population and may help inform targeted approaches to reduce exposure (Ashrap P. et al, 2018).

Publication policy	The research will be carried out in line with universal ethical principles. In order to conduct the research, permission was first obtained from Istanbul University-Cerrahpaşa Non-Interventional Ethics Committee. Participants in the study were given information in the Informed Volunteer Consent form, and their verbal and written consent was obtained. The monitoring and supervision of the study was carried out by the responsible researcher and the thesis advisor.