

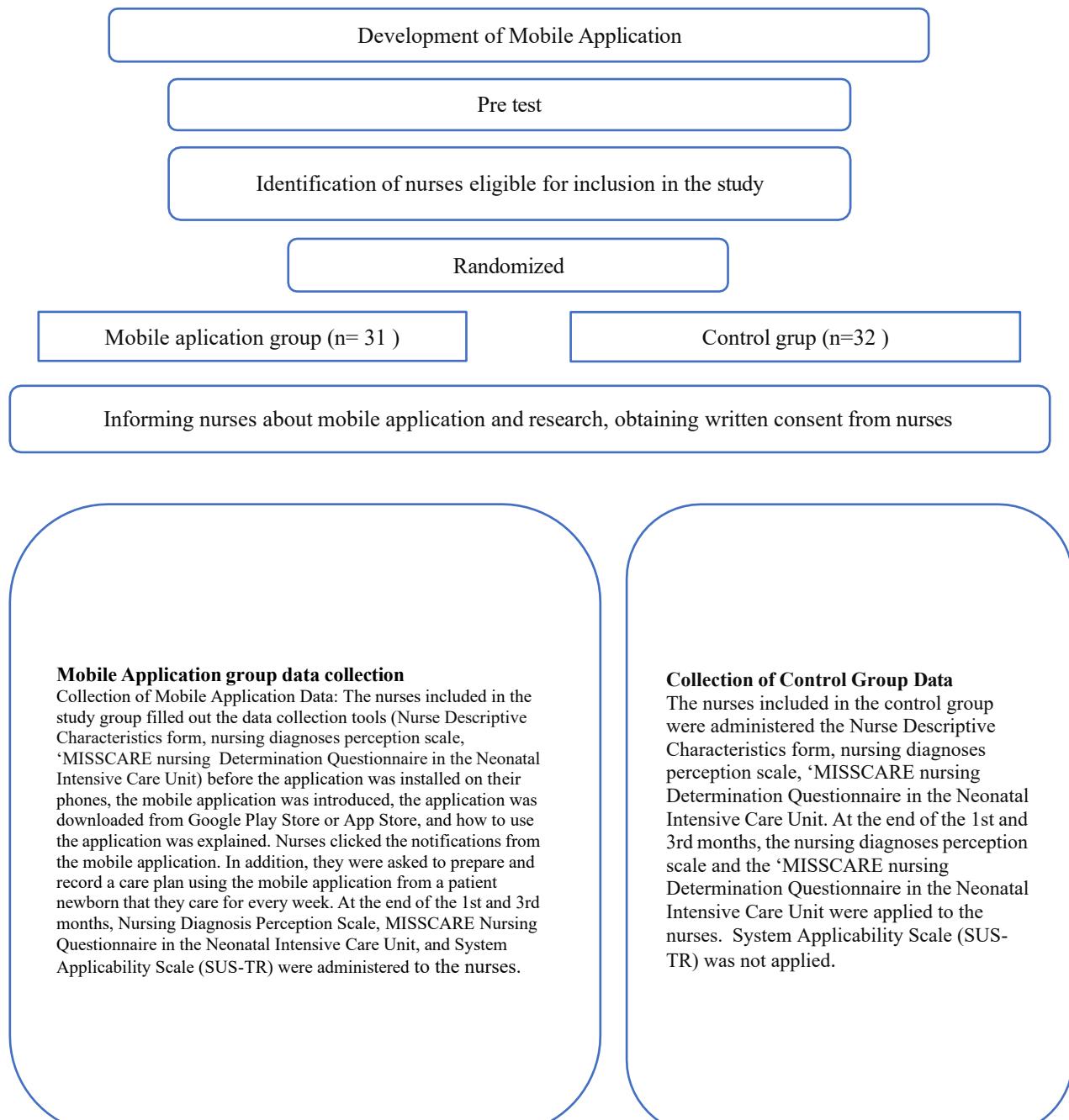
ID: HF-22003

Title: The Effect of the Mobile Application Developed for the Care of Sick Newborns

NCT Number: NCT05776615

Document Date: June 12, 2024 (IRB approval date)

Study Protocol



ANALYSING THE DATA AND REPORTING THE RESEARCH

Statistical Analysis Plan

Statistical analysis of the data was performed using SPSS (IBM SPSS Statistics 27) package programme. Frequency tables and descriptive statistics were used to interpret the findings of the study. The conformity of the measurements to normal distribution was analysed using Shapiro-Wilk analysis. Consistent with parametric methods, ‘Independent sample t test’ was used to compare the measurements of two independent groups. The Repeated Measures (F-table value) method was used to compare the measurements of three or more dependent groups. ‘Bonferroni’ correction was applied for pairwise comparisons of three or more groups. Nonparametric methods were used for measurements that did not fit the normal distribution. Consistent with nonparametric methods, the ‘Mann-Whitney U’ test (Z-table value) was used to compare the measurements of two independent groups. The Wilcoxon signed-rank test (Z-table value) was used to compare the measurements of two dependent groups. ‘Friedman’ test (χ^2 -table value) was used to compare the measurements of three or more dependent groups. ‘Bonferroni’ correction was applied for pairwise comparisons of three or more groups. The relationship between two qualitative variables was analysed by Pearson- χ^2 cross-tabulations. Spearman's correlation coefficient was used to examine the relationship between two quantitative variables that were not normally distributed. Biostatistics expert support was obtained in the analysis of the data.



AYDIN ADNAN MENDERES UNIVERSITY RECTORATE

Turkish Republic

Directorate of the Institute of Health Sciences
Non-Interventional Research Ethics Committee



Number: E-21347915-050.04-549014

June 24, 2024

Subject: Regarding your Ethics Committee Application
No. 2022/021.

Associate Professor Dr. Seher SARIKAYA KARABUDAK
Faculty Member

Below is the decision number I regarding your study taken at the regular meeting of the Health Sciences Institute Non-Interventional Research Ethics Committee held on June 12, 2024. I present it for your information.

DECISION: I**Protocol No:** 2022/021**Responsible Executive:** Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK

The petition of Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK, regarding the final report of her research titled "The Effect of the Mobile Application Developed for the Care of Sick Newborns on Nurses' Perception of Nursing Diagnoses and Unmet Care: A Randomized Controlled Experimental Study", which was approved by the Non-Interventional Research **Ethics** Committee of Aydýn Adnan Menderes University Health Sciences Institute on 10.06.2022, was discussed on **12.06.2024**.

The petition stated that the study had been completed, and the final report was attached. It was concluded that the study had been conducted and completed within ethical guidelines, and that the requested documents were complete. It was unanimously decided that the study should receive **Ethics Committee Approval**.

Prof. Dr. Turhan DOST

Chairman of the Board

This document has been signed with a secure electronic signature.

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Reporter

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This document has been signed with a secure electronic signature.

INFORMED CONSENT FORM

(Control Group)

The study titled “The Effect of the Mobile Application Developed for the Care of Hospitalized Newborns on Nurses’ Perception of Nursing Diagnoses and Miss Care: A Randomized Controlled Experimental Study” will be conducted by Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN.

This randomized controlled experimental study has been designed to determine the effect of the mobile application developed for the care of hospitalized newborns in the Neonatal Intensive Care Unit (NICU) on nurses’ perceptions of nursing diagnoses and unmet care, as well as to evaluate the usability of the mobile application. Participation in this study is voluntary. You may choose not to participate or may withdraw while filling out the questionnaires. Data collected through the questionnaires will be used for scientific purposes only. No adverse effects are expected from participating in this study.

During the study, you will be asked to complete the following:

- Nurse Descriptive Characteristics Form (19 items, including age, gender, work experience, etc.),
- Nursing Diagnoses Perception Scale (26 items),
- NICU “Unmet Nursing Care” Questionnaire (69 items).

Completing these forms will take approximately 20–30 minutes. Afterwards, at the end of the 1st month and at the end of the 3rd month, you will again be asked to complete the Nursing Diagnoses Perception Scale (26 items) and the NICU “Unmet Nursing Care” Questionnaire (69 items).

All questions related to the study will be answered by the researchers, Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN. At the end of the study, if you wish, the mobile application can also be installed on your device for your use.

For any questions related to this study, you may contact:

- Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK at 0505 448 37 03 or ssarikaya@adu.edu.tr
- Lecturer Canan Sümeyra GÜN at 0545 812 57 20 or canansumeyra.gun@ksbu.edu.tr

You may ask during or after the application, either via e-mail or by phone (mobile).

We thank you for your participation.

I, the undersigned, agree to participate in the study titled “The Effect of the Mobile Application Developed for the Care of Hospitalized Newborns on Nurses’ Perception of Nursing Diagnoses and Unmet Care: A Randomized Controlled Experimental Study.”

Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN have

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provided me with detailed verbal and/or written information about the structure, purpose, and possible duration of the study, what is expected from me, and what to do in case of an adverse situation.

I have had the opportunity to ask all questions I had regarding the study to the researchers, and I understood the answers and the information provided to me. I permit Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeye Gün to conduct this study with me, under the condition that they explain the details clearly and maintain the confidentiality of my personal information.

I agree to comply with all the rules throughout the study, to fully cooperate with the researchers, and to contact them immediately if any issue arises. I accept that the results of this study may be used without restriction in publications, reports, or other scientific documents. I also understand that I can withdraw from this study at any time

Participant

Name-Surname:

Date:

Phone No:

Signature:

Participant

Name-Surname:

Date:

Phone No:

Signature:

Researcher

Title, Name-Surname: Lecturer Canan Sümeye Gün/Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK

Date:

Phone No: 05458125729/0505 448 37 03

Signature:

Address: Aydin Adnan Menderes University, Central Campus, Faculty of Nursing, Aydin 09100

INFORMED CONSENT FORM

(Study Group)

The study titled “The Effect of the Mobile Application Developed for the Care of Hospitalized Newborns on Nurses’ Perception of Nursing Diagnoses and Miss Care: A Randomized Controlled Experimental Study” will be conducted by Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN. This randomized controlled experimental study has been designed to determine the effect of the mobile application developed for the care of hospitalized newborns in the Neonatal Intensive Care Unit (NICU) on nurses’ perceptions of nursing diagnoses and miss care, as well as to evaluate the usability of the mobile application. Participation in this study is voluntary. You may choose not to participate or may withdraw while filling out the questionnaires. Data collected through the questionnaires will be used only for scientific purposes. No adverse effects are expected from participating in this study. During the study, you will be asked to complete: - Nurse Descriptive Characteristics Form (19 items, such as age, gender, work experience, etc.), - Nursing Diagnoses Perception Scale (26 items), - NICU “MISSCARE” Questionnaire (69 items). Completing these forms will take approximately 30–40 minutes. Afterwards, the mobile application developed for the care of hospitalized newborns will be installed on your phone. You will be provided with a username and password to log in, its functionality will be checked, and you will be informed about its use. During the usage period, you will receive periodic notifications via the mobile application, and you will need to respond by selecting “Yes” or “No.” Paying attention to these notifications is important and valuable for the effectiveness of the study. In addition, it is your legal responsibility not to share the mobile application and its content with other nurses. Maintaining this confidentiality during the study is essential for the reliability and accuracy of the results. We kindly ask for your diligence regarding this matter. At the end of the study, this mobile application will also be installed for other nurses upon their request. All questions related to the study and the mobile application will be answered by the researchers, Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN.

At the end of the 1st month and at the end of the 3rd month after you start using the mobile application, you will again be asked to complete the Nursing Diagnoses Perception Scale (26 items), the NICU “MISSCARE” Questionnaire (69 items), and the System Usability Scale (10 items). For any questions related to this research, you may contact: - Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK at 0505 448 37 03 or ssarikaya@adu.edu.tr - Lecturer Canan Sümeyra GÜN at 0545 812 57 20 or canansumeyra.gun@ksbu.edu.tr You may ask during or after the application, either via e-mail or by mobile phone. We thank you for your participation.

I, the undersigned, agree to participate in the study titled “The Effect of the Mobile Application Developed for the Care of Hospitalized Newborns on Nurses’ Perception of Nursing Diagnoses and Miss Care: A Randomized Controlled Experimental Study.” Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN have provided me with detailed verbal and/or written information about the structure, purpose, and possible duration of the study, what is expected from me, and what to do in case of an adverse situation. I have had the opportunity to ask all questions I had regarding the study to the researchers, and I understood the answers and the information provided to me. I permit Assoc. Prof. Dr. Seher SARIKAYA KARABUDAK and Lecturer Canan Sümeyra GÜN to conduct this study with me, under the condition that they explain the details clearly and maintain the confidentiality of my personal information. Throughout the study, I pledge not to share the username, password, or application content provided to me with anyone else. I also agree to comply with all the

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rules, to fully cooperate with the researchers, and to contact them immediately if any issue arises. I accept that the results of this study may be used without restriction in publications, reports, or other scientific documents. I also understand that I can withdraw from this study at any time.

Participant Name-Surname:

Researcher

Title, Name-Surname: Lecturer Canan
Sümeyra Gün/Assoc. Prof. Dr. Seher
SARIKAYA KARABUDAK

Date:

Date:

Phone No:

Phone No: 05458125729/0505 448 37 03

Signature:

Signature:

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