Title:

A RANDOMIZED CONTROLLED TRIAL COMPARING TRAINING PROGRAMS DESIGNED TO IMPROVE AWARENESS, ATTITUDES, AND EMPATHY TOWARD INDIVIDUALS WITH DISABILITIES IN NURSING STUDENTS

Ethics Approval Number:

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BASKENT UNIVERSITY

CLINICAL RESEARCH ETHICS COMMITTEE

INFORMED CONSENT FORM FOR SCIENTIFIC RESEARCH

PLEASE READ CAREFULLY!!!

You are invited to participate in a scientific research study. Before deciding whether to participate, it is important that you fully understand the purpose, procedures, potential benefits, and possible risks of the study. This information sheet has been prepared to provide you with clear and detailed information about the research.
Please read this document carefully. If there is anything you do not understand, or if you feel that any aspect of the study has not been sufficiently explained, please ask the researcher for clarification. Your participation in this study is entirely voluntary. You are free to decide whether or not to take part, and you may take sufficient time to consider your decision before signing this form.
Regardless of your decision, the healthcare professionals involved will continue to fulfil their responsibilities to protect your well-being. Should you agree to participate, you will be asked to sign this consent form.

1. TITLE OF THE RESEARCH

A Randomized Controlled Trial Comparing Training Programs Designed to Improve Awareness, Attitudes, and Empathy Toward Individuals with Disabilities in Nursing Students

2. NUMBER OF PARTICIPANTS

A total of 66 participants are planned to be included in this study.

3. DURATION OF PARTICIPATION IN THE STUDY

You will participate in a Disability Awareness Training programme consisting of a total of 10 hours over 5 weeks (2 hours per week).

You will also be asked to complete a pre-test, an intermediate test, and a post-test. Each assessment will take approximately 30 minutes, with a total assessment time of approximately 90 minutes.

4. PURPOSE OF THE STUDY

The aim of this study is to determine which educational approach is more effective in improving nursing students' awareness, attitudes, and empathy toward individuals with disabilities.

5. CONDITIONS FOR PARTICIPATION

To be eligible to participate in this study, you must:

- Be a 3rd- or 4th-year student in the Department of Nursing, Faculty of Health Sciences, Baskent University
- Have no form of disability
- Have no visual impairment

6. STUDY PROCEDURES

Before the study begins, an informational session will be held to explain the objectives and procedures of the research in detail.
After this session, you will complete the pre-test. Participants will then be randomly assigned, using a computer-based randomisation process, to one of three groups:Intervention

- Intervention Group 1: Disability Awareness Training + Standardised Patient Simulation
- Intervention Group 2: Disability Awareness Training + Virtual Reality Application
- Control Group: Disability Awareness Training only

You may be assigned at random and with equal probability to one of the intervention groups or the control group. A computer programme will be used for this randomisation process.

Each group will receive training over a 5-week period in classrooms within the Department of Nursing. Training sessions will be scheduled in accordance with both your academic timetable and the researcher's availability.
An intermediate test will be administered at the end of the training period. The post-test will be conducted six weeks after the intermediate test.
For both intervention groups, debriefing sessions will be held following the practical applications. These sessions may include video recordings used solely for educational reflection during the study and will not be shared with third parties or used in other research.
During the debriefing sessions, you will be asked to reflect on your experiences, emotions, and clinical decision-making processes. You may be asked to provide written responses to open-ended questions. No grading or scoring will be applied.

7. RESPONSIBILITIES OF THE PARTICIPANT

As a participant, you are expected to:

- Follow the study procedures and the researcher's instructions
- Attend all scheduled training sessions
- Inform the researcher in advance if you are unable to attend a session and participate in the make-up session
- Inform the researcher immediately if you experience any discomfort during the virtual reality application (e.g., dizziness, nausea, headache, or loss of balance)

8. POTENTIAL BENEFITS OF THE STUDY

This study is conducted for scientific and educational purposes only. The findings may contribute to the improvement of nursing education methods related to disability awareness.
Through participation, you may develop greater awareness, more positive attitudes, and enhanced empathy toward individuals with disabilities, which may positively contribute to your professional development. A certificate of participation will be provided upon completion of the study.

9. Potential Risks Associated with the Study

Control Group & Intervention Group 1: No health-related risks are anticipated.
Intervention Group 2: Temporary side effects related to virtual reality use (e.g., dizziness, nausea, headache) may occur, particularly during the adaptation period. If any discomfort arises, the application will be stopped immediately.

10. LIABILITY / RESPONSIBILITY IN THE EVENT OF ANY HARM

If you suffer any harm as a result of participation in the study, the costs required for treatment will be covered by Baskent University.

11. CONTACT PERSON IN CASE OF PROBLEMS DURING THE STUDY

In the event of any problems arising during the study (such as inability to attend training sessions), you may contact the relevant researcher at any time using the address and telephone number provided below.

Address and Telephone Numbers of the Nurse Available 24 Hours a Day Upon Request:

Emine Koç +90 05079955152

12. COVERAGE OF EXPENSES AND PAYMENTS

No fee will be requested from you or from your institution for participating in this study or for any expenses that may arise as a result of the research. No payment will be made to you for your participation in this study.

13. INSTITUTION SUPPORTING THE STUDY

There is no institution supporting this study.

14. WHETHER ANY PAYMENT WILL BE MADE TO THE PARTICIPANT

If you participate in this study, any compulsory expenses related to the research will be covered by the research team. Apart from this, no financial payment or material contribution will be provided to you or to your legal representatives.

15. CONFIDENTIALITY OF INFORMATION

All information obtained about you during the course of the study will be recorded using your student identification number. All information relating to you will be kept strictly confidential. The results of the study will be used solely for scientific purposes, and even if the study is published, your identity will not be disclosed. However, where necessary, study monitors, auditors, ethics committees, and authorised official bodies may have access to your medical information. You will also be able to access your own medical information upon request.

16. CONDITIONS FOR WITHDRAWAL FROM THE STUDY

During the study, if you fail to participate or participate incompletely in the pre-test, intermediate test, or post-test, or if you do not attend the Disability Awareness Training, the researcher may remove you from the study without obtaining your consent. You may withdraw from the study at any time of your own free will, and no fee will be charged in this regard. In the event that you are withdrawn from the study, your data will not be used for scientific purposes.

17. OTHER INTERVENTIONS APART FROM THE STUDY INTERVENTION

As required by this study, the educational interventions to be applied to you, together with their potential benefits and possible risks, are described below.
For the simulation–standardised patient application, the potential benefits include providing a safe learning environment for nursing students, enhancing clinical decision-making skills, promoting effective and active learning, supporting long-term retention of knowledge, reducing errors, contributing to the development of teamwork and communication skills, increasing student confidence, reducing stress levels, improving care skills, increasing learning motivation, and enhancing problem-solving, critical thinking, and empathy skills. Possible side effects include experiences described as a lack of familiarity, such as confusion, tension, curiosity, surprise, doubt, or feelings of being intimidated during simulation-based educational activities. As part of this, you may experience negative emotions during the application.
For the simulation–virtual reality application, the potential benefits are similar, including providing a safe learning environment, enhancing clinical decision-making skills, supporting effective and active learning, ensuring long-term knowledge retention, reducing errors, improving teamwork and communication skills, increasing confidence, lowering stress levels, enhancing care skills, increasing learning motivation, and strengthening problem-solving, critical thinking, and empathy skills. Possible side effects during simulation activities may include confusion, tension, curiosity, surprise, doubt, or feelings of being intimidated due to lack of familiarity. Additionally, adverse effects such as dizziness, light-headedness, loss of balance, nausea or vomiting, and headache may occur due to the head-mounted display used during the virtual reality application.

18. REFUSAL TO PARTICIPATE OR WITHDRAWAL FROM THE STUDY

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any stage, and your decision to refuse participation or to withdraw after consenting will not have any negative consequences for you. In the event that you withdraw from the study or are removed by the researcher, your data will not be used for scientific purposes.

19. SHARING OF NEW INFORMATION AND SUSPENSION OF THE STUDY

During the course of the study, any new positive or negative information and results related to the research will be communicated to you as soon as possible. Such information may influence your willingness to continue participating in the study. In such cases, you may request that the study be suspended until you have made an informed decision.

(Participant's Statement)

I have been informed that a research study will be conducted by Ms Emine Koç at the Department of Nursing, Başkent University, and the above information regarding the study has been explained to me. Following this information, I have been invited to participate in this study as a volunteer participant.
If I agree to participate in this study, I believe that due care and respect will be shown for the confidentiality of my personal information during the study. I have been assured that my personal data will be carefully protected during the use of the research results for educational and scientific purposes.
I understand that I may withdraw from the study at any time without providing a reason (however, I am aware that it would be appropriate to inform the researchers in advance in order not to cause inconvenience). I also understand that I may be withdrawn from the study by the researcher, provided that no harm is caused to my medical condition.
I will not assume any financial responsibility for expenses related to the study, and no payment will be made to me.
I have been assured that, should any health problems arise as a result of participation in the study, all necessary medical interventions will be provided and that I will not incur any financial burden as a result of such interventions.
I understand that I am not obliged to participate in this study and that I may choose not to participate. I have not been subjected to any coercive behaviour regarding participation in the study. I am also aware that if I refuse to participate, this will not have any adverse effect on my medical care or my relationship with my physician.

CONSENT TO PARTICIPATE IN THE STUDY

I have read and listened to the seven-page document presented above, which contains the information that must be provided to the volunteer prior to the commencement of the study. I have asked the researcher all the questions that came to my mind, and I have fully understood all the explanations provided to me both verbally and in writing. I have been given sufficient time to decide whether or not I wish to participate in the study.

Under these conditions, I authorise the principal investigator to review, transfer, and process my personal medical information, and I voluntarily accept the invitation to participate in the aforementioned study without any coercion or undue influence. I am aware that by signing this form, I do not waive any of the rights granted to me under local laws.

A signed and dated copy of this form has been provided to me.

VOLUNTEER		**Signature**
NAME - SURNAME		
ADRESS		
PHONE		
DATE		

RESEARCHER		**Signature**
NAME – SURNAME and Title	Emine Koc, PhD Student-Ress.Ass.	
ADRESS	Department of Nursing, Faculty of Health Sciences, Başkent University, Bağlıca, Etimesgut, Ankara, Turkiye	
PHONE	+90 05079955152	
DATE		

INSTITUTIONAL REPRESENTATIVE WHO WITNESSED THE INFORMED CONSENT PROCESS FROM BEGINNING TO END		**Signature**
NAME – SURNAME and Title		
ADRESS		
PHONE		
DATE		