Effects of the Case-Based Learning Approach on the Ethical Sensitivity of Nursing Students: An Experimental Study

Hemşirelik Öğrencilerinde Vaka Temelli Öğrenme Yaklaşımının Etik Duyarlılığa Etkisi: Deneysel Bir Çalışma

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ABSTRACT Students may not be able to integrate ethical issues into their knowledge and practical competencies, which makes them unprepared to manage such situations. Therefore, using an innovative and student-centred approach in nursing education is essential to increase ethical sensitivity. This study is the pioneer in terms of using an authentic learning (AL) approach for the first time in nursing ethics education. This study aimed to determine the effects of the case-based learning approach developed in line with the integrated ethical decision-making model and AL approach on the ethical sensitivity of nursing students in the management of ethical dilemmas. This single-group experimental study was conducted on a nursing faculty that offers a 4-year degree in Türkiye between September and December 2020. This study sample included 74 second-year nursing students enrolled. An 8-week program was developed and implemented by researchers. Data were collected using the Modified Moral Sensitivity Questionnaire (MMSQ) at the beginning and end of the program. Mean post-test scores for the MMSQ were significantly higher than those of the pre-tests. The Transparent Reporting of Evaluations with Nonrandomized Designs checklist was used. When the mean scores for pre-test and post-test measurements were compared, the mean scores for ethical sensitivity were higher. The results suggest that a case-based learning approach can improve the levels of ethical sensitivity in nursing students. Nurse educators should continue to develop new educational strategies and continually evaluate training methodologies to help students develop their ethical sensitivities.

Keywords: Ethics; ethical sensitivity; experimental study;
nursing; nursing student

ÖZET Öğrenciler, etik konuları bilgi ve pratik yeterliliklerine entegre edemeyebilirler, bu da onları bu tür durumları yönetmeye hazırlıksız hâle getirir. Bu nedenle hemşirelik eğitiminde yenilikçi ve öğrenci merkezli bir yaklaşımın kullanılması etik duyarlılığın artırılması için esastır. Bu çalışma, hemşirelik etiği eğitiminde ilk kez otantik bir öğrenme yaklaşımı kullanması bakımından öncü nitelikte bir çalışmadır. Bu çalışma, bütünleşik etik karar verme modeli ve otantik öğrenme yaklaşımı doğrultusunda geliştirilen vaka temelli öğrenme yaklaşımının hemşirelik öğrencilerinin etik ikilemlerin yönetiminde etik duyarlılıkları üzerindeki etkilerini belirlemeyi amaçlamıştır. Bu tek gruplu deneysel çalışma, Türkiye'de 4 yıllık eğitim veren bir hemşirelik fakültesi üzerinde Eylül ve Aralık 2020 tarihleri arasında yürütülmüştür. Bu çalışmanın örneklemi, kayıtlı 74 2. sınıf hemşirelik öğrencisini içermektedir. Araştırmacılar tarafından 8 haftalık bir program geliştirilmiş ve uygulanmıştır. Veriler, programın başında ve sonunda Ahlaki Duyarlılık Anketi kullanılarak toplanmıştır. Ahlaki Duyarlılık Anketi için ortalama son-test puanları, ön-testlerden önemli ölçüde daha yüksekti. "Transparent Reporting of Evaluations with Nonrandomized Designs" kontrol listesi kullanıldı. Ön-test ve son-test ölçüm puan ortalamaları karşılaştırıldığında etik duyarlılık puan ortalamaları daha yüksek çıkmıştır. Sonuçlar, vaka temelli öğrenme yaklaşımının hemşirelik öğrencilerinde etik duyarlılık düzeylerini iyileştirebileceğini göstermektedir. Hemşire eğitimciler, öğrencilerin etik duyarlılıklarını geliştirmelerine yardımcı olmak için yeni eğitim stratejileri geliştirmeye ve eğitim metodolojilerini sürekli olarak değerlendirmeye devam etmelidir.

Anahtar Kelimeler: Etik; etik duyarlılık; deneysel çalışma;
hemşirelik; hemşirelik öğrencisi

Improvements in science and technology have led to new issues and dilemmas.[1] This situation has caused ethics to become increasingly important in the provision of health services.[2-4] The complexity of healthcare systems requires healthcare professionals to have strong ethical judgement and skills.[5] Ethics is an essential component of nursing care and practice. Existing ethics rules state that every nurse should

respect the human rights of the individuals they care for and conduct professional nursing care in accordance with ethical principles.[5,6] Therefore, developing ethical and clinical competence is a critical component of the nursing profession.[3] The ethical decisions of healthcare professionals greatly affect the safety and well-being of patients.[7] Ethical dilemmas are situations of indecision about the better option to choose when there are two or more alternative actions.[2] The most common ethical dilemmas faced by nurses include end-of-life care, allocation of scarce resources, patient privacy and the use of genetics in the prevention and treatment of diseases.[1] Notably, dealing with, solving or overcoming ethical dilemmas is difficult.[7] Ethical sensitivity is a necessary first step towards ethical actions and begins with developing an awareness of ethical dilemmas or issues.[8]

There is a general consensus that instruction in ethics and professionalism is essential to nursing education. Since nurses encounter ethically challenging situations in their professional lives, nursing students must develop their ethical sensitivities to provide holistic care for patients based on strong ethical decision-making skills.[7,9,10] Additionally, developing ethical sensitivity in nursing students can help them increase their critical thinking, moral reasoning, decision making, and professional values.[7,9,11] The nursing education process should be considered an opportunity to avoid difficulties in care practices by developing ethical sensitivity among students.[3] However, there is no clear understanding of how to develop ethical sensitivity in nursing students and which components of nursing education contribute to ethical sensitivity.[5,12] Moreover, studies have revealed that nurses feel insufficiently prepared to deal with ethical problems in daily practice.[1,13,14] These results raise the question of whether ethics education in nursing is effective in increasing ethical knowledge and skills during the educational process. Moreover, this situation reveals the need for nurses to engage in student-centred teaching approaches (e.g., case-oriented ethics training) during their undergraduate years.[5] There is a need to develop more comprehensive and empirically based interventions to support the development of ethical sensitivity.[1,8]

Existing studies have emphasized the importance of choosing appropriate teaching methods to increase the ethical performance of nurses.[1,4,5,9,14,15] Notably, scenario-based learning, case studies, lecture-based methods, and group discussions are recommended and have been implemented as appropriate methods for teaching ethics.[1,9,14-16] Nursing ethics is one of the subjects taught in nursing education programs in Türkiye and ethics education is considered important in nursing undergraduate programs.[2,17] It has been determined that more systematic approaches are needed to increase the level of ethical sensitivity among Turkish nursing students.[2,17] Therefore, using innovative and student-centred approaches for developing ethical sensitivity in nursing education is very important to empowering student nurses in tackling ethical problems.

Authentic learning (AL) occurs when educators support students in questioning themselves, finding meaning, critical thinking, problem-solving, and reflection in real-world and creative contexts. In AL, every student reaches a certain subjective knowledge. As students expand their discipline-specific knowledge, they use different disciplines to question any situation and increase their capacity. AL also contributes to individual empowerment by enabling students to develop awareness and find solutions to their own problems.[18] Above all, AL requires educators to create a space where students and educators can communicate with each other without fear.[19] Although it was found that the AL approach improves the identity of nursing and facilitates meaningful learning for students, AL is not used in nursing ethics education.[19-21] This study is the pioneer in terms of using the AL approach for the first time in nursing ethics education. The present study aimed to determine the effects of a case-based learning approach developed in line with the integrated ethical decision-making model (IEDM) and AL approach on the ethical sensitivity of nursing students in the management of ethical dilemmas.

◼ MATERIAL AND METHODS

STUDY DESIGN

A single-group pre-test-post-test experimental design was adopted. Transparent Reporting of Evaluations with Nonrandomized Designs checklist was used for reporting in the study (Appendix 1).[22]

Setting

The study was conducted on a nursing faculty that offers a 4-year degree at a public university in Türkiye.

Sample

This study was conducted with 74 nursing students who were enrolled in a nursing program that offered a 4-year degree at a public university in Türkiye during the 2020-2021 academic year. Inclusion criteria for the study required that participants be second-year nursing students that volunteered to participate in this study. Exclusion criteria for the study mandated that students could not have been previously exposed to nursing ethics training. Since the ethics course has been taken since the second year of the students, the study was carried out with second-year students. During the study period, 87 participants were recruited. During the 8-week program, 13 students voluntarily withdrew from the study. The study concluded with 74 second-year nursing students.

DATA COLLECTION

The study was conducted between September and December 2020. An 8-week program was developed and implemented by researchers to determine the effects of case-based learning approach developed in line with the IEDM and AL on the ethical sensitivity of nursing students. The aim, importance, and method of the study were explained to the second-year nursing students (n=125). The content of the program was explained to the students who agreed to participate (n=87). Written informed consent was then obtained and the scales were applied (i.e., the pre-test application). Students were divided into 10 groups, with each group consisting of 6-12 students. In line with the belief that ethics education should be based on real situations and problems, this study used lived care ethics stories as part of the case-based learning approach method.[9,11] Previous studies have emphasised the importance of establishing a link between ethics and daily practices.[13,14] For this reason, a case analysis was created for this study based on lived care ethics stories. Guided by the IEDM and AL approach, one group was asked each week to analyse a lived care ethics story. Groups were counselled for 8 weeks on case selection, linking the model with its steps and

creating debate questions. A post-test was applied to students who completed the program at the end of 8 weeks.

IEDM

Park reviewed 20 structured ethical decision making models and developed a six-step IEDM with useful questions and tools that help improve performance at each step.[7] In previous studies, nursing students reported that the IEDM is easy and useful for understanding how to manage ethical conflicts. They also reported that they would likely use the IEDM in their future nursing roles.[7,16]

The steps of the IEDM include;

1. Identification of an ethical problem,

2. Collection of additional information to identify the problem and develop solutions,

3. Development of alternatives for analysis and comparison,

4. Selection of the best alternatives and justification,

5. Development of diverse, practical ways to implement ethical decisions and actions,

6. Evaluation of effects and development of strategies to prevent similar occurrences.[7]

Furthermore, studies have proven that the use of models is effective in teaching ethics and values in nursing.[16,23,24] In the present study, the ethical analysis of lived care ethics stories was conducted according to the IEDM using student-centred education methods such as reflection, debate, and an AL approach.

Intervention

First, interviews were conducted with nursing students to explain the purpose, importance and methodology of the program with an IEDM and AL approach. As an educator, both researchers were authentic and approached students with warmth and sincerity to create a sense of commitment that transcended class boundaries and created a space where students could communicate without fear. The students who agreed to participate in this study were administered a pre-test. After the pre-test, students completed an 8-week program. A diagram of the

workflow for this study is provided in Figure 1. In the first 45 minutes of session 1, the purpose, importance, and methodology of the study were explained. Information was provided about how the groups would be implemented, expectations were expressed and the students were divided into 10 groups of 6-12 people. A case study based on the IEDM was presented in the second 45 minutes of the session. In session 2, a case study based on the IEDM with an AL approach was presented and discussed with the groups. Each week, 2 groups presented their analysis of a lived care ethics story under the guidance of the IEDM over the next 5 sessions. Two academic nurses who specialised in the field of nursing ethics reviewed the contents of the analysed ethical cases for

each step of the decision-making process to determine their appropriateness. Groups were counselled on case selection, linking the model with its steps and creating debate questions. Each session involved using methods such as group discussions and interactive teaching to encourage participants to explain their ideas. Presentations and discussions of the case studies were prepared by students in 5 sessions. Evaluation and summarisation were conducted in session 8. Feedback was received from the students and their post-tests were applied.

Instruments

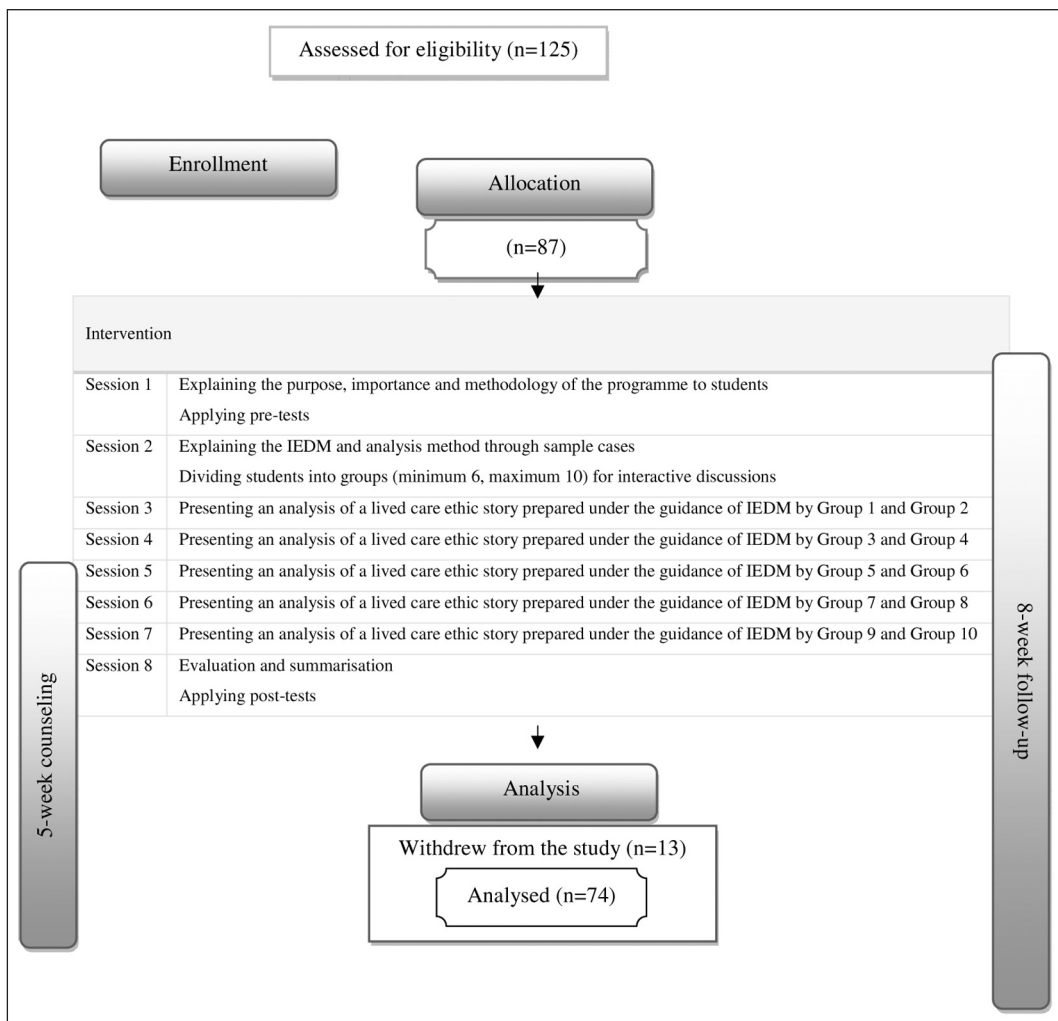The student information form was developed by the researchers after an extensive literature review and

FIGURE 1: Flow diagram of the study.
IEDM: Integrated ethical decision-making model.

consisted of nine questions.[1,2,9,15,17] The Modified Moral Sensitivity Questionnaire (MMSQ) was developed by Lützén to measure the moral sensitivity of nurses.[25] Comrie later revised Lu¨tze´n's scale to measure the moral sensitivity of student nurses. According to Comrie, determining the level of ethical sensitivity of student nurses can determine what nursing education programs should do to develop ethical sensitivity.[26] Therefore, this measurement tool was preferred in this study. The MMSQ consists of 30 items and is a Likert-type scale scored from 1 to 7. The 1-point answer option is "completely disagree", while the 7-point answer option is "completely agree". Higher scores indicate higher and lower scores indicate lower for ethical sensitivity. Mean scores for this scale were grouped and evaluated as 5.9-7.0 (very important), 5.0-5.8 (important), 3.1-4.9 (neutral) and less than 3.1 (not important). The scale has 6 sub-dimensions: (a) interpersonal orientation (having relationships with patients based on trust and finding ways to support them by fulfilling their needs), (b) modified autonomy (recognising the principle of patient autonomy and the need for patients to make their own decisions in situations requiring the physical and psychological protection of the patient or others; alternatively, limiting patients' autonomy), (c) beneficence (performing good deeds and acting in favour of patients), (d) creating ethical meaning (a process that reflects and comments on decisions that may limit patient decisions), (e) experiencing an ethical dilemma (first recognizing the presence of an ethical dilemma and then defining emotions and intuitions, recognizing the cognitive perception of ethical problems and awakening the requirements) and (f) obtaining expert opinions (consulting with experts to solve patient care problems). Based on Cronbach's alpha coefficient, the reliability and validity of the scale made in Türkiye was determined to be 0.73.[2] In the present study, Cronbach's alpha coefficient of the scale was determined to be 0.89 in the pre-test and 0.88 in the post-test.

DATA ANALYSIS

Statistical analyses were performed using SPSS 23.0 (IBM Corporation, Armonk, NY, USA) package program licensed to Akdeniz University. Cronbach's alpha coefficient was used to assess the reliability of the scale. To evaluate the demographic data of the participants, percentage distributions were used, while mean and standard deviation were used for continuous data. To evaluate the pre-test and post-test scores, an independent-samples t-test was used. The significance level was set at 0.05.

ETHICAL CONSIDERATIONS

In order to conduct this study, ethics committee approval was obtained from Akdeniz University Clinical Trials Ethics Committee (date: November 27, 2019; number: 1121). This study was conducted according to the Declaration of Helsinki.[27] The researchers obtained permission to use the MMSQ. Nursing students were informed verbally and in writing and informed consent was obtained with an explanation. Students who agreed to participate in this study were informed that they could withdraw from the study at any time.

RESULTS

PARTICIPANTS' SOCIO-DEMOGRAPHIC CHARACTERISTICS

The majority of participants (71.6%) were female and their mean age was 19.74±1.36 (minimum=18, maximum=28). The education level of the majority of students' maternal (73.1%) and paternal (58.1%) was primary education. Also, the majority of participants had a medium income level (64.9%). Most of the participants (93.2%) stated that they were satisfied with the program (Table 1).

STUDENTS' ETHICAL SENSITIVITY

The total scores for ethical sensitivity for the pre-test and post-test were 4.53±0.83 and 5.20±0.74, respectively. The post-test ethical sensitivity levels of the nursing students showed a significant increase when compared to their pre-test scores (t=5.187, p=0.001). The case-based learning approach study developed in accordance with the IEDM and AL approach increased the ethical sensitivities of nursing students. Simultaneously, increases in all sub-dimensions of the scale including interpersonal orientation (t=2.948, p=0.001), modifying autonomy (t=3.941, p=0.001), expressing benevolence (t=5.080, p=0.001), structuring moral meaning (t=4.492, p=0.001), experiencing

TABLE 1: Demographic profile of the students (n=74).		
Variables	**n**	**%**
Gender		
Female	53	71.6
Male	21	28.4
Maternal education level		
Primary education	54	73.1
High school	14	18.9
University	6	8.1
Paternal education level		
Primary education	43	58.1
High school	21	28.4
University	10	13.5
Income status		
Wealthy	22	29.7
Moderate	48	64.9
Poor	4	5.4
Response to "Are you satisfied with the program?"		
Yes	69	93.2
Partially	3	4.1
No	2	2.7

moral conflict (t=3.782, p=0.001) and trusting in professional knowledge (t=2.985, p=0.001) were statistically significant (Table 2).

DISCUSSION

The present study found that the case-based learning approach method was effective in encouraging the ethical sensitivities of students. The study was conducted with nursing students educated in Türkiye. In this study, nursing ethics education was held for 8 weeks using the IEDM and AL approach. The results indicate that the level of ethical sensitivity increased among nursing students who were exposed to the case-based learning approach method. While the level of ethical sensitivity among participants before the 8-week program was neutral, it increased to a significant level after the program was implemented. This increase is statistically significant and represents an important indicator of the effectiveness of the case-based learning approach method in developing ethical sensitivity.

Based on the national and international literature, new approaches for teaching ethics in nursing have been attempted. It has been determined that the problem-based learning approach and reflection method is the preferred approach to teaching nursing ethics.[9,11,28] In addition to traditional teaching and problem-based learning methods, role-playing is also accepted as an effective teaching strategy for nursing ethics education.[5,29] In this study, lived care ethics stories were used for the case-based learning approach method. The case-based learning approach method was applied in this study using lived care ethics stories and was determined to be a highly effective method for developing student nurses' ethical sensitivities. This result is consistent with previous studies using different nursing ethics training methods that increase ethical sensitivity. As a result of the quasi-experimental study conducted by Khatiban et al. with nursing students and the longitudinal study by Kim et al., it was determined that lecture-based versus problem-based learning was effective on ethical sensitivity.[9,10] In addition, according to a different interventional study, debate-based ethics education was very effective in improving moral reasoning and ethical decision-making skills in nursing students.[15] Kyle

TABLE 2: Students' ethical sensitivity scores for the pre-test and post-test (n=74).								
		Pre-test			**Post-test**			
		X̄±SD	Minimum	Maximum	X̄±SD	Minimum	Maximum	t value	p value
MSQ		4.53±0.83	1.00	7.00	5.20±0.74	1.00	7.00	5.187	0.01*
Sub-dimensions	Interpersonal orientation	5.20±1.27	1.00	7.00	5.76±1.04	1.50	7.00	2.948	0.01*
	Modifying autonomy	4.52±1.08	1.00	6.60	5.19±0.99	2.80	7.00	3.941	0.01*
	Expressing benevolence	4.48±1.06	1.00	6.38	5.30±0.89	2.88	6.50	5.080	0.01*
	Structuring moral meaning	4.24±0.89	1.00	7.00	4.87±0.82	1.00	7.00	4.492	0.01*
	Experiencing moral conflict	3.71±1.14	1.00	7.00	4.43±1.19	1.00	7.00	3.782	0.01*
	Trusting in professional knowledge	4.51±1.04	1.00	7.00	5.03±1.07	1.00	7.00	2.985	0.01*

*Remains statistically significant; MSQ: Moral Sensitivity Questionnaire; SD: Standard deviation.

"anonymised reflection" and Lee et al. presented evidence that "visual, auditory and kinaesthetic learning model" approaches positively affect the ethical sensitivities of nursing students.[24,28] To improve the effects of learning from the nursing ethics course, systematic approaches to proven methods along with the traditional course format are required.[2,5,17] Therefore, using an innovative approach to nursing education is essential to increase ethical sensitivity among students in Türkiye. Turkish nursing students attend nursing ethics lessons in their undergraduate education and the importance of these lessons is recognised.[2,17] Using the case analysis method is recommended when teaching ethics in nursing education so that students can comprehend the ethical problems and dilemmas that exist in Türkiye.[30] Additionally, case study-based learning is considered an effective teaching method.[14,17,31-33]

It is extremely important for students to be active, take responsibility for learning, and learn from real-life experiences. This allows graduates to keep up with changes in nursing practices, especially in the management of ethical dilemmas. AL, which is a student-centred approach based on the constructivist learning paradigm, is a framework that can be used to educate graduates.[19-21] In this study, AL was used for the first time as a method in nursing ethics education. In the 21st century, approaches such as AL should be integrated into education so that nursing graduates can evolve to solve complex ethical problems in the real world.[34,35] Notably, this approach should be tested in nursing ethics education.

STRENGTHS AND LIMITATIONS

This study was developed based on the IEDM. Thus, all participating nursing students did not take any formal nursing ethics course before collecting data. This feature a strength of the study, which increases the homogeneity of the group as study subjects. Also, ethics education in the AL approach and the integration of learner-centred approaches increased the strength of this study. Another strength of this study is that an easy-to-understand scale with high validity and reliability was used, with all measurements being made with this scale. Additionally, an important limitation of this study is the single-group pre-test and post-test design with no control group. Therefore, no conclusions could be drawn regarding causality. Another limitation is that a convenience sample of 74 nursing students recruited from one nursing faculty cannot be generalized.

CONCLUSION

The results of this study indicate that the ethical sensitivities of nursing students can be improved through a case-based learning approach. Case-based learning approach developed in line with the IEDM and AL approach is an effective method for developing nursing students' ethical sensitivities. Educators in nursing schools should continue to develop new educational strategies and continually evaluate educational methods to help students develop their ethical sensitivities.

It is recommended that the case-based learning approach and AL approach be added to the nursing education curriculum to improve students' ethical sensitivity. In future interventional studies, these methods could be assessed with a larger sample. Further qualitative research could also define the ethical sensitivities of nursing students and the situations that affect them.

APPENDIX 1: TREND Statement Checklist.			
Paper section/topic	**Item no**	**Descriptor**	**Reported?**
Title and Abstract			
Title and abstract	1	• Information on how unit were allocated to interventions	✔
		• Structured abstract recommended	✔
		• Information on target population or study sample	✔
Introduction			
Background	2	• Scientific background and explanation of rationale	✔
		• Theories used in designing behavioral interventions	✔
Methods			
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✔
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✔
		• Recruitment setting	✔
		• Settings and locations where the data were collected	✔
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✔
		o Content: what was given?	✔
		o Delivery method: how was the content given?	✔
		o Unit of delivery: how were the subjects grouped during delivery?	✔
		o Deliverer: who delivered the intervention?	✔
		o Setting: where was the intervention delivered?	✔
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✔
		o Time span: how long was it intended to take to deliver the intervention to each unit?	✔
		o Activities to increase compliance or adherence (e.g., incentives)	✔
Objectives	5	• Specific objectives and hypotheses	✔
Outcomes	6	• Clearly defined primary and secondary outcome measures	✔
		• Methods used to collect data and any methods used to enhance the quality of measurements	✔
		• Information on validated instruments such as psychometric and biometric properties	✔
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	✔
Assignment method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	✔
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	✔
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	✔
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed	✔
Unit of analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	✔
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	✔
Statistical methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	✔
		• Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	✔
		• Methods for imputing missing data, if used	✔
		• Statistical software or programs used	✔
Results			
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	✔
		o Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	✔
		o Assignment: the numbers of participants assigned to a study condition	✔
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	✔
		o Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition	✔
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition	✔
		• Description of protocol deviations from study as planned, along with reasons	✔

APPENDIX 1: TREND Statement Checklist *(continue)*.			
Paper section/topic	**Item no**	**Descriptor**	**Reported?**
Recruitment	13	• Dates defining the periods of recruitment and follow-up	✔
Baseline data	14	• Baseline demographic and clinical characteristics of participants in each study condition	✔
		• Baseline characteristics for each study condition relevant to specific disease prevention research	✔
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	✔
		• Comparison between study population at baseline and target population of interest	✔
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	✔
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	✔
		• Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	✔
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	✔
		• Inclusion of null and negative findings	✔
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	✔
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	✔
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	✔
Discussion			
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	✔
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	✔
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	✔
		• Discussion of research, programmatic, or policy implications	✔
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	✔
Overall evidence	22	• General interpretation of the results in the context of current evidence and current theory	✔

From: Des Jarlais DC, Lyles C, Crepaz N; TREND Group. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. Am J Public Health. 2004;94(3):361-6. For more information, visit: http://www.cdc.gov/trendstatement/

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