

The Impact of Motivational Interviewing Guided by Watson's Theory of Human Caring on Adherence, Self-Efficacy, and Satisfaction in Patients with Diabetic Foot Ulcers: A Randomized Controlled Trial Protocol

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Abstract

Background: Diabetic foot ulcers (DFUs) are serious complications that diminish quality of life and increase healthcare costs. Effective management requires holistic, evidence-based approaches. Watson's Theory of Human Caring (THC) and motivational interviewing (MI) address both the physical and psychological dimensions of care.

Aim: This study examines the effects of motivational interviewing, guided by Watson's Theory of Human Caring, on treatment adherence, self-efficacy, and patient satisfaction among individuals with diabetic foot ulcers.

Methods: This single-blind randomized controlled trial included 76 participants with Wagner grade 1 DFUs. Participants were randomly assigned to either an experimental group receiving an eight-week motivational interviewing intervention based on Watson's THC or a control group receiving standard care. Data was collected at weeks 1, 8, and 12 using validated instruments: the Diabetic Foot Care Self-Efficacy Scale, the Medication Adherence Reporting Scale, and the Watson Caritas Patient Score. Data was analyzed using independent-samples t-tests, repeated-measures analyses, and chi-square tests.

Results: This study is expected to provide preliminary evidence regarding the effectiveness of motivational interviewing guided by Watson's Theory of Human Caring in individuals with diabetic foot ulcers. It is anticipated that participants in the intervention group may demonstrate improvements in treatment adherence, diabetic foot care self-efficacy, and patient satisfaction compared with those receiving standard care. Potential improvements in secondary clinical outcomes, including wound size and HbA1c levels, are also expected to be explored.

Conclusion: The study is expected to provide evidence supporting the integration of motivational interviewing and Watson's THC in DFU management. The findings may inform future research and clinical practice, supporting the delivery of more holistic care and improved outcomes for patients with DFUs.

Keywords: Diabetic foot, motivational interviewing, patient adherence, patient satisfaction, self-efficacy

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Introduction

According to the International Diabetes Federation (IDF), approximately 537 million people worldwide are living with diabetes, including more than 61 million in Europe. Projections indicate that this number increased to 69 million by 2045. In Türkiye, where the adult population is estimated at 57 million, the prevalence of diabetes is 15.9%, with the total number of affected adults exceeding 9 million.¹ The rising prevalence of diabetes has led to a corresponding increase in its associated complications.² Diabetic foot ulcers (DFUs), among the most serious complications, not only compromise patients' overall health and social well-being but also place a substantial burden on healthcare systems and nursing practice.³

Diabetic foot ulcers, a common complication of diabetes, typically develop due to sensory loss associated with peripheral neuropathy, ischemia resulting from peripheral artery disease, infection, and inadequate foot care practices.^{2,4} The prognosis for patients with diabetes, peripheral artery disease, and foot ulcers requiring amputation is poorer than that of many common cancers, with up to 50% of such patients surviving less than five years.⁵ These findings highlight the need for interventions that promote positive health behaviors and improve the management of diabetes-related complications.⁶

Nursing theories have been developed to support professionalization and autonomy in the field, establish standards and a common language, and contribute to nursing research and education.^{7,8} Among widely adopted nursing models, Jean Watson's Theory of Human Caring (THC), developed between 1975 and 1979, emphasizes the delivery of high-quality patient care alongside the cultivation of meaningful therapeutic relationships.⁷ Addressing DFUs within the framework of THC aligns with the objectives of this study and introduces a novel perspective to nursing practice. This approach facilitates a comprehensive, holistic model of care for individuals with DFUs. Consequently, such care has the potential to prevent disease progression, reduce hospital admission rates and treatment costs, and promote sustainable healthcare outcomes.

Motivational interviewing (MI), originally introduced by clinical psychologists William R. Miller and Stephen Rollnick to address alcohol dependence, has evolved into a key strategy for facilitating behavioral change in chronic disease management. Extensive international literature demonstrates its effectiveness in improving

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clinical outcomes in conditions such as cardiovascular diseases, diabetes mellitus, and hypertension.^{10,11} However, despite its established success in general diabetes care, there remains a notable lack of research examining its specific application to diabetic foot ulcers, a complication often associated with high levels of non-adherence and significant psychological burden.

Both national and international studies indicate that traditional patient education methods frequently fail to achieve sustained behavioral change in individuals with DFUs, resulting in recurrent ulcerations and increased rates of amputation.^{2,4-6} While MI presents a promising alternative, its integration with nursing-specific theoretical frameworks remains insufficiently explored. This study addresses this gap by integrating MI with Watson's Theory of Human Caring, thereby offering a holistic approach that extends beyond conventional clinical instruction. Through this framework, the study aims to evaluate the impact of a structured, patient-centered intervention on treatment adherence, self-efficacy, and patient satisfaction. The findings are expected to provide a clinical framework for nurses, contributing to enhanced patient-centered care and a reduction in the global burden of DFU-related complications.

Materials and Methods

This study aims to evaluate the effects of motivational interviewing, grounded in Watson's THC, on treatment adherence, self-efficacy, and patient satisfaction among individuals with DFUs. The study was registered on April 12, 2023 in the ClinicalTrials.gov database [Identifier: NCT06023810].

Study Design

This study is designed as a single-blind randomized controlled trial. Participants were randomly assigned to either an experimental group, which received motivational interviewing sessions based on Watson's Theory of Human Caring, or a control group, which received standard care. The study protocol adheres to CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Research Hypotheses

H1: Diabetic foot care self-efficacy differed between individuals with diabetic foot ulcers who receive motivational interviewing-based education grounded in Watson's Theory of Human Caring and those who receive conventional education.

H2: Individuals with diabetic foot ulcers who receive education through motivational interviewing aligned with Watson's Theory of Human Caring demonstrated more positive and consistent diabetic foot care behaviors than those receiving standard education.

H3: Individuals with diabetic foot ulcers who receive diabetic foot care education based on Watson's Theory of Human Caring through motivational interviewing exhibited higher levels of treatment adherence compared to those receiving traditional education methods.

H4: Individuals with diabetic foot ulcers who receive a motivational interviewing approach grounded in Watson's Theory of Human Caring reported higher satisfaction levels with diabetic foot care education compared to those receiving standard education.

Study Population

Participants are recruited from a tertiary healthcare institution and included adults aged 18 years or older with type 1 or type 2 diabetes who present with Wagner grade 1 diabetic foot ulcers and provide informed consent. Exclusion criteria include severe cognitive impairment, advanced musculoskeletal conditions, or other comorbidities that may limit participation. Participants are randomly assigned to one of two groups: the experimental group receives four weekly individual motivational interviewing sessions (45–60 minutes each) based on Watson's Theory of Human Caring, delivered by a trained nurse; the control group receives a single 30-minute session of conventional foot care education. The primary outcome of this study is diabetic foot care self-efficacy, measured at baseline and four weeks post-intervention. Secondary outcomes include foot care behaviors, treatment adherence, and patient satisfaction, all assessed using standardized questionnaires. The study is designed as a single-blind randomized controlled trial and adheres to the CONSORT guidelines to ensure reproducibility.

Randomization and Blinding

Participants were allocated to the experimental or control group using a computer-assisted simple randomization method to ensure equal group sizes. An independent researcher generated two sets of random numbers (ranging from 1 to 76) using the random.org platform. Group allocation was determined by a lottery system assigning each set of numbers to either the experimental or control group. The numbers were then placed on slips of paper, sealed in opaque envelopes, and prepared for allocation. Following eligibility assessment and informed consent, a hospital staff member independent of the study selected an envelope to determine each participant's group assignment.

The study is conducted in accordance with the CONSORT Checklist 2010¹² and the CONSORT eHealth Checklist 2011¹³ to enhance clarity, integrity, and transparency.

Randomization procedures were performed by an independent researcher using random.org. The primary researcher remained blinded to group allocation until the intervention phase begins (i.e., when participants select the numbered envelopes). Data analysis was conducted by an independent statistician who was blinded to both group allocation and intervention conditions to minimize bias.¹⁴

Although double blinding is not feasible due to the nature of the intervention, blinding was implemented wherever possible. The researcher delivering the motivational interviewing did not have access to the randomization list and remained unaware of participants' group assignments prior to allocation. Randomization was conducted by an independent researcher who was not involved in recruitment, intervention delivery, or data collection. The hospital staff member responsible for distributing sealed envelopes was blinded to the study protocol and hypotheses. Due to the behavioral nature of the intervention, participant blinding was not feasible. However, outcome assessors and the statistician remained blinded to group allocation. This single-blind design was intended to minimize assessment and analysis bias.

Sample Size and Power Analysis

The sample size was determined using the G*Power statistical power analysis program (version 3.1; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany, released 2010). A dependent-samples t-test was planned to assess changes in self-efficacy within each group. The study followed a single-blind randomized controlled experimental design with experimental and control groups to examine the effects of motivational interviewing, grounded in Watson's Theory of Human Caring, on treatment adherence, self-efficacy, and satisfaction among individuals with diabetic foot ulcers.

In the absence of directly comparable studies, Cohen's standardized effect size was used.¹⁵⁻¹⁷ The sample size calculation was based on a medium effect size (0.5),¹⁸ an alpha level of 5%, and a statistical power of 80%, resulting in a minimum required sample of 34 participants per group.

To account for potential attrition and limit data loss to below 10–15%,¹⁹⁻²² an additional 10% of participants were included. Accordingly, a total of 76 individuals were randomized, with 38 allocated to the experimental group and 38 to the control group (Fig. 1).

Outcome Measures

Primary Outcome Measures

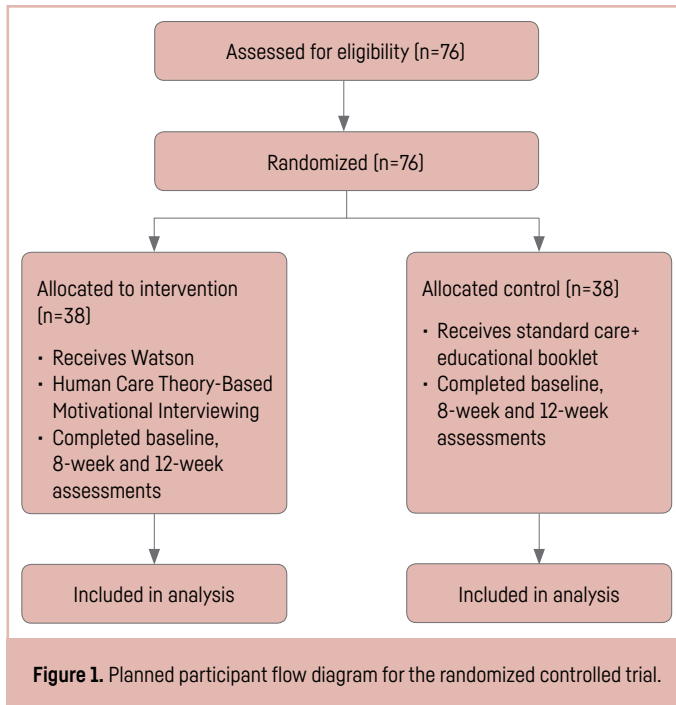
The primary outcomes of this study are treatment adherence and diabetic foot care self-efficacy.

- **Diabetic foot care self-efficacy:** Assessed using the Turkish version of the Diabetic Foot Care Self-Efficacy Scale, which has demonstrated good reliability (Cronbach's $\alpha=0.86$). Higher scores indicate greater self-efficacy.^{23,24}
- **Medication adherence:** Measured using the Turkish version of the Medication Adherence Report Scale (MARS), which has been validated and shown to be reliable in the target population. Higher scores indicate better adherence.²⁵⁻²⁷

Secondary Outcome Measures

Secondary outcomes include patient satisfaction, foot care behaviors, wound size, and hemoglobin A1c (HbA1c) levels.

- **Patient satisfaction:** Evaluated using an instrument based on Watson's Theory of Human Caring, consisting of items rated on a 7-point Likert scale and an open-ended question capturing caring experiences.^{28,29}



- **Foot care behaviors:** Assessed using the Turkish version of the Foot Care Behavior Scale (FCBS); higher scores indicate better adherence to American Diabetes Association (ADA) foot care recommendations.³⁰
- **Wound size:** Measured using a standardized ruler, with area calculated as length × width (mm²).
- **HbA1c levels:** Obtained from participants' recent clinical laboratory results and included as descriptive clinical data.

Intervention

Experimental Group

Participants in the experimental group received a motivational interviewing program grounded in Watson's Theory of Human Caring, delivered through weekly home visits over eight consecutive weeks. The first session lasted approximately 60 minutes, followed by seven sessions of approximately 30 minutes each.

Data were collected at three time points: baseline (week 1), post-intervention (week 8), and follow-up (week 12).

At baseline (week 1), data collection included the Patient Information Form, Diabetic Foot Assessment Form, Wagner Wound Assessment Form, Medication Adherence Report Scale, Foot Care Behavior Scale, wound size measurement, and the Diabetic Foot Care Self-Efficacy Scale.

At week 8 (post-intervention), the Diabetic Foot Assessment Form, Wagner Wound Assessment Form, Medication Adherence Report Scale, Foot Care Behavior Scale, wound size measurement, Diabetic Foot Care Self-Efficacy Scale, and the Watson Caritas Patient Score were administered.

At week 12 (follow-up), the Diabetic Foot Assessment Form, Wagner Wound Assessment Form, Medication Adherence Report Scale, Foot Care Behavior Scale, wound size measurement, HbA1c levels, and the Diabetic Foot Care Self-Efficacy Scale were collected.

A follow-up appointment was scheduled at the end of each visit.

The intervention was structured in accordance with the core principles of motivational interviewing, including open-ended questioning, reflective listening, affirmation, summarization, and elicitation of change talk, and was guided by Watson's Caritas Processes. Each session was designed to enhance patients' awareness, motivation, and sense of responsibility regarding foot care and treatment adherence.

The initial session focused on establishing a therapeutic relationship, assessing patients' beliefs and readiness for change, and introducing diabetic foot care within a caring-healing framework. Subsequent sessions aimed to strengthen self-efficacy, resolve ambivalence toward treatment adherence, reinforce positive foot care behaviors, and support emotional well-being through caring moments aligned with Watson's Theory of Human Caring.

All sessions were delivered by a nurse researcher trained in motivational interviewing and Watson's Theory of Human Caring, who had completed formal MI training and had prior clinical experience in diabetic foot care.

The detailed content of each session is summarized in Table 1. A comprehensive semi-structured intervention manual is provided as supplementary material.

Control Group

Participants in the control group receive standard care, defined as routine clinical follow-up, wound assessment, and treatment provided by healthcare professionals, without any additional structured intervention from the research team. To ensure ethical transparency and comparability between groups, all control participants received an educational booklet at the beginning of the study.

Data collection in the control group followed the same schedule as in the experimental group, with assessments conducted at baseline (week 1), week 8, and week 12.

At baseline (week 1), data was collected using the Patient Information Form, Diabetic Foot Assessment Form, Wagner Wound Assessment Form, Medication Adherence Report Scale, Foot Care Behavior Scale, wound size measurement, and the Diabetic Foot Care Self-Efficacy Scale.

Table 1. Structure of the motivational interviewing program based on Watson's Theory of Human Caring

Session	Core focus of the session	Motivational interviewing techniques	Watson's Caritas processes
1	Establishing rapport, assessing readiness for change	Open-ended questions, affirmations, reflective listening, summarizing	Humanistic-altruistic values, helping-trusting relationship, teaching-learning
2	Exploring illness experiences and emotional responses	Open-ended questions, reflective listening, affirmations	Sensitivity to self and others, expression of feelings
3	Addressing fears related to illness and treatment	Reflective listening, affirmations, summarizing	Expression of positive and negative feelings, existential openness
4	Discussing experiences and challenges related to diabetic foot care	Open-ended questions, reflective listening	Faith-hope, sensitivity to self and others
5	Enhancing treatment adherence and foot care behaviors	Eliciting change talk, decisional balance, affirmations	Teaching-learning, supportive caring relationship
6	Problem-solving and strengthening self-efficacy	Change talk, reflective listening, summarizing	Creative problem solving, helping-trusting relationship
7	Reinforcing progress and addressing remaining concerns	Open-ended questions, affirmations, change talk	Supportive and protective environment
8	Closure, future planning, and consolidation of gains	Reflection, summarizing, affirmations	Existential-phenomenological-spiritual care

Table 2. Timing and details of data collection

Measure	Experimental group			Control group		
	Week 1	Week 8	Week 12	Week 1	Week 8	Week 12
Information Form	+	-	-	+	-	-
Diabetic Foot Assessment Form	+	+	+	+	+	+
Wagner Wound Assessment Form	+	+	+	+	+	+
Medication Adherence Report Scale	+	+	+	+	+	+
Foot Care Behavior Scale	+	+	+	+	+	+
Diabetic Foot Care Self-Efficacy Scale	+	+	+	+	+	+
Wound Size Measurement	+	+	+	+	+	+
Watson Caritas Patient Score	-	+	-	-	-	-
HbA1c	+	-	+	+	-	+

At week 8, the Diabetic Foot Assessment Form, Wagner Wound Assessment Form, Medication Adherence Report Scale, Foot Care Behavior Scale, wound size measurement, and the Diabetic Foot Care Self-Efficacy Scale were administered.

At week 12, data collection included the Diabetic Foot Assessment Form, Wagner Wound Assessment Form, Medication Adherence Report Scale, Foot Care Behavior Scale, wound size measurement, HbA1c levels, and the Diabetic Foot Care Self-Efficacy Scale.

No motivational interviewing techniques or theory-based structured counseling was provided to the control group during the study period. At the conclusion of the study, motivational interviewing was offered to participants in the control group, ensuring equitable access to the intervention after all outcome measurements had been completed (Table 2).

Statistical Analysis

Data obtained from the study was entered into and analyzed using IBM SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA; released 2012). The normality of the variables was assessed using skewness and kurtosis values. If the data were normally distributed, parametric tests were applied. Differences between groups were analyzed using the independent-samples t-test, while within-group comparisons were conducted using the paired-samples t-test. Repeated measures were evaluated using analysis of variance (ANOVA) with Bonferroni analysis. If the data were not normally distributed, nonparametric tests were used. Between-group comparisons were performed using the Mann-Whitney U test, within-group comparisons using the Wilcoxon signed-rank test, and repeated measures using the Friedman test with Dunn-Bonferroni analysis. Statistical significance was set at $p < 0.05$.

Ethics Committee Approval

This study was conducted in accordance with the principles of Good Clinical Practices and the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of İstanbul Okan University (Approval Number: 162, Date: 11.01.2023). The study was registered on April 12, 2023, in the ClinicalTrials.gov database (Identifier: NCT06023810). Institutional permission was obtained from the hospital where the study was conducted. All participants were informed about the study, and both written and verbal informed consent were obtained.

Discussion

Improving treatment adherence, self-efficacy, and patient satisfaction in individuals with diabetic foot ulcers is essential for reducing complications and improving clinical outcomes. This study evaluated the impact of integrating motivational interviewing with Watson's Theory of Human Caring within a holistic, patient-centered framework. By addressing both physical and emotional dimensions of care, the intervention aimed to support patients in managing their condition more effectively.

Motivational interviewing is a well-established strategy for enhancing self-care behaviors and treatment adherence in chronic disease populations. A systematic

review by Miller and Rollnick demonstrated its effectiveness in improving medication adherence and glycemic control in individuals with diabetes.¹¹ Watson's Theory of Human Caring emphasizes therapeutic relationships and caring processes, which are associated with improved patient satisfaction and engagement in self-care.³¹ By integrating these approaches, this study examined whether a structured intervention can positively influence adherence, self-efficacy, and satisfaction in diabetic foot ulcer care.

Diabetic foot ulcers present multifactorial challenges that require coordinated medical treatment, lifestyle modifications, and psychological support. Evidence suggests that addressing emotional and psychological factors alongside physical care improves healing outcomes and reduces recurrence.³² This protocol incorporates motivational interviewing and Watson's Caritas Processes to evaluate whether such an integrated approach can enhance patient self-efficacy and adherence while supporting wound healing.

Holistic, patient-centered approaches grounded in Watson's Theory highlight the importance of caring moments and supportive therapeutic relationships. These principles align closely with motivational interviewing, which encourages patients to actively participate in their care.³³ Evaluating the feasibility and effectiveness of combining these approaches may provide valuable insights into strategies for improving adherence to foot care regimens and overall clinical outcomes.

Although both motivational interviewing and Watson's Theory have demonstrated individual benefits, research on their combined application in diabetic foot ulcer management is limited. This study aimed to address this gap and contribute to the growing body of evidence supporting holistic, patient-centered models in chronic disease care. By integrating physical and emotional care dimensions, the findings are expected to inform future research and the development of evidence-based clinical guidelines, particularly for populations with complex care needs.³⁴

Limitations of the Study

This study has some limitations. First, due to the behavioral nature of the motivational interviewing intervention, blinding of the participants is not feasible, which may introduce performance bias. Second, the study is conducted in a single tertiary healthcare institution, which may limit the generalizability of the findings to different healthcare settings.

Conclusion

Based on the study hypotheses, integrating motivational interviewing within Watson's Theory of Human Caring is expected to positively influence treatment adherence, self-efficacy, and patient satisfaction among individuals with diabetic foot ulcers. The findings may provide practical insights into how nurses can incorporate evidence-based interventions into clinical practice. By adopting roles as educators and consultants, nurses may enhance holistic care delivery, improve treatment effectiveness, and contribute to better quality of life for patients managing chronic conditions such as diabetic foot ulcers.

Ethics Committee Approval: The study was approved by the İstanbul Okan University Ethics Committee [Approval Number: 162, Date: 11.01.2023].

Informed Consent: Written informed consent was obtained from the patients.

Conflict of Interest: The authors have no conflicts of interest to declare.

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