Study Protocol

Title:

Effects of a Virtual Reality–Based Empathy Program on Empathy, Attitudes Toward Older Adults, and Empathic Behavior Among Nursing Assistants: A Cluster Randomized Controlled Trial

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Principal Investigator: Principal Investigator (PI)

1. Background and Rationale

Empathy is a fundamental component of high-quality long-term care and is associated with improved interpersonal relationships, communication, and emotional well-being among older adults. Nursing assistants (NAs) provide the majority of direct daily care in long-term care institutions and play a critical role in empathic caregiving interactions. However, conventional empathy training approaches are often didactic in nature and may have limited impact on sustained empathic outcomes.

Virtual reality (VR)–based training provides immersive, first-person experiential learning that may enhance perspective-taking and emotional engagement. When combined with structured reflective debriefing, VR-based interventions have the potential to improve empathy-related outcomes, including empathic attitudes and observable empathic behaviors. This study evaluated the effectiveness of a VR-based empathy program with structured debriefing among nursing assistants working in long-term care settings, using a cluster randomized controlled trial design.

2. Objectives and Hypotheses

2.1 Primary Objective

To examine the effect of a virtual reality–based empathy training program on empathy level among nursing assistants.

2.2 Secondary Objectives

1. To evaluate changes in attitudes toward older adults.
2. To assess changes in empathic behavior over time.

2.3 Hypothesis

Nursing assistants in the intervention group will show significantly higher

empathic behavior scores over time compared with the control group.

3. Study Design

This study was a two-arm, parallel-group, cluster randomized controlled trial (cluster RCT).

Clusters were defined as care building or floor level within long-term care institutions.

Eligible clusters were randomized in a 1:1 ratio to either:

- Virtual Reality (VR) with Structured Debriefing Group, or
- Control Group.

Outcome assessments were conducted at three time points:

- Baseline (pre-intervention),
- End of intervention (week 3), and
- Follow-up at one month post-intervention (week 7).

4. Study Setting

The study was conducted in long-term care institutions in Taiwan. Clusters were defined as care units at the building or floor level within institutions. All interventions and outcome assessments were implemented within participating.

5. Participants

5.1 Inclusion Criteria

Participants were eligible if they met all of the following criteria:

- Certified nursing assistants
- Aged 20 years or older
- Employed in the current institution for at least three months
- Able to communicate in Mandarin Chinese

- Provided written informed consent to participate

5.2 Exclusion Criteria

- Currently on long-term leave during the intervention period
- Severe visual, auditory, or cognitive impairment preventing participation in VR training

6. Randomization and Allocation

Clusters (care units/wards) were randomly assigned in a 1:1 ratio to either:

- Control Group (C)
- Virtual Reality (VR) with Debriefing Group

Randomization was conducted by an independent researcher not involved in recruitment or assessment.

7. Intervention

7.1 Control Group

Participants in the control group received routine education or standard practice during the study period and were provided with an empathy manual, but did not receive the VR-based empathy program.

7.2 VR With Debriefing Group

Participants in the intervention group received a virtual reality–based empathy training program designed to simulate the lived experiences of older adults in long-term care contexts. Each VR session was followed by a structured debriefing session facilitated by trained personnel, focusing on emotional reflection, perspective-taking, and application to daily caregiving practice.

The intervention was delivered over a three-week period.

8. Outcome Measures

8.1 Primary Outcome

Empathy Level

Empathy level was measured using the full, unabbreviated Jefferson Scale of Empathy–Health Professions Version (JSE-HP), which constructs and assesses the multi-dimensional empathy levels of healthcare professionals (including perspective taking, compassionate care, and standing in patient's shoes).

The JSE-HP consists of 20 items answered on a 7-point Likert scale. The total score ranges from a minimum of 20 to a maximum of 140. A higher total score indicates a greater level of empathy (a better outcome), whereas a lower total score represents a worse outcome. Individual subscale scores were combined by summation to compute the final total score.

8.2 Secondary Outcomes

Attitudes Toward Older Adults

Attitudes toward older adults were measured using the full, unabbreviated Kogan's Attitudes Toward Older People Scale (KAOP), which constructs and assesses the positive and negative sentiments toward elderly populations.

The KAOP consists of 34 items answered on a 6-point Likert scale. The total score ranges from a minimum of 34 to a maximum of 204. A higher total score indicates a more positive attitude toward older adults (a better outcome), whereas a lower total score represents a more negative attitude (a worse outcome).

Empathic behavior

Empathic behavior was measured using a Structured Empathic Behavior Rating Scale, which constructs and evaluates observable empathic behaviors exhibited by nursing assistants during direct resident caregiving interactions.

The scale utilizes a standardized checklist to rate specific behavioral interactions. The total score ranges from a minimum of 12 to a maximum of 84. A higher total score indicates a higher frequency or better quality of demonstrated empathic behaviors (a better outcome), while a lower score represents fewer or poorer empathic behaviors.

8.3 Timing of Assessments

All outcomes were assessed at:

- Baseline (pre-intervention),
- End of intervention (week 3), and
- Follow-up at one month post-intervention (week 7).

9. Data Collection Procedures

Data were collected using standardized questionnaires administered by trained research assistants. All assessors were blinded to group allocation where feasible.

10. Sample Size

A total of 103 nursing assistants participated in the study:

- Control Group: 50 participants
- VR with Debriefing Group: 53 participants

11. Adverse Events

The intervention was educational and non-invasive. Adverse events were monitored throughout the study period using participant self-report and

investigator observation. No adverse events were observed or reported in either study group.

12. Ethics and Informed Consent

The study was conducted in accordance with ethical principles for research involving human participants. The study protocol was reviewed and approved by the Institutional Review Board of Taipei Medical University (TMU-JIRB approval number: N202203004). All procedures were conducted in accordance with relevant ethical guidelines and regulations. Written informed consent was obtained from all participants prior to participation.

13. Data Management and Confidentiality

All data were de-identified prior to analysis. Study data were securely stored and accessed only by authorized research personnel.

14. Limitations

Limitations of the study include the limited number of participating institutions, reliance on self-reported measures, a relatively short follow-up period, and the inability to blind participants due to the nature of the intervention.

15. Protocol Status

This protocol was prepared retrospectively for results reporting purposes. All reported analyses and outcomes reflect the procedures actually implemented in the completed study.