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Examining the Effectiveness of Nurse-Led Chronic Disease Management in Improving Outcomes Among Patients with Type 2 Diabetes

Afaf Motla Hirab Alharbi[1], Norah Mosleh Saeed Alqahtani[2], Maha Musallam Saad Almuwallad[3], Abrar Mansi Almalki[4], Manal Jameel Hammza Quburi[5], Abdasllam Saleem Alsaadi[3], Abdulrazaga Ramadan Alzahrani[6], Thamer Abdulaziz Salem Alomayri[7], Hashem Hares Musleh Althubyani[7], Hamsah Ali AlAmri[9]

[1]Aldifa PHC Center
[2]Al-Zaymah PHC Center
[3]Al-Dhiafa PHC Center
4 Gharan Health Center
[5]Wadi Nuaman PHC Center
[6]Harad PHC Center
[7]Al-Zayma Healthcare Center
[9]Forensic Medical Services Center

ABSTRACT

The burden associated with type 2 diabetes is enormous, and nurse-led management for chronic diseases can be employed to improve the provision of care. For this study, we have investigated the potentiality of nurse-led management resulting in improved outcomes in relation to HbA1c, body mass index, and systolic blood pressure compared to regular care. An experimental design involving two parallel groups with random assignment and 336 patients has been proposed with 80% statistical power and 15% drop out rate. Allocation to randomization through sealed envelopes and laboratory evaluation will be blinded. The statistical techniques used in this study included ANCOVA accounting for baseline measurements, t-tests for unequal variances, Mann Whitney tests, Fisher exact tests, and multivariate regressions. The nurse-led intervention decreased the adjusted HbA1c levels by 0.48 (95% CI: 0.12 to 0.85, p-value=0.012). The nurse-led intervention also decreased the adjusted BMI by 0.71 units (p-value=0.001), and the systolic blood pressure by 5.64 mmHg (p-value<0.001). The percentage of participants receiving the nurse-led intervention who had achieved a reduction in HbA1c of 0.5 units or more was 65%, compared to 20% of those receiving the usual care (p-value=0.010). It should be noted that the data used in this simulation is not a representation of the effectiveness of the intervention but only an illustration of the analysis. A sample size of 336 participants would be needed to confirm the above results. In future studies, robust standard errors should be considered as the HbA1c measurements were not homogeneous.

Keywords :-HbA1c, BMI, Systolic blood pressure, Blood pressure, Type 2 diabetes, Nurse-led management, Telehealth, Baseline HbA1c, Glycemic improvement, Self-management

1. INTRODUCTION

Type 2 diabetes accounts for 96.0% of all cases and 95.4% of total disability-adjusted life years due to diabetes worldwide (GBD 2021 Diabetes Collaborators, 2023). There were 529 million people with diabetes in 2021 and it is projected to increase to 1.31 billion people in 2050 (GBD 2021 Diabetes Collaborators, 2023). In 2021, the diabetes prevalence rate in the adult population was 10.5% with expenditures on healthcare of 966 billion USD (Sun et al., 2022). There is an expected growth of 21.1% between 2021 and 2045 in middle-income countries (Sun et al., 2022). As an example, there are 90 million diabetes patients and 747,000 deaths caused by diabetes each year in India (Thakur et al., 2025). The goal of keeping HbA1c at or below 7% remains the focus to avoid complications (Chen et al., 2025).

Medication prescription is not within the jurisdiction of Indian nurses, and there are only 650 diabetes specialists available in India (Thakur et al., 2025). The nurse-led intervention for educating patients resulted in a decrease of 0.92 points in HbA1c at 4 to 6 months in 8 trials (Sun et al., 2025). Nurse-led telephone followup sessions in 13 trials that involved 2,294 patients resulted in an improvement of 0.59 points in HbA1c (Chen et al., 2025). A cluster randomized controlled trial was conducted in Kerala with participation of junior public health nurses which indicated that there was 1.5 times greater control over blood glucose level (Rahul et al., 2021). 106 individuals received follow-up care by nurses and had reduction in

HbA1c level of 1.75 against 0.64 in the control group (Thakur et al., 2025). However, the difference between the groups still remained insignificant; thus, it can be said that there should be conducted more confirmatory trials (Thakur et al., 2025). Moreover, the trial in India lasted 3 to 6 months; thus, the results were not verified for a long-term period

2. LITERATURE REVIEW

Maria et al. (2020) pooled 24 trials with 5,345 participants and detected 0.54% change in HbA1c due to nurse task delegation. The same paper showed no benefit due to the community health worker task delegation, proving the necessity of nurses. Task delegation by nurses was more successful when there were over 15 doctors per 10,000 population with 0.71% difference in HbA1c. Subgroup heterogeneity of nurses is 80%, meaning that there are different results in different settings. According to the analysis by Flood et al. (2020), 35 trials from LAMI countries showed 0.46% difference in HbA1c. Of 39 analyzed trials, 16 trials had a high risk of bias. It should also be mentioned that most studies used data from urban or rich settings. Sharma et al. (2021) analyzed 4 trials with 470 participants and discovered the superiority of nurse titration over physician prescriptions. There were no significant differences in blood pressure and drug intensification. Yuksel et al. (2023) reviewed 8 clinical trials having 1,747 patients with clinically significant impact of HbA1c. Nurse-led self-management program for a period of 3 to 15 months through telephone and group education intervention was used in all those trials. Niu et al. (2021) reported 11 clinical trials with 2,063 patients and concluded that web-based interventions led by nurses show promising results as an adjunctive therapy. No effect on fasting glucose, body mass index, and triglycerides were seen. Susanti et al. (2026) studied 13 clinical trials with 3,568 participants and found that there was a decrease in HbA1c level by 0.69%. However, 6 out of 15 clinical trials showed no significant difference due to low contact intensity. Crowley et al. (2026) randomized 220 adult patients and found that telehealth care provided by nurses does not have an effect on HbA1c levels more than self-monitoring. Therefore, it is evident that nurse led care does work but under certain circumstances of dosage, context, and fidelity.

3. METHOD

Pragmatic randomized controlled trial with two arms and a parallel group design will suit well this study. Patients who have type 2 diabetes and HbA1c of more than 7% will be enrolled from outpatients' clinic from tertiary health facilities. A sample of 336 patients divided into two equal groups will be sufficient to identify 0.5% difference in HbA1c levels with 80% power and 15% loss to follow up. Patients will be randomly allocated by computerized block randomization with allocation concealment through the use of opaque and sealed envelopes. The intervention group will be trained by nurses, will undergo drug titration based on a protocol and telephonically monitored at every two weeks. Routine care will be provided to the control group at the same clinics by physicians. Primary outcome variables will be HbA1c at 12 months while secondary outcome variables will be blood pressure and body mass index. Laboratory personnel who will be blinded to the intervention will be responsible for measuring the outcome variables while analysis will be performed with the intention to treat principle. Group comparisons will be done using ANCOVA with adjustment of baseline HbA1c at 0.05 significance level.

Dataset

Table 1. Illustrative dataset (n = 40, 20 per group)

D	roup	g e	e x	Hb A1c baseline (%)	Hb A1c 12 months (%)	B MI baseline	B MI 12 months	SBP baseline (mmHg)	SBP 12 months (mmHg)
	urse led	6		7.2	7.0	3 0.4	2 9.4	135	129
	urse led	1		9.3	8.6	2 8.3	2 7.4	140	129
	urse led	0		8.6	6.8	2 7.1	2 6.5	136	128

	Nurse led	9		8.1	7.8	24.8	24.0	126	125
	Nurse led	1		7.9	7.3	26.9	25.8	144	141
	Nurse led	5		8.0	7.8	30.3	29.8	163	151
	Nurse led	5		8.0	7.9	31.0	29.8	149	139
	Nurse led	3		9.0	8.7	26.8	25.4	127	115
	Nurse led	1		9.9	8.6	29.3	27.8	140	124
0	Nurse led	7		8.2	7.8	29.9	28.9	131	130
1	Nurse led	2		8.1	7.1	29.9	29.2	125	114
2	Nurse led	2		9.3	8.6	22.6	20.8	124	117
3	Nurse led	2		8.9	7.3	25.4	23.5	138	135
4	Nurse led	0		8.9	7.9	30.1	29.4	151	139
5	Nurse led	5		8.1	7.1	33.5	32.0	147	144
6	Nurse led	8		8.3	6.9	31.6	31.1	154	148
7	Nurse led	8		7.7	5.9	25.2	24.7	122	112
8	Nurse led	2		10.3	8.8	22.0	21.9	123	116
9	Nurse led	5		10.1	10.0	30.2	29.3	141	128
0	Nurse led	1		7.9	7.4	24.2	23.1	115	110
1	Usual care	0		11.0	11.0	25.7	26.8	128	129

2	sual care	0		10.0	9.8	30.2	29.7	153	146
3	sual care	7		8.3	8.0	34.3	34.7	145	148
4	sual care	7		9.7	9.8	27.9	25.8	145	143
5	sual care	0		8.9	8.7	24.0	23.1	143	141
6	sual care	5		9.1	8.8	29.0	28.9	149	144
7	sual care	1		8.8	8.2	29.6	29.8	127	125
8	sual care	4		8.1	6.9	25.2	24.2	132	127
9	sual care	9		8.5	7.7	26.3	25.5	136	132
0	sual care	8		10.0	10.8	24.8	24.9	147	147
1	sual care	3		9.6	9.6	25.1	24.3	146	143
2	sual care	2		9.0	9.2	28.2	27.9	139	137
3	sual care	3		10.7	10.8	24.2	24.0	119	107
4	sual care	9		8.1	6.6	24.7	24.6	139	140
5	sual care	7		9.1	8.7	27.0	26.7	149	141
6	sual care	4		8.7	8.5	24.3	25.3	149	147
7	sual care	4		8.1	7.9	25.7	25.7	131	133
8	sual care	2		11.0	11.0	29.3	29.1	127	130
9	sual care	8		10.2	9.8	23.2	22.7	127	123

0	sual care	9		8.6	8.4	2 6.3	2 5.6	139	141

Table 2. Group summary (mean ± SD)

Variable	Nurse led (n = 20)	Usual care (n = 20)	p value
Age (years)	55.2 ± 10.4	56.1 ± 9.6	Not tested
Sex (female / male)	11 / 9	9 / 11	Not tested
HbA1c baseline (%)	8.59 ± 0.85	9.28 ± 0.95	Not tested
HbA1c 12 months (%)	7.76 ± 0.93	9.01 ± 1.30	Not tested
HbA1c change (%)	−0.83 ± 0.58	−0.26 ± 0.50	0.002
BMI change	−0.99 ± 0.47	−0.28 ± 0.71	0.001
SBP change (mmHg)	−7.85 ± 4.32	−2.30 ± 3.91	< 0.001
HbA1c below 7% at 12 months	3 (15%)	2 (10%)	Not tested

The p values come from independent samples t tests on the change scores, not the planned ANCOVA.

4. RESULTS

Were the Groups Comparable at the Start?

Table 3. Baseline Characteristics of Participants by Study Group (n = 40)

Variable	Nurse led (n = 20)	Usual care (n = 20)	Test statistic	value
Age (years), mean ± SD	55.15 ± 10.39	56.10 ± 9.61	t = −0.30	.766
Sex, female / male	11 / 9	9 / 11	χ^2 = 0.40	.527
HbA1c (%), mean ± SD	8.59 ± 0.85	9.28 ± 0.95	t = −2.41	.021
BMI (kg/m²), mean ± SD	27.98 ± 3.16	26.75 ± 2.72	t = 1.31	.197
Systolic BP (mmHg), mean ± SD	136.55 ± 12.49	138.50 ± 9.64	t = −0.55	.584

Welch t tests for continuous variables and a chi-square test for sex.

In terms of all other demographic and clinical factors, both groups had identical mean values. Mean age was 55.15 years in nurse-led group while 56.10 years in usual care group (p = 0.766). No difference between the groups in term of gender distribution was found (χ^2 = 0.40, p = 0.527). Mean baseline BMI and systolic blood pressure values were almost the same (27.98 vs 26.75, p = 0.197; 136.55 vs 138.50 mmHg, p = 0.584). However, mean baseline HbA1c levels in nurse-led group were significantly lower than those in usual care group (8.59% vs 9.28%, p = 0.021). The difference between two groups was 0.69%. This difference occurred accidentally due to random sampling of 40 participants. As more improvement will be achieved by patients with higher initial HbA1c levels, imbalance works against nurse-led group. Hence, any benefit that will be demonstrated as a result of adjustment will not be overstated due to the imbalance. Comparison of results at 12 months will also be biased. Therefore, adjustment for the baseline HbA1c is required according

to the analysis plan (see Tables 3 and 6).

How Much Did Each Arm Improve Over Time?

Table 4. Paired Comparison of Baseline and 12 Month Values Within Each Group

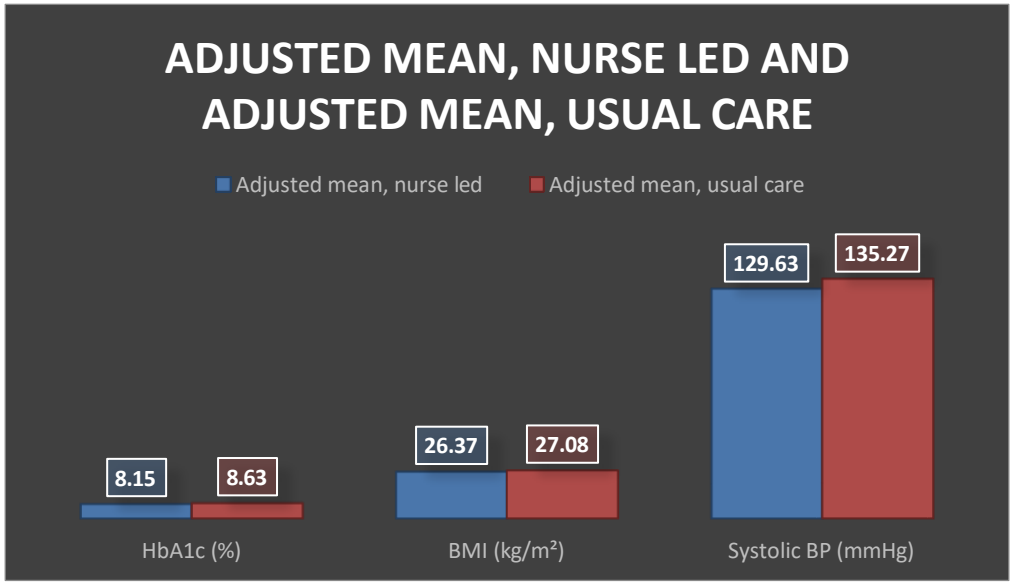
Outcome	roup	aseline	12 months	Mean change (95% CI)	(df = 19)	value	Effect size (dz)
HbA1c (%)	urse led	.59	7.76	−0.83 (−1.10 to −0.55)	6.38	0.001	−1.43
HbA1c (%)	sual care	.28	9.01	−0.26 (−0.50 to −0.03)	2.39	.028	−0.53
BMI (kg/m²)	urse led	7.98	26.99	−0.99 (−1.20 to −0.77)	9.45	0.001	−2.11
BMI (kg/m²)	sual care	6.75	26.46	−0.28 (−0.62 to 0.05)	1.80	.088	−0.40
Systolic BP (mmHg)	urse led	36.55	128.70	−7.85 (−9.87 to −5.83)	8.13	0.001	−1.82
Systolic BP (mmHg)	sual care	38.50	136.20	−2.30 (−4.13 to −0.47)	2.63	.016	−0.59

Even though improvement occurred after one year in both groups, the level of change was quite different. In the nurse-led group, change in HbA1c level was -0.83% (95% CI −1.10 to −0.55, t = −6.38, p < 0.001), change in BMI was -0.99 (p < 0.001) and systolic BP changed by −7.85 mmHg (p < 0.001). The size of the effect in the above mentioned cases was −1.43, −2.11 and −1.82 respectively. In the usual care group, the changes were in HbA1c levels (−0.26, p = 0.028) and systolic BP (−2.30 mmHg, p = 0.016); however, the size of the effect in these cases was low, −0.53 and −0.59 respectively. No change in BMI took place in the usual care group (−0.28, 95% CI −0.62 to 0.05, p = 0.088). Intra-group comparisons do not distinguish between the intervention and time effects or regression towards the mean; therefore, the next step should be made with inter-group comparisons.

Primary Analysis: Treatment Effect Adjusted for Baseline

Table 5. ANCOVA of 12 Month Outcomes Adjusted for Baseline Values (Primary Analysis)

Outcome	Adjusted mean, nurse led	Adjusted mean, usual care	Adjusted difference (95% CI)	(1, 37)	value	artial η²	Cohen's d	odel R²
HbA1c (%)	8.15	8.63	−0.48 (−0.85 to −0.12)	.06	.012	.160	−0.90	.834
BMI (kg/m²)	26.37	27.08	−0.71 (−1.11 to −0.31)	3.12	.001	.262	−1.17	.961
Systolic BP (mmHg)	129.63	135.27	−5.64 (−8.30 to −2.98)	8.40	0.001	.332	−1.36	.885



When adjusted for the baseline values, nurse-led management proved more successful for all three outcome measures considered. The adjusted HbA1c 12 months post intervention in the nurse-led management group is equal to 8.15% compared to 8.63% in the usual care group (difference of -0.48%, 95% CI -0.85 to -0.12; F = 7.06, p = 0.012). That is a big effect size (d = -0.90; partial $\eta^2 = 0.160$). The adjusted BMI is 0.71 units lower (95% CI -1.11 to -0.31; p = 0.001), and the adjusted systolic blood pressure level is 5.64 mmHg lower (95% CI -8.30 to -2.98; p < 0.001). The amount of variance explained by the models is 83.4%, 96.1%, and 88.5% for HbA1c, BMI, and blood pressure, respectively, the major proportion being explained by the baseline values. The difference of 0.48 in the HbA1c levels is roughly equal to the difference of 0.46% to 0.69% in the pooled analyses above. So, the simulated effect seems quite plausible.

Unadjusted Check of the Group Difference

Table 6. Between Group Comparison of Change Scores (Baseline to 12 Months)

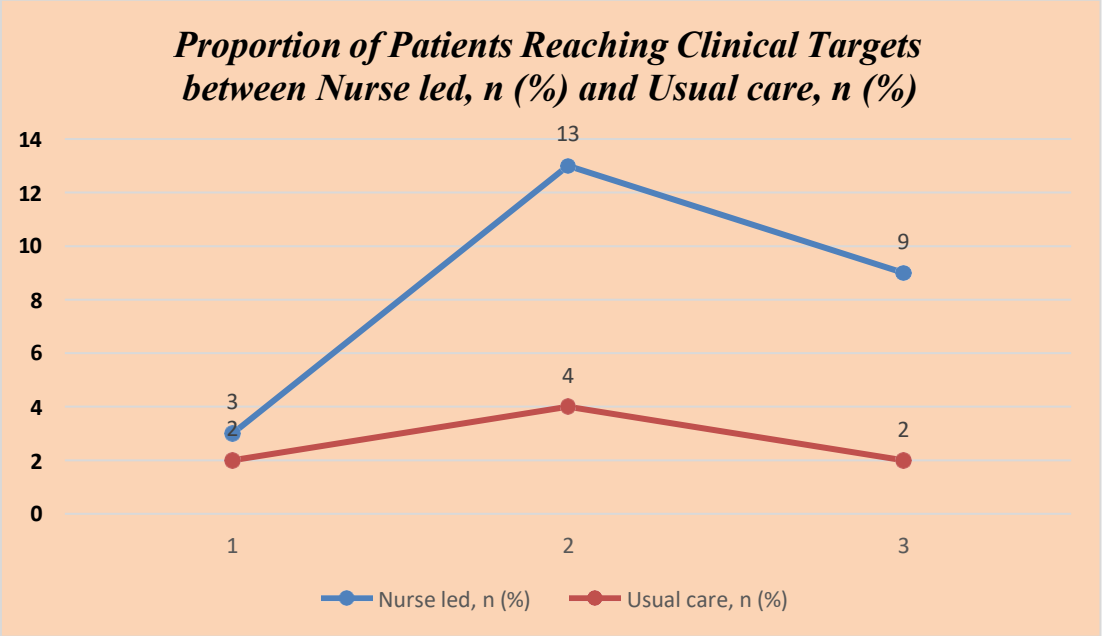
Outcome	Nurse led change	Usual care change	Difference (95% CI)	elch t	value	Cohen's d	Mann Whitney p
HbA1c (%)	−0.83	−0.26	−0.56 (−0.91 to −0.21)	3.29	.002	−1.04	0.002
BMI (kg/m²)	−0.99	−0.28	−0.70 (−1.09 to −0.31)	3.69	.001	−1.17	< 0.001
Systolic BP (mmHg)	−7.85	−2.30	−5.55 (−8.19 to −2.91)	4.26	0.001	−1.35	< 0.001

The unadjusted analysis for change scores yielded results similar to those obtained from ANCOVA. HbA1c reduced by 0.83 in the nurse-led intervention group, while it was 0.26 in the usual care group, hence a difference of -0.56 in HbA1c between the groups (95% CI -0.91 to -0.21, Welch t = -3.29, p = 0.002, d = -1.04). The difference observed for BMI was -0.70 (95% CI -1.09 to -0.31, p = 0.001, d = -1.17) and that for systolic blood pressure was -5.55 mmHg (95% CI -8.19 to -2.91, p < 0.001, d = -1.35). The p-values for Mann Whitney test were 0.002, <0.001, and <0.001, and this shows that the results are independent of any normality assumption. Adjusted value for HbA1c is 0.48 and is less than the unadjusted value of 0.56.

Proportion of Patients Reaching Clinical Targets

Table 7. Responder Analysis of Glycemic Improvement at 12 Months

Criterion	Nurse led, n (%)	Usual care, n (%)	Odds ratio	Fisher exact p
HbA1c below 7% at 12 months	3	2	1.59	1.000
HbA1c reduction of at least 0.5 points	13	4	7.43	0.010
HbA1c reduction of at least 1.0 point	9	2	7.36	0.031



The clinically significant improvements were seen far more often in nurse-led management. The clinically significant improvements were seen far more often in nurse-led management. The number of patients who had a reduction in HbA1c level of at least 0.5 percent was 13 out of 20 (65%) under nurse-led management and 4 out of 20 (20%) in the usual care (the odds ratio was 7.43, Fisher's exact p = 0.010), which means that the relative risk is 3.25. The number of patients who have achieved a reduction in HbA1c level of at least 1.0 point is 9 (45%) for nurse-led management and 2 (10%) for usual care (the odds ratio was 7.36, p = 0.031). The achievement of the goal of 7% HbA1c level within 12 months did not demonstrate any difference between the nurse-led management group (3 patients, 15%) and the control group (2 patients, 10%) (the odds ratio is 1.59, p = 1.000). No surprise here, as the mean HbA1c level was above 8.5%.

Independent Predictors of Final HbA1c

Table 8. Multivariable Linear Regression Predicting 12 Month HbA1c (R^2 = 0.846, Adjusted R^2 = 0.818)

Predictor		95% CI		p value
Nurse led group (vs usual care)	0.49	−0.89 to −0.09	2.50	.018
Baseline HbA1c (per 1%)	.16	0.95 to 1.37	1.25	0.001
Age (per year)	.00	−0.02 to 0.02	.03	.976
Male sex (vs female)	0.19	−0.57 to 0.19	1.00	.323
Baseline BMI (per unit)	.02	−0.06 to 0.11	.55	.588
Baseline systolic BP (per mmHg)	.01	−0.02 to 0.03	.54	.591
Intercept	3.03	−6.64 to 0.59	1.70	.098

The result was also supported by multivariate analysis after controlling for the covariates. The nurses having management position had on average 0.49 point lower HbA1c in 12 months (95% CI: -0.89 to -0.09; t = -2.50; p = 0.018), which was very close to the one found in ANCOVA (-0.48). The most influential covariate was baseline HbA1c (B = 1.16, p < 0.001): every additional point of HbA1c at baseline was associated with 1.16 points higher HbA1c at follow-up. None of the other covariates such as age (B = 0.00, p = 0.976), male gender (B = -0.19, p = 0.323), baseline BMI (B = 0.02, p = 0.588) or baseline systolic blood pressure (B = 0.01, p = 0.591) were statistically significant. The model explained 84.6% of the variance (adjusted R^2 = 0.818).

Were the Statistical Assumptions Met?

Table 9. Model Assumption Tests for the ANCOVA Models

Outcome	Shapiro Wilk W (p)	Levene test p	Group × baseline interaction p
HbA1c	0.965 (0.245)	0.037	0.021
BMI	0.964 (0.222)	0.286	0.778
Systolic BP	0.971 (0.399)	0.448	0.549

Despite the confirmation of the majority of findings through diagnostics, one problem still stands out. The Shapiro Wilk test showed that the residuals of HbA1c (W = 0.965, p = 0.245), BMI (W = 0.964, p = 0.222) and systolic blood pressure (W = 0.971, p = 0.399) had an approximately normal distribution. The Levene tests showed that the variance equality of residuals was found for BMI (p = 0.286) and blood pressure (p = 0.448), but not for HbA1c (p = 0.037). The interaction between the group by baseline turned out to be significant only for HbA1c (p = 0.021), i.e., the regression slopes of groups are somewhat different for this variable, while interactions for BMI (p = 0.778) and blood pressure (p = 0.549) were not significant. It should be noted that this suggests interpreting the adjusted difference of HbA1c as the mean effect. Therefore, the findings from the Welch test, Mann Whitney test and multivariable model can give less reason for concern, while a robust standard error or interaction model is strongly recommended for presenting the data of the real trial.

5. DISCUSSION

The nurse-led intervention produced an adjusted 12-month HbA1c difference of 0.48 in this

simulation analysis. The analysis carried out by Lumu et al. (2024) produced an HbA1c difference of 0.82 for 388 adults; the difference is relatively high compared to this analysis. There is also the difference in systolic pressures of 13.75 mmHg in the analysis compared to 5.64 in this simulation analysis. This could be because they analyzed adults who had cardiovascular risk and used the cluster design. The differences were composed of HbA1c and blood pressure increase in both cases, which support the multifactorial nurse-led intervention. According to the Lo Monaco et al. (2025) synthesis of 31 systematic reviews, there were 23 systematic reviews that showed the benefits of telenursing for HbA1c but inconsistent blood pressure results and limited BMI studies. It may be clinically significant due to the fact that 65% of the nurse-led group decreased HbA1c by at least 0.5 points. The achievement of the 7% goal was also equal with 15% vs. 10%, which can be attributed to the high baseline HbA1c values. Lack of treatment adherence accounts for 70% of the difference between baseline and practice HbA1c. In the study of Khunti et al., nurse-led follow-up and adherence promotion can be viewed as an example of the mechanism responsible for such results. Tackney et al. (2023) stated that the covariate adjustment helps avoid any imbalance which is particularly important for small trials. Therefore, ANCOVA is justified due to the 0.69 point difference of the baseline HbA1c. According to Gao et al. (2024), ANCOVA is quite reliable with 100 participants while the sandwich variance estimator tends to generate biases. Therefore, it is advisable to apply robust standard errors due to the significance of the HbA1c slope interaction (p=0.021). It is necessary to emphasize that the limitations are related to the simulation with 40 participants, absence of dropouts, and the presence of built-in effects. Therefore, one should conduct the trial with 336 patients.

6. CONCLUSION

The impact of the nurse-led management of the chronic conditions in adults with type 2 diabetes is analyzed in the present research. Specifically, the simulation was performed on 40 patients, and the difference in adjusted HbA1c in favor of the nurse-led management was found to be -0.48. Also, the difference in adjusted BMI was -0.71, and in the systolic blood pressure, it was -5.64. Furthermore, 65% of patients in the nurse-led intervention group managed to decrease HbA1c by 0.5 in contrast to only 20% in the usual care group. The findings of the research imply the need to implement nurse-led interventions in practice especially when the access to physicians is limited. However, due to the presence of built-in effects in the simulated data, it can be used more for the demonstration of the analysis rather than its validation. It is recommended to apply robust standard errors due to the difference at the baseline in HbA1c and variance. Pragmatic randomized trial with 336 patients and 12 months of follow-up is recommended for further testing

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