# American Journal of Preventive Medicine

## **RESEARCH ARTICLE**

# Motivational Interviewing in the Management of Type 2 Diabetes Mellitus and Arterial Hypertension in Primary Health Care: An RCT



Pâmela L.S. Steffen, MSc,<sup>1</sup> Claunara S. Mendonça, PhD,<sup>1</sup> Elisabeth Meyer, PhD,<sup>2</sup> Daniel D. Faustino-Silva, PhD<sup>1</sup>

**Introduction:** Motivational interviewing is an effective style of collaborative communication for the promotion of lifestyle changes in the management of Type 2 diabetes and arterial hypertension. This study evaluates the effectiveness of motivational interviewing in the management of these conditions in primary health care.

**Study Design:** This study is a double-blind parallel-group RCT performed between June 2018 and July 2019.

**Setting/participants:** The RCT was conducted in Porto Alegre, Rio Grande do Sul, Brazil, and included individuals with Type 2 diabetes and arterial hypertension.

**Intervention:** The participants were randomized to the test/motivational interviewing and usual care groups. The test/motivational interviewing group received the nursing consultation intervention on the basis of motivational interviewing conducted by professionals with 20 hours of training, and the usual-care group received conventional nursing consultation.

**Main outcome measures:** The main outcome measure was the mean difference in HbA1c. The secondary outcome measures were the mean differences in blood pressure and adherence levels.

**Results:** After a mean follow-up of 6 months, 174 participants completed the study (usual-care group=80; test/motivational interviewing group=94). There were statistically significant differences between the groups, with improvement in the test/motivational interviewing group for systolic blood pressure (p<0.01), diastolic blood pressure (p<0.01), and total adherence score as measured by the Martín–Bayarre–Grade questionnaire (p=0.01) and its operational dimensions of treatment adherence and personal involvement (p=0.03, p=0.03). The test/motivational interviewing group showed significantly reduced HbA1c levels (0.4%) at the end of the study (p<0.01).

**Conclusions:** In the context of primary health care, the nursing consultation based on motivational interviewing was shown to be a more effective care strategy than usual care for improving blood pressure levels and adherence levels in individuals with Type 2 diabetes and arterial hypertension. Moreover, motivational interviewing was demonstrated to be useful in reducing HbA1c levels in diabetes management.

**Trial registration:** This study is registered at www.clinicaltrials.gov NCT03729323. *Am J Prev Med 2021;60(5):e203–e212.* © *2021 American Journal of Preventive Medicine. Published by Elsevier Inc. All rights reserved.* 

Conceição, 1º andar. Av. Francisco Trein, 596, CEP, Porto Alegre 91350-200, Brazil. E-mail: ddemetrio@gmail.com.

0749-3797/\$36.00 https://doi.org/10.1016/j.amepre.2020.12.015

From the <sup>1</sup>Graduate Program in Assessment and Production of Technologies for the SUS (PPGATSUS), Grupo Hospitalar Conceição (GHC), Porto Alegre, Brazil; and <sup>2</sup>Graduate Program in Health Sciences, Instituto de Cardiologia (IC/FUC), Porto Alegre, Brazil

Address correspondence to: Daniel D. Faustino-Silva, PhD, Gerência de Ensino e Pesquisa, Centro Administrativo, Hospital Nossa Senhora da

## INTRODUCTION

T ype 2 diabetes mellitus (T2DM) is a serious public health problem worldwide. When associated with a diagnosis of arterial hypertension (AH), T2DM has even higher morbidity and mortality, requiring increased efforts in its management. One of the main challenges in preventing, treating, and controlling T2DM and AH is strategizing with the person at the center of care, engaging patients and supporting patients' shared decision making—interventions in which primary care nurses play an important role.<sup>1–8</sup> In particular, the difficulties faced by individuals in adapting their habits to a healthy lifestyle and reconciling their daily activities with the medical treatment and different care technologies has been a gap that requires effective intervention from professionals.

Motivational interviewing (MI) is a collaborative style of communication. Clinical evidence has shown that MI strengthens the person's motivation and commitment to change behaviors in the interest of their health, on the basis of respect for their autonomy. The guiding principles of MI are based on resisting the righting reflex, understanding and exploring the patient's motivations, listening with empathy, and empowering the patient, thus stimulating hope and optimism.<sup>9</sup> In primary care environments, MI is an inexpensive and high-potential impact strategy that can be learned by different categories of health professionals and applied regardless of age, sex, or severity of the patient's health problem.<sup>9–12</sup>

However, despite the promising panorama reflected by the growing number of international studies, research into and dissemination of MI in professional training and practice for the management of T2DM and AH in routine primary health care is still in its early stages.<sup>13,14</sup> The prevailing reality is still that of epidemiologically alarming numbers of chronic conditions with standards of care that are generally inefficient, unsystematic, prescriptive, rushed, and with lack of dignity for the patient.<sup>1,5,6,15,16</sup> The aim of this study is to evaluate the effectiveness of MI in individual nursing consultations for the management of T2DM with AH in the context of primary health care.

## METHODS

This was a parallel-group RCT conducted in 3 health units in the *Zona Norte* (North Zone) of Porto Alegre, Rio Grande do Sul, Brazil, between June 2018 and July 2019. The methods followed the recommendations of the CONSORT 2010 information list, and the project was previously registered at clinicaltrials.gov under NCT03729323. Study participants, the person responsible for randomization and allocation, the people responsible for

measurement of outcome variables, and those responsible for data analysis were blinded. It was impossible to blind interventionists because of the requirement for training and the procedures necessary to conduct the study.

#### Study Population

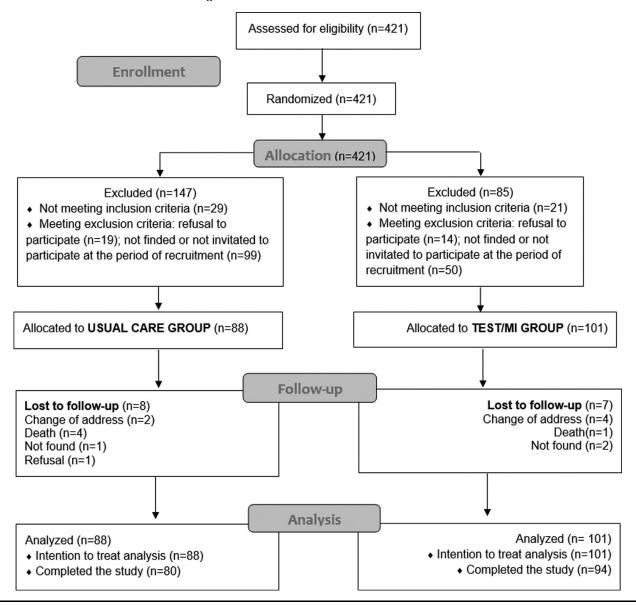
Study participants were individuals with T2DM and an associated diagnosis of AH, were registered in the health units established as the research settings, and were with Risk Strata 3 and 4. Risk strata were based on the stratification model used at those services, which considers the severity of the chronic condition and the patient's self-management capabilities, on the basis of the Chronic Care Model.<sup>17</sup> Risk Stratum 3 is an intermediate stratum in which the disease represents moderate or high cardiovascular risk level according to the Framingham Risk Score, but cardiovascular disease has not been established. Risk Stratum 4 covers the population with a chronic condition of high cardiovascular risk, with or without established complications but with severe difficulties in self-management.

The health units were selected on the basis of the similarity of epidemiologic profile and health indicators in T2DM and AH, being the 3 largest in the *Serviço de Saúde Comunitária do Grupo Hospitalar Conceição* (SSC/GHC) (Community Health Service of the Conceição Hospital Group). The inclusion criteria were being aged  $\geq 18$  years, having a medical diagnosis of T2DM associated with AH, and being registered in the programmatic actions of the study units in Risk Strata 3 and 4. The exclusion criteria were refusal to sign the informed consent form, patient not found after 3 attempts to contact by phone or in person at home, and illiteracy or a medical diagnosis of mental and behavioral disorders with impaired mental faculties.<sup>18</sup>

Because of the absence of a pilot study, a study with a similar research protocol was used to anticipate the expected effect size. On the basis of that study, investigators added 10% for possible losses and refusals, and the sample size was estimated at 248 patients by Winpepi, version 11.61. The authors considered a power of 80%, a significance level of 5%, and an SD of 2% for a mean difference of 0.75% in HbA1c.<sup>19</sup>

#### Measures

Simple individual randomization was performed electronically by the SSC/GHC Monitoring and Evaluation center by a professional who was not part of the study team. The professional randomized and allocated all possible eligible patients into 2 groups-test/MI group and usual-care group-before the research team initiated recruitment. Participants allocated in each group were recruited in ascending order, and if they met the inclusion and acceptance criteria, they were electronically scheduled for the corresponding intervention. Blinded allocation was guaranteed by the protection of randomized lists in an electronic file and respective electronic scheduling system with access restricted to those responsible for recruiting the participants in each research setting. Recruiters were trained community health agents who used a single, standardized invitation model that followed the process of scheduling appointments, without any differentiation between the groups. On acceptance to participate, individuals received at home a brown envelope with the informed consent form and instructions for the start of interventions from the community health agent. At the end of the study, the electronic lists were verified for the



**Figure 1.** Study flow chart. MI, motivational interviewing.

purposes of the fidelity test by a professional who was not part of the study team.

Because of the period stipulated for recruitment, some of the eligible patients were not contacted according to their order in the list. Except for patients who were not contacted or who did not meet inclusion criteria/met the exclusion criteria at the time of the recruitment, all patients who consented to participate were analyzed, regardless of whether they received both intervention sessions or had final outcomes collected (Figure 1).

The test/MI group received 2 MI-based nursing consultation sessions lasting 30–50 minutes and conducted monthly by nurses who received 20 hours of training in the use of MI.<sup>10,19</sup> The usual-care group received 2 nursing consultations lasting 30–50 minutes and conducted monthly by professional nurses not trained in the use of MI.<sup>20</sup> The 3 research settings followed the

May 2021

evidence-based multiprofessional protocol of the SSC/GHC and its regular updates for the organization of the work process and care of people with diabetes and hypertension.

The period between study consultations depended on the patient's health needs and availability. The overall mean time between the first and second nursing consultations was 45 days, with a median of 38 days in the usual-care group and 37 days in the test/MI group. At least 1 telephone call was made to all individuals between the second nursing consultation and the end-of-study call to reinforce what had been agreed on and minimize losses to follow-up.<sup>12</sup>

A total of 8 nurses specializing in public health with  $\geq$ 5 years of professional experience in primary care were responsible for applying the nursing consultations. Nurses responsible for delivering the nursing consultation to the test/MI group received

intensive training in active learning of basic principles, spirit, and techniques of MI, focusing on the development of empathic communication skills, simple and advanced reflective listening to work on resistance, dealing with ambivalence, exploring discrepancies, and promoting conversation about change.<sup>21</sup> The workshop was conducted by a psychologist member of the study team who has a PhD in psychiatry and extensive experience in conducting MI training workshops for different health segments. The training included didactic presentations and experiential exercises, as recommended by Moyers et al.,<sup>22</sup> with a total work load of 20 hours. Experiential exercises, such as roleplaying, occupied 70% of the total training time, being performed in pairs and, eventually, with a third participant as an observer. The instructor provided feedback on the exercises throughout the training.

Before and after the training, nurses filled out 3 validated questionnaires to assess the importance and confidence in the use of MI and their mastery of the initial basic skills to apply MI in practice: the Importance and Confidence Ruler<sup>21</sup> to use MI; the Conversational Interview Exercise,<sup>21</sup> which identifies the key elements of MI, such as the use of reflections and open-ended questions; and the Helpful Responses Questionnaire,<sup>23</sup> plus MI skills indicators, according to the Motivational Interviewing Skill Code,<sup>24,25</sup> used to assess training effectiveness.

The outcomes were measured at baseline and at 3 months after the second nursing consultation as final outcomes. The measurements were conducted in a blinded form, except for the participant profile questionnaire, which was completed by a nurse during the interventions because it contained important clinical data that required confirmation and updating of these records in the patient's medical records.

The main outcome measure was the mean difference in HbA1c. HbA1c was measured through laboratory tests of blood samples collected in the outpatient department, following the routine practices of these services and without any differentiation between the groups. The secondary outcome measures were the mean differences in blood pressure (BP) measured in the Health Unit by nursing technicians who were not included in the study team; following the routine and technical guidelines inherent to the procedure, without differentiation between the groups<sup>7,26</sup>; and the level of adherence and its dimensions, which was collected using a specific, self-report questionnaire delivered to the participant's home by community health workers. Because of the correlation among adherence, motivation, and depression in chronic diseases, symptoms of depression were measured at baseline as a risk factor for poorer clinical outcomes and therefore were a possible confounder.7

A semistructured interview for sociodemographic profile and health history instrument was developed by the researchers and contains the variables presented in Table 1.

The Beck Depression Inventory is a self-report and depression screening instrument composed of 21 items, including symptoms and attitudes, in which 20 points is the cut off differentiating a higher level of depressive symptoms.<sup>28,29</sup>

The Martín–Bayarre–Grade Questionnaire is a Cuban questionnaire, but the version used in this study was adapted to the Brazilian context.<sup>30</sup> It is a self-reported questionnaire that determines patients' level of adherence on the basis of the WHO concept of adherence, which includes the adoption of healthy behaviors, personal involvement in the process, and the professional–patient relationship, in addition to taking medication as prescribed.<sup>6,31,32</sup> The questionnaire comprises 12 statements that are answered on a Likert scale with scores of 4–0 points for the responses: *always, almost always, sometimes, almost never*, and *never*.<sup>30</sup> On the basis of the scores given, people are classified as having full adherence, partial adherence, or nonadherence. Moreover, the questionnaire allows for analyzing adherence through its operational dimensions: treatment adherence (i.e., execution and follow-up of prescribed medical indications), personal involvement (i.e., patient search for strategies and efforts necessary to adhere to the prescribed treatment), and patient–therapist relationship (i.e., a collaborative relationship established between the patient and the professional).<sup>30,31</sup>

The study began after submission to and approval by the Research Ethics Committee of the *Grupo Hospitalar Conceição*, under Number 18051 of April 11, 2018. The study complied with Resolution 466/12 of the National Health Council of the Ministry of Health, which deals with research involving human beings, and with the Code of Ethics of Nursing Professionals.<sup>33</sup> After accepting the invitation, all individuals received and signed an informed consent form as a requirement before receiving the interventions.

#### Statistical Analysis

Researchers used SPSS, version 20.0, for statistical analysis. To assess the normality of continuous variables, the Shapiro-Wilk test was performed. To compare the participants' baseline characteristics, Pearson chi-square test was used and, where necessary, Fisher's exact test and the Student's t-test were applied. For the intragroup analysis, the generalized estimating equation model was used, followed by multiple comparisons with Bonferroni correction. For statistical adjustment, because of the significant differences between groups in relation to the baseline variables systolic BP (SBP) and consultation with a nurse in the previous year and because of the influence of the possible confounder of change in pharmacological medical prescription, which could affect the investigated clinical outcomes, ANCOVA was performed for each outcome, considering delta as a dependent variable and the aforementioned variables and baseline values as independent variables. Intention-to-treat analysis was performed, and for dropouts (n=15), simple data imputation by last observation carried forward was used. To assess the effect of MI, Cohen's d was applied. The significance level considered for all the analyses was 0.05 (*p*<0.05) with 95% CIs.

## RESULTS

Of the 421 eligible randomized and allocated participants, 189 individuals with T2DM and AH were contacted during the recruitment period (June 2018–March 2019), met the inclusion criteria, and agreed to participate. Of these, 174 participants completed the study after a mean time of 6 months between the first consultation and the conclusion of the research protocol with the collection of the final outcomes. Exclusions were based on the inclusion/exclusion criteria. Losses to follow-up were balanced between the groups and were attributed to death, refusal, or delay in collecting the outcomes within the period stipulated for completion of the study and change of address/inability to locate the subject, making

Variables	Usual care, % (n) (n=88)	Test/MI, % (n) (n=101)	p-value
Sex			0.60
Male	35.2 (31)	41.6 (42)	
Female	64.8 (57)	58.4 (59)	
Age, mean $\pm$ SD	$66 \pm 12$	66 ± 8	0.90 <sup>t</sup>
Race/ethnicity			0.24ª
White	83 (73)	78.2 (79)	
Black	14.8 (13)	13.9 (14)	
Mixed	2.3 (2)	7.9 (8)	
Lives alone, yes	20.5 (18)	22.8 (23)	0.53
Education level	2010 (10)	22.0 (20)	0.25
Incomplete primary education	29.5 (26)	21.2 (21)	0.20
Complete primary education	70.5 (62)	78.8 (78)	
Marital status	70.3 (02)	10.0 (10)	0.03
	17 (15)	0.0 (10)	0.03
Single	17 (15)	9.9 (10)	
Married	50 (44)	54.5 (55)	
Separated/divorced	9.1 (8)	21.8 (22)	
Widow/widower	23.9 (21)	13.9 (14)	0.073
Per capita income <sup>d</sup>			0.27ª
<1 minimum wage	26.1 (23)	34.7 (34)	
≥1 minimum wage	73.9 (65)	65.3 (64)	
AH diagnosis time, years			0.88
1–5	9.1 (8)	9 (9)	
5–10	21.6 (19)	18 (18)	
>10	69.3 (61)	73 (73)	
T2DM diagnosis time, years			0.17 <sup>a</sup>
1–5	26.1 (23)	19.8 (20)	
5–10	27.3 (24)	19.8 (20)	
>10	46.6 (41)	60.4 (61)	
CVD family history, yes	85.9 (73)	90 (90)	0.53ª
Associated diseases			
CVD	26.1 (23)	27.7 (28)	0.94ª
Neoplasms	10.2 (9)	10.9 (11)	>0.99ª
Osteomuscular	8 (7)	24.8 (25)	<0.05ª
Respiratory tract	9.1 (8)	15.8 (16)	0.24 <sup>a</sup>
Diabetic retinopathy	2.3 (2)	5 (5)	0.45 <sup>c</sup>
Nephropathy	1.1 (1)	2 (2)	>0.99 <sup>c</sup>
Diabetic foot	3.4 (3)	5.9 (6)	0.51 <sup>c</sup>
Polypharmacy			0.31 <sup>ª</sup>
≥4 medications	75 (66)	82.2 (83)	
Depression symptoms by BDI score		- ()	>0.99ª
Positive score	15.9 (14)	16 (16)	
Smoking	2010 (21)	20 (20)	0.16 <sup>c</sup>
Smoker	8 (7)	9.9 (10)	0.110
Never smoked	58 (51)	59.4 (60)	
Former smoker	34 (30)	30.7 (31)	
Alcohol consumption	0+ (00)	00.1 (01)	0.07 <sup>ª</sup>
	2.2 (2)	0.0 (10)	0.07
Above maximum dose/week	2.3 (2)	9.9 (10)	0.40
Time of physical exercise <sup>e</sup>	70.4 (00)	074 (00)	0.16
<150 minutes/week	78.4 (69)	87.1 (88)	
≥150 minutes/week	21.6 (19)	12.9 (13)	
		(000	tinued on next page

Variables	Usual care, % ( <i>n</i> ) ( <i>n</i> =88)	Test/MI, % (n) (n=101)	<i>p</i> -value
Regular medical follow-up for T2DM/AH			0.31 <sup>a</sup>
Minimum of 1 consultation per year	71.3 (62)	65.3 (66)	
Consultation with a nurse in the previous year			0.02 <sup>a</sup>
Yes	14.8 (13)	4 (4)	
No	85.2 (75)	96 (97)	
Adherence—MBG Questionnaire			0.43 <sup>c</sup>
Total adherence	42 (37)	34.7 (35)	
Partial adherence	58 (51)	64.4 (65)	
No adherence	0.0 (0)	1(1)	

Table 1. Comparison of Baseline Sociodemographic and Health History Characteristics of Patients (continued)

<sup>a</sup>p-value obtained from chi-square test.

<sup>b</sup>Value obtained by *t*-test.

Value obtained by Fisher's exact test.

<sup>d</sup>Minimum wage: R\$998,00.

<sup>e</sup>Time in minutes per week.

AH, arterial hypertension; BDI, Beck Depression Inventory; CVD, cardiovascular disease; MBG, Martín–Bayarre–Grade Questionnaire; MI, motivational interviewing; T2DM, Type 2 diabetes mellitus.

it impossible to collect the final data (Figure 1). The measurement of the main outcome involved blood tests, and blood samples had to be collected in another outpatient clinic, so these were factors that led to dropouts.

Table 1 shows the characteristics of the test/MI and usual care groups. There were no significant differences between the groups for most of the baseline characteristics. An exception was the variable of consultation with the nurse in the previous year, which was statistically adjusted as described in the data analysis because it represented a higher amount of intervention received by the usual-care group from baseline. The mean age of the participants was 66 (SD=9.91) years; most had a diagnosis of T2DM and AH for >10 years and were on a polypharmacy regimen with regular medical follow-up in the previous year, had partial levels of adherence, and were nonsmokers and sedentary.

Table 2 shows the comparison between the groups for the outcomes investigated before and after the interventions. At the conclusion of the study, there were no statistically significant differences in HbA1c levels (p=0.07) between the groups. However, at the end of the study, there was a 0.4% (p<0.01) reduction in HbA1c levels for the test/MI group with a statistical significance and a small effect size (0.3). There was no significant difference in HbA1c levels of the participants in the usual-care group (-0.1%, p=0.70).

There were statistically significant differences between groups with improvement in the test/MI group for the outcomes SBP (p<0.01), diastolic BP (DBP) (p<0.01), total Martín-Bayarre-Grade adherence score (p=0.04), and Martín-Bayarre-Grade questionnaire dimensions of treatment adherence and personal involvement (p=0.03 and p=0.04). The test/MI group had a significant mean reduction of 13.7 mmHg in SBP compared with the usual-care group, with a large effect size (0.87). Regarding DBP, there was a decrease of 5.7 mm Hg with a medium effect size (0.71). For adherence, the magnitude of the effect found was reduced (0.29).

As a secondary outcome, nurses referred patients to a general practitioner for a review consultation, depending on the identified needs, in 60.7% (n=51) of the usual-care group participants and 69.7% (n=69) of the test/MI group (p=0.26). Moreover, 31 (30.7%) participants in the test/MI group and 16 (18.2%) in the usual-care group required therapeutic maintenance until the conclusion of the study, with increased or reduced doses of drugs such as antihypertensives, antidiabetics, antidyslipidemic drugs, and antidepressants. In this regard, there was no difference between the groups (p=0.07).

## DISCUSSION

This trial compared nursing consultations on the basis of MI with usual care nursing visits in 174 participants with T2DM and AH. It found differences between the groups with improvements in the test/MI group for BP and adherence score after a mean follow-up of 6 months. The 0.4% reduction in HbA1c levels (p<0.01) among participants who received MI was clinically relevant, especially considering that MI was used as an adjunct and part of the care routine for diabetes management in primary health care.<sup>7,34</sup> However, MI was no more effective than the usual care in reducing HbA1c levels. Mean baseline HbA1c levels of participants, associated with other characteristics such as age, time of diagnosis, polypharmacy, and associated diseases, may have represented a restricted margin for reduction according to the

Variables	n	Baseline Mean ± SD	a <i>p</i> -value Baseline	Study completion Mean ± SD	Delta value intragroup Mean (95% CI)	b p-value Intragroup	Effect size (Cohen's d) (95% Cl)	Adjusted delta value between groups Mean (95% CI)	<i>p</i> -value <sup>c</sup> Between groups	Adjusted difference between groups Mean (95% Cl)
Clinical outcomes										
HbA1c, %			0.82				0.31		0.07	-0.3 (-0.6, 0)
Test/MI	101	$\textbf{7.6} \pm \textbf{1.6}$		$\textbf{7.2} \pm \textbf{1.4}$	-0.4 (-0.7, -0.2)	<0.01		-0.4 (-0.7, -0.1)		
Usual care	88	$\textbf{7.5} \pm \textbf{1.6}$		$\textbf{7.5} \pm \textbf{1.7}$	-0.1 (-0.3, 0.2)	0.60		-0.1 (-0.4, 0.1)		
SBP (mm Hg)			0.03				0.87		<0.01	-13.7 (-18.5, -8.9)
Test/MI	101	$147.2\pm23.3$		$132.7{\pm}\ 18.4$	-14.4 (-18, -10.8)	<0.01		-13.5 (-18,5, -8.6)		
Usual care	88	$139.9\pm21$		$142.3\pm20.3$	+2.4 (-1.7, 6.6)	0.26		+0.21 (-4.4, 4.8)		
DBP (mm Hg)			0.30				0.71		<0.01	-5.7 (-8.2, - 3.2)
Test/MI	101	$75.1\pm10.7$		$68.7 \pm 9.8$	-6.4 (-8.2, -4.7)	<0.01		-5.4 (-8, -2.8)		
Usual care Self-administered questionnaires	88	$73.5 \pm 11$		67.8 ± 9.4	0.3 (-1.7, 2.3)	0.77		+0.3 (-2.2, 2.8)		
Total MBG adherence score			0.43				0.29		0.04	+1.5 (0.1, 3)
Test/MI	101	$\textbf{34.3} \pm \textbf{7.3}$		$\textbf{38.4} \pm \textbf{5.9}$	4.1 (2.9, 5.4)	<0.01		+4.6 (3, 6.1)		
Usual care	88	$\textbf{35.1} \pm \textbf{6.2}$		$\textbf{37.4} \pm \textbf{5.7}$	2.3 (1.1, 3.4)	<0.01		+3 (1.6, 4.5)		
MBG score by dimensions										
Treatment adherence			0.42				0.32		0.03	+0.5 (0, 1)
Test/MI	101	$13.5\pm2.2$		$14.3\pm1.6$	0.8 (0.4, 1.2)	<0.01		+1 (0.3, 1.1)		
Usual care	88	$13.8\pm1.6$		$14\pm1.7$	0.2 (-0.1, 0.5)	0.19		+0.3 (-0.2, 0.7)		
Personal implication			0.27				0.13		0.04	+1 (0, 1.6)
Test/MI	101	$13.6\pm3.2$		$14.7\pm3.1$	1.1 (0.5, 1.7)	<0.01		+2.1 (0.9, 3.3)		
Usual care	88	$13.1\pm3.2$		$13.8\pm313$	0.7 (0.04, 1.4)	0.04		+1.2 (-0.1, 2.4)		
Therapist-patient relationship			0.06				0.26		0.56	+0.2 (-0.6, 1.1)
Test/MI		$7.2 \pm 4.1$		$9.6\pm3$	2.4 (1.6, 3.1)	<0.01		+2.2 (1.4, 3)		
Usual care	88	$\textbf{8.2}\pm\textbf{3.7}$		$9.7\pm3$	1.4 (0.7, 2.2)	<0.01		+2 (1.2, 2.8)		

Note: Boldface indicates statistical significance (p<0.05). <sup>a</sup>p-value obtained by the *t*-test analysis. <sup>b</sup>p-value obtained by GEE. <sup>c</sup>p-value obtained by ANCOVA test.

DBP, diastolic blood pressure; GEE, generalized estimating equation; MBG, Martín-Bayarre-Grade Questionnaire; MI, motivational interviewing; SBP, systolic blood pressure.

. .

clinical recommendations to individualized HbA1c goals.<sup>7</sup> Similar results were shown in studies that investigated MI in primary care environments on the basis of different modalities of delivery and with weak quality of evidence.<sup>34,35</sup>

In contrast, the significant finding of a reduction in BP levels found in favor of the test/MI group deserves to be emphasized. The differences of -13.7 mmHg (95% CI= -18.5, -8.9) in SBP and -5.7 mmHg in DBP (95% CI = -8.2, -3.2) in relation to those in the usual-care group were greater than what was found in the literature consulted. In a systematic review analyzing the effectiveness of MI in primary care, the mean effect size was also higher in BP results.<sup>12</sup> Ma and colleagues<sup>36</sup> reported lower levels of SBP and DBP in the group with MI than in the control group, with differences of 4.92 and 2.58 mmHg, respectively. In a meta-analysis of RCTs evaluating the effect of MI on BP, a significant effect was found for SBP (-1.64 mm Hg) but not for DBP (-0.58 mm Hg).<sup>37</sup> Although the mean baseline BP was higher in the test/MI group than in the usual-care group, the statistical adjustments, including changes in medical prescription during the period as a possible confounder, confirm that the results found were independent of these variables.

Likewise, MI was more effective than usual care in improving adherence levels among participants. The main effects of adherence in the test/MI group were seen in the domains of treatment adherence (which includes correct intake of prescribed drugs, a healthy diet, physical activity, and regular follow-up at the Health Unit) and personal involvement (which includes participation in a support network, mobilization of efforts, and the extent to which treatment decisions are shared with the patient). This suggests how much the quality of the relationship, the form of communication, and shared decision making provided by MI could be the decisive factors for the effectiveness of care.<sup>7,16</sup> Over the years, MI has been associated with comparable evidence of behavioral changes, such as improvement in regular medication use, cessation of substance abuse, change in eating habits, and maintenance of body weight, as well as qualitative perceptions of the patient's active role and partnership with the health professional.<sup>9,14,15,19,21,35,36,38–42</sup> These results corroborate those of trials that show MI as a promising strategy for the management of chronic conditions, especially regarding lifestyle interventions.<sup>7,9–12,19,38–40</sup>

Ultimately, the interventions in the usual-care group did not result in statistically significant improvements in intragroup clinical results or in relation to interventions in the test/MI group. These findings propose a link with the criticisms established >2 decades ago regarding the need for effective change in the current biomedical health model toward a model more centered on the patient and on the multiprofessional team.<sup>7,16,40–43</sup> The generalized lack of nursing follow-up for people with T2DM and AH at baseline is a cause for concern, given that the team approach is strongly recommended.<sup>7,43</sup> In this perspective, the effect of referral to the general practitioner and changes in medical prescription during the study period are interpreted as a positive effect of the nursing consultations because nurses play a key role in coordinating care and identifying risk factors for adherence and their repercussions for treatment.<sup>6,7</sup> Gabbay et al.<sup>38</sup> report the same findings, with nurses prompting physicians to re-evaluate the patient's medications. However, physicians did not always respond, which implies that strategies are required to reduce clinical inertia and promote interdisciplinary care.

### Limitations

The main limitation of this study was that no feedback on MI was offered to nurses during the study (only before and after the 20 hours of training) to use MI in clinical practice. This impairs the analysis in terms of fidelity to the MI methods used during the interventions, and better outcomes could be achieved by professionals with higher levels of training and experience.<sup>9,19,22</sup>

Furthermore, the ideal sample size was not reached because of the lack of resources for the research. The existence of dropouts and the need to use the last observation carried forward for data analysis may have, together with the other limitations, generated underfit in the estimation of the parameter and reduced the effect of the intervention. In this context, the method used for the sample calculation, with the absence of a pilot study and the inclusion of all participants regardless of whether their baseline HbA1c levels were within the therapeutic target, contributed to the prediction of the restricted margin for reduction, considering the baseline profile of the study population. Finally, because this is a pragmatic trial evaluating aspects related to the followup of people with chronic diseases in primary care environments, with all their subjectivity, external interference, and psychosocial specificities, data allow for only a partial portrait of this population rather than an absolute one.

## CONCLUSIONS

In the context of primary health care, the nursing consultation based on MI was shown to be a more effective care strategy than the usual care to improve BP levels and adherence levels in individuals with T2DM and AH. Moreover, MI was demonstrated to be useful in reducing HbA1c levels in diabetes management, even in a short time. Therefore, it is hoped that this study will contribute to the consolidation of MI as an effective tool for improving care responses in chronic conditions. Nevertheless, additional evidence is needed to examine and support the forms of implementation of MI in primary care with larger and more representative samples for evaluating the effects on the professional skills and on the knowledge, attitudes, and outcomes of patients with T2DM, particularly in HbA1c levels.<sup>14,34,35,44</sup>

Finally, qualitative scientific methodologies should be included to determine how people receiving treatment for hypertension and diabetes who receive MI and the professionals who apply MI feel about it, which can be another good reason to implement MI widely in primary care settings, aiming to transform the healthcare reality, raise standards, and promote lifestyle changes.

## ACKNOWLEDGMENTS

No financial disclosures were reported by the authors of this paper.

## REFERENCES

- 1. WHO. World Health Statistics 2018: Monitoring Health for the SDGs, Sustainable Development Goals. Geneva, Switzerland: WHO, 2018.
- Felipe GF, de Abreu RN, Moreira TM. Aspects of the nursing appointments with hypertensive patients cared for in the Family Health Program [in Portuguese]. *Rev Esc Enferm USP*. 2008;42(4):620–627. https://doi.org/10.1590/s0080-62342008000400002.
- Glynn LG, Murphy AW, Smith SM, Schroeder K, Fahey T. Interventions used to improve control of blood pressure in patients with hypertension. *Cochrane Database Syst Rev.* 2010(3):CD005182. https://doi.org/10.1002/14651858.cd005182.pub4.
- Welch G, Garb J, Zagarins S, Lendel I, Gabbay RA. Nurse diabetes case management interventions and blood glucose control: results of a meta-analysis. *Diabetes Res Clin Pract.* 2010;88(1):1–6. https://doi. org/10.1016/j.diabres.2009.12.026.
- Moura Dde J, Bezerra ST, Moreira TM, Fialho AV. Nursing care to the client with hypertension: a bibliographic review. *Rev Bras Enferm.* 2011;64(4):759–765. https://doi.org/10.1590/s0034-71672011000400020.
- WHO. Enhancing nursing and midwifery capacity to contribute to the prevention, treatment and management of noncommunicable diseases. Geneva, Switzerland: WHO. https://www.who.int/hrh/resources/observer12/en/. Published 2013. Accessed June 11, 2019.
- American Diabetes Association. Introduction: standards of medical care in diabetes - 2020. *Diabetes Care*. 2020;43(suppl 1):S1–S2. https:// doi.org/10.2337/dc20-sint.
- Brasil, Ministério da Saúde, Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Ciência e Tecnologia. Síntese de evidências para políticas de saúde: adesão ao tratamento medicamentoso por pacientes portadores de doenças crônicas. Brasília, Brasil: Ministério da Saúde. https://pesquisa.bvsalud.org/portal/resource/pt/biblio-971867. Published 2016. Accessed August 23, 2019.
- Steinberg MP, Miller WR. Motivational Interviewing in Diabetes Care (Applications of Motivational Interviewing). New York, NY: Guilford Press, 2015. https://doi.org/10.7861/clinmedicine.16-2-205.
- Lundahl BW, Burke BL. The effectiveness and applicability of motivational interviewing: a practice-friendly review of four meta-analyses. J Clin Psychol. 2009;65(11):1232–1245. https://doi.org/10.1002/jclp.20638.

- Cedillo IG, Antúnez BV. Eficacia de la entrevista motivacional para promover la adherencia terapéutica en pacientes con diabetes mellitus tipo 2. Universitas Psychologica. 2015;14(2):511–522. https://doi.org/ 10.11144/javeriana.upsy14-2.eemp.
- Vanbuskirk KA, Wetherell JL. Motivational interviewing used in primary care populations: a systematic review and meta-analysis. J Behav Med. 2014;37(4):768–780. https://doi.org/10.1007/s10865-013-9527-4.
- Andretta I, Meyer E, Kuhn RP, Rigon M. A entrevista motivacional no Brasil: uma revisão sistemática. *Mudanças – Psicologia da Saúde*. 2014;22(2):15–21. https://doi.org/10.15603/2176-1019/mud.v22n2p15-21.
- Thepwongsa I, Muthukumarb R, Kessomboon P. Motivational interviewing by general practitioners for type 2 diabetes patients: a systematic review. *Fam Pract.* 2017;34(4):376–383. https://doi.org/10.1093/fampra/cmx045.
- Dellasega C, Añel-Tiangco RM, Gabbay RA. How patients with type 2 diabetes mellitus respond to motivational interviewing. *Diabetes Res Clin Pract.* 2012;95(1):37–41. https://doi.org/10.1016/j.diabres.2011.08.011.
- Dickinson JK, Guzman SJ, Maryniuk MD, et al. The use of language in diabetes care and education. *Diabetes Care*. 2017;40(12):1790–1799. https://doi.org/10.2337/dci17-0041.
- Mendes EV. O cuidado das condições crônicas na atenção primária à saúde: o imperativo da consolidação da estratégia da saúde da família. Brasília, Brasil: Organização Pan-Americana da Saúde. http://bvsms. saude.gov.br/bvs/publicacoes/cuidado\_condicoes\_atencao\_primaria\_ saude.pdf. Published 2012. Accessed July 15, 2019.
- 18. Centro Colaborador da OMS para a Classificação de Doenças em Português-CBCD. Classificação Estatística Internacional de Doenças e Problemas relacionados à Saúde-10<sup>ª</sup>. Revisão. São Paulo, Brasil: Centro Latino-Americano e do Caribe de Informação em Ciências da Saúde. https://pesquisa.bysalud.org/portal/resource/pt/lis-LISBR1.1-16207. Published 2001. Accessed July 15, 2019.
- Chen SM, Creedy D, Lin HS, Wollin J. Effects of motivational interviewing intervention on self-management, psychological and glycemic outcomes in type 2 diabetes: a randomized controlled trial. *Int J Nurs Stud.* 2012;49(6):637–644. https://doi.org/10.1016/j.ijnurstu.2011.11.011.
- 20. Brasil, Ministério da Saúde, Grupo Hospitalar Conceição, Gerência de Saúde Comunitária. A organização do cuidado às pessoas com hipertensão arterial sistêmica em serviços de atenção primária à saúde. Organização de Sandra R. S. Ferreira, Itemar M. Bianchini, Rui Flores. Porto Alegre, Brasil: Hospital Nossa Senhora daConceição. https:// ensinoepesquisa.ghc.com.br/images/Publicacao/a%20organizao%20do %20cuidado.pdf. Published 2011. Accessed August 18, 2019.
- Miller WR, Rollnick S. Motivational Interviewing: Helping People Change. 3rd ed. New York, NY: Guilford Press, 2013.
- Moyers TB, Martin T, Manuel JK, Miller WR, Ernst D. Revised global scales: Motivational Interviewing Treatment Integrity 3.0 (MITI 3.0). Albuquerque, NM: University of New Mexico, Center on Alcoholism, Substance Abuse and Addictions (CASAA); 2007. https://casaa.unm. edu/download/miti3.pdf.
- Miller WR, Hedrick KE, Orlofsky DR. The Helpful Responses Questionnaire: a procedure for measuring therapeutic empathy. J Clin Psychol. 1991;47(3):444–448. https://doi.org/10.1002/1097-4679(199105) 47:3≤444::aid-jclp2270470320≥3.0.co;2-u.
- Miller WR, Moyers TB, Ernst D, Amrhein P. Manual for the Motivational Interviewing Skill Code (MISC) Version 2.1. Albuquerque, NM: University of New Mexico, Center on Alcoholism, Substance Abuse and Addictions; 2008. http://casaa.unm.edu/download/misc.pdf.
- Lord SP, Can D, Yi M, et al. Advancing methods for reliably assessing motivational interviewing fidelity using the motivational interviewing skills code. J Subst Abuse Treat. 2015;49:50–57. https://doi.org/10. 1016/j.jsat.2014.08.005.
- Nerenberg KA, Zarnke KB, Leung AA, et al. Hypertension Canada's 2018 Guidelines for Diagnosis, Risk Assessment, Prevention, and Treatment of Hypertension in Adults and Children. *Can J Cardiol.* 2018;34(5):506–525. https://doi.org/10.1016/j.cjca.2018.02.022.

- Huang Y, Wei X, Wu T, Chen R, Guo A. Collaborative care for patients with depression and diabetes mellitus: a systematic review and meta-analysis. *BMC Psychiatry*. 2013;13(1):260. https://doi.org/ 10.1186/1471-244x-13-260.
- 28. Gorestein C, Andrade L. Inventário de depressão de Beck: propriedades psicométricas da versão em português. *Rev Psiq Clín.* 1998;25(5):245– 250. http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?IsisScrip t=iah/iah.xis&src=google&base=LILACS&lang=p&nextAction=ln k&exprSearch=228051&indexSearch=ID. Accessed February 10, 2021.
- Cunha JA. Manual da versão em português das Escalas Beck. São Paulo, SP: Casa do Psicólogo, 2001.
- Matta R, Luiza S, Lucia V, Azeredo TB. Adaptação brasileira de questionário para avaliar adesão terapêutica em hipertensão arterial. *Rev* Saúde Pública. 2013;47(2):292–300. https://doi.org/10.1590/s0034-8910.2013047003463.
- Alfonso LM, Vea HDB, Ábalo JA. Validación del cuestionario MBG (Martín-Bayarre-Grau) para evaluar la adherencia terapéutica en hipertensión arterial. *Rev Cub Salud Pública*. 2008;34(1).. https://doi. org/10.1590/s0864-34662008000100012.
- **32.** WHO. Adherence to Long Term Therapies: Evidence for Action. Geneva, Switzerland: WHO, 2003.
- Resolução Cofen nº 0544/2017. Cofen. http://www.cofen.gov.br/resolucao-cofen-no-05442017\_52029.html. Updated May 18, 2017. Accessed May 12, 2017.
- Christie D, Channon S. The potential for motivational interviewing to improve outcomes in the management of diabetes and obesity in paediatric and adult populations: a clinical review. *Diabetes Obes Metab.* 2014;16(5):381–387. https://doi.org/10.1111/dom.12195.
- Ekong G, Kavookjian J. Motivational interviewing and outcomes in adults with type 2 diabetes: a systematic review. *Patient Educ Couns.* 2015;99(6):944–952. https://doi.org/10.1016/j.pec.2015.11.022.
- Ma C, Zhou Y, Zhou W, Huang C. Evaluation of the effect of motivational interviewing counselling on hypertension care. *Patient Educ Couns.* 2014;95(2):231–237. https://doi.org/10.1016/j. pec.2014.01.011.

- Ren Y, Yang H, Browning C, Thomas S, Liu M. Therapeutic effects of motivational interviewing on blood pressure control: a meta-analysis of randomized controlled trials. *Int J Cardiol.* 2014;172(2):509–511. https://doi.org/10.1016/j.ijcard.2014.01.051.
- Gabbay RA, Añel-Tiangco RM, Dellasega C, Mauger DT, Adelman A, Van Horn DHA. Diabetes nurse case management and motivational interviewing for change (DYNAMIC): results of a 2-year randomized controlled pragmatic trial. J Diabetes. 2013;5(3):349–357. https://doi. org/10.1111/1753-0407.12030.
- Martins RK, McNeil DW. Review of motivational interviewing in promoting health behaviors. *Clin Psychol Rev.* 2009;29(4):283–293. https://doi.org/10.1016/j.cpr.2009.02.001.
- Song D, Xu TZ, Sun QH. Effect of motivational interviewing on self-management in patients with type 2 diabetes mellitus: a metaanalysis. *Int J Nurs Sci.* 2014;1(3):291–297. https://doi.org/10.1016/j. ijnss.2014.06.002.
- Fisher L, Polonsky WH, Hessler D, Potter MB. A practical framework for encouraging and supporting positive behaviour change in diabetes. *Diabet Med.* 2017;34(12):1658–1666. https://doi.org/10.1111/dme.13414.
- Rutten GEHM, Alzaid A. Person-centred type 2 diabetes care: time for a paradigm shift. *Lancet Diabetes Endocrinol.* 2018;6(4):264–266. https://doi.org/10.1016/s2213-8587(17)30193-6.
- 43. Williams B, Mancia G, Spiering W, Rosei EA, Azizi M, Burnier M. 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD: the Task Force for diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD). *Eur Heart J.* 2018;34(39):3021–3104. https://doi.org/10.1093/eurheartj/eht108.
- 44. Jansink R, Braspenning J, Keizer E, van der Weijden T, Elwyn G, Grol R. No identifiable Hb1Ac or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomised trial. *Scand J Prim Health Care*. 2013;31(2):119–127. https://doi.org/10.3109/02813432.2013.797178.