

## Special Article – Tobacco and Smoking Cessation

# Motivational Interviewing and Smoking Cessation: Translating Research into Practice with Fidelity

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Received: April 22, 2016; Accepted: May 26, 2016;

Published: May 30, 2016

## Abstract

**Background:** Motivational interviewing (MI) is an evidence based communication style effective for helping patients change their health behaviors such as smoking. We integrated an MI-based smoking cessation intervention into a home telehealth program for patients with Posttraumatic Stress Disorder (PTSD). This study presents treatment fidelity data that can be of use when implementing an MI intervention for individuals with PTSD into clinical practice.

**Method:** We assessed and monitored the MI-based smoking cessation intervention using a treatment fidelity framework which included five domains (study design, training, treatment delivery, patient receipt and enactment).

**Results:** Eighty-nine Veterans with PTSD who smoked were enrolled in the intervention arm of this study. Treatment fidelity was established by designing a study that mapped to a stage of change theory to deliver MI-based smoking cessation curricula via home telehealth plus weekly MI counseling calls. Initial and ongoing training by an MI expert ensured treatment delivery fidelity by nurse care managers. On average, participants received 12.25 calls lasting 16.7 minutes. They were satisfied with MI curricula (M= 9.1/11) and nurse counseling (98.5%). A majority (73.1%) of participants stated they wanted to quit. There was a significant difference in stage of change between baseline call and the last call with higher levels of stage of change at the last call ( $p < 0.0001$ ). Enactment measures revealed participants smoked nine fewer cigarettes over time ( $p < 0.0001$ ).

**Conclusion:** Implementing studies in health behavior change necessitates monitoring and demonstrating treatment fidelity. The results of this study can help guide translating smoking cessation research into practice in this hard to treat population.

**Keywords:** Motivational interviewing; Smoking cessation; Treatment fidelity; Posttraumatic Stress Disorder; Veterans

## Abbreviations

AARM: Avoid, Alarm, Replace, Mentally Cope; IQR: Interquartile Range; M: Mean; MI: Motivational Interviewing; MIA-STEP: Motivational Interviewing Assessment; Supervisory Tools for Enhancing Proficiency; MINT: Motivational Interviewing Network of Trainees; MITI: Motivational Interviewing Treatment Integrity; NIH BCC: National Institutes of Health Behavioral Change Consortium; NRT: Nicotine Replacement Therapy; PTSD: Posttraumatic Stress Disorder; RCT: Randomized Control Trial; R:Q; Reflection to Question Ratio; SD: Standard Deviations; TTM: Transtheoretical Model of Change; VA; Veterans Administration

## Introduction

Motivational interviewing (MI) is a patient-centered, strengths-focused communication approach to help patients change problematic behaviors [1], which is often used in clinical settings when the patient's behavior affects treatment outcomes [2]. In 30 randomized controlled trials (RCTs) with over 9,000 total participants, MI has proven efficacious for multiple difficult-to-change behaviors including diet change, exercise, medication adherence, problem gambling, alcohol

consumption, and various types of drug use.

The evidence for MI as a smoking cessation intervention is equally strong [3], although in one meta-analysis effect sizes for smoking tobacco were only about half as large as those that have been found for other types of behavior change [4]. One interpretation of this pattern of results is that smoking tobacco is a particularly difficult behavior to change [5]. Despite smaller effect sizes for smoking cessation in some MI studies, tobacco smoking remains a leading cause of mortality in the U. S. [6], and further intervention research is therefore essential. MI works at least as well as any other intervention for this intractable problem and better than many [4], and can be delivered in a relatively brief amount of time compared to other well-studied patient counseling interventions [7].

MI is a good fit for Veterans with posttraumatic stress disorder (PTSD) who smokes because it is a non-confrontational communication style [8]. Smoking rates are higher among Veterans seen in the Veterans' Administration (VA) health care system than in the general U. S. population [9], and military service is a frequent time of smoking initiation for patients. Furthermore, Veterans with PTSD have smoking rates of 45% to 66% [10], and PTSD appears

to be a risk factor for treatment failure, with lower success rates in smoking cessation intervention among patients with PTSD compared to the general population [11,12]. Based on this combination of risk factors, helping Veterans with PTSD to quit smoking may be one of the most challenging applications of MI for health behavior change. Identifying successes as well as failures of MI in this context therefore may inform the use of MI in other clinical settings where the same type of barriers occur in less extreme forms.

We previously pilot tested the feasibility and treatment fidelity of MI for smoking cessation in a telephone-and-technology-based MI intervention to help this hard to treat population of Veterans with PTSD to reduce their tobacco use [13]. This small scale pilot study examined MI delivered by a single research nurse to a sample of 11 Veterans with PTSD. We then initiated a RCT to evaluate our MI-based smoking cessation intervention, which included a 90-session smoking cessation curriculum integrated into a PTSD home telehealth care management program with 12 weeks of MI telephone counseling to determine if smoking behaviors improved. Outcomes of this study are discussed elsewhere [14]. For this study, we used data obtained from the smoking cessation curricula and the weekly MI counseling treatment to test the treatment fidelity of the intervention delivered by two nurse care managers to Veterans with PTSD enrolled in the intervention arm of RCT.

The usual goal of treatment fidelity studies is to show that an intervention was delivered in a research study according to its original design; in other words, it is a manipulation check on the independent variable of an RCT [15]. Training on MI [16] and behavioral rating of counselors' MI performance [17] are two elements of treatment fidelity. These factors are usually reported in MI research studies yet they may or may not have any direct impact on treatment outcomes [3]. Nevertheless, treatment fidelity measures also provide crucial information about how well an experimental intervention can be translated into practice settings, including barriers and facilitators that inhibit or enhance its use [18]. The current study therefore presents treatment fidelity data on MI for smoking cessation among Veterans with PTSD, with a focus on how and what these data have to say about the use of MI for smoking cessation in high-risk populations more generally.

## Methods

### Overview of treatment fidelity methods

The treatment fidelity framework [15] suggests five domains for evaluating MI interventions: 1) study design, 2) provider training, 3) treatment delivery by providers, 4) patient receipt of intervention, and 5) patient enactment of treatment. Study design includes elements such as an adequate dose and frequency of intervention [19], as well as considerations about the delivery method and whether these interact appropriately with the intervention content. For example, telehealth methods facilitate more frequent interaction with patients at distant locations [20], but they also might reduce the human connection that has been found particularly important for the success of MI [21]. Study design also captures theory problems such as those that have been noted when a more directive cognitive-behavioral intervention with specific goals for behavior change is combined with an MI intervention for increasing patients' engagement in care and autonomous decision-making about their own health [22].

The second and third domains of the treatment fidelity framework are the most commonly reported in RCT research, focusing on training and successful delivery of interventions by providers [19]. Researchers report the details of the training procedure, qualifications of the trainers, amount of training, and follow-up supervision procedures, as well as behavioral measures of MI treatment delivery such as the Motivational Interviewing Assessment: Supervisory Tools for Enhancing Proficiency (MIA-STEP) [23] or the Motivational Interviewing Treatment Integrity (MITI) [24]. Although a recent large-scale meta-analysis found no relationship between provider training characteristics or behavioral MI implementation measures and MI treatment outcomes [3], information at these levels nevertheless provides important insights into the process of implementing MI in diverse practice settings.

The last two domains of the framework may require adaptation for studies of motivational methods such as MI in which patients are not necessarily expected to enact specific behaviors. Although the framework is clearly delineated for cognitive-behavioral interventions that rely on knowledge transfer from providers to their patients [19], the focus of MI is on helping patients to make decisions about their health behaviors. In this context, studies have sometimes evaluated patient receipt and enactment of MI interventions via data on the number and type of intervention components actually completed – this is related to the number *intended* at the study design level, but focused on the actual receipt of interventions by participants rather than what was originally designed. Patient satisfaction is another metric related to receipt of intervention, as in our pilot study [13]. Studies have also looked at patient-provided data on motivation or readiness for change as evidence for enactment in MI [25]. In our previous studies we included quit attempts as a measure of enactment in smoking cessation [13,14].

### Participants

There were 89 participants who were randomly allocated to a MI telehealth intervention in a study of 178 total Veterans with PTSD who smoked. We enrolled Veterans who regularly smoked at least one cigarette/day whether or not they were ready or trying to quit.

### Procedure

The integrated smoking cessation intervention was designed to be completed over 12 weeks with a six-month follow-up period. Participants in the intervention group received 90 daily sessions of the MI-based smoking cessation curricula via a PTSD home telehealth program (the Enhanced PTSD home telehealth program) and weekly individual telephone MI counseling calls from three nurse care managers intended to last for 20 minutes. Our stage-based MI intervention was built upon the core tenets of the transtheoretical model of change (TTM) [26]. TTM provided a conceptual framework of how and why change occurs and MI enhanced personal motivation to change [27]. We “nudged” participants using a MI counseling through stages (precontemplation, contemplation, preparation, action, and maintenance), from no interest in making a change (precontemplation) to sustained change over time (maintenance). We integrated TTM and MI to increase smoking cessation in a high-risk, vulnerable population.

Throughout the smoking cessation telehealth written curricula, participants were asked to think about a topic and if ready, discuss

it with their nurse care manager during the next weekly call. For example in a daily addiction curriculum, we addressed prior quit attempts and if the participant had tried to quit twice before the written curriculum stated, *So, you've practiced twice before to quit smoking. If you haven't done so already, tell your nurse care manager about it the next time you speak.* When the nurse care manager spoke to such a participant she then tailored her MI counseling to his stage of change to encourage the participant to make a behavior change. If the participant was in the contemplation stage of change and had tried to quit twice before, the nurse care manager would explore what happened during those quit attempts, how long they lasted, how the participant felt, or what benefits he noticed. Based on a manualized treatment protocol, the nurse care managers explored how important the participant believed it was to quit smoking, how confident the participant felt that he/she could succeed, and/or what resources the participant needed to be successful.

## Measures

**Study design fidelity:** Design fidelity is achieved when the components of an intervention map cleanly to its underlying theory [19]. This can be challenging to achieve in the case of motivational interviewing, which evolved clinically in the absence of a strong theory base [28]. Our assessment of design fidelity included review of the intervention protocol by independent experts in MI [13], a review of the number and type of participant contacts, and a check on the qualifications of providers who delivered the MI intervention [19].

**Training fidelity:** Training fidelity was measured based on the MI training the nurse care managers completed as well as the qualifications of the trainers, the number and type of training sessions provided, and the type of follow-up training and supervision provided.

**Treatment delivery fidelity:** Treatment delivery fidelity was measured using several strategies. A treatment manual was used to standardize the intervention and a self-report MI skills checklist was completed by the nurse care managers after each MI session was delivered. The checklist served to document frequency and type of MI consistent skills such as reflection, educating, using elicit-provide-elicited, and open or closed questions, as in our prior study [13]. Additionally, a small subset of sessions was evaluated using a validated behavioral coding system, the MITI [29], completed by an independent rater who is a member of the *Motivational Interviewing Network of Trainers (MINT)*. Participants were surveyed about their satisfaction with the MI counseling phone calls at the end of the intervention period, which captured their opinions regarding how the treatment was delivered by the nurse care managers.

**Patient receipt of intervention:** Receipt was measured by patient satisfaction scores with MI content.

Additionally, we monitored the participant's stage of change as evidence that the nurse care managers' successfully reached the patient for each intended component of the MI-based smoking cessation intervention. We also considered data on the amount and reasons for attrition as evidence related to patient receipt of the intervention; this type of data may provide important information about the feasibility of MI in practice.

**Patient enactment:** We evaluated enactment based on several

MI scales completed by participants via the Enhanced PTSD home telehealth program. These included: readiness to change, importance of change, and confidence level to make a change. Additionally, we assessed answers to specific questions in smoking cessation curricula and stage-of-change on a monthly basis in the written telehealth curricula and during the weekly MI counseling calls. We also assessed number of cigarettes smoked/day over time. Moreover, we tracked the participants' change talk during each MI counseling call.

## Data analysis

Descriptive statistics including means and standard deviations (SDs), median, ranges, and frequency distributions were used to describe baseline characteristics, study completion rates, MI skills checklist data, participant satisfaction surveys, and MI rating scales. Dichotomous variables were summarized with proportions. Measures for evaluating treatment fidelity of the MI-based smoking cessation intervention used the treatment fidelity framework by the National Institutes of Health Behavioral Change Consortium (NIH BCC) which includes five domains of treatment fidelity [19] as described above.

Repeated measures analysis using linear mixed modeling was conducted to evaluate number of cigarettes smoked/day during the intervention and during the follow-up periods. We limited our analysis on number of cigarettes smoked/day to participants who completed the study to ensure a consistent sample size for the repeated measures analysis. During the intervention period, if a participant missed a quit attempt question, we were able to impute with their daily quit attempt responses. However, for the follow-up period, we had eight participants who missed at least one quit attempt question and were removed from the analysis because these patients were not asked quit attempts question daily.

The Wilcoxon signed-rank test was used to test for a difference in stage of change between the first and last calls (movement up or down the range of stages). To test for a difference in the proportion of subjects mentioning change talk in the first call vs. the last call, McNemar's test for correlated proportions was used. This method was subsequently applied to use of commitment change talk and taking steps change talk individually. Analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

## Results

We enrolled 89 Veterans with PTSD who smoked into the intervention arm of an integrated care management telehealth and smoking cessation intervention. We only assessed the intervention arm for treatment fidelity. Table 1 shows baseline characteristics for those enrolled in the intervention (n=89). These characteristics did not differ from those randomly assigned to the control group [13,14]. The majority of participants were male (83.1%), white (67.4%), and unemployed (87.6 5%). The average age was 54.6 years with a greater proportion of participants being older than 50 years (74.2%). Slightly over half (57.3%) of participants self-reported being in the contemplation stage of change when asked on the Enhanced PTSD home telehealth program at the beginning of the study.

## Study design fidelity

Pre-study review of the treatment protocol and nurse training process suggested good adherence to both the principles of TTM and

**Table 1:** Baseline Characteristics of Intervention Group.

		Intervention Group (N=89) (% (n))	Completers (n=61)	Non-Completers (n=28)	p-value
Age, Years	Mean	54.6 (SD=11.2)	55.6 (SD=10.3)	52.3 (SD=13.0)	0.4259
	Proportion of participants ≤50 years old	25.8 (n=23)	21.3	35.7	0.1495
	Proportion of participants >50 years old	74.2 (n=66)	78.7	64.3	
Gender	Male	83.1 (n=74)	83.6	82.1	1.0000
	Female	16.9 (n=15)	16.4	17.9	
Ethnicity	White	67.4 (n=60)	73.8	53.6	0.0590
	Other	32.6 (n=29)	26.2	46.4	
Employment Status	Employed	12.4 (n=11)	11.5	14.3	0.7358
	Unemployed	87.6 (n=78)	88.5	85.7	
Education Level	High school or less	25.8 (n=23)	28.8 (n=17)	24.0 (n=6)	0.8423
	Some college	48.3 (n=43)	49.2 (n=29)	56.0 (n=14)	
	College graduate or more	20.2 (n=18)	22.0 (n=13)	20.0 (n=5)	
	Unknown	5.6 (n=5)			
Lives Alone	Yes	40 (n=34)	45.0 (n=27)	28.0 (n=7)	0.1449
Stage of Change	Precontemplation	7.9 (n=7)	11.7 (n=7)	-	0.2285
	Contemplation	57.3 (n=51)	58.3 (n=35)	61.5 (n=16)	
	Preparation	29.2 (n=26)	26.7 (n=16)	38.5 (n=10)	
	Action	2.3 (n=2)	3.3 (n=2)	-	
	Unknown	3.4 (n=3)			
Fagerström Test for Nicotine Dependence*	Mean	5.4 (SD=2.0) (n=87)	5.4 (SD=2.0) n=59	5.3 (SD=2.1) (n=26)	0.8057
PTSD Checklist**	Mean	57.3 (SD=11.9) (n=84)	56.7 (SD=11.4) n=59	58.7 (SD=13.3) (n=25)	0.4795
Geriatric Depression Scale***	Mean	8.9 (SD=3.7) (n=86)	8.8 (SD=3.8)	9.3 (3.6) (n=25)	0.5536
Medical Comorbidities	Chronic Pulmonary Obstructive Disease (COPD)	22.5 (n=20)	24.6	17.9	0.4798
	Coronary Artery Disease	12.4 (n=11)	9.8	17.9	0.3117
Psychiatric Comorbidities	Depressive disorder	61.8 (n=55)	63.9	57.1	0.5403
	Substance abuse	31.5 (n=28)	31.2	32.1	0.9252
	Bipolar disorder	14.6 (n=13)	14.8	14.3	1.0000
	Anxiety disorder	6.7 (n=6)	6.6	7.1	1.0000
	Traumatic Brain Injury	7.9 (n=7)	4.9	14.3	0.1999
	Sexual abuse	12.4 (n=11)	13.1	10.7	1.0000

\*Fagerström Test for Nicotine Dependence 0-3 Low dependence, 4-6 Medium dependence, 7-10 High dependence,

\*\*PTSD Checklist range of 17-85; >50 indicating PTSD diagnosis,

\*\*\*Geriatric Depression Scale range of 1-15 with > 6 indicating probable depression.

the practices of MI. Additionally, the number, length, and frequency of MI calls were determined prior to implementation. This frequency and duration of contact is consistent with best practices in the MI

literature [3]. Based on their clinical background and MI training, the nurse care managers were qualified to deliver the intervention and contacted patients as needed to provide care management for PTSD

**Table 2:** Treatment Delivery Fidelity: MI Call Guideline.

Weeks of Intervention	Sample Topics to Discuss
Week 1	<ul style="list-style-type: none"> <li>• Reasons for joining the study</li> <li>• Day in the Life</li> <li>• Smoking cessation goal</li> <li>• How can the study provide support</li> <li>• How would life be different as a non-smoker</li> <li>• Importance of quitting smoking</li> <li>• Confidence in quitting smoking</li> <li>• Home telehealth device assessment</li> </ul>
Week 2	<ul style="list-style-type: none"> <li>• Pros and cons of smoking</li> <li>• The core concern (the main obstacle to quitting)</li> <li>• Roadblock to change</li> <li>• Establish a reason to quit</li> <li>• Nicotine Replacement Therapy (NRT)</li> </ul>
Week 3	<ul style="list-style-type: none"> <li>• Ask to share effective quitting strategies</li> <li>• Reduced smoking-what is best for you?</li> <li>• Resisting cravings</li> <li>• Challenges to resisting cravings</li> <li>• Build confidence</li> <li>• Setting a quit date</li> <li>• Identifying triggers</li> <li>• Coping with triggers</li> <li>• Support system</li> <li>• Healthcare providers</li> <li>• Provide information about ways to quit and support available if permission granted</li> </ul>
Week 4	<ul style="list-style-type: none"> <li>• Establish a quit date</li> <li>• Learning to not smoke</li> <li>• AARM (Avoid, Alarm, Replace, Mentally Cope)</li> <li>• Cost of smoking</li> <li>• Health effects of smoking</li> <li>• Discuss barriers and problem solve ways to overcome</li> </ul>
Week 5	<ul style="list-style-type: none"> <li>• Review triggers and coping strategies</li> <li>• Social support</li> <li>• Revisit Quit Date</li> <li>• Importance of quitting smoking</li> <li>• Confidence in quitting smoking</li> <li>• Pros and cons of smoking</li> <li>• Support autonomy</li> </ul>
Week 6	<ul style="list-style-type: none"> <li>• Relaxation techniques</li> <li>• Dealing with stress and strategies for reducing stress</li> <li>• What to do on the quit date</li> <li>• 4Ds (dispose, drink water, distract, deep breathing)</li> <li>• Feelings/thoughts about Quit Date</li> <li>• Provide information about ways to quit and support available if permission granted</li> </ul>
Week 7	<ul style="list-style-type: none"> <li>• Support self-efficacy</li> <li>• What techniques have been used in past to overcome a challenge? How can those be applied?</li> <li>• Discuss barriers and problem solve ways to overcome</li> <li>• Support self-efficacy</li> </ul>
Week 8	<ul style="list-style-type: none"> <li>• Address common concerns: <ul style="list-style-type: none"> <li>◦ Stress relief</li> <li>◦ Weight gain</li> <li>◦ Withdrawal symptoms</li> </ul> </li> <li>• Discuss coping strategies</li> </ul>
Week 9	<ul style="list-style-type: none"> <li>• Quit Date reached?</li> <li>• Revisit pros and cons of smoking</li> <li>• Barriers and how to address</li> <li>• Life as a non-smoker <ul style="list-style-type: none"> <li>◦ What does your life look like as a non-smoker?</li> <li>◦ What would be different?</li> <li>◦ What would be better? What would you miss?</li> </ul> </li> <li>• Revisit triggers</li> <li>• Alternatives to smoking</li> </ul>
Week 10	<ul style="list-style-type: none"> <li>• Relapse prevention</li> <li>• Role of NRT in relapse prevention</li> <li>• Identifying social support</li> <li>• What are rewards of not smoking?</li> <li>• What are roadblocks to quitting</li> </ul>
Week 11	<ul style="list-style-type: none"> <li>• Review coping with triggers</li> <li>• Reviewing skills to resisting triggers</li> <li>• Importance of quitting smoking</li> <li>• Confidence in quitting smoking</li> <li>• Stress reduction</li> <li>• Relaxation techniques</li> <li>• Dealing with stress</li> </ul>
Week 12	<ul style="list-style-type: none"> <li>• Summary of discussions</li> </ul>

in addition to weekly MI smoking cessation counseling. Integrated care management helped the nurse address cessation in the context of PTSD. Intervention participants (68.1%) stated they were better able to manage these chronic conditions as a result of their participation.

**Training fidelity**

- To prepare and support the nurse care managers delivering the MI intervention in this study, the nurses received the following training two days (16 hours) of experiential-based MI training in a group setting
- ongoing phone supervision and support as needed
- in-person booster training sessions
- direct observations of calls with feedback and coaching at the end of the call

The two-day training in MI was provided by MINT trainer and covered the spirit of MI, basic skills, recognizing, eliciting and reinforcing change talk, and working with discord. Ongoing phone support was available to the nurses to discuss difficulties using the intervention or to gather ideas for navigating difficult patient situations.

**Treatment delivery fidelity**

Treatment delivery was assessed and monitored in several ways to ensure treatment components were delivered as intended. A MI treatment manual was developed to help standardize the intervention and provide guidance to the nurse care managers. Based on feedback and coaching from the trainer, the nurse care managers added MI consistent material to the manual over time to continuously improve treatment delivery. For example, the nurse care managers created a guide for discussing smoking cessation (Table 2) with participants during weekly calls to help facilitate these conversations. This guide was especially helpful when participants wandered off the subject of smoking or behavior change.

A self-reported checklist was utilized to monitor treatment adherence by nurse care managers to document MI skills. The checklist included open-ended questions, affirmations, reflections, summarization, and elicit-provide-elicited utilized in each MI counseling call. Nurse care managers used an average of 3.4 unique types of MI skills (SD=1.12) per call. Fidelity of the MI counseling was also assessed by having an external observer listen to a selection of MI counseling calls and then provide feedback to the nurses using both the MIA-STEP [23] and the MITI [29]. A total of eight calls were observed and the nurses met MI adherent skills criteria by demonstrating adherence to global ratings per MITI, reflection to question ratio (R:Q), percent of open-ended questions, percent of complex reflections, and percent of MI-adherent skills (Table 3).

Finally, the participants (n=66) were surveyed at the end of the intervention to ascertain their overall satisfaction with MI counseling calls. Based on a four-point Likert scale (strongly agrees, agree, disagree, strongly disagree), 98.5% of participants strongly agreed or agreed they were satisfied with the weekly calls with the nurse care manager. Other questions assessed if participants felt respected, listened to, and that they were working collaboratively with the nurse care manager during these weekly encounters (Table 4).

**Table 3:** Treatment Delivery Fidelity: Nurse Care Manager Adherence to MI Skills.

Behaviors	Scores
Global Ratings per MITI	Average of 4 on a of 1-6 scale
Reflection to Question Ratio (R:Q)	2
Percent Open Questions	70%
Percent Complex Reflections	50%
Percent MI-Adherent skills	100%

**Table 4:** Treatment Delivery Fidelity: Satisfaction with the Nurse MI Counseling Calls.

Question	N=66 Count Strongly Agree/Agree	Percent (%) Strongly Agree/Agree
My freedom to smoke was respected whether I smoked or chose to quit?	63	95.4%
If I chose to do something different with my smoking, the study nurse supported my change and helped me plan.	62	93.9%
The study nurse asked me what I wanted to discuss about my smoking.	64	97.1%
The study nurse was curious about my thoughts and feelings.	66	100%
The study nurse first asked me what I knew about a topic before she shared information with me.	56	84.8%
The study nurse helped me know my options for changing my smoking by offering me choices.	65	98.5%
I felt comfortable talking with the study nurse.	65	98.5%
I have talked with my study nurse about what I liked and disliked about smoking.	64	97%
The study nurse invited me to imagine myself as a former smoker.	59	89.4%
The study nurse asked me if she could share information about what other smokers have done to change their smoking habits.	59	89.4%

**Patient receipt of intervention**

Of those participants who were enrolled in the intervention arm (n=89), 61 completed the study, 22 dropped-out, and six were censored (dropped because they no longer met eligibility criteria). The mean number of calls completed per participant was 12.25 (SD 5.45), with a median of 12 calls (IQR: 9 – 15), a range that is consistent with the number of contacts in effective MI interventions in prior meta-analytic research [3]. Each call lasted an average of 16.7 minutes. Participants spent an average of 16 weeks completing the 12 weekly counseling calls and a median of 112 days (SD=65.7) completing the 90-session curriculum. The written smoking cessation curriculum was delivered through the home telehealth program platform. Although a novel approach at the time, the technology limited our ability to assess how well the participants understood the information. For an example, participants could not write free text answers to a question and for this reason we prompted participants to speak to their healthcare providers about specific concerns throughout the curriculum. However, only 72.5% of participants actually thought they were prompted to speak to their providers.

The nurse developed strong relationships with participants. They were highly satisfied with the cessation curriculum (mean score 9.1/11, n=69, SD=1.96). Participants (n=69) were specifically queried if the smoking cessation curricula influenced their desire (88.4% of participants answered yes), reasons (92.8% of participants answered

**Table 5:** Patient Receipt: Stage of Change by Baseline Stage of Change Assessment.

Baseline Stage	N (%)	Stage of Change at Last Call	N*(%)
Precontemplation	14(16.09%)	PC	9(64.29%)
		C	3 (21.43%)
		P	1(7.14%)
		A	1(7.14%)
Contemplation	53(60.92%)	PC	6 (11.32%)
		C	22(41.51%)
		P	10(18.87%)
		A	15 (28.3%)
Preparation	19(21.84%)	PC	2(10.53%)
		C	2(10.53%)
		P	8(42.11%)
		A	7(36.84%)
Action	1(1.15%)	C	1(100%)

\*One participant completed first call only.

yes), ability (91.3% of participants answered yes), and commitment (92.8% of participants answered yes) to change their smoking behaviors. Approximately half (49.3%) saw themselves as a former smoker, 40.6% saw themselves as smoking fewer cigarettes, and 10.1% saw themselves as making no change to their smoking. The nurse care managers assessed stage of change during each MI counseling session. Table 5 shows the nurse care managers' assessment of stage of change at the first call and the last call. Most participants vacillated throughout the study and these may differ slightly from the participants' monthly self-assessment. Overall, there was a significant difference in stage of change between first call (baseline stage of change) and the last call with higher levels of stage of change at the last call ( $p < 0.0001$ ).

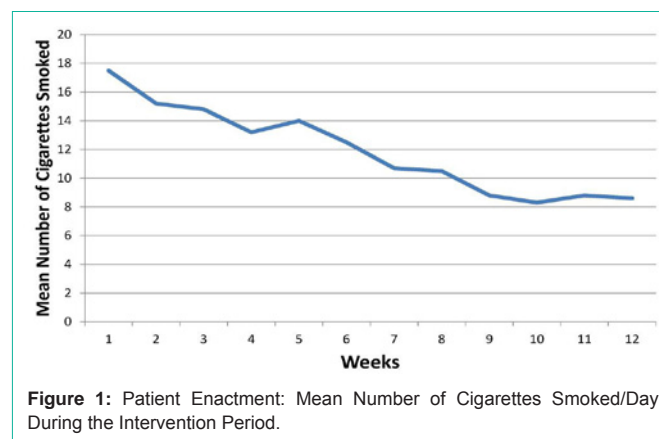
**Patient enactment**

Specific MI questions using a 10-point ruler were asked to evoke change talk: desire to quit ( $M=7.74/10$ ,  $n=80$ ,  $SD=2.87$ ), confidence in quitting ( $M=6.68/10$ ,  $n=79$ ,  $SD=2.7$ ), importance of quitting ( $M=7.48/10$ ,  $n=80$ ,  $SD=2.97$ ), and readiness to quit ( $M=6.83/10$ ,  $n=78$ ,  $SD=2.78$ ). Other MI questions were asked to ascertain whether the participant was going to change his or her smoking behavior. For example, participants were asked if they wanted to quit (don't want to quit 12.5%, somewhat want to quit 16.3%, very much want to quit 71.3%,  $n=80$ ), if they picked a specific date to quit smoking (yes 39%, no 53.3%, not going to pick a date 7.8%,  $n=77$ ), and which option for quitting fits them best (quitting using nicotine replacement 45.3%,  $n=29$ ; using nicotine fading 32.8%,  $n=21$ ; going "cold turkey" 21.9%,  $n=14$ ). Participants were asked by nurse care managers what they wanted to talk about during the weekly MI counseling calls. A majority of the time (69%) participants wanted to talk about smoking, 16.2% of the time they wanted to talk about mental health issues, and 14.8% of the time they wanted to talk about other topics such as stress (3.4%) or physical health (6.1%).

The proportion of participants engaging in any type of change talk during the first and last MI counseling calls as well as "commitment" and "taking steps" change talk was measured (Table 6). As noted in Table 2, the first call was scripted to obtain information about goals

**Table 6:** Patient Enactment: Summary of Change Talk. Summary of Change Talk Mentioned at First and Last Calls.

	First Call	Last Call	p
Any Change Talk, % (n)	97.7(84)	89.7(78)	<0.0001
Commitment Change Talk, % (n)	41.9(36)	57.5(50)	0.9068
Taking Steps Change Talk, % (n)	62.8(54)	58.6(51)	0.0578



**Figure 1:** Patient Enactment: Mean Number of Cigarettes Smoked/Day During the Intervention Period.

and the last call addressed future plans. As a result, the first call had a lot of change talk based on directed questions and the last call had a lot of "commitment" talk given that the MI calls were ending.

Another area we monitored was the number of cigarettes smoked/day. There was no statistical difference in baseline characteristics of participants who completed and did not complete for those enrolled in the intervention group and no statistical difference in baseline characteristics of participants who were enrolled in the intervention and control groups. Figure 1 illustrates that during the intervention period, participants who completed the study smoked fewer cigarettes/day over time (baseline  $M=17.5$  cigarettes/day, end of intervention  $M=8.2$  cigarettes/day,  $n=61$ ,  $p < 0.0001$ ). On average, participants smoked nine fewer cigarettes per day between baseline and the end of the intervention period. Although the mean number of cigarettes smoked/day increased slightly by end of the six-month follow-up period, it remained constant and still lower than at baseline (range of mean number of cigarettes smoked during follow-up period was 9-10.8 cigarettes/day,  $n=53$ ,  $p=0.4699$ ).

**Discussion**

The goal of this study was to evaluate treatment fidelity data as a way to examine a MI-based smoking cessation intervention for Veterans with PTSD implemented as part of routine clinical practice. We assessed fidelity using the best practice recommendations from the NIH BCC [19], which identified five domains associated with treatment fidelity tailored for health behavior change trials. Evaluating treatment fidelity enhances internal validity thereby increasing the chance that the treatment was delivered as intended and can be replicated [19]. We focused our efforts on what these data have to say about the use of MI for smoking cessation with high-risk populations, which can be used when translating research into practice.

There were several strengths of our MI-based smoking cessation intervention study. We employed a multifaceted evaluation plan to assess fidelity and to understand whether the nurse care managers

delivered the targeted treatment, were competent to delivery it, and delivered the treatment as intended. We used a theoretical model as the basis for designing the MI-based intervention which included both smoking cessation curricula and weekly MI telephone counseling. The smoking cessation curricula were written as if a participant was moving through the stages of change. However, participants could always indicate that they were not ready to make a change. The nurse care managers also matched MI responses to the participant's stage of change during weekly MI counseling calls by listening for, eliciting, and responding to change talk.

According to Miller and Rollnick, MI is "simple but not easy [27] and like many other skill-based practices, providers need to be trained to certain established thresholds of competency in order to use MI to reliably produce positive effects [30]. The assessment and monitoring of training fidelity is crucial whether it is used in research or in a real-world setting even though training and coaching can be intensive and time consuming. Booster training sessions also have been shown to significantly increase adherence to MI skills and spirit [29]. We supported the nurse care managers in the current study with direct observation, coaching, and quarterly booster sessions to maintain fidelity and improve their MI skills [17] and were able to show the nurses were adherent to treatment delivery.

Two key components appear to be the facilitators of change in a MI intervention. These are developing a strong working relationship and strategically reinforcing and eliciting change language from the patient [28,30]. By measuring satisfaction, we learned that the participants developed a trusting relationship with nurse care managers. Participants felt the nurse care managers listened carefully, were respectful, and were comfortable talking with their nurse. Participants also stated they were highly satisfied with the MI-based smoking cessation curricula and felt it stimulated their thinking to make a change to in their smoking. Participant performance was evaluated throughout the intervention in both the written curricula and the MI counseling calls.

There were several limitations related to assessing and monitoring treatment fidelity. We did not audiotape participants' MI telephone interactions to record treatment content and dosage. We also did not evaluate treatment fidelity in the control group. Therefore, we are unable to comment on any deviations from our treatment protocol or if the control group received any active treatment ingredient. The self-reported checklist used by the nurse care managers to identify MI skills during each counseling call did not provide the nurses an opportunity to identify MI non-adherent communication. Finally, participants chose when and how to participate in the intervention. At times, participants were unavailable for their weekly MI call and they did not complete the Enhanced PTSD home telehealth program on a daily basis. As a result, it is unclear if the treatment dose was consistent across all participants because they did not always engage in the intervention as originally intended.

## Conclusion

We demonstrated treatment fidelity of a MI-based smoking cessation intervention by designing a study that mapped to a theory and trained nurse care managers to delivery MI. Furthermore, participants' demonstrated receiving and acting on the information.

Having conversations with patients about health behavior change is a common occurrence in today's practice environment. Implementation of MI necessitates monitoring fidelity while honoring patients' autonomy. The results of this study can help to guide translating smoking cessation research into practice in this hard to treat population.

## Acknowledgement of VA Research Support

This material is based upon work supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development - *Nursing Research Initiative which is administered by the Veterans Health Administration Department of Health Services Research & Development.*

**Disclaimer:** The contents of this article do not represent the views of the Department of Veterans Affairs or the United States Government.

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