

INSURANCE FOR AN INTERVENTION:

Testing the Treatment Fidelity of a Behavioral Intervention

Susan Benson, DNP, APRN

Catherine Battaglia, PhD, RN

Paul Cook, PhD

Objective 1

The learner will be able to list 3 factors the practitioner/researcher needs to consider when choosing a behavioral intervention such as motivational interviewing.

The feasibility study will serve to illustrate the objective.

Needs of study population

Veterans have a high rate of smoking

SMOKING	RATE
US population	20.9 % (McFall et al., 2007)
Soldiers 18-24 yrs Returning from Iraq & Afghanistan 20% with PTSD/MD	42% (Fu, 2008) Even 50 % higher than non-deployed military (Rand, 2008)
Veterans (no PTSD Dx)	28 % (McFall et al., 2005)
VA enrolled vets	30 % (McFall et al., 2005)
Veterans with PTSD	55 – 63 % (McFall et al., 2007)



Hyper arousal and anger

results in being angered easily and “hair trigger tempers” and “bunkering down” – includes avoiding caregivers

POST-TRAUMATIC STRESS DISORDER

- Recurring intrusive recollection of the traumatic event
- Persistent avoidance of stimuli associated with the trauma or numbing of general responsiveness
- Persistent symptoms of increased arousal -- physiological hyper-reactivity

All rights reserved © 2009 Bruce D. Perry

Smoking worsens
PTSD symptoms

(Fu et al., 2007)

Need an intervention
that:

Does not arouse
anger

Can be delivered to
the patient at home

Let patient choose
amount of contact

A New Way of Being with Patients

MI definition: Therapeutic style that enhances readiness for change by helping clients explore and resolve ambivalence. (Hettema, Steele, & Miller, 2005)

“MI Principles

-  - **optimistic collaboration between practitioner and client**
-  - **evokes client intrinsic motivation for change & commitment talk**
-  - **respects client autonomy and choice**
(Rollnick, Miller & Butler, 2008)
-  **Non-confrontational, so a good match for veterans with PTSD**
(Hettema, Steele, & Miller, 2005)

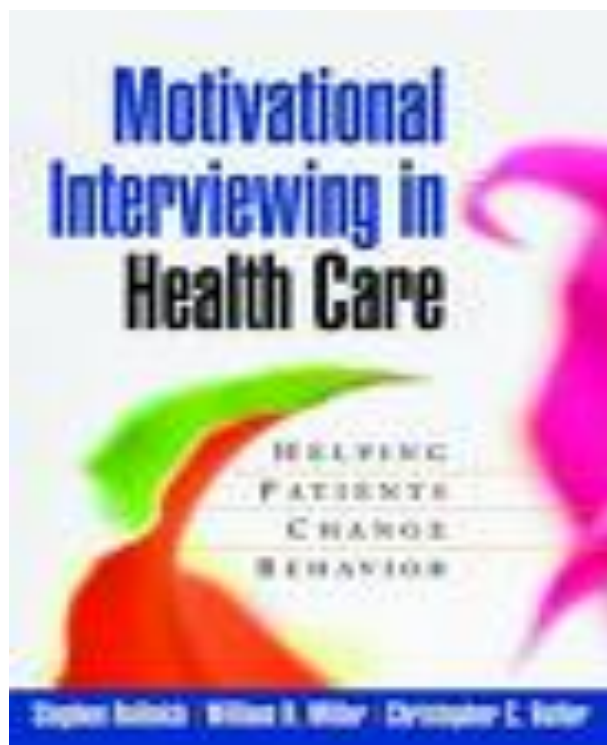
MI increases readiness to make health behavior change



Stages of Change

Prochaska – Cancer Prevention
Research Center definition

Skills of the practitioners -



Historically, MI used for addictions - trained therapists.

In the last 20 years, smoking cessation moved into the public health/community settings and is often delivered by physician or other provider; not trained therapists.

MI in Health Care is especially **written for primary care givers** and book can be used as a manual for counseling

Rollnick, Stephen, Miller, William R. & Butler, Christopher C. (2008). *Motivational Interviewing in health care; helping patients change behavior*. New York, NY: The Guildford Press.



MODES OF DELIVERY: TELEHEALTH COMES TO EACH VETERAN IN THEIR HOME



Phone Counseling



**Weekly counseling (12 weeks) by
study nurse to customize MI to
the veteran**

Health Buddy®



90 sessions of MI text for 90 days



Objective 2

The learner will be able to discuss the importance of measuring treatment fidelity for a behavioral intervention.

The feasibility study will serve to illustrate the objective.

Intervention = Stage-based MI

“When a counseling style is hypothesized to be the critical factor and is treated as the independent variable, it is all the more important to document that the *treatment as delivered did, in fact, represent that style with fidelity.*”

William R Miller , 2001

Only 3.5% of studies that have a behavioral intervention report *Treatment Fidelity* measures.

Lack of Treatment Fidelity impacts:

- **Internal validity**
- **External validity**
- **Effect size**
- **Power**
- **Comparative Effective Research (CER) in meta-analysis of behavioral intervention studies**
- **Use of MI as an intervention in future studies**

Objective 3

The learner will be able to identify 5 guidelines of Treatment Fidelity and discuss these as illustrated in the pilot feasibility study. In 1998, Behavior Change Consortium was formed as trans-National Institutes of Health to foster translational health behavior change research.

DESIGN of behavioral Intervention

TRAINING of Interventionists

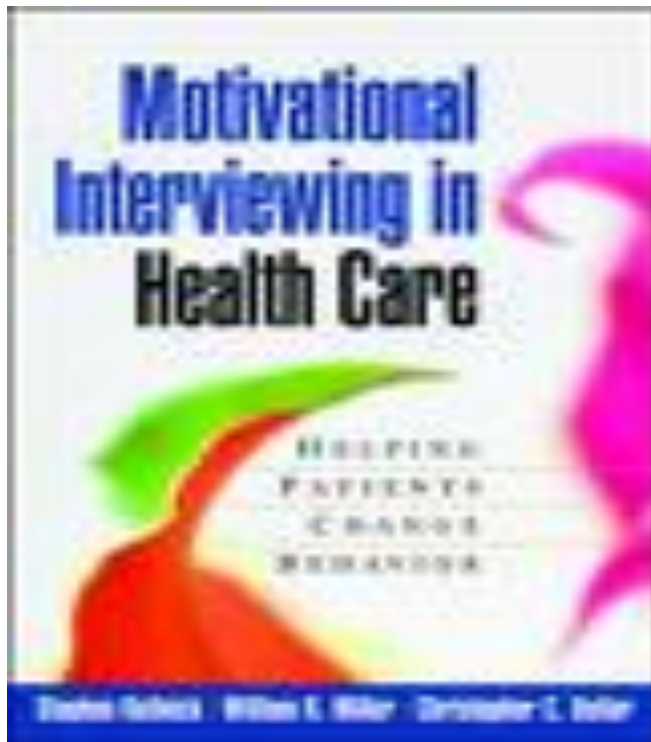
DELIVERY of Intervention

RECEIPT of Intervention by Client

ENACTMENT of Intervention behavior by Client

DESIGN of behavioral Intervention

GUIDELINE: The interventions utilized specified theoretical concepts and were manifested through a clinical process.



Prochaska & Norcross, 2001

DESIGN for clinical process

- **Training manual** – stage based MI –
 - used to create Health Buddy® text
 - used for weekly counseling
- **Smoking cessation library** in electronic, telehealth format – 90 units
 - State of change assessment – every 28 days
 - Current history survey – every 7 days – quit? # of cigs?
- **Satisfaction surveys (2)**
 - Patient Satisfaction with MI Health Buddy® Content
 - Patient Satisfaction with MI Counseling
- **Weekly counseling template**
 - Fidelity checklist
 - Dose data

All designs were validated by experts as being true to selected theoretical concepts

TRAINING of Interventionists

GUIDELINE: The measures for Treatment Fidelity aim to ensure that the interventionists have satisfactorily acquired a new skill or have been trained to deliver the intervention to the study participants.

Initial training – 2 days with certified MI trainer. Notes put into manual. PI, not specialized therapist, had beginning level of competency.

Ongoing support to prevent “drift” by SR on almost weekly basis and included affirmation, feedback, and direct audio observation. No gold standard MI skill code.

Weekly template (fidelity checklist) provided log of self reported MI behaviors.

DELIVERY of Intervention

GUIDELINE: Processes were needed to monitor and improve delivery of the intervention so that it was delivered as intended.



12 weeks of counseling



Designed Dose:

90 sessions of Health Buddy[®] for 90 days

RECEIPT of Intervention by Client

GUIDELINE: Receipt refers to the extent the patient's speech or behavior endorsed the increased level of motivation which could be quantified based on stage of change.



Weekly counseling template reports MI process and self reports MI consistent behaviors. Study nurse can hear patient strategies to change.



Health Buddy[®] gathered data:

1. the veteran's readiness scores
2. stage of change stratification
3. verbal commitment or behavioral strategy for change

	MI	MI	MI	MI	MI	MI
1. I understand the benefits of MI and how it works.						
2. I feel comfortable talking to my counselor about my health.						
3. I am confident in my counselor's advice.						
4. I am satisfied with the care I am receiving.						
5. I am satisfied with the way my counselor communicates with me.						
6. I am satisfied with the way my counselor listens to me.						
7. I am satisfied with the way my counselor explains things to me.						
8. I am satisfied with the way my counselor helps me make decisions.						
9. I am satisfied with the way my counselor respects my privacy.						
10. I am satisfied with the way my counselor respects my beliefs and values.						
11. I am satisfied with the way my counselor respects my autonomy.						
12. I am satisfied with the way my counselor respects my dignity.						
13. I am satisfied with the way my counselor respects my right to refuse treatment.						
14. I am satisfied with the way my counselor respects my right to give or withhold consent.						
15. I am satisfied with the way my counselor respects my right to be informed.						
16. I am satisfied with the way my counselor respects my right to participate in decisions.						
17. I am satisfied with the way my counselor respects my right to be heard.						
18. I am satisfied with the way my counselor respects my right to be treated with respect.						
19. I am satisfied with the way my counselor respects my right to be treated with kindness.						
20. I am satisfied with the way my counselor respects my right to be treated with compassion.						

Patient Satisfaction with MI counseling and Patient Satisfaction with Health Buddy[®] surveys gather veteran's perception of what it was like to a recipient of the MI interventions.

	MI	MI	MI	MI	MI	MI
1. I understand the benefits of MI and how it works.						
2. I feel comfortable talking to my counselor about my health.						
3. I am confident in my counselor's advice.						
4. I am satisfied with the care I am receiving.						
5. I am satisfied with the way my counselor communicates with me.						
6. I am satisfied with the way my counselor listens to me.						
7. I am satisfied with the way my counselor explains things to me.						
8. I am satisfied with the way my counselor helps me make decisions.						
9. I am satisfied with the way my counselor respects my privacy.						
10. I am satisfied with the way my counselor respects my beliefs and values.						
11. I am satisfied with the way my counselor respects my autonomy.						
12. I am satisfied with the way my counselor respects my dignity.						
13. I am satisfied with the way my counselor respects my right to refuse treatment.						
14. I am satisfied with the way my counselor respects my right to give or withhold consent.						
15. I am satisfied with the way my counselor respects my right to be informed.						
16. I am satisfied with the way my counselor respects my right to participate in decisions.						
17. I am satisfied with the way my counselor respects my right to be heard.						
18. I am satisfied with the way my counselor respects my right to be treated with respect.						
19. I am satisfied with the way my counselor respects my right to be treated with kindness.						
20. I am satisfied with the way my counselor respects my right to be treated with compassion.						

ENACTMENT of Intervention health behavior change by Client

GUIDELINES: Enactment refers to how and the extent to which the veteran is performing the behavioral skill and using cognitive strategies.

Enactment data includes:

- 1. number of cigarettes smoked in last 24 hours**
- 2. self reported smoking status**
- 3. quit attempts**





Study population Characteristics

Number	11 veterans
Age	Mean 53.6 years (26-65)
Gender	73% male, 27% female
Ethnicity	African American=4, Hispanic=2, Caucasian=4, Other=1
Marital Status	45.4% married, 45.4% divorced
Lives alone	Yes=3, No=8
Education	82% with post secondary education
Employment	91% unemployed, 1 employed
Stage of Change	Precontemplation = 1, Contemplation=4 Preparation = 6

Delivery Results - DOSE




WEEKLY Counseling calls by study nurse

Design Dose: 1 call/12 weeks = (132 total calls)

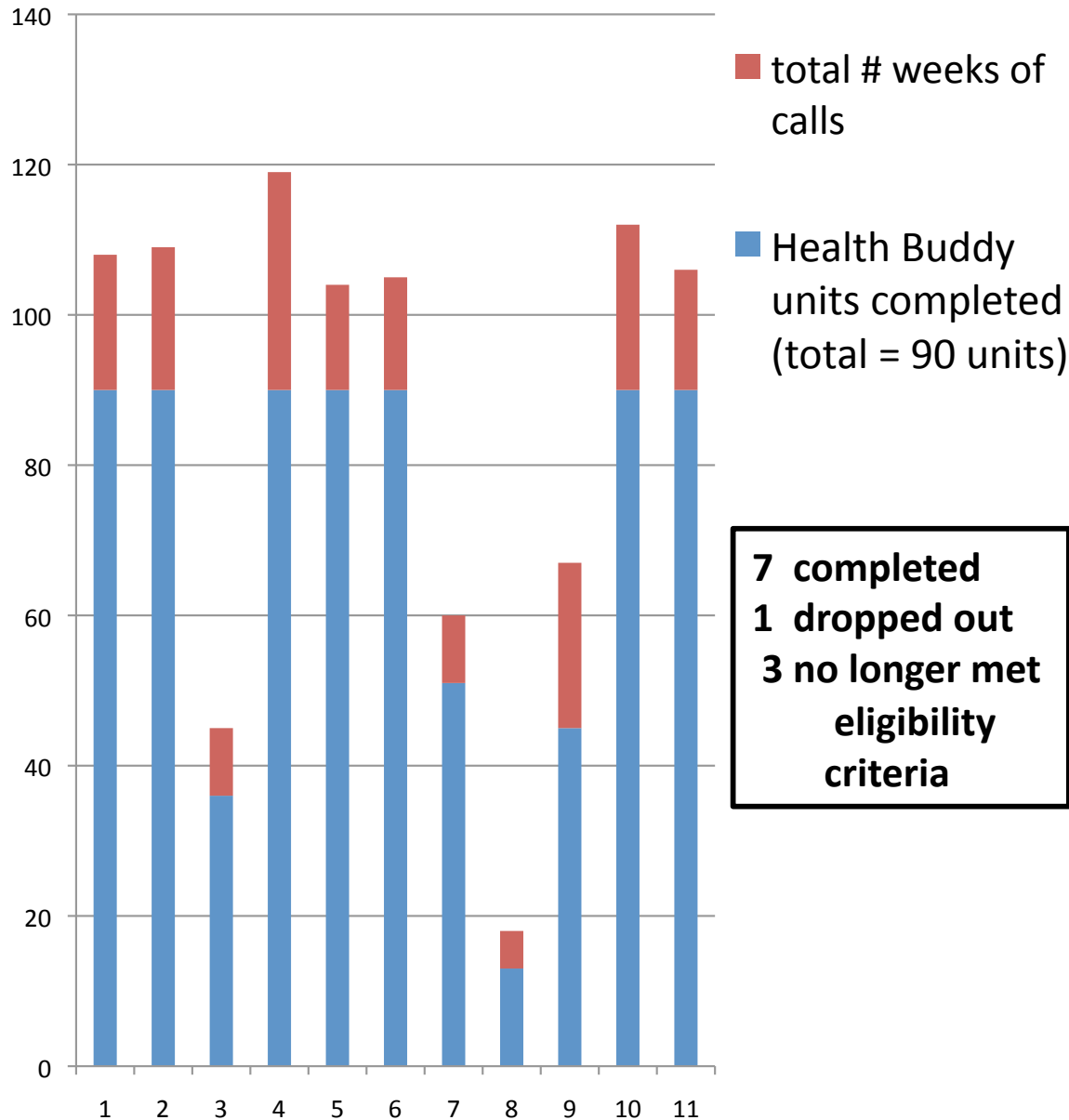
-  Total calls = 140 completed calls of 220 attempted calls (64% completion rate)
-  Total average call length/study/client = 21.03 minutes
-  Average minutes per veteran = 273.36
-  Average number of calls/veteran = 12.727

HEALTH BUDDY®

Design Dose: 90 sessions in 90 days

-  Total % of Health Buddy® sessions completed in the study = 70.8% (n=11)
-  Average time to complete Health Buddy® = 110 days
-  Average time for those who completed = 128

Delivery Results



The veteran
dosed
themselves
at their own
pace...and
they exercised
choice...to dose
themselves

4. Receipt-SATISFACTION SURVEYS

GUIDELINE: Receipt refers to the extent the patient's speech or behavior endorsed the increased level of motivation which could be quantified based on stage of change.

SATISFACTION WITH MI COUNSELING N=9	MEAN	RANK
5. I felt the nurse took time to listen to me.	4.9	1 and 2
18. I sensed that the nurse felt that changing a habit, like smoking, is always possible.	4.9	1 and 2
4. I felt comfortable talking with the nurse.	4.7	3 and 4
19. I valued my relationship with my study nurse.	4.7	3 and 4
2. My freedom to smoke was respected whether I smoked or chose to quit.	4.6	5-11
13. The nurse and I were able to talk in a calm manner.	4.6	5-11
6. The nurse asked me what I wanted to discuss about my smoking.	4.6	5-11
12. When I talked, the nurse often interrupted me. (reverse scoring – between rarely & never)	4.6	5-11
13. Now I know the reasons I want to make changes to my smoking.	4.6	5-11
14. When and if I choose to do something different with my smoking, the nurse would support my change and help me plan.	4.6	5-11
20. If and when I needed any kind of help, I knew who to call.	4.6	5-11
9. I learned about taking better care of my health by reducing the risks of smoking.	4.4	12-14
10. The nurse first asked me what I knew about smoking before she shared information with me.	4.4	12-14
15. The nurse asked me what I knew about medications that could help me quit smoking.	4.4	12-14
16. Some of the information I received helped me open my eyes to the effects of smoking.	4.3	15
1. At first, the nurse spent time getting to know me.	4.2	16-18
11. I have talked with my study nurse about what I liked and disliked about my smoking.	4.2	16-18
17. The nurse invited me to imagine myself as a former smoker.	4.2	16-18
16. When the nurse asked how sure I was that I could change my smoking on a scale of 1-10, I knew what my answer was.	4.1	19
7. The nurse seemed to think she knew what was best for me. (reverse scoring – between often & sometimes)	2.7	20

Patient Satisfaction with Health Buddy MI Content Survey			MEAN SCORE
1	On a scale of 1-10, I rate my readiness to consider making changes to my smoking. 8,9,10=2 5,6,7=1 1,2,3,4=0	0-2	1.75
2	HB gave me new info, but respected my choice to smoke or not smoke. Yes =1, No=0	0-1	1
3	HB questions helped me feel I might have the desire to quit. Yes =1, No=0	0-1	1
4	HB helped me see how I might be able to quit. Yes =1, No=0	0-1	1
5	HB helped me see my needs or reasons to quit. Yes =1, No=0	0-1	1
6	HB helped me consider a commitment to changing something about my smoking. Yes =1, No=0	0-1	1
7	HB helped me take one step to change my smoking. Yes =1, No=0	0-1	1
8	HB leads me to see myself as a: -former smoker=2, -a smoker who smokes fewer cigarettes=1, -a smoker who makes no changes=0	0-2	1.2
9	HB prompted me to talk with study nurse. Yes =1, No=0	0-1	1
1 0	HB told me to quit smoking. Yes =1, No=0	0-1	.5
			21 15.9

Receipt/Enactment RESULTS

Collected every 28 days	Pre Contemplation Stage 1	Contemplation 2	Preparation 3	Action 4	# cigarettes Collected every 7 days
T 1 N-11	1	4 SOC mean = 2.54	6		45.5% <10 cig 54.5% >10 cigs Mean = 2.54
T Last Last time stage of change was entered N=10		3 SOC mean = 2.9	5	2	20% 0 cigs 30% <10 cigs 50% >10 cigs Mean = 2.27
	No adverse events	<i>Significant correlation between Time Last Stage of Change and Time Last of cigarettes smoked per day (R = 0.6767; P = 0.0316)</i>			Key: 0 cigs = 1 <10 cigs = 2 >10 cigs = 3 >20 cigs = 4

Summary of Treatment Fidelity

Guideline	Results	Treatment Fidelity Measure
Design	<p>Specific theory used-manual derived from-validated by experts- Δ # cigs collected daily-need 90 units in 90 days-need to consider the stages of change on each weekly call</p>	Highest
Training	<p>Miller endorsed learn-to-learn training-ongoing support-used fidelity checklist-provided ongoing support Δ use MI skill code to prevent 'drift'</p>	More than adequate
Delivery	<p>Manual increases treatment quality-call length adequate- Δ veteran needs to do 90 sessions in 90 days - veteran choice to be available for weekly call</p>	More than adequate
Receipt & Enactment	<p>Patient satisfaction high-finding is above average. Δ Smoking cessation goal needs longer time frame-reassess at 6 months in RCT</p>	High

CONCLUSIONS

The stage-based MI interventions were found to satisfy the fidelity requirements which **insured that the intervention was delivered as intended**.

The integrity and validity of the MI interventions used in the pilot study are supported, increasing their relevance as novel translational strategies to deliver evidence-based smoking cessation interventions to veterans with PTSD.

These fidelity measures uphold the integrity of MI so inferences can be drawn about the relationship between stage-based MI treatment interventions and health behavior change outcomes.

Will be used in 4 year RCT now in progress.

REFERENCES

- American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2000.
- Bellg, Albert, J., Borrelli, Belinda, Resnick, Barbara, Hecht, Jacki, Minicuci, Daryl Sharp, Ory, Marcia, et.al. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and Recommendations from the NIH Behavior Change Consortium. *Health Psychology*, 23(5), 443-451.
- Cancer Prevention Research Center. Retrieved April 14, 2009, from <http://www.uri.edu/research/cprc>
- Dunn, Chris, Deroo, Lisa & Rivara, Frederick P. (2001). The use of brief interventions adapted from motivational interviewing across behavioral domains: a systematic review. *Addiction*, 96, 1725-1742.
- Fu, Steven. (2008). Research, marketing campaigns promote smoking cessation within DoD and VA. *U.S. MEDICINE Compendium of Federal Medicine*. 73-77.
- Fu, Steven S., McFall, Miles, Saxon, Andrew J., Beckham, Jean C., Carmody, Timothy P., Baker, Dewleen G., & Joseph, Anne M. (2007). Post-traumatic stress disorder and smoking: A systematic review. *Nicotine & Tobacco Research*, 9 (11), 1071-1084.
- Hettema, Jennifer, Steele, Julie, & Miller, William R. (2005). Motivational Interviewing. *Annu. Rev. Clini. Psychol.* 1, 91-111.
- McFall, M, Saxon, A.J., Thaneemit-Chen, S., Smith, Mark W., Joseph, Anne M., Carmody, Timothy P., Beckham, Jean C., Malte, Carol A., Vertrees, Julia E., Boardman, Kathy D., & Lavori, Philip W. (2007). Integrating smoking cessation into mental health care for post-traumatic stress disorder. *Society for Clinical Trials*, 4(2), 178-189.
- McFall, M., Saxon, A.J., Thompson, C.E., Yoshimoto, D., Malte, C., Strats-Troster, K., Kanter, E., Zhou, X., Dougherty, C. M., & Steele, B. (2005). Improving the rates of quitting smoking for veterans with posttraumatic stress disorder. *American Journal of Psychiatry*, 162:7.

Miller, William R. (2001). Commentaries: When is it motivational interviewing? *Addiction, 96*, 1770-1771.

Perepletchikova, Francheska, Treat, Teresa A. & Kazdin, Alan E. (2007). Implementation of treatment integrity scale: Rater Manual. Obtained from Francheska Perepletchikova upon request.

Perepletchikova, Francheska, Treat, Teresa A. & Kazdin, Alan E. (2007). Treatment integrity in psychotherapy research: Analysis of the studies and examination of the associated factors. *Journal of Consulting and Clinical Psychology, 75(6)*, 829-841.

Prochaska, J. O. (2005). Health behavior change research: A consortium approach to collaborative science. *Annals of Behavioral Medicine, Vol. 29, Special Supplement*, 4-6.

Prochaska, J.O. & Norcross, J. C. (2001). Stages of change. *Psychotherapy, Vol. 38, No. 4*.

Rand News Release. (2008). One in five Iraq and Afghanistan veterans suffer from PTSD or major depression. Retrieved April 12, 2009, from <http://www.rand.org/news/press/2008/2008/04/17>.

Resnick, Barbara, Bellg, Albert J., Borrelli, Belinda, DeFrancesco, Carol, Breger, Rosemary, Hecht, Jacki, et al. (2005). Examples of Implementation and Evaluation of Treatment Fidelity in the BCC Studies; Where We Are and Where We Need To Go. *Annals of Behavioral Medicine, Vol. 29, Supplement*.

Rollnick, Stephen, Miller, William R. & Butler, Christopher C. (2008). *Motivational Interviewing in health care; helping patients change behavior*. New York, NY: The Guildford Press.



This study is the result of work supported with resources and the use of facilities at the Denver VA Medical Center.