

Award Number: W81XWH-05-2-0015

TITLE:

Facilitating smoking cessation and preventing relapse in primary care: Minimizing weight gain by reducing alcohol consumption.

PRINCIPAL INVESTIGATOR:

Mark B. Sobell, Ph.D., ABPP
Col. Alan Peterson, Ph.D.
Linda C. Sobell, Ph.D., ABPP
Maj. Christopher Hunter, Ph.D.
Maj. Christine Hunter, Ph.D.)

CONTRACTING ORGANIZATION:

Nova Southeastern University
Fort Lauderdale, Florida 33314

REPORT DATE:

January 2010

TYPE OF REPORT:

Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

X Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

| | | | | | |
|--|-------------------------|---------------------------------|---|--|---|
| 1. REPORT DATE (DD-MM-YYYY) 01-01-2010 | | 2. REPORT TYPE Annual | | 3. DATES COVERED (From - To) 27 Dec 08 - 26 Dec 09 | |
| 4. TITLE AND SUBTITLE Facilitating smoking cessation and preventing relapse in primary care: Minimizing weight gain by reducing alcohol consumption | | | | 5a. CONTRACT NUMBER | |
| | | | | 5b. GRANT NUMBER W81XWH-05-2-0015 | |
| | | | | 5c. PROGRAM ELEMENT NUMBER | |
| 6. AUTHOR(S) Mark B. Sobell, Ph.D. | | | | 5d. PROJECT NUMBER | |
| | | | | 5e. TASK NUMBER | |
| | | | | 5f. WORK UNIT NUMBER | |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Nova Southeastern University Fort Lauderdale, Florida 33314 | | | | 8. PERFORMING ORGANIZATION REPORT NUMBER | |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materials Command Fort Detrick, Maryland 21702-5012 | | | | 10. SPONSOR/MONITOR'S ACRONYM(S) | |
| | | | | 11. SPONSOR/MONITOR'S REPORT NUMBER(S) | |
| 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited | | | | | |
| 13. SUPPLEMENTARY NOTES | | | | | |
| 14. ABSTRACT A randomized controlled trial was conducted evaluating two smoking cessation interventions for use in primary care settings. Both included the nicotine patch and bupropion (Zyban) if desired. The Brief Counselor Assisted Program (BCAP; 2 in person and 2 telephone counseling sessions) combined motivational interviewing and behavioral counseling with an emphasis on reducing alcohol consumption to minimize weight gain. Participants in the Self-Guided Program (SGP) received a pamphlet discussing change strategies for tobacco cessation, minimizing weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up were randomized to receive no further counseling or an in person booster session focusing on obstacles to change. There were 317 participants, 158 in BCAP and 159 in SGP. Follow-up was completed on 92.1% of participants at 3-months, 90.85% at 6-months, and 88.33% at 12-months. Of those found at 3-months, 46.8% of BCAP and 34.4% of SGP participants were non-smokers (p=.031). The difference lost significance when an intent to treat analysis was conducted, but more sensitive analyses (e.g., logistic regression) may still find the difference to be significant. Weight loss and alcohol reduction changes at 3 months were in the predicted direction, but will need to be statistically evaluated by multivariate methods. The current focus is on statistical analyses and dissemination of findings. | | | | | |
| 15. SUBJECT TERMS smoking cessation, weight, alcohol, stepped care, primary care | | | | | |
| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT UU | 18. NUMBER OF PAGES 15 | 19a. NAME OF RESPONSIBLE PERSON USAMRMC |
| a. REPORT U | b. ABSTRACT U | c. THIS PAGE U | | | 19b. TELEPHONE NUMBER (include area code) |

Table of Contents

| | <u>Page</u> |
|-----------------------------------|-------------|
| Introduction..... | 4 |
| Body..... | 4 |
| Key Research Accomplishments..... | 9 |
| Reportable Outcomes..... | 9 |
| Conclusion..... | 10 |
| References..... | 10 |
| Appendices..... | 10 |

Annual Report Award Number W81XWH-05-2-0015

Introduction

This report summarizes progress made on Award Number W81XWH-05-2-0015 for the third project year, from December 27, 2008 through December 26, 2009. The project, "Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption," involves developing and testing a brief smoking cessation intervention for use in primary care settings. The intervention is intended to help participants stop smoking cigarettes and stay quit by use of motivational interviewing, behavioral counseling and nicotine replacement therapy with an emphasis on reducing alcohol consumption as a strategy for minimizing weight gain related to smoking cessation. Participants are randomly assigned to one of two groups: a Brief Counselor Assisted Program (BCAP), or a Self-Guided Program (SGP), with the nicotine patch and bupropion (Zyban) available to all participants. Participants in the BCAP attend two 30-minute clinic appointments and have two counseling sessions by phone over a period of 8-10 weeks, where tobacco cessation skills are integrated with weight and alcohol reduction strategies. Participants in the SGP receive, in addition to the medication, a pamphlet discussing the most effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up, blocked by original group assignment, are randomized either to receive no further counseling or to attend one clinic booster session focusing on dealing with their individual obstacles to change. All participants are followed up for 12 months. The study addresses three research questions: (1) Does an alcohol reduction strategy designed to minimize weight gain produce higher smoking cessation rates than a control treatment? (2) Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse? (3) Does providing a stepped care intervention (booster) for participants who initially are unsuccessful at stopping improve long-term tobacco cessation rates?

Body

The original Statement of Work was itemized for each investigator and consultant and by necessity, therefore, included considerable redundancy. To make this report better organized and easier to follow, we first discuss progress made toward objectives shared among the investigators. Following that, individual Statements of Work will be presented. The project was approved for a two-year no cost extension in April, 2008.

During Project Year 5 our focus was on completing remaining treatment sessions for participants, continuing to gather follow-up data as specified in the research protocol, double entering and cleaning the large amount of data accumulated, making some initial presentations of preliminary analyses, and planning analyses and publications. Our final sample consists of was 317, with 158 in the BCAP group and 159 in the SGP group. To attain this sample we we had contact with 1,391 total individuals, and of those we screened 1,296 (48 were not screened because they first asked if we offered Chantix,

and when they found out we did not offer it they withdrew from consideration because they could receive Chantix through the smoking cessation program at the base Health and Wellness Center; 47 left initial contact information but never responded to repeated attempts to contact them). The major reasons for screening out were not enough alcohol consumption (549 of 961 total screenouts, or 57%), and wanted Chantix (42), followed by a variety of other reasons such as not wanting to be further contacted. Beside wanting Chantix, which could not be made available because it would have introduced a new medication midway through the trial and possible adverse side effects of Chantix were under investigation at the time, the major reason for screening out was not meeting the alcohol consumption criteria (≥ 4 drinks per week). This was unexpected because, as stated in our original grant proposal, the 2002 DoD Survey of Health-Related Behaviors among Military Personnel reported that, among other things, more than 40% of DoD personnel drank 5 or more drinks at least monthly. In screening for our project, however, more than half of the screenouts resulted from insufficient alcohol consumption. As noted previously, during screening there may have been underreporting of alcohol consumption because our informed consent form was required to include the statement “complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.” This is in contrast to surveys for which respondents typically can remain anonymous. In any event, our final sample was smaller than we had wished but is adequate to test our group comparison.

A strong point of the implementation of the project is that our rate of retrieving data for follow-up has been excellent, especially for a large scale study. At 3-month follow-up, we obtained data on 92.10% of the participants, consisting of 94.97% of the BCAP group and 89.24% of the SGP. Of those found, 46.8% of the BCAP group and 34.4% of the SGP group were non-smokers at three months. This difference was statistically significant ($p = .031$) when evaluated for the 92.1% found for follow up, but it was no longer significant ($p = .095$) when a bare bones intent-to-treat analysis was performed (i.e., every case for which data were not found was considered to be a failure). We anticipate that the finding may still be significant when more sensitive analyses such as logistic regression analyses are conducted as the inclusion of other variables is likely to reduce the error variance somewhat. We also have conducted some very preliminary analyses of changes in weight and in drinking at three months follow-up. These found that the SGP group had gained a mean of 2.22 pounds while the BCAP group had gained a mean of 0.84 pounds. Likewise, the SGP group had reduced its drinking a mean of 2.86 drinks per week (29.1% of baseline) while the BCAP group had reduced its drinking by a mean of 4.29 drinks per week (41.7% of baseline). Both of these differences are in the expected direction but the time X group interaction failed to reach significance in our initial analyses. For weight, there was a significant time effect (baseline to 3-mos), $F(1,286) = 8.05$, $p=.005$, but no interaction with condition $F=2.63$, $p=.106$. Similarly, for drinks per week there was a significant time effect (baseline to 3-mos), $F(1,289) = 73.79$, $p<.001$, but no interaction with condition $F=2.92$, $p=.089$. Again, more sensitive analyses may yield significant differences.

The follow-up data collection was just recently completed, and we continued to have excellent data retrieval rates. For the 6-month follow-up, data were collected from 91.14% of the BCAP group and 90.57% of the GSP group, for an overall rate of 90.85%. For the 12-month follow-up, data were collected from 89.24% of the BCAP group and 87.42% of the GSP group, for an overall rate of 88.33%. Often studies only retrieve data on 70%-80% of cases, so our follow-up rate is exemplary.

During the reporting period initial findings were presented in a poster presentation at the annual meeting of the Research Society on Alcoholism in June, 2009, and at the Military Health Research Forum in September, 2009. At the Military Health Research Forum the findings were also presented in a short PowerPoint presentation. Our emphasis during Project Year 6 will be on data analysis and reporting. Beyond the group comparison there are several other central analyses to conduct (e.g., examining weight gain and alcohol reduction) as well as several ancillary but important analyses (e.g., the possible role of depression as a moderating variable). To facilitate the analyses and reporting we are presently preparing a request or modification to our award that will only require internal re-budgeting. Some of what is proposed will include a small revision of the Statement of Work, but that revision will not occur until our proposed modification is approved. Thus, the following Statement of Work is the one approved in May, 2008 with added entries for Dr. Ann Hryshko-Mullen who was appointed Chief of the Clinical Health Psychology Service at Wilford Hall Medical Center during the course of the project.

The following completes the body of this report in a more standard format, reporting achievement of benchmarks in the Statement of Work.

Mark B. Sobell, Ph.D.

Nova Southeastern University

1. Hire project team members: Y01 M03 Completed
2. Finalize formal protocol, manuals: Y01 M09 Completed
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
4. Monitor compliance with, and integrity of, the treatment protocols: Completed
5. Monitor the quality control of all the data collection required for the project: Completed
6. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
7. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: On-going
8. Develop and implement plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Completed
9. Generate the final manuscripts of study results: Y05-06 M12 Ongoing

10. Disseminate results and materials produced by the study: Y05-06 M12 Ongoing

Linda C. Sobell, Ph.D.

Nova Southeastern University

1. Hire project team members: Y01 M03 Completed
2. Finalize formal protocol, manuals: Y01 M09 Completed
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
4. Train personnel in project intervention: Y01 M12 Completed
5. Monitor compliance with, and integrity of, the treatment protocols: Completed
6. Monitor the quality control of all the data collection required for the project: Completed
7. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
8. Oversee the conduct of project follow-up: Y04-05 M12 Completed
9. Generate the final manuscripts of study results: Y05-06 M12 Ongoing
10. Disseminate results and materials produced by the study: Y05-06 M12 Ongoing

Lt Col Alan Peterson, Ph.D.

Wilford Hall Medical Center

1. Review/coordinate IRB approvals: Y01 M09 Ongoing
2. Hire project team members: Y01 M03 Completed
3. Secure office space for WHMC grant staff: Y01 M09 Completed
4. Finalize formal protocol, manuals: Y01 M09 Completed
5. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
6. Coordinate the training of phone counselors this project: Y01 M12
7. Provide weekly clinical supervision of phone counselors and monitor compliance with, and integrity of, the treatment protocols: Completed
8. Monitor the quality control of all the data collection required for the project: Completed
9. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
10. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: On-going
11. Supervise WHMC military and grant staff in assessment and intervention procedures: Y04 M12 Completed
12. Assist in developing and implementing a plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Completed
13. Generate scientific conference presentations of study preliminary results: Y05-06 M12 Ongoing
14. Review/coordinate IRB amendments and annual reports: Y05-06 M12 Ongoing

15. Generate the final manuscripts of study results: Y05-06 M12 Ongoing
16. Disseminate results and materials produced by the study: Y05-06 M12 Ongoing

Maj Christopher Hunter, Ph.D.

Wilford Hall Medical Center

1. Revise intervention manuals: Y01 M09 Completed
2. Assist in finalization of assessment instruments Y01 M09 Completed
3. Assist in training of military and grant staff to work in the primary care setting Y01 M09 Completed
7. Generate manuscripts of study results: Y05-06 M12 Ongoing

Maj Christine Hunter, Ph.D.

Wilford Hall Medical Center

1. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed
2. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 1. Completed
3. Assist in training of telephone counselors: Y01 M12 Completed
Assist in weekly supervision of phone counselors: Completed
4. Generate manuscripts of study results: Y05-06 M12 On-going

Capt Jeffrey Goodie, Ph.D.

Wilford Hall Medical Center

1. Finalize formal protocol manuals: Yo1 M09 Completed
2. Assist in training staff to work in primary care setting: Y012 M12 Completed
3. Generate manuscripts of study results: Y05-06 M12 Ongoing

Keith Haddock, Ph.D.

University of Missouri, Kansas City

1. Provide consultation on development of data base for study and computerize data entry: Y01 M12 Completed
2. Oversee entry of project data, plan for statistical analyses: Y04-05 M12
3. Conduct statistical analyses, consult on interpretation of findings: Y04-05 M12
4. Generate manuscripts of study results: Y05-06 M12

Carlos Poston, Ph.D.

University of Missouri, Kansas City

1. Provide consultation on development of data base for study and computerize data entry: Y01 M12 Completed
2. Oversee entry of project data, plan for statistical analyses: Y04-05 M12
3. Conduct statistical analyses, consult on interpretation of findings: Y04-05 M12
4. Generate manuscripts of study results: Y05-06 M12

Timothy Baker, Ph.D.

University of Wisconsin, Madison

1. Provide consultation on smoking cessation treatment protocol and development of data base: Y01 M12 Completed
2. Help monitor integrity of study implementation: Y03 M06 Not needed
3. Provide consultation on data analysis strategies Y04 M12 Ongoing
4. Provide consultation on interpretation of results: Y04 M12 Ongoing

Lt.Col. Ann Hryshko-Mullen, Ph.D. (Brought forward from the January 2009 annual report)

Dr. Hryshko-Mullen is a Wilford Hall Medical Center staff member added to the research team after the Permanent Change of Station (PCS) of Capt. Jeffrey Goodie, Ph.D. in August 2005. Dr. Mullen is the Chief of the Clinical Health Psychology Service at Wilford Hall.

1. Maintained Wilford Hall office space for all grant staff personnel: Completed
2. Coordinated with Lackland AFB Tobacco Cessation Program to limit any overlap or conflict with proposed study and ongoing Tobacco Cessation programs: Completed
3. Manuals: Completed
4. Assist in training staff to work in primary care setting: Completed
5. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6: Ongoing

Key Research Accomplishments.

- Achieved a very high data retrieval rate for follow-up (3-month follow-up, 92.10% of all participants; 6-month follow-up, 90.85% of all participants; 12-month follow-up, 88.33% of all participants).
- Analyses of 3-month outcomes based on data from the 92.10% of all participants found for follow-up showed that 46.8% of the experimental (BCAP) group and 34.4% of the control (SGP) group were non-smokers. This difference was statistically significant ($p = .03$) but when analyzed using a conservative intent-to-treat analysis (i.e., all cases not found for follow-up were assumed to be still smoking) the difference was not significant ($p = .095$).
- Weight loss and alcohol consumption reduction means were in the direction predicted by the study hypotheses but did not attain significance when analyzed in isolation. The control group gained a mean of 2.22 pounds while the experimental group gained a mean of 0.84 pounds. The control group reduced its drinking a mean of 2.86 drinks per week (29.1% of baseline) while the experimental group reduced its drinking by a mean of 4.29 drinks per week (41.7% of baseline). More sensitive analyses (i.e., including other factors) will further probe this potential mediation effect.

Reportable Outcomes

During the reporting period, two poster presentations and one oral presentation of project results occurred:

Sobell, M.B., Sobell, L.C., Peterson, A.L., Brundige, A., & Hryshko-Mullen, A. Using reduced alcohol consumption as a strategy to minimize weight gain when stopping smoking.

Poster presented at the annual meeting of the Research Society on Alcoholism. San Diego, CA., June 2009.

Sobell, M.B., Peterson, A. L., Sobell, L.C., Hunter, C.L., Hunter, C.M., Brundige, A., Goodie, J.L., & Mendoza, C. (2009). Smoking cessation: minimizing weight gain and preventing relapse by reducing alcohol consumption. Poster presented at the Congressionally Directed Medical Research Programs Military Health Research Forum, Kansas City, MI, September, 2009.

Sobell, M.B., Peterson, A. L., Sobell, L.C., Hunter, C.L., Hunter, C.M., Brundige, A., Goodie, J.L., & Mendoza, C. (2009). Smoking cessation: minimizing weight gain and preventing relapse by reducing alcohol consumption. Oral presentation at the Congressionally Directed Medical Research Programs Military Health Research Forum, Kansas City, MI, September, 2009.

Conclusions

Although the final sample size was less than our target our rates of retrieval of follow-up data have been excellent. Early evaluations of short-term outcomes (3-month) showed a significantly higher smoking cessation rate for the experimental (BCAP) group than the control (SGP) group when only the 92.10% of participants for whom follow-up data were gathered were included in the analyses. When participants for whom data were missing were considered to all be still smoking, the group difference was no longer significant, but this was largely because there was a higher follow-up rate for the experimental group than the controls. At 6-month and 12-month follow-ups the difference in find rates between the groups is much less so those analyses will be less affected when an intent-to-treat approach is used. Also, differences between the groups in terms of amount of weight gain and reduction in alcohol consumption were in the direction of the hypotheses but were not significantly different using isolated analyses. When these factors are combined in more sophisticated analyses such as logistic regression analyses and mediation and moderation analyses it is possible they will reach significance, as the error variance is likely to be greatly reduced. If significance is attained, the findings will add another tool to the arsenal in terms of ways to facilitate smoking cessation. This is especially important for the military where smoking affects readiness and where concern about weight gain related to smoking cessation can be an obstacle to attempting to stop smoking. In this regard, a number of materials developed for use in the experimental condition could be easily disseminated. An example of such an aid is included as an appendix. It is a chart that can be given to smokers that shows the number of calories typically contained in various types of popular alcoholic drinks.

References

See reportable outcomes. No journal articles at this time.

Appendices

Sobell, M.B., Sobell, L.C., Peterson, A.L., Brundige, A., & Hryshko-Mullen, A. Using reduced alcohol consumption as a strategy to minimize weight gain when stopping smoking. Poster presented at the annual meeting of the Research Society on Alcoholism. San Diego, CA., June 2009.



Using Reduced Alcohol Consumption as a Strategy to Minimize Weight Gain When Stopping Smoking

Mark B. Sobell¹, Ph.D., Linda Carter Sobell¹, Ph.D., Alan L. Peterson^{2,3}, Ph.D.,
Antoinette Brundige³, M.A., & Ann Hryshko-Mullen³, Ph.D.

1. Nova Southeastern University, 2. University of Texas Health Science Center at San Antonio, 3. Wilford Hall Medical Center



Introduction

- Concern about weight gain is a well-established barrier to smoking cessation.
- In the military, concern about weight gain after quitting is heightened because excessive weight can result in being unfit for service.
- This study targets smoking cessation and minimizing weight gain in patients seen in military primary care settings.
- A unique feature of this study is counseling to reduce alcohol consumption to minimize weight gain after smoking cessation.
- Reduction of alcohol consumption is also included as a treatment component because it is highly correlated with smoking relapse and may increase weight gain due to its relatively high caloric value.
- It is expected that participants counseled to reduce alcohol consumption to minimize weight gain will have higher smoking cessation rates and a lessened risk of relapse than participants who do not receive such counseling.

Design

- 317 eligible participants, blocked by gender, were randomly assigned to two groups.
- Those who had not stopped smoking at the 3-month follow-up, blocked by initial treatment condition, were randomly assigned to receive or not receive a booster session.
- Follow-up is for 1 year post-treatment.

3-Month Outcome

- At the 3-month follow-up, of the 92.1% of participants for whom data were available 40.0% were nonsmokers (7-day window):
 - BCAP = 46.8% Nonsmokers
 - PP = 34.4% Nonsmokers
- The above difference, on the basis of the 92.1% of participants found, is significant: χ^2 (df = 1, N = 292) = 4.63, $p = .031$.
- If an intent to treat analysis is performed and all missing participants are considered failures, the nonsmoking rates (BCAP = 41.8%; PP = 32.7%) no longer differ significantly: χ^2 (df = 1, N = 317) = 2.79, $p = .095$.

Treatment Conditions

1. Brief Counselor Assisted Program (BCAP):

Tobacco cessation procedures integrated with weight and alcohol reduction strategies, including nicotine replacement therapy (NRT) and Bupropion SR (Zyban). Two clinic sessions and two phone sessions over 8-12 weeks.

2. Pharmacotherapy plus Pamphlet (PP): Self-help pamphlet describing how to implement effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to deal with possible relapses. NRT and Bupropion SR provided.

- The **Booster session** focused on overcoming barriers to smoking cessation, and development of new quit and relapse prevention plans.

Participants

- Primary care clinics at Wilford Hall Medical Center (San Antonio, TX) are the primary source of participants.
- All participants are eligible military medical beneficiaries.
- Inclusion Criteria: ≥ 21 years of age, smoke a mean of ≥ 5 cigarettes/day for past year, consume a mean of ≥ 4 standard drinks/week, concerned about weight gain, plan to stay in area ≥ 1 year.
- Exclusion criteria: Pregnant, trying to become pregnant, breastfeeding; health conditions that contraindicate cessation medication; used weight loss medication within past 6 mos.; at base temporarily; recent or current major depression; DSM-IV alcohol use disorder; other medical contraindications

Participant Characteristics

| Variable | Group | |
|--------------------------------------|----------------|--------------|
| | BCAP (n = 158) | PP (n = 159) |
| Mean (SD) yrs age | 37.3 (13.1) | 37.6 (12.9) |
| % Male | 69.6 | 72.3 |
| % Married | 62.7 | 58.5 |
| % White/Caucasian | 72.2 | 68.6 |
| M (SD) yrs education | 13.7 (1.7) | 13.5 (1.8) |
| % Active duty | 63.3 | 64.8 |
| M (SD) Fagerström score | 3.7 (2.2) | 4.0 (2.1) |
| M (SD) yrs reg. smoker | 18.1 (12.9) | 18.7 (13.0) |
| % Health most important reason | 79.1 | 76.7 |
| M (SD) no. past quit attempts | 6.1 (6.0) | 5.9 (6.2) |
| % Definitely quit next 2 wks. | 44.9 | 47.8 |
| % Def. be nonsmoker in 6 mos. | 40.5 | 43.4 |
| % Def. quit next 6 mos. | 79.1 | 80.4 |
| M (SD) readiness quit (1-5) | 4.7 (.5) | 4.6 (.5) |
| M (SD) goal importance (0-100) | 81.8 (15.1) | 80.6 (15.4) |
| M (SD) goal confidence (0-100) | 82.2 (18.5) | 82.0 (19.3) |
| M (SD) concern weight gain (1-10) | 6.7 (2.9) | 6.7 (3.0) |
| M (SD) days ≥ 5 drinks past yr. | 19.9 (44.0) | 16.3 (34.4) |

Note: No differences were statistically significant

Follow-up Rates

| Found for 3-mo. follow-up: | 92.1% |
|----------------------------|-------|
| BCAP | 89.2% |
| PP | 95.0% |

Sobell, M.B., Peterson, A. L., Sobell, L.C., Hunter, C.L., Hunter, C.M., Brundige, A., Goodie, J.L., & Mendoza, C. (2009). Smoking cessation: minimizing weight gain and preventing relapse by reducing alcohol consumption. Poster presented at the Congressionally Directed Medical Research Programs Military Health Research Forum, Kansas City, MI, September, 2009.

Smoking Cessation: Minimizing Weight Gain and Preventing Relapse by Reducing Alcohol Consumption



Mark B Sobell, Ph.D., Nova Southeastern University
 Alan L. Peterson, Ph.D., University of Texas Health Science Center at San Antonio
 Linda C. Sobell, Ph.D., Nova Southeastern University
 Christopher L. Hunter, Ph.D., Tricare Management Activity
 Christine M. Hunter, Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases
 Antoinette Brundige, M.A., San Antonio Military Medical Center
 Jeffrey L. Goodie Ph.D., Uniformed Services University of the Health Sciences
 Crystal Mendoza, M.A., San Antonio Military Medical Center



Introduction

- ★ Concern about weight gain is a well-established barrier to smoking cessation.
- ★ In the military, concern about weight gain after quitting is heightened because excessive weight can result in being unfit for service.
- ★ This study targets smoking cessation and minimizing weight gain in patients seen in military primary care settings.
- ★ A unique feature of this study is counseling to reduce alcohol consumption to minimize weight gain after smoking cessation.
- ★ Reduction of alcohol consumption is also included as a treatment component because it is highly correlated with smoking relapse and may increase weight gain due to its relatively high caloric value.

It is expected that participants counseled to reduce alcohol consumption to minimize weight gain will have higher smoking cessation rates and a lessened risk of relapse than participants who do not receive such counseling.

Specific Aims

This study will address three research questions:

1. Does a weight gain minimization through an alcohol consumption reduction strategy produce higher smoking cessation rates than a control treatment?
2. Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse?
3. Does providing a stepped care intervention for participants who are unsuccessful at stopping in the short-term improve long-term tobacco cessation rates?

Treatment Conditions

Brief Counselor Assisted Program (BCAP): Tobacco cessation procedures integrated with weight and alcohol reduction strategies, including nicotine replacement therapy (NRT) and Bupropion SR (Zyban). Two clinic sessions and two phone sessions over 8-12 weeks.

Pharmacotherapy plus Pamphlet (PP): Self-help pamphlet describing how to implement effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to deal with possible relapses. NRT and Bupropion SR provided.

The Booster session focused on overcoming barriers to smoking cessation, and development of new quit and relapse prevention plans.

Participants

- ★ Primary care clinics at Wilford Hall Medical Center (San Antonio, TX) are the primary source of participants.
- ★ All participants are eligible military medical beneficiaries.
- ★ Inclusion Criteria: ≥ 21 years of age, smoke a mean of ≥ 5 cigarettes/day for past year, consume a mean of ≥ 4 standard drinks/week, concerned about weight gain, plan to stay in area ≥ 1 year.
- ★ Exclusion criteria: Pregnant, trying to become pregnant, breastfeeding; health conditions that contraindicate cessation medication; used weight loss medication within past 6 mos.; at base temporarily; recent or current major depression; DSM-IV alcohol use disorder; other medical contraindications.

Participant Characteristics

| Variable | Group | |
|--|------------------------|----------------------|
| | BCAP (<i>n</i> = 158) | PP (<i>n</i> = 159) |
| Mean (<i>SD</i>) yrs age | 37.3 (13.1) | 37.6 (12.9) |
| % Male | 69.6 | 72.3 |
| % Married | 62.7 | 58.5 |
| % White/Caucasian | 72.2 | 68.6 |
| <i>M</i> (<i>SD</i>) yrs education | 13.7 (1.7) | 13.5 (1.8) |
| % Active duty | 63.3 | 64.8 |
| <i>M</i> (<i>SD</i>) Fagerström score | 3.7 (2.2) | 4.0 (2.1) |
| <i>M</i> (<i>SD</i>) yrs reg. smoker | 18.1 (12.9) | 18.7 (13.0) |
| % Health most important reason | 79.1 | 76.7 |
| <i>M</i> (<i>SD</i>) no. past quit attempts | 6.1 (6.0) | 5.9 (6.2) |
| % Definitely quit next 2 wks. | 44.9 | 47.8 |
| % Def. be nonsmoker in 6 mos. | 40.5 | 43.4 |
| % Def. quit next 6 mos. | 79.1 | 80.4 |
| <i>M</i> (<i>SD</i>) readiness quit (1-5) | 4.7 (.5) | 4.6 (.5) |
| <i>M</i> (<i>SD</i>) goal importance (0-100) | 81.8 (15.1) | 80.6 (15.4) |
| <i>M</i> (<i>SD</i>) goal confidence (0-100) | 82.2 (18.5) | 82.0 (19.3) |
| <i>M</i> (<i>SD</i>) concern weight gain (1-10) | 6.7 (2.9) | 6.7 (3.0) |
| <i>M</i> (<i>SD</i>) days ≥ 5 drinks past yr. | 19.9 (44.0) | 16.3 (34.4) |

Note: No differences were statistically significant

Follow-up Rates

Found for 3-mo. follow-up: 92.1% BCAP: 89.2% PP: 95.0%

3-Month Outcome

- ★ At the 3-month follow-up, of the 92.1% of participants for whom data were available 40.0% were nonsmokers (7-day window):
 - BCAP = 46.8% Nonsmokers
 - PP = 34.4% Nonsmokers
- ★ The above difference, on the basis of the 92.1% of participants found, is significant: χ^2 (df = 1, *N* = 292) = 4.63, *p* = .031.
- ★ If an intent to treat analysis is performed and all missing participants are considered failures, the nonsmoking rates (BCAP = 41.8%; PP = 32.7%) no longer differ significantly: χ^2 (df = 1, *N* = 317) = 2.79, *p* = .095.

Example of project-generated smoking cessation materials available for dissemination: Chart on How Many Calories are in a Drink?



BEER (12 oz)

| | | | | | |
|------------------------------|-----|-------------------------------|-----|----------------------------|-----|
| Anchor Porter | 209 | Leinenkugel Northwoods Lager | 163 | Red Hook ESB | 179 |
| Anchor Steam | 153 | Leinenkugel Original | 152 | Red Hook IPA | 188 |
| Anheuser Busch Natural Light | 95 | Leinenkugel Creamy Dark | 170 | Rolling Rock Extra Pale | 142 |
| Anheuser Busch Natural Ice | 157 | Leinenkugel Red | 166 | Rolling Rock Premium Beer | 120 |
| Aspen Edge | 94 | Leinenkugel Light | 105 | Sam Adams Boston Lager | 160 |
| Blatz Beer | 153 | Leinenkugel Amber Light | 110 | Sam Adams Boston Ale | 160 |
| Blue Moon | 171 | Lowenbrau Dark | 160 | Sam Adams Cherry Wheat | 166 |
| Bud Dry | 130 | Lowenbrau Special Beer | 160 | Sam Adams Cream Stout | 195 |
| Bud Ice | 148 | Magnum Malt Liquor | 157 | Sam Adams IPA | 175 |
| Bud Ice Light | 110 | Michelob Amber Boch | 166 | Sam Adams Light | 124 |
| Bud Light | 110 | Michelob Beer | 155 | Sam Adams Pale Ale | 145 |
| Budweiser | 145 | Michelob Golden Draft | 152 | Schaefer Beer | 142 |
| Busch Beer | 133 | Michelob Golden Draft Light | 110 | Schlitz Beer | 146 |
| Busch Ice | 169 | Michelob Honey Lager | 175 | Schlitz Light | 110 |
| Busch Light | 110 | Michelob Light | 113 | Schlitz Malt Liquor | 185 |
| Carling Black Label | 138 | Michelob Ultra | 95 | Sierra Nevada Pale Ale | 200 |
| Colt 45 Malt Liquor | 174 | Mickey's Fine Malt Liquor | 157 | Sierra Nevada Porter | 200 |
| Coors Banquet Beer | 142 | Miller Genuine Draft | 143 | Sierra Nevada Stout | 210 |
| Coors Light | 102 | Miller Genuine Draft Light | 110 | Signature Stroh Beer | 153 |
| Genesee Beer | 148 | Miller High Life | 143 | Stroh's Beer | 149 |
| Genesee Cream Ale | 162 | Miller High Life Light | 110 | Stroh's Light | 113 |
| Genesee Ice | 156 | Miller Lite | 96 | Tuborg Deluxe Dark Export | 163 |
| Genesee Red | 148 | Milwaukee's Best | 128 | Tuborg Export Quality | 156 |
| George Killian's Irish Red | 163 | Milwaukee's Best Light | 98 | Weinhard's Private Reserve | 150 |
| Icehouse | 132 | Milwaukee's Best Ice | 144 | Weinhard's Amber Light | 135 |
| Icehouse | 149 | O'Doul's | 70 | Weinhard's Hefeweizen | 151 |
| Hamm's Beer | 144 | Old Milwaukee Light | 114 | Weinhard's Blonde Lager | 161 |
| Hamm's Golden Draft | 144 | Old Milwaukee Beer | 146 | Weinhard's Pale Ale | 147 |
| Hamm's Special Light | 110 | Olde English 800 Malt Liquor | 160 | Yuengling Ale | 145 |
| Keystone Premium | 108 | Olympia Premium Lager | 146 | Yuengling Porter | 150 |
| Keystone Light | 104 | Pabst Blue Ribbon | 153 | Yuengling Premium Beer | 135 |
| Keystone Ice | 143 | Pabst Extra Light Low Alcohol | 67 | Yuengling Light | 98 |
| Leinenkugel Honey Weiss | 149 | Pete's Wicked Ale | 174 | Yuengling Lager | 135 |



WINE (4 oz)

| | |
|--------------------|-----|
| Beaujolais | 95 |
| Bordeaux, red | 95 |
| Burgundy, red | 95 |
| Burgundy, white | 90 |
| Cabernet Sauvignon | 90 |
| Chablis | 85 |
| Champagne, dry | 105 |
| Champagne, pink | 100 |
| Chardonnay | 90 |
| Chianti | 100 |
| Liebfraumilch | 85 |
| Madeira | 160 |
| Marsala | 80 |
| Merlot | 95 |
| Mosell | 100 |
| Muscatel | 160 |
| Port, ruby | 185 |
| Port, white | 170 |
| Reisling | 90 |
| Rhone | 95 |
| Rose | 95 |
| Sangria | 115 |
| Sauterne | 115 |
| Sauvignon Blanc | 80 |
| Tokay | 165 |
| Zinfandel, red | 90 |
| Zinfandel, white | 80 |



SPECIALTY DRINKS

| | | | |
|-------------------------|-----|----------------------|-----|
| Alexander | 244 | Martini | 210 |
| Bacardi | 144 | Mimosa | 137 |
| Between The Sheets | 141 | Mint Julep | 115 |
| Black Russian | 137 | Old Fashioned | 156 |
| Bloody Mary | 86 | Pina Colada | 342 |
| Bocci Ball | 135 | Planter's Punch | 184 |
| Brandy Alexander | 253 | Rob Roy | 194 |
| Bronx | 191 | Rum Sour | 128 |
| Bull Shot | 91 | Rum Swizzle | 102 |
| Cuba Libre (Rum & Cola) | 127 | Rum Toddy | 114 |
| Daiquiri | 125 | Rusty Nail | 223 |
| Dubonnet Cocktail | 173 | Sangria | 225 |
| French 75 | 170 | Screwdriver | 181 |
| Gibson | 207 | Sherry Flip | 195 |
| Gimlet | 110 | Side Car | 225 |
| Gin & Bitter Lemon | 181 | Silver Bullet | 210 |
| Gin Fizz | 130 | Singapore Sling | 241 |
| Gin Rickey | 104 | Slow Gin Fizz | 167 |
| Gin & Tonic | 175 | Sombrero | 232 |
| Golden Cadillac | 250 | Stinger | 235 |
| Golden Dream | 269 | Strawberry Daiquiri | 150 |
| Grasshopper | 255 | Strawberry Margarita | 210 |
| Harvey Wallbanger | 258 | Tequila Sunrise | 219 |
| Hot Buttered Rum | 158 | Toasted Almond | 286 |
| Irish Coffee | 218 | Tom Collins | 169 |
| Kir | 121 | Tom & Jerry | 252 |
| Madras | 123 | Vodka & Tonic | 175 |
| Mai Tai | 310 | Vodka Martini | 210 |
| Manhattan | 183 | Whiskey Sour | 126 |
| Margarita | 185 | Zombie | 254 |