Protocol Summary

(IRB approved; last approved continuing review 2.27.2020)

Study Title: The use of public messaging for the promotion of firearm safety to Veterans

Clinical Trials ID: NCT03417752

Clinical Trials Protocol #: 910434

Research Site: VISN 2 Center of Excellence for Suicide Prevention (CoE)
Canandaigua Veterans Affairs Medical Center
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1. OBJECTIVES

Our objectives are to determine if exposure to the VA's firearm safety messaging is associated with changes related to cognitive and behavioral outcomes reported below (e.g., injury; firearm safety practices). Comparisons of findings may be made across those exposed to the VA firearm safety message and those exposed to a health promotion (comparison) video.

2. RESEARCH DESIGN & METHODS

DATA

Data were collected by GfK Group, a U.S. market research firm, on behalf of the VA to pilot test the Firearm Safety messaging with a sample of Veterans. While the majority of participants were exposed to the firearm safety message, subsamples were also exposed to a health promotion video to serve as a comparison. The survey was carried out by GfK using sample from their KnowledgePanel®, a probability-based web panel designed to be representative of the United States. KnowledgePanel® is the largest online panel that relies on probability-based sampling techniques for recruitment; hence, the largest national sampling frame from which fully representative samples can be generated to produce statistically valid inferences for study populations. GfK panel provides samples with the highest level of representativeness available in online research for measurement of public opinions, attitudes, and behaviors. The panel was first developed in 1999 by Knowledge Networks, a GfK company. Panel members are randomly selected so that survey results can properly represent the U.S. population with a measurable level of accuracy, features that are not obtainable from non-probability panels.

The survey was administered online at two time points (pre/post message exposures) with a nationally representative sample of U.S. adult Veterans (18+, non-institutionalized) that belong to the GfK KnowledgePanel®. Military service status was determined using GfK's profile data. All data are de-identified and no personal or health information is included in the dataset. The GfK survey was designed to provide preliminary insights to the VA on message response. Demographic characteristics were also provided in the dataset. A de-identified analytic dataset has been received by the PI from GfK, and is currently stored in an access restricted file on the secure drive behind the VA firewall.

RESEARCH DESIGN:

Sampling: GfK Group uses scientific random probability-based sampling techniques for recruitment of U.S. households. This probability-based sampling methodology improves population coverage, and provides a more effective sampling infrastructure for recruitment of hard-to-reach individuals, such as young adults and those from various minority groups. It should be noted that under this recruitment, households without Internet connection are provided with a web-enabled device and free Internet service. Once panel members are recruited and profiled by taking the Core Profile Survey, they become eligible for selection for surveys. Generally, the specific survey samples represent an equal probability selection method (EPSEM) sample from the panel for general population surveys.

Data Collection: To sample the population, GfK sampled eligible adults limited to one member per household. Selected panel members received an email invitation to complete the Baseline survey and were asked to do so at their earliest convenience. In the Baseline survey, each panel member was randomly assigned to one of three survey conditions. Next, panel members were then asked to view a

message based on the survey condition assigned. Finally, panel members were asked to complete the same survey 3-weeks post-baseline to determine how the video exposure may have influenced their opinions at exit.

Data included in the analytic file were collected from 12/15/2015 through 1/5/2016. The dataset includes responses from 474 participants that completed the baseline survey, with 358 of these participants also successfully completing the subsequent message exposures and exit survey within 3 weeks post-baseline.

Waivers of Consent & HIPAA Authorization: A consent waiver has been submitted for consideration. We believe this waiver does not adversely affect the rights or welfare of the participants as survey topics are minimally invasive and do not request identifiable information. Individuals also have several opportunities to opt out of participation during the recruitment process. A waiver of HIPAA Authorization has also been submitted to the IRB as no PHI or PII is collected as part of the survey. Analytic data files will be limited with no PHI or PII included.

Despite the request for waivers, each participant will still receive study information including a detailed description of purpose, procedures, risk/benefits, and voluntary nature. Prior to moving forward with any study procedures, participants will confirm their understanding of the study and their willingness to participate.

ANALYSIS PLAN:

All data analyses will be conducted at the VISN2 Center of Excellence for Suicide Prevention (COE) at the Canandaigua VAMC. All analyses will use data from the de-identified GfK dataset. The project under approval of this protocol will make no attempt to link data from GfK with any additional resources containing identifiable information. All analysis will be restricted to participants who are 18 years or older. Statistical analysis methods will include frequencies and standard deviations to describe sample characteristics. Bivariate analysis will be utilized to identify potential covariates to include in the multivariate models. Multivariate modeling will be used to examine hypotheses concerning the different effects of exposure on changes in outcomes across and within study conditions/groups. Changes in outcomes for each aim will be modeled over time for each condition, controlling for covariates of interest. Appropriate contrasts will then be used to identify significant differences in outcomes (as appropriate). All data management and analyses will be conducted by experienced team members listed on this protocol using SAS 9.4 (Cary, NC). Further ad hoc analyses may be conducted as needed.

4. DATA MANAGEMENT & STORAGE

For the purposes of this research project only a final analytic dataset was received from GfK, and will be user restricted with only members of the study team having access to this database. All data will be stored within the VA firewall. The data can only be retrieved from within the VA network and will be user restricted so that only members of the research team can access the data.

All data is stored in 'access restricted' files behind the VA firewall on the VA's secure drive and will be backed up at a secure VA data storage location. Access to research study data will be terminated for study personnel when they are no longer part of the research team. Current VA regulations require all

identifiable data collected and used for research be maintained as defined in the VHA Records Control Schedule. Therefore, no data will be destroyed until confirmed in compliance with these regulations.

VINCI

Study data may also be stored on a centralized research data repository, such as the VA Informatics and Computing Infrastructure (VINCI). VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans' Health Administration Office of Research and Development (VHA ORD). VINCI provides the storage and server technologies to securely host suites of databases integrated from select national data. These servers reside at the Austin Information Technology Center (AITC), located in Austin, Texas. To ensure the protection of Veterans data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO).

ADVERSE EVENT REPORTING:

If any Adverse Event (AE) or Serious Adverse Event (SAE) are encountered, the research team is responsible for reporting such events to their IRB either as part of continuing review (AE) or within 5 days of a SAE report.

CONFIDENTIALITY:

Data were de-identified and formatted by GfK before being released to the VA. All participants of the GfK survey agree to have their information kept for research purposes. In order to ensure confidentiality, no identifiable information is collected, and participants' data are coded with a random study identification number. All participating study personnel have completed the VA's mandatory ethics and research trainings and have submitted academic transcripts and currents CV's for IRB review.

CLINICAL RELATIONSHIPS:

No clinical relationships will be necessary for this study.

REFERENCES

1. Rockett, I.R.H., Regier, M.D., Kapusta, N.D., Coben, J.H., Miller, T.R., Hanzlick, R.L.,...Smith, G.S. (2012). Leading causes of unintentional and intentional injury mortality: United States, 2000–2009. American Journal of Public Health, 102, e84–92. doi 10.2105/AJPH.2012.300960
2. U.S. Centers for Disease Control and Prevention. Deaths: Final Data for 2013. National Vital Statistics Report, 64 (2). Retrieved from: http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf
3. Kemp, J.E., & Bossarte, R.M. (2013). VA Suicide Data Report, 2012. Department of Veterans Affairs, Washington, DC.
4. Gibbons RD, Brown CH, Hur K. Is the rate of suicide among veterans elevated? American journal of public health. Mar 2012;102 Suppl 1:S17-19.
5. Katz IR, McCarthy JF, Ignacio RV, Kemp J. Suicide among veterans in 16 states, 2005 to 2008: comparisons between utilizers and non-utilizers of Veterans Health Administration (VHA) services based on data from the National Death Index, the National Violent Death Reporting System, and VHA administrative records. American journal of public health. Mar 2012;102 Suppl 1:S105-110.
6. McCarthy JF, Blow FC, Ignacio RV, Ilgen MA, Austin KL, Valenstein M. Suicide among patients in the Veterans Affairs health system: rural-urban differences in rates, risks, and methods. American journal of public health. Mar 2012;102 Suppl 1:S111-117.
7. McCarthy JF, Valenstein M, Kim HM, Ilgen M, Zivin K, Blow FC. Suicide mortality among patients receiving care in the veterans health administration health system. American journal of epidemiology. Apr 15 2009;169(8):1033-1038.
8. Kaplan MS, McFarland BH, Huguet N. Firearm suicide among veterans in the general population: findings from the national violent death reporting system. The Journal of trauma. Sep 2009;67(3):503-507.
9. Dahlberg LL, Ikeda RM, Kresnow M-J. Guns in the home and risk of a violent death in the home: findings from a national study. American journal of epidemiology. 11/15 2004;160(10):929-936.
10. Kellermann AL, Rivara FP, Somes G, et al. Suicide in the home in relation to gun ownership. The New England journal of medicine. 08/13 1992;327(7):467-472.
11. Kung HC, Pearson JL, Liu X. Risk factors for male and female suicide decedents ages 15-64 in the United States. Results from the 1993 National Mortality Followback Survey. Social psychiatry and psychiatric
12. Miller M. Preventing Suicide by Preventing Lethal Injury: The Need to Act on What We Already Know. American Journal of Public Health: 2012 (102), No. S1, pp. e1-e3. doi: 10.2105/AJPH.2012.300662
13. Mann, JJ, Apter, A, Bertolote, J, Beautrais, A, Currier, D, Haas, A, Hegerl, U, Lonnqvist, J, Malone K, Marusic, A, Mehlum, L, Patton G, Phillips M, Rutz W, Rihmer, Z, Schmidtke, A, Shaffer D, Silverman, M, Takahasi, Y, Varnik A, Wasserman D, Yip P, & Hendin H. (2005). Suicide prevention strategies: A systematic review. JAMA, 16, 2064-1074.
14. Miller M, Azrael D, Barber C. Suicide mortality in the United States: the importance of attending to method in understanding population-level disparities in the burden of suicide. Annu Rev Public Health. 2012;33(1):393–408.
15. Grossman DC, Mueller BA, Riedy C, et al. Gun storage practices and risk of youth suicide and unintentional firearm injuries. JAMA : the journal of the American Medical Association. 02/09 2005;293(6):707-714.
16. Kellermann AL, Rivara FP, Somes G, et al. Suicide in the home in relation to gun ownership. The New England journal of medicine. 08/13 1992;327(7):467-472.
17. Hoffmire, C.A., Karras, E., Elder, H., Bossarte, R.M., Azrael, D., & Miller, M. (in preparation). A comparison of firearm ownership prevalence and storage practices between Veterans and non-

Veterans: Findings from the 2004 Behavioral Risk Factor Surveillance Survey (BRFSS). To be submitted for review to Injury Prevention.
18. Ajzen, I. (2012). Attitudes and persuasion. In K. Deaux & M. Snyder (Eds.), The Oxford Handbook ofPersonality and Social Psychology (pp. 367-393). New York: Oxford University Press.
19. Ajzen, I., & Gilbert Cote, N. (2008). Attitudes and the prediction of behavior. In W. D. Crano & R. Prislin (Eds.), Attitudes and attitude change (pp. 289-311). New York: Psychology Press.
20. Sidman, EA, Grossman, DC, Koepsell, TD, Ambrosia, L., Britt, J, Simpson, ES, Rivera, P, & Bergman AB. (2005). Evaluation of a community based handgun storage campaign. Pediatric, 115, 654-661.
21. Coyne-Beasley, T Achenbach, VJ, & Johnson, RM. (2001). "Love our kids, lock your guns." A community-based firearm safety counseling and gun lock distribution program. JAMA Pediatrics, 155(6), 659-664.
22. Karras, E., Lu, N., Zuo, G., Tu, X., Draper, J., Thompson, C., & Bossarte, RM. (2016). Measuring the associations of the Department of Veterans Affairs' suicide prevention campaign on the use of crisis support services. Suicide and Life-Threatening Behavior, 1-10.
23. Bossarte, R. M., Karras, E., Lu, N., Tu, X., Stephens, B., Draper, J., & Kemp, J. E. (2014). Associations between the Department of Veterans Affairs' suicide prevention campaign and calls to related crisis lines. Public Health Reports, 129(6), 516–525.
24. Elder, H., Karras, E., & Bossarte, RM. (accepted for publication). Promoting help seeking to veteran households: Associations between exposure to multiple health messages and intentions to utilize related hotlines. Military Medicine.
25. Karras, E., Stephens, B., Kemp, J. E., & Bossarte, R. M. (2014). Using media to promote suicide prevention hotlines to Veteran households. Injury Prevention, 20(1), 62–65.