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14. ABSTRACT

The purpose of this multi-site study is to conduct a Department of Defense (DoD) Telemedicine and Advanced Technology Research Center (TATRC) funded randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The "caring letters" concept was originally developed and evaluated by Motto and colleagues in the 1970's (1). In Motto's trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These "caring letters" are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial. Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years.

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Table of Contents

Introduction:
The purpose of this multi-site study was to conduct a randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among U.S. Service Members and Veterans. The caring letters concept was originally developed and evaluated by Motto and colleagues in the 1970s (1). In Motto's trial, civilian psychiatric inpatients were sent brief caring messages by postal mail following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the caring letters group had a significantly lower suicide rate for the first two years of the trial.

The caring letters suicide prevention intervention is one of the only interventions shown to reduce suicide mortality in a randomized controlled trial (2). Despite the initial promising results of the original Caring Letters trial, there had not been any published replications of the original intervention or tests of the intervention among military personnel or veterans in a large randomized-controlled trial. This study was conducted in order to fill an important gap in the evidence base for the Caring Letter intervention and is timely given the heightened risk for suicide following psychiatric treatment discharge and the steady increase of military suicide in recent years (3).

Body:
Overview
The study was planned as a five-year multi-site randomized-controlled trial that compared the caring letters intervention (with usual care) to usual care without the caring letters (4). Participants were recruited from inpatient psychiatry units of collaborating military and Veterans Affairs (VA) sites and randomized to either a group that received letters (caring letters group [CL]) or a group that did not receive letters (usual care group [UC]). This study was intended to fill an important gap in the evidence base for the Caring Letter (or "caring contacts") intervention by testing it in a large randomized-controlled trial and by sending emails instead of letters via postal mail.

Participants consented to study procedures during their inpatient stay and then completed a semi-structured interview with a trained research coordinator. The purpose of the interview was to collect baseline data and facilitate a caring connection between the interviewer and participant. Qualifying participants were then randomized to condition (either caring letters group or usual care group) to begin at discharge. In the CL group, participants were emailed letters for two years on a planned schedule. The emailed letters were simple expressions of care and included standard contact information for available health care services. The participants in the UC group did not receive the emails. Participants were not asked to respond to any of these emails. All-cause mortality and suicide mortality (the primary outcomes) in both groups were examined at the end of the two-year period. Rates of suicide attempts and hospital readmissions (the secondary outcomes) were also assessed for both the CL and UC groups. Patient satisfaction with the program was assessed for the CL group.

The objectives of the study were as follows:
1. To conduct a multi-site randomized controlled trial of the CL intervention.
2. To evaluate the utility of the CL intervention in reducing suicide mortality and self-inflicted injuries among service members and veterans.
3. To evaluate whether the time period preceding the suicidal act is greater among service members and veterans randomly assigned to the CL intervention.

Pursuant to the aforementioned aims, the following hypotheses were tested:
1. During a two-year follow up after the index hospital discharge, the frequency of suicide will be lower among participants in the CL group compared to those in the UC group.
2. The frequency of medically admitted, self-inflicted injuries will also be lower in the CL group compared to the UC group.
3. The time to suicidal event, among those who do subsequently exhibit one, will be longer among participants in the CL group compared to the UC group.

Participants
Inpatient psychiatric patients, either male or female, age 18 years and older, to include pregnant women, were recruited from Madigan Army Medical Center (MAMC) 5 North Inpatient Psychiatric Unit (main study site) and at collaborating psychiatric inpatient units at three military (Tripler Army Medical Center, 4B2; Landstuhl Regional Medical Center, 9C; and Navy Medical Center San Diego; 1 North and 1 West) and two VA hospitals (VA Palo

Alto and VA Western New York). Participants were permitted to participate regardless of psychiatric diagnoses, personality disorders, or history of suicide attempt, suicidal behavior or suicidal ideation. To be eligible for the study, participants had to be currently admitted to one of the psychiatric inpatient units, possess an active email account, provide informed consent, and be a member of the active-duty military, a reservist, a veteran, or a retiree. Potential participants were excluded if they were not competent to provide informed consent, had adverse behavioral problems, were under arrest/incarcerated, were involuntarily committed for psychiatric care, of if the care providers determined the study to be clinically inappropriate for a given individual. All participants met diagnostic and inclusion/exclusion criteria prior to enrollment in the study.

Recruitment

Enrollment was open to all current inpatients meeting inclusion criteria. A total of 1,318 participants were enrolled during the study. A total of 269 participants were recruited from among all service members approached during their inpatient stays at 5N Madigan Army Medical Center, JBLM. In addition, a total of 187 were recruited at Naval Medical Center San Diego (1 North and 1 West), a total 167 were recruited from Western NY VA Medical Center, a total of 342 were recruited from VA Palo Alto Medical Center, a total of 149 were recruited from Tripler Army Medical Center (4B2), and a total of 204 were recruited from Landstuhl Regional Medical Center (9C).

Outcome Measures

Data regarding participant demographics, psychosocial background/functioning, as well as scores on several clinical measures were collected during the initial interview (baseline) from each participant. Participants completed the following measures at baseline:

Lifetime Parasuicide Count (LPC; Linehan & Comtois, 1996 (5)). The LPC is a brief two-page instrument used for determining the date, method, intent to die (i.e., intent to die, ambivalent, no intent to die), highest level of medical treatment received (i.e., none, doctor/clinic visit, Emergency Room, admission to a medical unit, and admission to an intensive care or cardiac care unit), and lethality for the first, most recent, and most severe suicide attempt or non-suicidal self-injury (SASI). The number of SASIs for each of 11 methods of SASI is calculated and the number with and without the intent to die, the number resulting in medical treatment, highest lethality, and the level of treatment received is specified.

Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001 (6)). The PHQ-9 is the Depression Scale of the PHQ and consists of nine items that specifically target the DSM-IV diagnostic criteria for major depressive disorder. Items are rated on a 4-point scale (0 = not at all; 1 = several days; 2 = more than half the days; 3 = nearly every day), and possible scores range from 0 to 27. Internal consistency reliability at baseline was 0.85.

Rudd Suicide Ideation Scale (RSIS; Rudd, 1989 (7)). The 10-item Suicidal Ideation Scale provides critical information about the presence or absence of suicidal thinking, the intensity of those thoughts, and the presence or absence of prior suicide attempts. Respondents are to read each item and then select the response that best describes the way they felt or behaved in the past year on a five-point scale (1 = “never”, 2 = “infrequently”, 3 = “sometimes”, 4 = “frequently”, and 5 = “always”). The total score ranges from 10 to 50. The RSIS has previously demonstrated high internal consistency, as well as adequate item-total correlations (rs = .45 to .74; Rudd, 1989 (7). Strong support for the construct validity and reliability of the RSIS tested in a clinical military sample has also been reported (7). The internal consistency reliability at baseline was 0.90.

Interpersonal Needs Questionnaire (INQ; Van Orden, Witte, Gordon, Bender, & Joiner, 2008 (8)). The 18-item Interpersonal Needs Questionnaire is intended to measure the constructs of thwarted belongingness and perceived burdensomeness. Respondents are asked to read each item and then select the response that best describes the way they felt recently (including the present day) on a seven-point scale (1 = “not at all like me”, 2, 3, 4 = “somewhat true for me”, 5, 6, 7 = “very true for me”). The internal consistency reliability for the perceived burdensomeness subscale was 0.91 and for the thwarted belongingness subscale was 0.89.

Acquired Capability for Suicide Scale (ACSS; Van Orden, Witte, Gordon, Bender, & Joiner, 2008 (8)). The 20-item acquired capability for suicide scale aims to measure the construct of acquired capability for lethal self-injury. Responses to items are scored on a five-point scale (0 = “not at all like me”, 1, 2, 3, 4 = “very much like me”). Internal consistency reliability for this sample at baseline was 0.80.

Positive Assets Search Semi-Structured Interview Tool (PASSIT; Luxton, Armstrong & June, 2014 (4)). The PASSIT is a semi-structured interview tool comprised of 27 questions with additional open-ended follow-up questions intended to help identify positive aspects in a person’s life. The content domains are social support/activities, school and work, religion/spirituality,

recreation/leisure activities, and personal attributes. Sub-domains include: coping skills, giving/benevolence, past successes, and hope. The PASSIT also provided personalized information that provided personalized content for the caring emails. Items and content domains of the PASSIT were developed and piloted in the initial CL pilot study (9).

Soldier's Perceptions of Unit Cohesion Scale (Wright et al., 2009 (10)). The Soldier's Perceptions of Unit Cohesion scale is a three-item measure that aims to measure a soldier's subjective view of the level of cohesion of their military unit. Items are rated on a 5-point Likert scale (1=strongly disagree to 5=strongly agree). Items are summed to create a cohesion score which ranges from 3 to 15.

Patient Satisfaction Survey. Participants were asked to complete a patient satisfaction survey at the end of the initial interview. The patient satisfaction survey includes 13 questions regarding their subjective view of the interview process. Participants will respond with how much they agree or disagree with each statement (completely disagree, somewhat disagree, neither agree nor disagree, somewhat agree, or completely agree). Space is available at the end of the survey to include any additional comments they may have regarding the interview process.

The following data were collected at the two-year follow-up mail survey or phone call:

Final Survey. The final survey consisted of a phone interview and assessed participant suicidal behaviors and medical/psychiatric treatment utilization over the previous two years. Participants completed a web form version of the PHQ-9, the RSIS, the INQ, and the ACSS. Participants were asked to indicate the occurrence of a suicide attempt and any psychiatric hospital readmission during the two years since study enrollment. Finally, they were asked to complete a patient satisfaction survey (the satisfaction survey was provided only to participants in the experimental condition).

All-cause Mortality. Deaths from any cause were ascertained from death certificates as recorded in the Center for Disease Control and Prevention's (CDC) National Death Index Plus (NDI-Plus) and through the DoD Suicide Prevention Office. The primary cause of death code was used to identify suicide deaths as a specific subgroup of interest for analysis.

Hospital readmission. Medical encounter data from the VA and the military records were reviewed to identify any readmissions to a hospital. Data were not consistently available regarding the nature of the readmission. Therefore, the total count of all readmissions irrespective of reason was used in analysis.

Additional Data. Additional data that were collected include rates of undeliverable addresses, psychiatric care re-admittance rates, length of participant stay on the unit, feedback from the inpatient unit and Caring Letters staff about the process and counts of adverse events (i.e., completed suicide, non-fatal suicide events, indications of self-harm or harm to others in communication with study staff or the treatment team). We also examined the content of email responses from participants enrolled in the study.

Key Research Accomplishments: The time to attain Institutional Review Board (IRB) and DoD research regulatory approval took between six months and more than a year for all sites, thus significantly delaying recruitment start. The study team recruited participants from February 2012 to December 2014. A total of 1,318 (27.9% of the planned sample size of 4,730) participants were enrolled in the study. Follow up for participants began in 2014 and continued until December 2016 to coincide with the end of two years for the last-enrolled participants. A total of 421 participants (31.9% of enrolled participants) were able to be contacted (mail or telephone) for follow-up survey data collection. Data on mortality through the end of calendar year 2015 were acquired in February 2018 for final data analysis. Records reviews for hospital readmission data were completed for 1,303 (98.9%) of participants.

Reportable Outcomes: The primary outcome for the study was all-cause mortality. As of December 31, 2015, there were 10 deaths from any cause in the CL group and 14 in the UC group during the individual two-year follow-up intervals. There were 1,170 person-years of observation available for the CL group (out of 1,304 possible) and 1,198 person-years of observation available for the UC group (out of 1,332 possible). Approximately 10% of person years was not yet available at the time the mortality data was collected. While death outcome trended in the hypothesized direction, there was no statistically significant difference in the observed all-cause mortality rate. The rate ratio, adjusting for enrollment site, was 0.77 [95% confidence interval (CI) = 0.34, 1.73]. The post hoc statistical power to detect a rate ratio of 0.50 or stronger was 0.45.
Of the deaths reported above, three in the CL group and seven in the UC group were identified as deaths by suicide. With the same person-years of observation for analysis, while trending in the hypothesized direction, there was no statistically

significant difference between the two study groups. The ratio, adjusting for enrollment site, was 0.42 [95% CI = 0.11, 1.64]. The post hoc statistical power to detect a rate ratio of 0.50 or stronger was 0.25.

Medical record review identified 457 hospital readmissions in the CL group and 414 in the UC group. The person-years available for analysis were 750 and 756 for the CL and UC groups, respectively. There was no statistically significant difference in the rate of all-cause hospital readmission between the study groups. The rate ratio was 1.08 [95% CI = 0.82, 1.41]. The post hoc statistical power to detect a rate ratio of 0.50 or greater was effectively 1.00. There was no difference between the study groups in the rate of first hospital readmission after study enrollment with a rate ratio of 1.08 [95% CI = 0.85, 1.36].

Similar to the mortality and medical record outcomes, there was no difference observed between the study groups on self-reported psychiatric hospital readmission, self-reported suicide attempt, and on the scale measures administered at the two-year follow-up data collection (RSIS, PHQ-9, INQ, ACSS).

Personnel Receiving Pay from the Research Effort

- Ayat, Lei
- Bermudez, Nina
- Boykin, Karyna
- Canorro, Cassidy
- Cosimo, Heather
- Crews, Jessica
- Dorrenbacher, Briana
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- Getman, Briana
- Johnson, Kristine
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- June, Jennifer
- Lauterwasser, Sarah
- Liskiewicz, Amylynn
- Munoz, Martha
- Neubauer, Cassidy
- Stack, Jill
- Thomas, Drew
- Thomas, Elissa

Publications Resulting from the Research Effort

Luxton, D. D. (2017). Caring Letters for Military Suicide Prevention. In Sullivan, James, & Bongar (Eds.) The Oxford Handbook of Suicide in Military and Veteran Populations. New York: Oxford University Press.

Luxton, D. D., Thomas, E. K., Chipps, J., Relova, R. M., Brown, D., McLay, R., Lee, T., Nakama H., & Smolenski, D. J., (2014). Caring Letters for Suicide Prevention: Implementation of a Multi-Site Randomized Clinical Trial in the U.S. Military and Veteran Affairs Healthcare Systems. Contemporary Clinical Trials. 37(2), 252-260. doi: 10.1016/j.cct.2014.01.007

Luxton, D. D., June, J. D. & Comtois, K. A. (2013). Can Post-Discharge Follow-up Contacts Prevent Suicide and Suicide Behavior?: A Review of the Evidence. Crisis: The Journal of Crisis Intervention and Suicide Prevention, 34, 32-41. doi: 10.1027/0227-5910/a000158

Presentations Resulting from the Research Effort

Luxton, D. D., Relova, M., & MacRae, F. (2017, August). Caring Letters for Suicide Prevention: Implementation Strategies for the Military and VA Healthcare Systems. DoD/VA Annual Suicide Prevention Conference, Denver, CO.

Luxton, D. D. (2015, June). Caring Emails for Military Suicide Prevention. In D. D. Luxton (Chair), Post-Treatment Technology-Based Caring Contacts for Suicide Prevention. 28th World Congress of the International Association for Suicide Prevention, Montreal, Canada.

Luxton, D. D. (2015, June). Caring Contacts for Suicide Prevention, Key Note, Vermont Suicide Prevention Symposium, Fairlee, VT.

Kolade, L., Shere, L., Gill, S., G. Saini, G., MacRae, F. Kuppuswamy, M., Relova, R. M., Lee, T., & Luxton, D. D. (2015, March). Post-hospitalization Caring Contacts for Suicide Prevention Provide Active Crisis Intervention Benefit at VA Palo Alto. Society for the Advancement of Violence and Injury Research. New Orleans, LA.

Luxton, D. D. (2015, January). Post Treatment Caring Contacts for Suicide Prevention. American Association of Suicidology, 2015 Webinar.

Luxton, D. D., June, J., & Comtois, K. (2014, August). Can Post Treatment Follow-up Contacts Prevent Suicide Behavior?, American Psychological Association 2014 Annual Convention, Washington DC.

Saini, G., Gill, S., Shere, L., MacRae, F., Kuppuswamy, M., Relova, R., Lee, T., & Luxton, D. D., (2013, June). Caring Letters for Suicide Prevention: Implementation of A Randomized Controlled Trial at the VA Palo Alto Healthcare System. 3rd Annual Stanford University School of Medicine Neuroscience Research Forum, Palo Alto, CA.

Luxton, D. D. & Kinn, J. T. (2010, January). Caring Letters Project. Invited talk given at the 2010 DoD/VA Suicide Prevention Conference, Washington DC.

Luxton, D. D. (2010, October). Caring Letters: A Suicide Prevention Strategy. Grand Rounds presentation at the University of Washington's Department of Psychiatry and Behavioral Sciences, Seattle, WA.

Conclusion: The data from this trial did not support the efficacy of caring emails at reducing the number of deaths among U.S. service members and veterans discharged from psychiatric inpatient units. The planned sample size used a population rate of suicide that was approximately double what was observed in the study sample, and the study recruited approximately one-quarter of the planned sample. These two issues resulted in inadequate power to provide a strong answer to the primary research question with mortality rates as the outcome. There were too few deaths in either study group to estimate a statistically stable rate; subsequently, the rate ratios demonstrated very low precision. Thus, evidence of the efficacy of caring letters in prevention of mortality, all-cause or suicide-specific, could not be adequately tested by the present study. There were no adverse advents associated with the intervention, and implementation of the procedures was generally feasible in the military and Veteran hospital settings. These results provide important information for planning future caring contact trials in military populations.

The comparison of rates of hospital readmission were adequately powered in this study. The lack of a difference in the rate between the two study groups is supportive of the null hypothesis that there is no difference between the treatments on this outcome. Analysis of the self-report measures were of limited utility since less than one-third of the enrolled sample completed a follow-up assessment. The analysis produced similar results to those for mortality and hospital readmission.

Analysis of the full sample's mortality data (approximately 10% was not yet available) and follow-up at five-years post hospital discharge is not possible due to the end of the funding performance period and the closure of the IRB protocol at the main study site.

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