PI: NEIGHBORS, CLAYTON	Title: Guilt and expressive writing for reducing alcohol use in college students		
Received: 02/03/2014	FOA: PA13-302	Council: 10/2014	
Competition ID: FORMS-C	FOA Title: RESEARCH PROJECT GRAN	T (PARENT R01)	
1 R01 AA023495-01	Dual:	Accession Number: 3660702	
IPF: 1449402	Organization: UNIVERSITY OF HOUSTO	N	
Former Number:	Department: Psychology		
IRG/SRG: AA-2	AIDS: N	Expedited: N	
Subtotal Direct Costs (excludes consortium F&A) Year 1: 175,000 Year 2: 200,000 Year 3: 200,000 Year 4: 200,000 Year 5: 175,000	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: N Early Stage Investigator: N	
Senior/Key Personnel:	Organization:	Role Category:	
Clayton Neighbors Ph.D.	University of Houston	PD/PI	
Qian Lu Ph.D.	University of Houston	Co-Investigator	
Lindsey Rodriguez	University of Houston	Other Professional-Research Assistant Professor	
Ronda Dearing Ph.D	University of Buffalo	Consultant	

Appendices

 $appendix_2__measures_1010448470, appendix_1__prompts_101044846$

OMB Number: 4040-0001 Expiration Date: 06/30/2016

APPLICATION FO		ISTANCE		3. DATE RECEIVED BY STATE	State Application Identifier
1. TYPE OF SUB	MISSION*			4.a. Federal Identifier	<u>I</u>
O Pre-application	Application	O Changed/Corr Application	rected	b. Agency Routing Number	
2. DATE SUBMIT 2014-02-03	ITED	Application Identifier		c. Previous Grants.gov Tracking	Number
5. APPLICANT IN	NFORMATION				Organizational DUNS*: 036837920
Legal Name*:	University of	Houston			
Department:					
Division:					
Street1*:	Office of Con	ntracts and Grants			
Street2:	316 E. Cullen	n Building			
City*:	Houston				
County:	Harris				
State*:	TX: Texas				
Province:					
Country*:	USA: UNITE	ED STATES			
ZIP / Postal Code	e*: 77204-2015				
Person to be cont	tacted on matters i	nvolving this application ise Middle N	lame.	Last Name*: McG	uire Suffix:
Position/Title:		rch Administrator	iaiiio.	zact name : Mee	une Gunza
Street1*:	4800 Calhour				
Street2:	4000 Carriour	1			
City*:	Houston				
-	Houston Harris				
County: State*:					
	TX: Texas				
Province:	TIGA INTERES	TD GTT 4 TTEG			
Country*:	USA: UNITE	ED STATES			
ZIP / Postal Code					
Phone Number*:	(713) 743-9237	Fax Number: (/13) /43-9		ROPOSALS@listserv.uh.edu
6. EMPLOYER II	DENTIFICATION I	NUMBER (EIN) or (TIN)*		1-746001399-A3	
7. TYPE OF APP	PLICANT*			H: Public/State Controlled Institution	n of Higher Education
Other (Specify): Small I	Business Organiz	zation Type	Vomen O	wned O Socially and Econo	omically Disadvantaged
8. TYPE OF APP	PLICATION*		If Revis	ion, mark appropriate box(es).	
New	O Resubmission			ocrease Award O B. Decrease Av	
O Renewal	O Continuation	O Revision	O D. D	ecrease Duration O E. Other (special	'y) :
Is this application	on being submitte	d to other agencies?*	OYes	●No What other Agencies?	
9. NAME OF FEI National Institute	DERAL AGENCY* es of Health	ŧ		10. CATALOG OF FEDERAL DOM TITLE:	IESTIC ASSISTANCE NUMBER
		ICANT'S PROJECT* ng alcohol use in college stude	nts		
12. PROPOSED		16 alcohol use ili college stude	1110	13. CONGRESSIONAL DISTRICTS	S OF APPLICANT
Start Date*		ding Date*		TX-018	O AFFLICANI
09/01/2014		31/2019		17-010	

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

Page 2

14	PROJECT	DIRECTOR/PRINCIPA	I INVESTIGATOR	CONTACT INFO	ORMATION
	1 11000001				

Prefix: First Name*: Clayton Middle Name: Last Name*: Neighbors Suffix: Ph.D.

Position/Title: Professor

Organization Name*: University of Houston

Department: Psychology

Division: Liberal Arts & Social Sciences

Street1*: 126 Heyne Building

Street2:

City*: Houston
County: Harris
State*: TX: Texas

Province:

Country*: USA: UNITED STATES

ZIP / Postal Code*: 77204-5022

Phone Number*: 713-743-2616 Fax Number: 713-743-8588 Email*: cneighbors@uh.edu

15. ESTIMATED PROJECT FUNDING 16.IS APPLICATION SUBJECT TO REVIEW BY STATE **EXECUTIVE ORDER 12372 PROCESS?*** THIS PREAPPLICATION/APPLICATION WAS MADE \$1,429,750.00 a. Total Federal Funds Requested* AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 b. Total Non-Federal Funds* \$0.00 PROCESS FOR REVIEW ON: c. Total Federal & Non-Federal Funds* \$1,429,750.00 DATE: d. Estimated Program Income* \$0.00 b. NO PROGRAM IS NOT COVERED BY E.O. 12372; OR O PROGRAM HAS NOT BEEN SELECTED BY STATE FOR **REVIEW**

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

File Name:

I agree*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Suzanne Middle Name: Last Name*: Kieffer Suffix: Ph.D.

Position/Title*: Dir of Admin and Acad Affairs

Organization Name*: University of Houston

Department: Psychology
Division: CLASS

Street1*: 126 Heyne Building

Street2:

City*: Houston
County: Harris
State*: TX: Texas

Province:

Country*: USA: UNITED STATES

ZIP / Postal Code*: 77204-5022

Phone Number*: 713-743-8504 Fax Number: 713-743-8588 Email*: uhproposals@listserv.uh.edu

Signature of Authorized Representative*

Suzanne Kieffer 02/03/2014

20. PRE-APPLICATION File Name:

Tracking Number: GRANT11568330

21. COVER LETTER ATTACHMENT File Name:Cover_Letter1010448451.pdf

Date Signed*

^{*} The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

424 R&R and PHS-398 Specific Table Of Contents

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Appendix

Number of Attachments in Appendix: 2

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OMB Number: 4040-0010 Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

O I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: University of Houston

Duns Number: 036837920

Street1*: 126 Heyne Building

Street2: 4800 Calhoun

City*: Houston
County: Harris
State*: TX: Texas

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 77204-5022

Project/Performance Site Congressional District*: TX-018

File Name

Additional Location(s)

OMB Number: 4040-0001 Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● Y	es O No
1.a. If YES to Human Subjects	
Is the Project Exempt from Federal re	gulations? O Yes ● No
If YES, check appropriate exer	mption number: 1 2 3 4 5 6
If NO, is the IRB review Pendir	ng? ● Yes ○ No
IRB Approval Date:	
Human Subject Assura	nce Number 00005994
2. Are Vertebrate Animals Used?* O	es ● No
2.a. If YES to Vertebrate Animals	
Is the IACUC review Pending?	Yes O No
IACUC Approval Date:	
Animal Welfare Assurance Nur	mber
3. Is proprietary/privileged information in	cluded in the application?* ○ Yes • No
4.a. Does this project have an actual or po	otential impact - positive or negative - on the environment?* O Yes • No
4.b. If yes, please explain:	
4.c. If this project has an actual or potential in	mpact on the environment, has an exemption been authorized or an O Yes O No
environmental assessment (EA) or environm	ental impact statement (EIS) been performed?
4.d. If yes, please explain:	
5. Is the research performance site desig	nated, or eligible to be designated, as a historic place?* Yes No
5.a. If yes, please explain:	
6. Does this project involve activities out:	side the United States or partnership with international O Yes • No
collaborators?*	
6.a. If yes, identify countries:	
6.b. Optional Explanation:	
Filena	ame
7. Project Summary/Abstract* Project	ct_Summary1010448452.pdf
8. Project Narrative* Project	ct_Narrative1010448453.pdf
9. Bibliography & References Cited References	ences1010448454.pdf
10.Facilities & Other Resources Facili	ties_and_Other_Resources1010448455.pdf
11.Equipment Equip	oment1010448456.pdf

PROJECT SUMMARY/ABSTRACT

The current application proposes to evaluate expressive writing as a novel intervention for problem drinking among college students. College students are at increased risk for alcohol misuse compared to other adults, and development of efficacious intervention approaches is an urgent priority for NIAAA. The vast majority of individually focused brief interventions targeting college drinking have focused on personalized feedback approaches and recent innovations have largely been limited to finer distinctions of these, which require assessment and programming for implementation. The present research proposes expressive writing as a novel alternative, which has been used extensively in other domains but not as an alcohol intervention strategy. We propose a theoretically-based approach, which incorporates expression of the self-conscious emotion of guilt and the written analogue of change talk as proposed mechanisms of intervention efficacy. We will also examine individual differences in propensity for guilt as a moderator of intervention efficacy. Heavy drinking college students (N=600) will be randomly assigned to one of six expressive writing conditions based on the 2 (alcohol vs. distress) x 2 (guilt vs. no guilt) + 1 (neutral control) + 1 (personalized feedback) design. Participation in the study involves completion of a screening assessment, a baseline assessment, the intervention, post-intervention assessment, and follow-up assessments at one-month, three-months, sixmonths, and twelve-months. There will be three intervention (expressive writing) prompts to take place every week for three weeks, the first of which will occur immediately following the baseline assessment. All baseline assessments, narrative intervention assignments, and immediate post-tests for all conditions will be conducted in-lab. All other assessments including screening and follow-up assessments will be completed remotely by web. Pilot data has provided some support for a single session of expressive writing in reducing drinking intentions, as well as event-related guilt as a mediator of intervention efficacy. The present research builds on these studies by incorporating multiple sessions and multiple follow-up assessments to evaluate actual changes in drinking and psychological well-being, in a complex experimental design and will evaluate theoretically-based mediators and moderator. If effective, this intervention approach will offer a novel intervention which will not require any pre-assessment or programming of personalized feedback, and would serve as an alternative to existing approaches, which is capable of being more easily disseminated.

PROJECT NARRATIVE

Excessive alcohol consumption among college students continues to be a serious public health concern associated with a wide range of negative consequences. Development of efficacious intervention approaches remains a priority for NIAAA. The present research proposes expressive writing as a novel intervention approach, which has been used extensively in other domains but not as an alcohol intervention strategy. If effective, this intervention approach will offer an innovative advance which will obviate the need for any pre-assessment or programming of personalized feedback as currently required in most existing individually focused alcohol interventions for college students. In sum, the proposed expressive writing intervention approach has the potential to serve as an alternative to existing approaches and is capable of being more easily disseminated.

Project Narrative Page 7

FACILITIES AND OTHER RESOURCES

The University of Houston (UH) is a Carnegie-designated Tier-One public research university recognized throughout the world as a leader in energy research, law, business and environmental education. UH serves the globally competitive Houston and Gulf Coast region by providing world-class faculty, experiential learning, strategic industry partnerships and state-of-the-art facilities such as the interdisciplinary Energy Research Park and the Nanofabrication Facility. Located in America's fourth-largest city, UH is the most ethnically diverse metropolitan research university in the United States, serving more than 40,700 students in one of the most culturally diverse regions in the country.

The scientific environment in the Psychology Department at UH will contribute to the likelihood of success for the proposed research. UH maintains an extremely diverse undergraduate population, and the proposed study will benefit from the unique features associated with this diverse environment.

<u>Laboratory</u>: Ample laboratory space is available for this research at the University of Houston (UH). UH maintains a comprehensive research library focused in the subject areas of funding. The Department of Psychology has research laboratories in four separate buildings, in addition to four student computer laboratories with over 30 computers with access to major statistical packages (i.e., SPSS, SAS, MPlus, R, Amos), and several high-quality printers. Dr. Neighbors' laboratory space includes a conference room and six adjoining individual rooms. Individual subject testing rooms allow for simultaneous data collection with multiple participants.

<u>Clinical</u>: The University of Houston has a Psychological Research and Services Clinic (PRSC), to which referrals can be made as needed.

Animal: N/A

<u>Computer</u>: The Investigators and laboratory staff have desktop computers with access to secure servers. Individual subject testing rooms have available computers for data collection. Software appropriate for word processing, data storage, retrieval, and statistical analysis are readily available. All computers are on a protected and firewalled network, and require secure login credentials.

Other: Dr. Neighbors has obtained licenses for the DatStat Illume software platform and the associated Software Development Kit. DatStat Illume is a specialized package for online survey construction and administration, electronic recruitment, and data management. DatStat Illume allows us to flexibly create and modify surveys and feedback intervention protocols with Internet assessment and feedback. We also have extensive experience in utilizing the DatStat Software Development Kit (SDK), which allows for custom programming of surveys, feedback, email jobs, and data management. Participants will receive emails, access the surveys, and view feedback through the University of Houston DatStat platform.

<u>Major Equipment</u>: Access to the psychology department's copy and fax machines and campus mail services is readily available.

EQUIPMENT

None.

Equipment Page 9

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Clayton Middle Name Last Name*: Neighbors Suffix: Ph.D.

Position/Title*: Professor

Organization Name*: University of Houston

Department: Psychology

Division: Liberal Arts & Social Sciences

Street1*: 126 Heyne Building

Street2:

City*: Houston
County: Harris
State*: TX: Texas

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 77204-5022

Phone Number*: 713-743-2616 Fax Number: 713-743-8588 E-Mail*: cneighbors@uh.edu

Credential, e.g., agency login: CLAYTONN

Project Role*: PD/PI Other Project Role Category:

Degree Type: Ph.D. Degree Year: 2000

File Name

Attach Biographical Sketch*: Neighbors_Biosketch1010448458.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: First Name*: Qian Middle Name Last Name*: Lu Suffix: Ph.D.

Position/Title*: Assistant Professor
Organization Name*: University of Houston

Department: Psychology

Division: Liberal Arts & Social Sciences

Street1*: 4800 Calhoun St.

Street2:

City*: Houston
County: Harris
State*: TX: Texas

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 77204-2015

Phone Number*: 713-743-8515 Fax Number: 713-743-8588 E-Mail*: qlu3@uh.edu

Credential, e.g., agency login: LUQIAN2

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Ph.D. Degree Year: 2005

File Name

Attach Biographical Sketch*: Lu_Biosketch1010448457.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: First Name*: Lindsey Middle Name Last Name*: Rodriguez Suffix:

Position/Title*: Graduate Student
Organization Name*: University of Houston

Department: Psychology

Division: Liberal Arts & Social Sciences

Street1*: 126 Heyne Building

Street2:

City*: Houston
County: Harris
State*: TX: Texas

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 77204-5022

Phone Number*: 713-743-8500 Fax Number: 713-743-8588 E-Mail*: lindsey.rodriguez1@gmail.com

Credential, e.g., agency login: LRODDY

Project Role*: Other Professional Other Project Role Category: Research Assistant Professor

Degree Type: M.A. Degree Year: 2010

File Name

Attach Biographical Sketch*: Rodriguez_Biosketch1010448459.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: First Name*: Ronda Middle Name Last Name*: Dearing Suffix: Ph.D

Position/Title*: Research Scientist
Organization Name*: University of Buffalo

Department:

Division:

Street1*: 1021 Main St.

Street2:

City*: Buffalo

County:

State*: NY: New York

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 14203-1016

Phone Number*: 716-887-2566 Fax Number: E-Mail*: rdearing@ria.buffalo.edu

Credential, e.g., agency login: DEARING

Project Role*: Consultant Other Project Role Category:

Degree Type: Ph.D. Degree Year: 2001

File Name

Attach Biographical Sketch*: Dearing_Biosketch1010448474.pdf

Attach Current & Pending Support:

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Clayton Neighbors, Ph.D.	Professor
eRA COMMONS USER NAME (credential, e.g., agency login) CLAYTONN	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Lamar University, Beaumont, TX	B.S.	1989-1994	Psychology
Lamar University, Beaumont, TX	M.S.	1994-1996	I/O Psychology
University of Houston, Houston, TX	Ph.D.	1996-2000	Social Psychology
University of Washington, Seattle, WA	Postdoc	2001-2002	Alcohol Research

A. Personal Statement

The proposed research extends our previous research on college alcohol interventions. We have conducted seminal work in the development and evaluation of personalized feedback interventions. I have been a PI or co-PI on six RCTs evaluating brief interventions for college student drinking. I have also collaborated on work evaluating brief interventions for drinking in the general adult population. This proposal represents an innovative extension of our previous work and has the potential to establish a novel alternative brief intervention strategy in the form of expressive writing. We have laid a foundation for this work with two completed promising preliminary trials supporting expressive writing as a brief alcohol intervention. Dr. Lu, Rodriguez, and I are currently working on a third preliminary study which focuses on guilt in expressive writing. This modular R01 is intended to provide a comprehensive evaluation of this approach. Furthermore, we expect the focus on guilt and "change thought" to offer rich and novel theoretical contributions to the literature. We also anticipate significant contributions based on the analysis of the content provided in the expressive writing interventions. I have a strong background and have multiple publications in which I have utilized advanced statistical procedures such as those referred to in the analysis plan. I have a good track record of leading and collaborating on NIH funded projects. I have served as a PI on three NIH R01's including a current NIAAA funded multi-site evaluation brief alcohol interventions with college students. Overall, I have demonstrated a consistent history of high productivity in funded research.

B. Positions and Honors

2010-present	Professor and Director of Social Psychology Program, Department of Psychology,
	University of Houston, Houston, TX
2010-present	Affiliate Professor, Department of Psychiatry and Behavior Sciences,
	University of Washington, Seattle, WA
2007-2010	Associate Professor, Department of Psychiatry and Behavior Sciences,
	University of Washington, Seattle, WA
2004-2007	Assistant Professor, Department of Psychiatry and Behavior Sciences,
	University of Washington, Seattle, WA
2002-2004	Assistant Professor, Department of Psychology, North Dakota State University
2002-2002	Acting Assistant Professor, Department of Psychiatry and Behavior Sciences,
	University of Washington, Seattle, WA
2000-Present	Member, APA Division 8: Society of Personality and Social Psychologists
2002-Present	Member, APA Division 50: Addictive Behaviors; 2007 Program Chair; 2009-2011
	Member at Large, Science
2002-Present	Member, APA Division 38: Health Psychology
	•

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Page ___

Program Director/Principal Investigator (Last, First, Middle):

2002-Present Member, Association for Behavior and Cognitive Therapies; 2006-2008 President Addictive

Behaviors Special Interest Group:

2002-Present Member, Research Society on Alcoholism

2007-Present Advisory Board of the National Institute on Social Norms

2007 Award for Distinguished Scientific Early Career Contributions, APA, Division 50 (Addictions)

C. Selected Peer-reviewed Publications (Selected from 185 peer-reviewed publications)

- Miller, M. B., Leffingwell, T., Claborn, K., Meier, E., Walters, S., & Neighbors, C. (in press). Personalized feedback interventions for college alcohol misuse: An update of Walters & Neighbors (2005). Psychology of Addictive Behaviors. PMID: 23276309
- 2. Rodriguez, L. M., **Neighbors, C.,** & Foster, D. W. (in press). Priming effects of self-reported drinking and religiosity. *Psychology of Addictive Behaviors*. PMID: 23528191
- 3. **Neighbors, C.,** Foster, D. W., Walker, D. D., Kilmer, J. R., & Lee, C. M. (2013). Social identity as a moderator of the association between perceived norms and marijuana use. *Journal of Studies on Alcohol and Drugs, 74*(3), 479-483. PMID: 23490578
- 4. Atkins, D. C., Baldwin, S., Zheng, C., Gallop, R. J., & Neighbors, C. (2013). A tutorial on count regression and zero-altered count models for longitudinal substance use data. Psychology of Addictive Behaviors, 27: 166-177. doi: 10.1037/a0029508. PMCID: PMC3513584
- Neighbors, C., Brown, G., Dibello, A., Rodriguez, L. M., & Foster, D. W. (2013). Reliance on God, prayer, and religion reduces peer influences on drinking. *Journal of Studies on Alcohol and Drugs*, 2013,74, 361-368. PMID: 23490564
- 6. Rodriguez, L. M., Overup, C. S., & **Neighbors, C.** (2013). Perceptions of partners' drinking problem affect relationship outcomes beyond partner self-reported drinking: Alcohol use in committed relationships. *Psychology of Addictive Behaviors*. PMID: 23438240
- 7. Young, C. M., Rodriguez, L. M., & **Neighbors, C.** (2013). Expressive writing as a brief intervention for reducing drinking intentions. *Addictive Behaviors*, *38*, 2913-2917.
- 8. **Neighbors, C.,** Lee, C. M., Atkins, D. C., Lewis, M. A., Kaysen, D., Mittmann, A., Fossos, N., Geisner, I. M., Zheng, C., & Larimer, M.E. (2012). A Randomized Controlled Trial of Event Specific Prevention Strategies for Reducing Problematic Drinking Associated with 21st Birthday Celebrations. *Journal of Consulting and Clinical Psychology, 80,* 850-862. PMCID:22823855
- 9. Lee, C. M., Maggs, J. L., **Neighbors, C.,** & Patrick, M. E. (2011). Positive and negative alcohol-related consequences: Associations with past and planned drinking. *Journal of Adolescence, 34,* 87-94. doi: 10.1016/j.adolescence.2010.01.009. PMCID: PMC3174525
- 10. Collins, S. E., Logan, D. E., & **Neighbors, C.** (2010). Which comes first: The readiness of the change? Longitudinal relationships among readiness to change and drinking outcomes. *Addiction, 105,* 1899-1909. PMID: 20854333
- 11. **Neighbors, C.,** Lewis, M. A., Atkins, D. C., Jensen, M. M., Walter, T., Fossos, N., Lee, C. M., & Larimer, M. E. (2010). Efficacy of web-based personalized normative feedback: A two-year randomized controlled trial. *Journal of Consulting and Clinical Psychology, 78*, 898-911. PMCID: 20873892.
- 12. **Neighbors, C.,** Lee, C. M., Lewis, M. A., Fossos, N., & Walter, T. (2009). Internet-based personalized feedback to reduce 21st birthday drinking: A randomized controlled trial of an Event Specific Prevention Intervention. *Journal of Consulting and Clinical Psychology, 77*, 51-63. PMCID: 19170453.
- 13. **Neighbors, C.**, Walker, D. D., Roffman, R. A., Mbilinyi, L. F., & Edleson, J. L. (2008). Self-determination theory and motivational interviewing: Complementary models to elicit voluntary engagement by partner-abusive men. *American Journal of Family Therapy*, *36*, 126-136. PMCID: 22593609
- 14. Lewis, M. A., Phillippi, J., & **Neighbors, C.** (2007). Morally based self-esteem, drinking motives, and alcohol use among college students. *Psychology of Addictive Behaviors*, *21*, 398-403. PMID: 17874890.
- 15. Toumbourou, J. W., Stockwell, T., **Neighbors, C.**, Marlatt, G. A., Sturge, J., & Rehm, J. (2007). Interventions to reduce harm associated with adolescent substance use: An international review. *Lancet, 369*, 1391-1401.

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Program Director/Principal Investigator (Last, First, Middle):

D. Research Support

Ongoing Research Support

R01AA01476-07-12 (Neighbors-PI)

09/01/11-07/31/16

NIH/NIAAA

Social Norms and Alcohol Prevention (SNAP)

This competing renewal evaluates theoretical foundations underlying social norms based interventions among heavy drinking college students. Primary theoretical extensions focus on social identity. This work centers around three research studies and includes data collection at three universities.

Role: Principal Investigator

NCRG Large Grant

(Neighbors-PI)

01/15/14-01/14/16

National Center for Responsible Gaming

Evaluation and Implementation of Personalized Normative Feedback for Collegegambling.org

This research proposes to evaluate a publically available tool providing personalized normative feedback (PNF) hosted on the collegegambling.org website. Students will be screened from 12 representative schools with respect to region and size. This research will extend the PNF approach to gambling to multiple campuses and to web-based delivery. Moreover, this research will facilitate the implementation of a one-of-a-kind, freely available screening and brief intervention tool for at-risk college students across the U.S.

Role: Principal Investigator

DR081215 (Walker-PI)

09/01/09-08/31/14

U.S. Department of Defense

Motivating Treatment Seeking and Behavior Change by Untreated Military Personnel Abusing Alcohol or Drugs The objective of this research is to evaluate the feasibility of delivery and potential efficacy of personalized feedback for alcohol and other substances to active duty military personnel who meet criteria for substance abuse or dependence but who are not currently receiving treatment.

Role: Co-Investigator

R01AA021763 (Lindgren-PI)

09/01/09-08/31/14

NIH/NIAAA

Using Implicit Measures to Improve Prediction of Hazardous Drinking

The objective of this research is to evaluate the utility of implicit measures in accounting for unique variance in alcohol consumption and related consequences.

Role: Co-Investigator

Selected Completed Research Support

R01AA016099 (Neighbors/Lee-Pls)

2007-2013

NIH/NIAAA

Event Specific Prevention (ESP)

This research evaluated an Event Specific Prevention (ESP) intervention targeting 21st birthday celebratory drinking and Spring Break drinking. Role: Principal Investigator Years 1-2; Co-Principal Investigator Years 3-6 Role: Principal Investigator

NCRG large grant (Neighbors-PI)

07/01/11-12/30/13

National Center for Responsible Gaming

A Randomized Controlled Trial of Personalized Normative Feedback for Problem Gambling College Students This project evaluates in-person computer-based personalized norms feedback as an intervention for problem gambling college students.

Role: Principal Investigator

2R01DA017873 (Mbilinyi-PI)

2004-2012

National Institute on Drug Abuse

PHS 398/2590 (Rev. 06/09) Page ___ Continuation Format Page

Program Director/Principal Investigator (Last, First, Middle):

Motivating Substance Abusing Batterers to Seek Treatment

The objective of this program of research was to evaluate approaches for motivating substance abusing perpetrators of intimate partner violence to take steps in the direction of positive behavior change.

Role: Co-Investigator

R01AA012547 (Larimer-PI)

2007-2011

NIH/NIAAA

Social Norms and Skills-training: Motivating Campus Change

This research comprehensively evaluated the impact of reference specificity on efficacy of computer delivered normative feedback. Overall, findings suggested little advantage of specificity on intervention efficacy.

Role: Co-Investigator.

R01AA012547 (Cunningham-PI)

2007-2011

NIH/NIAAA

Ultra-Brief Intervention for Problem Drinkers

This research evaluated a mailed pamphlet containing social norms information as a brief intervention targeting problem drinking. Pamphlets were sent to random households in the Toronto area. Assessments were conducted by telephone.

Role: Co-Investigator.

R01AA014576 (Neighbors-PI)

2004-2010

NIH/NIAAA

Social Norms Alcohol Prevention

The purpose of this research was to examine the efficacy of remote computer delivered personalized normative feedback in the prevention and reduction of problem drinking among college students.

Role: Principal Investigator

U01AA014742 (Larimer-PI)

2003-2009

NIH/NIAAA

Alcohol Research Collaborative: Peer Programs

This was one of five U01s funded as part of the NIAAA Rapid Response to College Drinking. Our team was paired with four Universities, each supported by U18 grants, to collaborate in developing and evaluating interventions targeting critical alcohol related issues on each campus.

Role: Co-Investigator.

R21MH067026 (Larimer-PI)

2003-2006

NIH/NIMH

Indicated Prevention with At-Risk Gamblers

This project evaluated a brief single-session MET for problem gambling college students relative to a multisession CBT intervention and control. Overall results indicated support for both interventions relative to control. Results were somewhat better for the brief MET group.

Role: Co-Investigator

PHS 398/2590 (Rev. 06/09) Page ___ **Continuation Format Page**

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Lu, Qian	Assistant Professor
eRA COMMONS USER NAME (credential, e.g., agency login) QIANLU	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Shandong Medical University, China	M.D.	06/97	Medicine
Shandong Medical University, China	Internship	06/97	Medicine
The Chinese Academy of Sciences, China	M.S.	06/00	Biopsychology
University of California at Los Angeles	M.A.	06/01	Psychology
University of California at Los Angeles	Ph.D.	06/05	Psychology

A. Personal Statement

During the past decade, my research focuses on developing novel social and behavioral interventions, particularly for vulnerable populations. I have developed a programmatic line of research to test expressive writing as an intervention paradigm among minorities and understudied populations. This paradigm is designed to improve health by prompting emotional and cognitive processes through writing. I have completed several funded studies using expressive writing paradigms in various populations. I examined the efficacy of expressive writing in healthy Caucasian and Asian college students and how the effects of expressive writing might vary as a function of ethnicity and personal attributes, which was the pilot study for this proposed project. Using a community based participatory research approach (CBPR), I completed an National Cancer Institute CNP pilot study entitled: Health Benefits of Expressive Writing among Chinese Breast Cancer Survivors, and expanded the pilot study to a randomized controlled trial in multiple Chinese American communities with a grant from the American Cancer Society. I have also completed a single-aim pilot study with the support from the Susan Komen Foundation to test the feasibility and potential effectiveness of a social support program for Chinese American breast cancer survivors. Besides expressive writing paradigm, I have also examined cultural influence on adjustment, coping, emotion regulation, and published extensively in these areas. I am a coinvestigator for a R01 study (PI: Dr. Kagawa-Singer) to investigate how culture and social support influence quality of life among Asian American breast cancer survivors. My experience and skills make me well-suited to be a co-investigator for this proposed project. I will bring my expertise on expressive writing and emotion regulation to this proposed project.

B. Research and Professional Experience

Positions and Employment

2005-2007 Post-doctoral Research Fellow, Pediatric Pain and Jonsson Comprehensive Cancer Center,

UCLA

2007-2008 Assistant Researcher, Department of Pediatrics, UCLA

2008-present Assistant Professor, Department of Psychology, University of Houston Director, Culture and Health Research Center, University of Houston

Professional Memberships

American Psychology Association, American Psycho-Oncology Society (APOS), American Pain Society, American Psychosomatic Society, Chinese Scholar Association

Honors (selected)

2001 AIDS Prevention Training Fellowship, School of Public Health, UCLA

2003	Institute of American Culture Research Grant, UCLA
2004	Bertram Raven Award for Best Social Issues Research Paper
2004-2005	Society for the Psychological Study of Social Issues Grant-in-Aid
2004-2005	American Psychological Foundation (APF)/ Council of Graduate Departments of
	Psychology (COGDOP) Graduate Research Scholarship in Psychology
2005	"Essentials of Pain Management: Principles and Practice" resident's program
2005-2006	Post-doctoral Fellowship, Jonsson Comprehensive Cancer Center at UCLA
2004-2009	American Pain Society Young Investigator Travel Award
2006	American Psychosomatic Society Young Scholar Award

- **C. Publications** (*indicates student or trainee, * indicates non-first but corresponding authorship) (Selected from peer reviewed 28 publications)
 - 1. **Lu, Q.**, Lin, W.J. & Wang, J.P. (2000). Psychosocial factors and human immunity. Advances in Psychological Science *(Chinese)*, V2.
 - 2. **Lu, Q.,** Lu, M., & Dunkel Schetter, C. (2005) Learning from success and failure in psychosocial interventions: An evaluation of low birth weight prevention trials. *Journal of Health Psychology.* 10, 185-195.
 - 3. Lu, Q., Zeltzer, L., Tsao, JCI, Kim, SC & Naliboff, B.D. (2005) Heart rate mediation of sex differences in pain tolerance in children. *Pain*, 118, 185-193.
 - 4. Lu Q., Tsao, J. C. I., Myers, C. D., Kim, S. C., & Zeltzer, L. K. (2007). Coping predictors of children's laboratory-induced pain tolerance, intensity, and unpleasantness. *Journal of Pain*, 8(9), 708-717.
 - 5. Zeltzer, L. K., **Lu, Q.,** Leisenring, W., Tsao, J. C. I., Recklitis, C., Armstrong, G., et al. (2008). Psychosocial Outcomes and Health-Related Quality of Life in Adult Childhood Cancer Survivors: A Report from the Childhood Cancer Survivor Study. *Cancer Epidemiology, Biomarkers and Prevention, 17*(2), 435-446.
 - 6. Allen, L. B.*, **Lu, Q.***, Tsao, J. C. I., Worthman, C. M., & Zeltzer, L. K. (2009). Sex differences in the association between cortisol concentrations and laboratory pain responses in healthy children. *Gender Medicine*, *6*(Part 2), 193.
 - 7. **Lu, Q.,** & Stanton, A. L. (2010). How benefits of expressive writing vary as a function of writing instructions, ethnicity and ambivalence over emotional expression. *Psychology & Health*, 25(6): p. 669-684
 - 8. **Lu, Q.,** Uysal, A.*, & Teo, I.*. (2011). Need Satisfaction and Catastrophizing: Explaining the Relationship among Emotional Ambivalence, Pain, and Depressive Symptoms. *Journal of Health Psychology, 16*(5), 819-27.
 - 9. Uysal, A. *, & Lu, Q. (2011). Self-concealment and Pain in Healthy and Chronic Pain Samples. *Health Psychology*, *30*(5), 606-14.
 - 10. Lu, Q., Kevin, K., Owen, J., Kawashima, T., Leisenring, W., Myers, C. D., Zebrack, B., Tsao, J. C. I., Mertens, A. C., Robison, L. L., & Zeltzer, L. K. (2011). Pain in Adult Childhood Cancer Survivors: a Report from the Childhood Cancer Survivor Study. *Pain*, *152*(11), 2616-24.
 - 11. Yang, Z., Meng, Q., Luo, J., **Lu, Q**., Li, X. J., Li, G. F., & Wan, C. H. (2011). Development and Validation of the Simplified Chinese Version of EORTC QLQ-H&N35 for Patients with Head and Neck Cancer. *Supportive Care in Cancer*, 1-10.
 - 12. Lu, Q., Zheng, D. H.*, Young, L., Kagawa-Singer, M., & Loh, A. (2012). A Pilot Study of Expressive Writing Intervention among Chinese-Speaking Breast Cancer Survivors. *Health Psychology*. doi:10.1037/a0026834
 - 13. Kaur, J. S., Coe, K., Rowland, J., Braun, K. L., Conde, F. A., Burhansstipanov, L., Heiney, S., Kagawa-Singer, M., **Lu, Q**., & Witte, C. (2012). Enhancing Life after Cancer in Diverse Communities. *Cancer.* doi: 10.1002/cncr.27491.
 - 14. Umezawa, Y., Lu, Q.*, You, J.*, Kagawa-Singer, M., & Maly, R. (2012). Belief in Divine Control, Coping, and Race/Ethnicity among Older Women with Breast Cancer. *Annals of Behavioral Medicine*, 44, 21-32.
 - 15. **Lu, Q.,** Tsao, J. C. I., Zeltzer, L. K. (2013). Ethnic differences in experimental pain response in children. *Health Psychology.* Advance online publication. doi: 10.1037/a0032428

D. Research Support Active

MRSGT-10-011-01-CPPB

Lu (PI)

1/2010-12/2014

American Cancer Society

To reduce psychosocial burdens among Chinese speaking breast cancer survivors.

The study aims to test the effect of an expressive writing intervention among Chinese speaking breast cancer survivors in multiple communities.

Role: Principal Investigator

1 R01 CA158314-01

Kagawa-Singer (PI)

4/2011-3/2016

National Cancer Institute

Culture, Support & Quality of Life: Asian American Breast Cancer Survivors

This study aims to explore cultural explanations for the cross-cultural differences found in quality of life studies among Asian and Asian American populations compared with Western countries

Role: Co- Investigator

Completed funded research projects

IAC research grant Lu (PI) 6/2003-12/2005

Institute of American Culture Research, UCLA

A Writing Intervention for Chinese Americans

The study aims to examine the effect of emotional disclosure writing on psychological and physiological health among Asian Americans.

Role: Principal Investigator

SPSSI grant-in-aid Lu (PI) 9/2004-9/2005

The Society for the Psychological Study of Social Issues

How Physical and Psychological Health Benefits of Instructed Writing Vary as a Function of the Writing Instructions, Ethnicity, and Personality Attributes

The study aims to examine under which condition instructed writing produce health benefits.

Role: Principal Investigator

APF/COGDOP research grant

Lu (PI)

9/2004-9/2005

American Psychological Foundation (APF)/COGDOP

How Physical and Psychological Health Benefits of Instructed Writing Vary as a Function of the Writing Instructions, Ethnicity, and Personality Attributes.

The study aims to examine under which condition instructed writing produce health benefits.

Role: Principal Investigator

U01 CA114640-02S5 Chen (PI) 10/2007-3/2009

The National Cancer Institute (UCLA Subaward No. Sub0600228, UH subaward)

Health Benefits of Expressive Writing among Chinese Breast Cancer Survivors

This study aims to test the feasibility of an expressive writing intervention among Chinese-speaking breast cancer survivors.

Role: Pilot Pl.

BCTR0707861 Lu (PI) 8/2007-9/2012

Susan G. Komen Breast Cancer Foundation

Testing a Culturally Sensitive Intervention among Chinese Breast Cancer Survivors

This study aims to evaluate the feasibility and potential psychological and physical health benefits of a culturally sensitive social support intervention program among Chinese-speaking breast cancer survivors.

Role: Principal Investigator

Community Research Grant *UCLA AANCART*

Young (PI)

8/2009-3/2010

Joy Luck Academy

This study aims to develop a 10-week, culturally and linguistically appropriate curriculum for a mentorship program specifically designed for Chinese breast cancer survivors who have completed primary treatment within the last eight months.

Role: Consultant (in-kind)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Lindsey M. Rodriguez		POSITION TITLE Research Assistant Professor		
eRA COMMONS USER NAME (credential, e.g., agency login) LRODDY				
EDUCATION/TRAINING (Begin with baccalaureate or other in residency training if applicable.)	itial professional education,	such as nursing, in	clude postdoctoral training and	
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY	
University of Florida	B.S.	05/2008	Psychology	
University of Houston	M.A.	07/2010	Social Psychology	
University of Houston	Ph.D.	05/2014	Social Psychology, minor in Quantitative Psychology	

A. Personal Statement

The proposed application will evaluate expressive writing as an innovative brief intervention focusing on reducing risky alcohol use among heavy drinking college students. We have comprised theoretically-based hypotheses to evaluate whether, for whom, and why expressive writing will be a low-cost, efficacious intervention for reducing alcohol use and related negative consequences among college students. Dr. Neighbors and I have a history of collaboration on funded mechanisms, including a National Research Service Award from the National Institute on Alcohol Abuse and Alcoholism (F31AA020442), which will be completed by the start date of the proposed research.

My background in health psychology, social psychological theories, and alcohol research has afforded me with expertise and substantial experience publishing research on alcohol interventions. I have conducted research and published manuscripts focused on reducing heavy drinking and related risky behaviors among college students, including the two pilot projects on expressive writing which formed the basis for this application. I have coauthored the publication supporting expressive writing as a brief intervention to reduce drinking intentions in the proposed population (Young, Rodriguez, & Neighbors, 2013) and the publication examining guilt as a mediator of intervention efficacy (Rodriguez et al., under review), coauthored with both Drs. Neighbors and Lu. My specific training and proficiency in areas consistent with this research application allow application of my knowledge, motivation, and ability to implement the proposed research with accuracy and enthusiasm. I will provide theoretical, substantive, and methodological expertise to guide multiple facets of the proposed research. Specifically, I will be responsible for leading the content-coding with the Linguistic Inquiry and Word Count (LIWC) software. I will also be primarily responsible for data management and data analysis. I will also collaborate with the research team in the dissemination of the research findings and preparation of all scientific reports.

In sum, I have demonstrated a successful and productive record of research projects in an area of high relevance to the current application. My expertise and experiences with social theories, college drinking, brief alcohol interventions, and expressive writing have prepared me to be a productive and resourceful member of Dr. Neighbors' research team.

Rodriguez, Lindsey M.

B. Positions and Honors

Positions:

Visiting Assistant Professor, Department of Psychology, University of Houston, Houston, TX.
 Present Graduate Research Assistant, Department of Psychology, University of Houston, Houston, TX. Advisors: C. Raymond Knee, Ph.D. and Clayton Neighbors, Ph.D.
 Data Analyst, Houston Center for Quality of Care and Utilization Studies, Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX. Supervisor: Melinda Stanley, Ph.D.

Academic and Professional Honors:

Awards and Scholarships	
University of Houston Dissertation Completion Fellowship	2013 – 2014
National Institute of Health F31 National Research Science Award,	2011 – 2014
Predoctoral Fellowship (F31AA020442)	
Primary Investigator	
National Institute of Alcohol Abuse and Alcoholism	
National Institute of Alcohol Abuse and Alcoholism/National Institute	2012
on Drug Abuse Early Career Poster Session and Social Hour	
Award Recipient	
Texas Research Society on Alcoholism John P. McGovern	2011
Medical Student Fellowship Recipient	
Society for Personality and Social Psychology Diversity Fund Travel	2011
Award Recipient	
Best Poster Award at the Annual Society for Southeastern Social	2010
Psychologists, Charleston, SC. Rodriguez, L. M., & Knee, C. R.	
Self-Monitoring and the Implications of Meeting Ideal Standards in	
Romantic Relationships	
University of Houston Dr. Arnold Genevive Psychology	2008 – 2011
Graduate Student Scholarship	
University of Houston Graduate Travel Award	2008 – 2011
University of Houston Presidential Graduate Scholarship	2008 – 2010
University of Houston Graduate Assistant	2008 – 2013
Tuition Fellowship	
Memberships in Professional Societies:	
International Association for Relationship Research	2012 - Present
University of Houston Department of Psychology	2011 - Present
Research Committee Graduate Student Representative	
Association for Behavioral and Cognitive Therapies	2011 - Present
Texas Research Society on Alcoholism	2011 - Present
Research Society on Alcoholism	2010 - Present
Society of the Southeastern Social Psychologists	2010 - Present

Rodriguez, Lindsey M.

Society for Personality and Social Psychology

American Psychological Association, Student Affiliate

American Psychological Association of Graduate Students (APAGS)

Division 8: Society for Personality and Social Psychology (SPSP)

Division 50: Addictions

2008 – Present 2008 – Present

C. Selected Peer-reviewed Publications

Selected Manuscripts and Book Chapters (in chronological order):

- **1. Rodriguez, L. M.,** Neighbors, C., & Knee, C. R. (in press). Problematic alcohol use and marital distress: An interdependence theory perspective. *Addiction Research and Theory.*
- **2. Rodriguez**, **L. M.**, Knee, C. R., & Neighbors, C. (in press). Relationships can drive some to drink: Relationship-contingent self-esteem moderates the relationship between relationship satisfaction and problem drinking. *Journal of Social and Personal Relationships*.
- **3.** Rodriguez, L. M., Neighbors, C., & Foster, D. W. (in press). Priming effects of self-reported drinking and religiosity. *Psychology of Addictive Behaviors*.
- **4.** DiBello, A., Neighbors, C., **Rodriguez, L. M.**, & Lindgren, K. (2014). Coping with jealousy: The association between maladaptive aspects of jealousy and drinking problems are mediated by drinking to cope. *Addictive Behaviors*, *39*, 94-100.
- **5.** Young, C. M., **Rodriguez**, **L. M.**, & Neighbors, C. (2013). Expressive writing as a brief intervention for reducing drinking intentions. *Addictive Behaviors*, *38*, 2913-2917.
- **6. Rodriguez, L. M.**, Overup, C. S., & Neighbors, C. (2013). Perceptions of partners' drinking problem affect relationship outcomes beyond partner self-reported drinking: Alcohol use in committed romantic relationships. *Psychology of Addictive Behaviors*, 27, 627-638.
- **7. Rodriguez, L. M.,** DiBello, A. M., & Neighbors, C. (2013). Perceptions of partner drinking problems, regulation strategies, and relationship outcomes. *Addictive Behaviors, 38,* 2949-2957.
- **8.** Knee, C. R., Hadden, B. W., Porter, B., & **Rodriguez**, **L. M.** (2013). Putting the self into the relationship: Self-determination theory and romantic relationships. *Personality and Social Psychology Review*, *17*, 307-324.
- Neighbors, C., Brown, G., DiBello, A. M., Rodriguez, L. M., & Foster, D. W. (2013). Reliance on God, prayer, and religion reduces peer influences on drinking. *Journal of Studies on Alcohol and Drugs*, 74, 361-368.
- **10.** Litt, D. M., Lewis, M. A., Patrick, M., **Rodriguez, L. M.**, Neighbors, C., & Kaysen, D. (2013). Spring Break or spring broken: Predicting extreme Spring Break drinking from intentions and willingness. *Prevention Science*. PMCID: 23404667
- **11.** Neighbors, C., Lindgren, K. P., **Rodriguez, L. M.**, Tidwell, J., & Zvorsky, I. (2013). Cognitive Factors in Addictive Processes. In P. M. Miller (Ed.), *Encyclopedia of Addictive Behaviors*. Elsevier: Amsterdam.
- **12.** Foster, D. W., Neighbors, C., **Rodriguez, L. M.**, Lazorwitz, B., & Gonzales, R. (2012). Self-identification as a moderator of the relationship between gambling-related perceived norms and gambling behavior. *Journal of Gambling Studies*. PMCID: 23143706
- 13. Neighbors, C., Atkins, D. C., Lewis, M. A., Lee, C. M., Kaysen, D., Mittmann, A., Fossos, N., & Rodriguez, L. M. (2011). Event specific drinking among college students. *Psychology of Addictive Behaviors*, 25, 702-707. PMCID: 21639597
- **14.** Foster, D. W., **Rodriguez, L. M.**, Neighbors, C., DiBello, A., & Chen, C. (2011). The magic number 21: Transitions in drinking. *The Addictions Newsletter, 18,* 17-19.

Rodriguez, Lindsey M.

15. Walker, D. D., Neighbors, C., Rodriguez, L. M., Roffman, R. A., & Stephens, R. S. (2011). Social norms and self-efficacy among heavy using adolescent marijuana smokers. Psychology of Addictive Behaviors, 25, 727-732. PMCID: 3342009

D. Research Support

Current

F31AA020442 (Rodriguez-PI)

August 2011 - May 2014

NIH/NIAAA

Alcohol Use and Relationship Distress in Married Couples

This research project utilizes data from married couples to further understand the relationship between problematic alcohol use and relationship distress, laying the groundwork for future prevention and intervention efforts to reduce depression, intimate partner violence, alcohol-related fatalities, and divorce rates. This goal will be achieved by disentangling and comparing the temporal relationships between alcohol use and marital distress, identifying the most important determinants (mediators and moderators), and testing a larger, more comprehensive model.

Role: Principal Investigator

NCRG Large Grant (Neighbors-PI)

January 2014 - January 2016

National Center for Responsible Gaming

Evaluation and Implementation of Personalized Normative Feedback for Collegegambling.org This research proposes to evaluate a publically available tool providing personalized normative feedback (PNF) hosted on the collegegambling.org website. Students will be screened from 12 representative schools with respect to region and size. Students who meet screening criteria will be randomly assigned to intervention versus attention control, with follow-up assessments 3 and 6 months post intervention. This research will extend the PNF approach to gambling to multiple campuses and to web-based delivery. Moreover, this research will facilitate the implementation of a one-of-a-kind, freely available screening and brief intervention tool for at-risk college students across the U.S.

Role: Co-investigator

Pending

R21AA022369 (Neighbors-PI) NIH/NIAAA

March 2014 - February 2016

Motivating Recruitment and Efficacy in Normative Feedback Interventions

This research proposes to evaluate motivational factors associated with recruitment into and efficacy of brief computer-delivered interventions for heavy drinking college students.

Role: Co-investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Ronda L. Dearing	POSITION TITLE Senior Research Scientist
eRA COMMONS USER NAME (credential, e.g., agency login) DEARING	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
California State University, Northridge	B.A.	1981-1985	Biology
Augusta Medical Center, Fishersville, VA	Certificate	1990-1991	Medical Technology
James Madison University, Harrisonburg, VA	B.S.	1993-1994	Psychology
George Mason University, Fairfax, VA	M.A.	1995-1997	Psychology (Clinical)
George Mason University, Fairfax, VA	Ph.D.	1997-2001	Psychology (Clinical)
Research Institute on Addictions, Buffalo, NY	Postdoc	2001-2004	Addictions

A. Personal Statement

Dr. Ronda L. Dearing is a senior research scientist at the Research Institute on Addictions and she is licensed as a psychologist in New York State. Of specific relevance to the present application, PI Dearing has been involved in research on shame and guilt for over a decade. She began this work while a graduate assistant working with June Tangney, a foremost expert in the study of shame and guilt. This experience resulted in Dr. Dearing's collaboration with Dr. Tangney writing a research-based book (Tangney & Dearing, 2002) that summarizes the empirical study of these important moral emotions. Drs. Dearing and Tangney subsequently developed an edited book entitled *Shame in the Therapy Hour* (Dearing & Tangney, 2011). In addition to research on shame and guilt, Dr. Dearing's research also includes a focus on various aspects of alcohol use. Combining these topic areas, Dr. Dearing published one of the few studies to empirically demonstrate a negative relation between guilt-proneness and alcohol consumption, suggesting that guilt may serve a protective function against problematic alcohol use (Dearing et al., 2005). PI Dearing's background and experience studying guilt and alcohol use make her uniquely suited as a consultant for the proposed research study.

B. Positions and Honors

Positions	
1982-1986	Medical Assistant, Calvin R. Elrod, M.D., P.C., Burbank, CA
1986-1989	Administrative Assistant, UCLA Medical Center, Los Angeles, CA
1989-1990	Temporary Payroll Assistant, Genicom Corporation, Waynesboro, VA
1990-1991	Phlebotomist, Augusta Hospital Corporation, Fishersville, VA
1991-1995	Medical Technologist, Augusta Hospital Corporation, Fishersville, VA
1995-1996	Graduate Teaching Assistant, George Mason University, Fairfax, VA
1996-2000	Graduate Research Assistant, George Mason University, Fairfax, VA
1997-1998	Psychology Extern, Arlington Mental Health Services, Arlington, VA
1998-2000	Mental Health Therapist, Arlington Mental Health Services, Arlington, VA
2000-2001	Psychology Intern, Veterans Affairs Maryland Health Care System, Perry Point, MD
2001-2004	Postdoctoral Fellow, Research Institute on Addictions, University at Buffalo, Buffalo, NY
2004, 2008,	Reviewer, Substance Abuse and Mental Health Services Administration, National
2011-present	Registry of Effective Programs and Practices
2004-2011	Research Scientist, Research Institute on Addictions, University at Buffalo, Buffalo, NY
2011-present	Senior Research Scientist, Research Institute on Addictions, University at Buffalo,
•	Buffalo, NY

Professional Memberships

American Psychological Association (2001-2011) APA Division 50 (Society of Addiction Psychology) Association for Behavioral and Cognitive Therapies Research Society on Alcoholism

Honors and Awards

2002 Research Society on Alcoholism, Junior Investigator Award

2002 Research Society on Alcoholism, Enoch Gordis Research Recognition Award

(Psychosocial Postdoctoral Category)

2003-2009 National Institutes of Health, Clinical Research Loan Repayment Program

2003 Research Society on Alcoholism, Junior Investigator Award 2004 Research Society on Alcoholism, Junior Investigator Award

Licensure and Certification

New York State Education Department, Division of Professional Licensing Services, Psychology License #68 015329

C. Peer-reviewed Publications (in chronological order)

- Fee (Dearing), R. L., & Tangney, J. P. (2000). Procrastination: A way of avoiding shame and guilt? *Journal of Social Behavior and Personality*, 15(5), 167-184.
- Dearing, R. L., Barrick, C., Dermen, K. H., & Walitzer, K. S. (2005). Indicators of client engagement: Influences on alcohol treatment satisfaction and outcomes. *Psychology of Addictive Behaviors* 19, 71-78. PMCID: PMC3106346
- Dearing, R. L., Stuewig, J., & Tangney, J. P. (2005). On the importance of distinguishing shame from guilt: Relations to problematic alcohol and drug use. *Addictive Behaviors*, *30*, 1392-1404.
- Dearing, R. L., Maddux, J. E., & Tangney, J. P. (2005). Predictors of psychological help seeking in clinical and counseling psychology graduate students. *Professional Psychology: Research and Practice*, *36*, 323-329.
- Walitzer, K. S., & Dearing, R. L. (2006). Gender differences in alcohol and substance use relapse. *Clinical Psychology Review*, *26*, 128-148.
- Parks, K. A., Hequembourg, A. L., & Dearing, R. L. (2008). Women's social behavior when meeting new men: The influence of alcohol and childhood sexual abuse. *Psychology of Women Quarterly, 32*, 145-158. PMCID: PMC2491329
- Stuewig, J., Tangney, J. P., Mashek, D., Forkner, P., & Dearing, R. L. (2009). The moral emotions, alcohol dependence, and HIV risk behavior in an incarcerated sample. *Substance Use and Misuse, 44*, 449-471. PMCID not applicable; accepted for publication prior to April, 2008.
- Walitzer, K. S., & Dearing, R. L. (2013). Characteristics of alcoholic smokers, nonsmokers, and former smokers: Personality, negative affect, alcohol involvement, and treatment participation. *Nicotine & Tobacco Research*, *15*, 282-286. doi: 10.1093/ntr/nts112; PMCID: PMC3524065
- Hequembourg, A. & Dearing, R. (2013). Exploring shame, guilt, and problematic alcohol use among sexual minority men and women. *Journal of Homosexuality, 60*, 1-24. doi: 10.1080/00918369.2013.760365; PMCID: PMC3621125. [Available on 4/1/2014].
- Dearing, R. L., Witkiewitz, K., Connors, G. J., & Walitzer, K. S. (2013). Prospective changes in alcohol use among hazardous drinkers in the absence of treatment. *Psychology of Addictive Behaviors, 27*, 52-61. doi: 10.1037/a0028170; PMCID: PMC3427414 [Available on 3/1/2014].
- Dearing, R. L., Twaragowski, C., Smith, P. H., Homish, G. G., Connors, G. J., & Walitzer, K. S. (in press). Super Bowl Sunday: Risky Business for At-Risk (Male) Drinkers? Substance Use and Misuse. PMCID: PMC Journal—In Process.
- Witkiewitz, K., Dearing, R. L., & Maisto, S. A. (in press). Alcohol Use Trajectories among Non-Treatment Seeking Heavy Drinkers. *Journal of Studies on Alcohol and Drugs*. PMCID: PMC Journal—In Process.

Books

Tangney, J. P., & Dearing, R. L. (2002). Shame and guilt. New York: Guilford Press.

Maisto, S. A., Connors, G. J., & Dearing, R. L. (2007). Alcohol use disorders. Gottingen: Hogrefe & Huber.

Dearing, R. L., & Tangney, J. P. (Eds.) (2011). *Shame in the therapy hour*. Washington, DC: American Psychological Association.

D. Research Support

Ongoing Research Support

R01 AA020253 (Connors/Maisto)

04/01/12 - 03/31/16

NIAAA

Enhancing Therapeutic Alliances in Alcoholism Treatment

This project will evaluate a feedback system designed to enhance alliances among patients in alcoholism outpatient treatment.

Role: Co-I

R21 AA020522 (Parks Marsh)

07/20/11 - 06/30/14

NIAAA

Video Vignettes: Measuring Risk Perception in Alcohol-Related Sexual Assault

A series of three video vignettes with cues indicative of three levels of risk (low, neutral, high) will be developed and validated over the course of three separate studies.

Role: Co-I

R03 AA020925 (Houston)

07/01/12 - 06/30/14

NIAAA

Heart rate variability and impulse control during alcohol dependence treatment

This pilot/feasibility study is designed to examine the relation between heart rate variability (HRV) and various aspects of impulse control in an alcohol dependent sample of men and women. In addition, the feasibility and effectiveness of administering HRV training in this sample will also be explored.

Role: Co-I

Completed Research Support

K01 AA014865 (Dearing)

03/10/05 - 02/28/11

NIAAA

Help-Seeking for Alcohol Problems: A Prospective Study

This career development award provided 5 years of training and mentoring in help-seeking and alcohol treatment research, as well as the resources for a 2-year prospective study of help-seeking in individuals with a range of alcohol problem severity (N = 208).

Role: PI

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

1. Project Director	/ Principal Investigator (PD/PI)	
Prefix:		
First Name*:	Clayton	
Middle Name:		
Last Name*:	Neighbors	
Suffix:	Ph.D.	
2. Human Subjects		
Clinical Trial?	No	O Yes
Agency-Defined Phase	•	O Yes
3. Permission State	ement*	
If this application does	not result in an award, is the Government	nent permitted to disclose the title of your proposed project, and the name,
		signing for the applicant organization, to organizations that may be
interested in contacting	g you for further information (e.g., poss	sible collaborations, investment)?
• Yes O No		
Tes 5 No		
	icipated during the periods for which the bove (indicating that program income is	ne grant support is requested? Yes No s anticipated), then use the format below to reflect the amount and source(s).
Budget Period*	Anticipated Amount (\$)*	Source(s)*

PHS 398 Cover Page Supplement

5. Human Embryonic Stem Cells
Does the proposed project involve human embryonic stem cells?* • No • Yes
If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:
Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.
6. Inventions and Patents (For renewal applications only)
Inventions and Patents*: O Yes O No
If the answer is "Yes" then please answer the following:
Previously Reported*: O Yes O No
Freviously Reported . Tes Two
7. Change of Investigator / Change of Institution Questions
Change of principal investigator / program director
Name of former principal investigator / program director:
Prefix:
First Name*:
Middle Name:
Last Name*:
Suffix:
☐ Change of Grantee Institution
Name of former institution*:

OMB Number: 0925-0001

Budget Period: 1						
Start Date: 09/01/2014						
A. Direct Costs				Funds Requested (\$)		
		Direct Cost	less Consortium F&A* Consortium F&A	175,000.00		
			Total Direct Costs*	175,000.00		
B. Indirect Costs						
Indirect Cost Type	Indirect Cost	Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)		
1. MTDC_On Campus FY2014		50.50	175,000.00	88,375.00		
2.						
3.						
4.						
Cognizant Agency (Agency Name, POC Name and Phone Number)	DHHS, Arif Karim, 214-767-	3261				
Indirect Cost Rate Agreement Date	11/20/2012		Total Indirect Costs	88,375.00		
C. Total Direct and Indirect Costs (A	. + B)		Funds Requested (\$)	263,375.00		

Budget Period: 2					
Start Date: 09/01/2015 End Date: 08/31/2016					
A. Direct Costs				Funds Requested (\$)	
		Direct Cost	less Consortium F&A* Consortium F&A	200,000.00	
			Total Direct Costs*	200,000.00	
B. Indirect Costs					
Indirect Cost Type	Indirect Cost	Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)	
1. MTDC_On Campus FY2014		50.50	200,000.00	101,000.00	
2.					
3.					
4.					
Cognizant Agency (Agency Name, POC Name and Phone Number)	DHHS, Arif Karim, 214-767-3	261			
Indirect Cost Rate Agreement Date	11/20/2012		Total Indirect Costs	101,000.00	
C. Total Direct and Indirect Costs (A	+ B)		Funds Requested (\$)	301,000.00	

Budget Period: 3					
	Start Date: 09/01/2016	End Dat	e: 08/31/2017		
A. Direct Costs				Funds Requested (\$)	
		Direct Cost	less Consortium F&A*	200,000.00	
			Consortium F&A		
			Total Direct Costs*	200,000.00	
B. Indirect Costs					
Indirect Cost Type	Indirect Cost I	Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)	
MTDC_On Campus FY2014		50.50	200,000.00	101,000.00	
2.					
3.					
4					
Cognizant Agency (Agency Name, POC Name and Phone Number)	DHHS, Arif Karim, 214-767-3.	261			
Indirect Cost Rate Agreement Date	11/20/2012		Total Indirect Costs	101,000.00	
C. Total Direct and Indirect Costs (A	л + В)		Funds Requested (\$)	301,000.00	

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200,000.00
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101,000.00
301,000.00

Budget Period: 5					
Start Date: 09/01/2018 End Date: 08/31/2019					
A. Direct Costs				Funds Requested (\$)	
		Direct Cost	less Consortium F&A* Consortium F&A	175,000.00	
			Total Direct Costs*	175,000.00	
B. Indirect Costs					
Indirect Cost Type	Indirect Cost	Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)	
1. MTDC_On Campus FY2014		50.50	175,000.00	88,375.00	
2.					
3.					
4.					
Cognizant Agency (Agency Name, POC Name and Phone Number)	DHHS, Arif Karim, 214-767-3	261			
Indirect Cost Rate Agreement Date	11/20/2012		Total Indirect Costs	88,375.00	
C. Total Direct and Indirect Costs (A			Funds Requested (\$)	263,375.00	

Cumulative Budget Information

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium F&A for Entire Project Period (\$) 950,000.00

Section A, Total Consortium F&A for Entire Project Period (\$)

Section A, Total Direct Costs for Entire Project Period (\$) 950,000.00

Section B, Total Indirect Costs for Entire Project Period (\$) 479,750.00

Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period (\$) 1,429,750.00

2. Budget Justifications

Personnel Justification Personnel_Justification1010448482.pdf

Consortium Justification

Additional Narrative Justification Additional_narrative_justification1010448467.pdf

PERSONNEL JUSTIFICATION

<u>Clayton Neighbors</u>, Ph.D., Principal Investigator (Effort = 2.4 months, 20% in all 5 years) will be responsible for the overall direction of the research project, as well as sharing responsibility for supervising screening, recruitment, development and implementation of the intervention, and adjusting protocols as needed, based on his experience with previous college drinking protocols. Dr. Neighbors will also share responsibility for analysis and dissemination of the results.

Qian Lu, Ph.D., Co-Investigator (Effort = 1 month summer, 8% in all 5 years) will also share responsibility for supervising screening, recruitment, development and implementation of the personalized normative feedback, and adjusting protocols as needed, based on her experience with previous expressive writing protocols. Dr. Lu will work with Dr. Rodriguez in content coding the narratives using the Linguistic Inquiry and Word Count (LIWC) software to achieve Aim 3. Dr. Lu will also share responsibility for analysis and dissemination of the results.

<u>Lindsey Rodriguez</u>, Ph.D., Research Assistant Professor (Effort = 3 months calendar, 25% effort in all 5 years) will share responsibility for conducting the research. Specifically, she will share responsibility for screening, recruitment, development and implementation of the intervention, database development and maintenance for participant tracking. She will also be primarily responsible for coding the content of the participant narratives for guilt and change thought via the Linguistic Inquiry and Word Count (LIWC) software. She will also work with Dr. Neighbors with regard to data management, analysis, and dissemination of results. She will contribute to the direction of daily tasks and operations associated with data collection and management.

<u>Dipali Rinker</u>, M.A., Research Lab Supervisor (Effort = 3 months calendar, 25% effort in Years 2-4, 50% in Years 1 and 5) will be responsible for assisting in preparation, review, and modification of human subjects forms, preparation of material to be mailed to participants, database development and maintenance for participant tracking, subject payments, scheduling project meetings, preparation of timely status reports and updates for the investigators, monitoring phone and email communications, and supervising the graduate research assistant.

<u>To be announced</u>, Staff Personnel (Effort = 6 months calendar, 50% effort in all 5 years) will assist in all aspects of the research project, from participant recruitment and tracking, preparation of material to be sent to participants, sharing responsibility for the preparation, review, and modification of human subjects forms, programming web-based surveys in DatStat Illume, administration of assessments and interventions, monitoring phone and email communications, organizing and scanning all screening data, scheduling participants, and supervising undergraduate research assistants.

<u>To be announced</u>, Graduate Research Assistant (Effort = 6 months calendar, 50% effort in all 5 years) will share responsibility with the lab supervisor for review and modification of human subjects forms, preparation of material to be mailed to participants, finalizing web-based surveys using DatStat Illume, participant tracking, monitoring phone and email communications, and supervising undergraduate research assistant volunteers.

Ronda Dearing, Ph.D., Consultant (Effort = 2 days in Years 1 and 5) will contribute to all phases of the research project and will dedicate two days each year during Years 1 and 5 for consultation. Specifically, in the first year of the project she will contribute her expertise on guilt to assist with the measurement and refinement of the narrative prompts regarding guilt. She will also assist in creating the event-related guilt items which will be evaluated as mechanisms underlying intervention efficacy. In the final year, she will collaborate with the research team on dissemination of the research findings, including manuscript preparation.

ADDITIONAL NARRATIVE JUSTIFICATION

The Direct Costs are \$200,000 for Years 2-4 of the project and \$175,000 for Years 1 and 5 of the project. We are requesting an additional module in Years 2-4 to procure participant payments for data collection.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)

2. Specific Aims SPECIFIC_AIMS1010448460.pdf

3. Research_Strategy* Final_Research_Strategy1010448484.pdf

4. Progress Report Publication List

Human Subjects Sections

5. Protection of Human Subjects Protection_of_Human_Subjects1010448462.pdf

6. Inclusion of Women and Minorities Inclusion_of_Women_and_Minorities1010448463.pdf

7. Inclusion of Children Inclusion_of_Children1010448464.pdf

Other Research Plan Sections

8. Vertebrate Animals

9. Select Agent Research

10. Multiple PD/PI Leadership Plan

11. Consortium/Contractual Arrangements

12. Letters of Support Dearing_support_Neighbors_20141010448483.pdf

13. Resource Sharing Plan(s)

Appendix (if applicable)

14. Appendix_1_Prompts_1010448469.pdf

Appendix_2_Measures_1010448470.pdf

SPECIFIC AIMS

Alcohol consumption among college students continues to be both prevalent and problematic. College students drink more than their same age non-college peers and experience negative alcohol-related consequences at a higher rate. The majority of efficacious prevention and intervention approaches for drinking among college students have followed a personalized feedback paradigm, where individuals complete survey questionnaires and receive personalized feedback based on their responses. While this approach has been promising, relatively few alternative innovative paradigms have been considered. The present research proposes to evaluate expressive writing as an innovative intervention for heavy drinking students.

Expressive writing as a brief intervention has been linked to various health and social benefits including improved immune response and psychological well-being. Despite impressive and consistent effects in other domains, it has received little attention among alcohol intervention researchers. Our pilot data shows that heavy drinking students asked to write in a single session about a bad time they drank a lot reported reduced drinking intentions relative to control participants. In a second pilot, event-related guilt mediated the effects of writing about a negative drinking event on readiness to change and drinking intentions. The proposed research builds on the pilot studies and on complementary expertise in alcohol intervention research and the expressive writing paradigm. We propose to recruit 600 students meeting hazardous drinking criteria and randomly assign them to one of six conditions. Participants will come for three 20-minute sessions over the course of one month. They will be randomly assigned to one of six conditions in the 2 x 2 + 1 + 1 factorial design, where they will be asked to write about specific drinking events or distressing events where they had a bad time or they did something they felt guilty about. The two control conditions will be a neutral writing prompt and a traditional

personalized normative feedback (PNF) condition. Follow-up assessments will occur 1, 3, 6, and 12 months post-baseline.

	Alcohol	Distress
Guilt		
No Guilt		

Neutral + Personalized Feedback

This approach is based on the following

premises: 1) Preliminary research has shown promising effects on intentions, and intentions have consistently been linked to future behavior; 2) Multiple sessions of expressive writing are preferable to single sessions; 3) Guilt has been shown to be an adaptive emotion with powerful influences on future behavior; 4) Writing about guilt will naturally elicit self-motivating change thoughts analogous to change talk. Guilt and change thought will be content coded using the Linguistic Inquiry and Word Count (LIWC) software. The significance of this application is underscored by the novelty of the intervention in this context and its potential to offer a new paradigm for college alcohol interventions that could be self-administered at low cost.

Specific aims of this research are as follows:

- 1. Provide experimental evidence of the efficacy of expressive writing as a brief intervention for hazardous drinking college students. The magnitude and duration of effect will be demonstrated by comparing drinking over time among participants in the expressive writing intervention conditions relative to neutral control. We also expect to replicate previous work showing the positive effects of distress narratives on well-being.
 - *H1a:* Participants writing about negative drinking events will show reduced drinking and drinking-related negative consequences relative to students in the neutral control group.
 - *H1b:* Participants writing about distressing non-alcohol events will show increased psychological well-being relative to students in the neutral control group.
 - *H1c:* Participants writing about negative drinking events will show reduced drinking and consequences compared with an empirically-supported brief intervention (i.e., PNF). This is an exploratory hypothesis.
- 2. Evaluate differences between guilt vs. no guilt narratives and distress vs. alcohol content in predicting changes in drinking. We expect differences between distress narratives and guilt narratives on drinking outcomes.
 - *H2a:* Alcohol narratives will have stronger effects on alcohol outcomes relative to distress narratives. *H2b:* Alcohol guilt narratives will have the strongest effect on alcohol outcomes relative to all other conditions.
- 3. Evaluate expression of guilt and change thought as mechanisms by which writing about drinking events results in reduced drinking and negative consequences.
 - *H3a:* Expression of guilt, assessed by self-report and by content coding with LIWC, will mediate intervention effects on drinking outcomes.
 - H3b: Change thought, assessed by LIWC coding, will mediate intervention effects on drinking.
- 4. Evaluate guilt-proneness as a moderator of intervention effects.
 - *H4:* Intervention effects will be moderated by guilt-proneness. Specifically, writing about drinking related guilt will be more effective in reducing drinking among those higher in guilt-proneness.

Specific Aims Page 38

SIGNIFICANCE

College drinking is a significant problem. Recent findings from the Monitoring the Future study (Johnston, O'Malley, Bachman, & Schulenberg, 2012) indicate that 60% of college students report having been drunk in the past year and 40% report having been drunk in the past 30 days. Moreover, 36% of students report having consumed five or more drinks at least once in the previous two weeks. Negative consequences related to heavy episodic drinking include poor class attendance, hangovers, engaging in risky sexual behavior, sexual assault, disordered eating, depression, trouble with authorities, injuries, and fatalities (Abbey et al., 2003; Dunn et al., 2002; Geisner et al., 2004; Hingson et al., 2009; Kaysen et al., 2006; Wechsler et al., 1994; Wechsler et al., 2000). An estimated 599,000 college students sustain unintended alcohol-related injuries annually and 1825 die each year as a result of alcohol-related injuries, including traffic fatalities (Hingson et al., 2009). Moreover, an estimated 696,000 students are victims of alcohol-related assaults, including 97,000 who experience sexual assault or date rape (Hingson et al., 2009). Further development of effective interventions which are low cost and easy to disseminate remains a high priority for this high-risk population.

Effective interventions lack significant innovation. Not surprisingly, significant efforts have identified efficacious individually-focused interventions for addressing problematic college drinking (Carey et al., 2007; Cronce & Larimer, 2012; Larimer & Cronce, 2007). The vast majority of these interventions involve the provision of personalized feedback and are directly or indirectly descended from Marlatt and colleagues' programmatic work initiated in the late 1980s (e.g., Baer et al., 1992; Kivlahan et al., 1990; Marlatt et al., 1998) and culminated with the BASICS program (Dimeff et al., 1998). The BASICS paradigm involves assessment of drinking behavior, norms, expectancies, risks, and alcohol-related consequences and then providing personalized feedback in a motivational interviewing style (Miller & Rollnick, 2013). When conducted in person, these interventions have come to be known as brief motivational interventions or BMIs. They have also commonly been referred to as personalized feedback interventions of PFIs. Innovations over the last 15 years or so to empirically-supported individual-focused college alcohol interventions have been primarily incremental advances to this basic approach. This includes variations on specific components included within feedbackbased interventions (e.g., Miller et al., in press; Walters & Neighbors, 2005); specific emphases on single components such as normative feedback (e.g., Doumas et al., 2011; LaBrie et al., 2013; Neighbors et al., 2013); the addition of new components such as protective behavioral strategies (Martens, Smith, & Murphy, 2013); and behavioral economic supplements (Murphy et al., 2012). Other incremental innovations have been adapting the feedback approach to other formats such as mailed feedback (e.g., Collins, Carey, & Sliwinski, 2002; Larimer et al., 2007) and, more prominently, in-person and web-based computer-delivered personalized feedback (e.g., Carey, Scott-Sheldon, Elliott, Bolles, & Carey, 2009; Elliott, Carey, & Bolles, 2008). At this point we can be relatively confident that these approaches are effective, with effect sizes in the small to medium range for reducing drinking for up to six months post-intervention (Miller et al., in press). Continued pursuit of finer and finer variations of this approach seems unlikely to yield significant paradigmatic advances in the field of alcohol prevention. Rather, it seems apropos to step back and consider the underlying mechanisms proposed to motivate changes in drinking and consider possible new paradigms for facilitating these processes. Furthermore, at minimum, feedback interventions require resources to process responses from intervention recipients and then provide information back to participants, which is based on their responses. An adaptation of the expressive writing paradigm, which has been used widely and successfully in other domains, is a prime candidate as a novel intervention approach for college student drinking which may be equally or more effective and requires fewer resources to disseminate.

Expressive writing has been established as an effective brief intervention for improving well-being. Expressive writing is a brief intervention that has been linked to various health and social benefits such as improved immune response (Pennebaker, Kiecolt-Glaser, & Glaser, 1988), psychological well-being (Barclay & Skarlicki, 2009), improved working memory capacity (Klein & Boals, 2001), and greater relationship satisfaction (Baddeley & Pennebaker, 2011). Research has demonstrated that expressive writing leads to improvements in physical and psychological health in both healthy college student populations (Pennebaker & Beall, 1986) as well as patient populations (Craft, Davis, & Paulson, 2013; Stanton et al., 2002). In the typical expressive writing paradigm, participants are instructed to reflect on a stressful experience and to write about their deepest thoughts and feelings about that experience for 20 minutes per session for four sessions (Pennebaker, 1997). This brief intervention has been shown to confer health benefits lasting months after the intervention among college students and patients populations (Lu & Stanton, 2010; Stanton et al., 2002). Expressive writing has been theorized to promote physical and psychological health and well-being through emotional disclosure and cognitive processing of traumatic events. In the traditional expressive writing

paradigm, participants are instructed to reflect on a traumatic experience and to express their thoughts and feelings about that experience in narrative form. Thus, expressive writing is tied both to emotion regulation (Smyth & Arigo, 2009) and cognitive processes (Smyth & Greenberg, 2000). Expressing emotions through writing can lead to decreased levels of stress and negative affect, thereby serving as a coping mechanism. Furthermore, expressive writing allows participants to reconstruct their traumatic experiences and reorganize their memory of these events into a narrative. This reorganization of memory may contribute to a better understanding of the event, which may aid with coping efforts (Smyth & Helm, 2003).

Despite repeated success of expressive writing in improving physical health and psychological well-being, the relationship between expressive writing and <u>behavior change</u> is unclear. The majority of expressive writing studies that focus on writing about stressful events either did not examine behavior change or did not find behavior change (Ames et al., 2005; Pennebaker et al., 1988). However, some expressive writing studies have shown promising results on behavior change. Specifically, expressive writing was shown to be effective in promoting healthy sleep habits (Harvey & Farrell, 2003), improving student grades (Lumley & Provenzano, 2003), decreasing absenteeism from work (Francis & Pennebaker, 1992), reducing time spent searching for a new job (Spera, Buhrfeind, & Pennebaker, 1994), and decreasing alcohol use (Spera et al., 1994; Young, Rodriguez, & Neighbors, 2013). These studies demonstrate potential for the use of expressive writing as a brief intervention to reduce drinking.

Recent research has begun to adapt the expressive writing paradigm to specifically target drinking (Young et al., 2013; also see Preliminary Studies). Young et al. (2013) randomly assigned students to write about a time they had a lot to drink which was either positive or negative or about their first day of college. Results indicated reduced drinking intentions after writing about a negative drinking event compared to control, suggesting that a narrative intervention may be effective in reducing drinking. An additional study (Rodriguez, Young, Neighbors, Campbell, & Lu, under review; described in Preliminary Studies) further suggests that feelings of guilt were more strongly associated with intentions to reduce drinking after writing about a negative drinking event, and that this event-related guilt mediated intervention effects. Further, initial content analysis of this data suggests that written expressions in describing negative drinking events often mirror descriptions of change talk, which has been identified as a principal goal in Motivational Interviewing (Miller & Rollnick, 2013).

The rationale for expressive writing as a brief alcohol intervention differs from traditional expressive writing interventions, which focus on emotional expression. Rather, the goal of expressive writing as a brief alcohol intervention is to facilitate processes that have been found to underlie successful changes in drinking coming from several other lines of work. For example, Nancy Barnett and colleagues' work with young adults in ER settings (Barnett et al., 2010), and among those cited for alcohol policy violations (Barnett et al., 2008; Barnett & Read, 2005), have demonstrated that acute negative incidents can be powerful motivators of change among young adults. Critical incidents offer "teachable moments" that make the costs of heavy drinking salient and may tip the scales in the direction of change. In those moments, students may declare that they will "never drink like that again" (Barnett, Goldstein, Murphy, Colby, & Monti, 2006). Expressive writing interventions aim to make these moments again salient and concrete as they are recalled and processed. More generally, research on self-change or "natural recovery" has consistently found that successful self-changers' motivations for change come from reflection on negative consequences of use (e.g., health, financial) and negative personal reasons (e.g., quilt; see Sobell, Ellingstad, & Sobell, 2000 for review).

In sum, extensive evidence has found traditional expressive writing to be an effective intervention for improving psychological well-being but less research has examined this approach as an intervention for behavior change. Building on promising preliminary work, and consistent findings regarding the motivating influence of reflection on negative events on behavior change, the proposed research will evaluate traditional distress-focused expressive writing and alcohol-focused expressive writing interventions. Based on previous work, we expect expressive writing about drinking events to be effective in reducing drinking (Hypothesis 1a) whereas writing about distressing events will be associated with improved psychological well-being (Hypothesis 1b). We are also comparing the two expressive writing approaches with an empirically-supported alcohol intervention (Hypothesis 1c).

Guilt as a motivating emotion for behavior change. Guilt is a negative, moral-focused, self-conscious emotion that is associated with behavior change (Tangney, 1991). Specifically, guilt is negative emotion regarding one's engagement in a certain behavior ("I *did* that horrible *thing*"), and is concerned with how one's actions will affect others (Lewis, 1971; Tangney & Dearing, 2002). When individuals experience guilt, they may feel tense or regretful and desire to alleviate this unpleasant feeling by making amends for their behavior. Thus guilt is associated with positive, responsible behaviors, working towards improving one's self, and making reparations for past mistakes, and as such is theorized to be an adaptive emotion (Tangney & Dearing, 2002).

Therefore, we expect guilt to mediate the association between the negative drinking narratives and drinking such that those who experience greater guilt related to their alcohol use will reduce their drinking at follow-up.

Guilt-proneness. Trait-level individual differences in how one tends to react cognitively, emotionally, and behaviorally to one's own indiscretions is referred to as guilt-proneness (Tangney & Dearing, 2002). Guilt-proneness has been associated with positive characteristics such as empathy, perspective taking, and endorsing a prescribed morality (Leith & Baumeister, 1998; Tangney, 1991, 1994), and also appears to exert a protective effect against problem alcohol use (Dearing, Stuewig, & Tangney 2005; Meehan, O'Connor, Berry, Weiss, Morrison, & Acampora; 1996; O'Connor, Berry, Inaba, Weiss, & Morrison, 1994). Furthermore, research has repeatedly demonstrated that guilt-proneness is negatively related to substance use and related problems among a wide variety of populations (Dearing et al., 2005; Hequembourg & Dearing, 2013; Tangney, Stuewig, Mashek, & Hastings, 2011). Thus, we expect that intervention efficacy will be moderated by guilt-proneness such that participants who write narratives about drinking-related guilt will show greater reductions in drinking if they are higher in guilt-proneness (Hypothesis 4).

Narrative topic (distress vs. alcohol) and focus (guilt vs. no guilt) in predicting changes in outcomes. Beyond the evaluation of expressive writing as a brief alcohol intervention, the proposed work considers the specific focus of expressive writing. While writing about distressing events or negative alcohol events are expected to have improvements in psychological well-being and reduced drinking respectively (Hypothesis 2a), we expect focusing on guilt in expressive writing to be particularly effective in reducing drinking when paired with writing about a negative alcohol-related event (Hypothesis 2b). Whereas writing about a negative alcohol-related event is likely to highlight associations between alcohol and negative outcomes, this may or may not be accompanied by attributions of personal responsibility or consideration of how similar events might be avoided in the future. In contrast, guilt is inherently tied to personal responsibility and focusing on feelings of guilt in the context of a negative alcohol-related event is expected to feature concrete associations between one's own actions and the negative event, which can be employed in considering how to prevent similar events in the future.

Explore the working mechanisms of writing by analyzing the content of written texts. Content analysis of written texts indicates that linguistic factors have reliably predicted improved physical health in several ways. Positive emotion words and a moderate number of negative emotion words predicted better subsequent health. Importantly, an increase in both causal and insight words was strongly associated with improved health. People who benefited from writing began with poorly organized descriptions and progressed to coherent stories by the last day of writing (Pennebaker, 1997).

The reasons why expressive writing has a beneficial effect on health outcomes are not very clear. In the context of this application, we propose two major mechanisms (guilt and change thought) to underlie the effectiveness of the writing intervention. Language use in written texts can be assessed in two ways to examine the working mechanisms of writing. First, the Linguistic Inquiry and Word Count (LIWC; Francis & Pennebaker, 1993; Pennebaker & Francis, 1996; Pennebaker & King, 1999) software is a standardized, quantitative method of assessing narratives and analyzes written text on specific types of emotional and cognitive words (Tausczik & Pennebaker, 2010). LIWC was developed by having groups of judges evaluate the degree to which words or word stems were related to each of several dozen categories. Categories from the default dictionary include negative emotion words (e.g., sad, angry), positive emotion words (e.g., happy, laugh), causal words (e.g., because, reason), and insight words (e.g., understand, realize). Thus, for each narrative essay, the percentage of total words that represent these (and other) linguistic categories will be quickly computed. The software also allows for the creation and implementation of custom "dictionaries" used to code text. We will use the LIWC to code the expressive writing narratives for change thought and for emotions such as negative affect and guilt. Coding for multiple specific constructs will facilitate further refinement of what emphasis future intervention efforts should place in focusing expressive writing prompts. Two judges will also code and rate the written text independently to compare written essays in the four groups and to examine the association between the features of the written text and psychological and physical outcomes. Judges will rate each of the essays along guilt and change thought (e.g., expressed intentions to change, recognition of the need to change) dimensions. Interrater reliability will be performed. Finally, both LIWC and the judge's ratings of emotional and cognitive dimensions are used to predict alcohol-related and health outcomes. Thus, expression of guilt, assessed by self-report and by content coding with LIWC, will mediate intervention effects on drinking outcomes (Hypothesis 3a).

Change talk/change thought as mediators of intervention efficacy. Motivational Interviewing (MI) is a collaborative conversation style, with a focus on guiding an individual by strengthening their motivation and commitment to change (Miller & Rollnick, 2013). It is a collaborative process allowing for the individual to voice their own motives for and commitment to change by resolving the ambivalence that exists for and against changing a behavior. It is based on the idea that people are more likely to be persuaded by what they hear themselves say, rather than what someone tells them. One mechanism of MI that is now receiving more attention is "change talk." Change talk refers to the self-expressed speech arguing for change (Miller & Rollnick, 2013). These include statements that express desire for, ability to, reasons for, and need for making a change, as well as statements indicating commitment to, preparation for, and steps toward making a change. In recent years, Miller and Rollnick have also discussed the opposing concept of change talk, called "sustain talk." Sustain talk refers to self-expressions arguing against change and for the status quo (Miller & Rollnick, 2009). Increasing change talk and/or reducing sustain talk is viewed as a principal mechanism underlying the success of MI and the similar motivational enhancement therapy.

A number of studies have examined the association between change talk/sustain talk and behavior change. A seminal article that first examined the association between change talk and abstinence from drug use found that statements focusing on commitment to change were associated with a greater number of days abstinent (Amrhein, Miller, Yahne, Palmer, & Fulcher, 2003). Another study found that the frequency and strength of desire, need, and ability to change was associated with a reduction in drinking at six months in a sample of 20 year-old men entering the army in Switzerland (Gaume, Bertholet, Faouzi, Gmel, & Daeppen, 2013). Additionally, the frequency and strength of desire, need, and ability to not change (i.e., sustain talk) was associated with no significant changes in drinking at six months. A study by Vader, Walters, Prabhu, Houck, and Field (2010) examined change talk in a sample of heavy-drinking college students. Participants were randomly assigned to receive either a single session of MI with personalized feedback about their drinking or a single session of MI only. Results indicated that among those who received MI with feedback, greater change talk was associated with improved drinking outcomes at three months, and greater sustain talk was associated with poorer drinking outcomes at three months.

To date, these studies have all focused on verbal change talk and sustain talk. The proposed research will seek to examine change talk and sustain talk through an expressive writing modality. Although our writing prompts will not specifically ask participants to write about changing their drinking behaviors, we will evaluate the written narratives for both desire to, ability to, reasons for, and need to change drinking. We will also evaluate the narratives for commitment to, preparation for, and steps toward changing drinking behaviors. Additionally, we will examine the narratives for desire to, ability to, reasons for, and need for not changing drinking, as well as commitment to, preparation for, and steps toward not changing drinking behaviors. We hypothesize that greater frequency in change thought (i.e., the written equivalent of change talk) will be associated with a decrease in drinking at follow-up, and that lower frequency of change thought will be associated with no significant changes in drinking behaviors. Likewise, we hypothesize that greater frequency in sustain thought will be associated with no significant changes in drinking behaviors. In a qualitative examination of expressive writing samples in our preliminary studies, we noted a significant proportion of statements indicative of change or sustain thought. We are currently conducting a pilot study to construct dictionaries for change thought, inspired by the work of Amrhein and colleagues (2003) and the operational definitions of change talk defined in the Manual for the Motivational Interviewing Skill Code (MISC; Miller, Moyers, Ernst, & Amrhein, 2008). Thus, change thought, assessed by LIWC coding, is expected to mediate intervention effects on drinking (Hypothesis 3b).

Current Research

The current research builds on previous research targeting heavy drinking among college students. A large volume of research has provided an impressive data base supporting one type of individually-focused alcohol intervention for this population (i.e., personalized feedback; Larimer & Cronce, 2007; Miller et al., 2012). The success of this paradigm has probably contributed to the dearth of consideration of alternative paradigms. Expressive writing is one such alternative, which has received extensive support in other domains but has only recently been considered as a potential intervention for heavy drinking. The preliminary data examining this approach is promising and provides a firm foundation for the proposed efficacy trial. Further, the proposed research incorporates novel theoretical constructs including the specific focus on guilt in expressive writing content as well as "change thought," as an analogue to the mechanism presumed to underlie motivational treatments for alcohol and other substance use disorders. We propose to employ similar methods which we have used successfully in other large NIAAA funded trials evaluating brief interventions for heavy drinking college students. We propose to recruit a large sample (N = 600) of heavy drinking students over a two year

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period. Participants will be randomly assigned to one of six conditions in a complex experimental design (2 × 2 +1 +1). Participants in the **Alcohol-No guilt, Alcohol-Guilt, Distress-No guilt, Distress-Guilt,** and the **neutral control** conditions will come into the lab once per week for three weeks and engage in expressive writing for 20 minutes during each session, with the focus corresponding to the condition. Participants in the **personalized normative feedback (PNF)** condition will receive a one-time administration of PNF, immediately after baseline, which has been found to reduce drinking in multiple randomized trials and will serve as an active comparison group in this trial. Follow-up assessments will occur 1, 3, 6, and 12 months post-baseline, which will allow for precise evaluation of the durability of intervention effects over the course of a year. If expressive writing is found to be effective in reducing problem drinking, it will provide an alternative intervention approach which can be readily disseminated and which will require fewer resources than the gold standard personalized feedback approach.

INNOVATION

Expressive writing is a novel intervention approach for heavy drinking college students. The expressive writing paradigm has been successful in other domains but has only recently been considered as a potential alcohol intervention. This approach offers a novel shift to otherwise modestly incremental adaptation of personalized feedback interventions, which have been the standard in college alcohol interventions over the past two decades. As such, the proposed research extends both the brief alcohol intervention field and the expressive writing paradigm, which has primarily been limited to psychological outcomes related to stress and psychological well-being.

Harnessing guilt to facilitate change. Self-conscious emotions have been extensively examined in basic research. A consistent finding is that guilt is associated with the desire to improve in the future. While some work has examined this construct in relation to alcohol and other substance use, it has not been incorporated into brief interventions. Dr. Ronda Dearing is the foremost expert on the application of self-conscious emotions to alcohol and substance use and has been instrumental in helping us incorporate guilt in the context of an expressive writing intervention. Extensive considerations were also given to the incorporation of shame as another condition, but all of the existing evidence argued against this approach. Rather, guilt appears to be the ideal candidate for targeting an expressive writing intervention aimed at reducing drinking. This represents a novel application of the theory of self-conscious emotions as well as a novel intervention approach.

Facilitation of "change thought." Change talk has increasingly become the focus of Motivational Interviewing approaches (Miller & Rollnick, 2013). Giving individuals the opportunity to recall and elaborate on specific negative or guilt-related alcohol events is anticipated to elicit thoughts that are equivalent to statements labeled as change talk in MI contexts. Change thought is a novel extension of a central mechanism underlying one of the most widely used approaches for treatment of problem drinking.

Content coding of guilt and "change thought." The use of LIWC as a coding mechanism for guilt and "change thought" is innovative. Both of these constructs are expected to mediate behavior change. This approach offers an innovative way of quantifying the content of expressive writing.

Innovation Summary. The proposed research is innovative in theoretical, methodological, and practical domains. We expect this research to inspire new theoretical directions in the applications of expressive writing, change thought, and guilt in brief alcohol interventions. Methodological and practical innovations are expected to proceed directly from the results of this research, which will be accompanied by concrete suggestions for implementation of interventions.

APPROACH

PRELIMINARY STUDIES.

The team of investigators has conducted several studies which establish a foundation for the proposed research. We have evaluated the effect of writing about a heavy drinking occasion on future drinking intentions, and have also examined guilt as a mediator of the intervention effect on drinking intentions. Moreover, in previous intervention studies, we have established successful protocols for screening and recruiting heavy drinking college students and consistently maintained retention rates above 80%. In our recently completed R01 intervention trial (R01AA014576), we recruited 818 heavy drinking students. Retention rates over the course of the study were 90.8%, 85.2%, 83.0%, and 80.7% at 6, 12, 18, and 24-month follow-ups respectively (Neighbors et al., 2010). In sum, the proposed research is a direct extension of existing work in this area and we have the resources and ability to complete the proposed research in a feasible amount of time. Although preliminary/pilot studies have evaluated narrative interventions, none have evaluated them in light of collecting actual drinking behavior, nor have the interventions themselves focused on guilt. In addition, while expressive

writing paradigms have been used as a framework for understanding and intervening in health behaviors, it has not extended to the behavioral realm of college drinking. However, this exploratory work is based on solid theoretical grounds and has important practical implications for evaluation and dissemination of brief, cost-effective, computer-based interventions.

Brief Alcohol Interventions. We have conducted multiple trials evaluating brief alcohol interventions among heavy drinking college students. These include three active or completed R01s as PI. Studies include multi-component interventions (e.g., Neighbors, Lee, Lewis, Fossos, & Walter, 2009; Neighbors et al., 2012; Larimer et al., 2007) as well as single component interventions focusing exclusively on perceived norms (e.g., Lewis & Neighbors, 2007; Lewis, Neighbors, Oster-Aaland, Kirkeby & Larimer, 2007; Neighbors et al., 2010; Neighbors, et al., 2011; Neighbors, Larimer, & Lewis, 2004; Neighbors, Lewis, Bergstrom, & Larimer, 2006). The majority of these intervention have been delivered in-person by computer, though some have been therapist-delivered (e.g., Neighbors et al., 2012) or mailed (Larimer et al., 2007). We have an extensive history of working with heavy drinking college students and have been successful in the recruitment and retention of large samples in longitudinal intervention studies. We have existing protocols which can be readily adapted for the proposed work.

Preliminary Study 1: Expressive writing as a brief alcohol intervention. The first examination of expressive writing and drinking among college students asked participants (N = 200) to write about a heavy drinking occasion that was positive, a heavy drinking occasion that was negative, or their first day of college (control). As found in Young, Rodriguez, and Neighbors (2013), participants intended to drink significantly fewer drinks per week and to engage in marginally fewer heavy drinking occasions after writing about a negative drinking occasion when compared to control. Writing about a negative event was associated with higher intentions among heavier drinkers, but lower intentions among those with higher AUDIT scores. Preliminary results provided some support for this innovative strategy but also suggested the need for further refinement, especially with heavier drinkers.

Preliminary Study 2: The role of guilt and shame in an expressive writing alcohol intervention and justification for not including shame. The second examination of expressive writing and drinking among college students (N = 495) included identical prompts to the original study, but incorporated measures of guilt and shame surrounding the described event. Results replicated the original pilot study in that writing about a negative heavy drinking event was associated with lower drinking intentions (Rodriguez et al., under review). Further, results suggested that this effect was mediated by event-related guilt. Conversely, shame did not mediate intervention effects on drinking intentions. For the purposes of the current proposal, shame will be measured, but will not be focused on as it has been repeatedly associated with negative outcomes such as anxiety, depression, drug use, and suicide (Hoblitzelle, 1987; Lewis, 1987; Tangney & Dearing, 2002). Thus, promoting shame would not be an effective intervention tactic. The study provides support for the current proposal to focus on guilt to facilitate desired behavioral change.

Preliminary Study 3: Expressive writing among ethnically diverse healthy college students. In order to test whether expressive writing works for ethnically diverse populations and to maximize the benefits of expressive writing, we randomly assigned 79 Asian-American and 51 Caucasian healthy young adults to one of four writing conditions conducted over three 20-minute sessions: a neutral control group (asked to write about a neutral topic), an emotional disclosure group (asked to write about deepest feelings and thoughts about a stressful event), a cognitive reappraisal group (asked to write about positive thoughts and reappraisals of a stressful event), and a self-regulation group (the combination of emotional disclosure and cognitive reappraisal, asked to write about their deepest feelings about a stressful event and then to cognitively reappraise it). Mixed linear modeling (i.e., hierarchical linear modeling) revealed that the self-regulation group showed reduced physical symptoms compared with the control group among Asian-Americans at one-month and two-month follow-ups. Self-regulation also improved positive affect. Further, those who were ambivalent about expressing emotions showed the most improvement in physical health after cognitive reappraisal and the most improvement in negative affect and depressive symptoms after emotional disclosure. These promising findings suggest that expressive writing produced long-term benefits among ethnically diverse samples and individual differences moderated the effects of writing.

Preliminary Study 4: Expressive writing among breast cancer survivors. In this line of studies, the co-PI Dr. Lu culturally tailored a psychosocial intervention using expressive writing and tested its efficacy in a randomized controlled trial among Chinese American breast cancer survivors using the community based participatory research (CBPR) paradigm to incorporate community' input in every stage of the study. Interventions using expressive writing have been shown to improve adjustment among Caucasian breast

cancer survivors (Stanton et al., 2002). We first culturally tailored this intervention among Chinese American breast cancer survivors by developing a self-regulation writing intervention using CBPR and mixed qualitative and quantitative methods in a pilot study. Self-regulation writing was associated with a variety of improvements in health outcomes 3 and 6 months post-intervention (quality of life, fatigue, posttraumatic stress, intrusive thoughts, and positive affect, $\eta p2 = 0.066 \sim 0.208$). The retention rate of the study was 90%. We have just completed a RCT among Chinese American breast cancer survivors to investigate the benefits of traditional emotional disclosure (n = 22) vs. self-regulation writing instruction (n = 22) in comparison to a control group (n = 22). The retention rate of the study was 85%. Together, these studies demonstrate the investigators' ability, experience, and success with the expressive writing paradigm.

RESEARCH DESIGN AND METHODS Overview and Rationale. This research consists of an intervention study to evaluate expressive writing as a brief

	Alcohol	Distress		Newtoni	I 1	B
Guilt			+	Neutral Control	+	Personalized Feedback
No Guilt]			

intervention in reducing drinking and improving psychological well-being among college students. Participation in the study involves completion of a screening assessment, a baseline assessment, the intervention procedure, post-intervention assessment, and follow-up assessments at 1-, 3-, 6-, and 12-months. Heavy drinking college students (N = 600) will be randomly assigned to one of six conditions based on the 2 (alcohol vs. distress topics) x 2 (guilt vs. no guilt focus) + 1 (neutral control) + 1 (personalized normative feedback) design. Before completing the baseline survey, students will be randomly assigned to one of six study conditions, five of which involve writing during three sessions over the course of one month. Specifically, participants will be assigned to write about a heavy drinking event, a heavy drinking event that elicited guilt, a distressing event, a distressing event that elicited guilt, or their first day of college (neutral control condition). Participants randomly assigned to the PNF condition will receive traditional personalized normative feedback regarding how their drinking compares with other students of the same gender at the university. The norms will come from a large recently completed alcohol survey conducted at the University of Houston examining social norms and alcohol prevention (Neighbors et al., in preparation; R01AA014576). To maintain consistency across conditions, participants in the PNF condition will still come into the lab three times. They will receive feedback during the first intervention session and will be asked to complete the same narrative prompts as the neutral control condition for their second and third session. For individuals in the expressive writing conditions, there will be three narrative prompts to complete every week for three weeks, the first of which will occur immediately following the baseline assessment. All baseline assessments, narrative intervention assignments, and immediate post-tests for all conditions will be conducted in-lab. All other assessments including screening and follow-up assessments will be completed remotely by web. The rationale for including a personalized normative feedback condition is to be able to compare the efficacy of expressive writing interventions with existing brief alcohol interventions. Thus, the present design allows not only for evaluation of efficacy relative to a control condition but also will evaluate comparative efficacy relative to an existing empirically-supported brief alcohol intervention.

Assessment Procedures and Measures. We will recruit a sample of 600 heavy-drinking UH students (n=100 for each cell), beginning the Fall semester of 2015. This will be accomplished by inviting a random sample of UH students, stratified by age and class standing, to complete a brief web-based screening survey. Students with AUDIT scores of 8 or higher will be invited to participate in the intervention. Data collection will occur via the web using the Datstat Illume platform. Security and data integrity are supported by requiring participants to log into a secure server and enter a unique PIN developed for study purposes. The baseline survey is expected to take approximately 40 minutes to complete, with each writing intervention expected to take 20 minutes to complete. Each follow-up survey is expected to take approximately 30 minutes to complete. All measures will be assessed at all time points with the exception that the post-intervention assessment will only include drinking intentions and event-related guilt.

Multiple measures will be included for each core construct to ensure our ability to effectively evaluate each aim. The following measures will be used (all measures may be found in Appendix 2):

<u>1. Demographic Information</u> will include age, height, weight, sex, race, ethnicity, fraternity/sorority membership, most recent grade point average, year in school, class standing, full-time/part-time enrollment status, and residence (dormitory, off-campus housing, with parents, etc.). Weight is included to estimate Blood Alcohol Level (BAL).

Manipulation Check

2. Manipulation Check items will be given after the final narrative session for participants in the five

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narrative conditions. Sample items include, "How emotional were you during the course of writing?" "Did you write about alcohol during the assigned writing time?" "How distressing was the event you wrote about?" and "How guilty did you feel during the course of the writing?" Additionally, two judges, blind to conditions, will read the narratives and judge to which condition the participants belonged.

Primary Outcomes

- Alcohol Consumption will be assessed with multiple indices: The Timeline Follow-Back (TLFB: Sobell & Sobell, 2000; Tonigan et al., 1997), the Alcohol Use Disorders Identification Test (AUDIT; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001), the Alcohol Consumption Index (ACI; Knee & Neighbors, 2002), Quantity-Frequency-Peak Alcohol Use Index (Baer, 1993; Marlatt, Baer, & Larimer, 1995), and the Daily Drinking Questionnaire (DDQ; Collins, Parks, & Marlatt, 1985; Kivlahan, et al., 1990). The TLFB is a calendarbased measure assessing daily drinking (and abstinence) over a designated period of time and provides memory aids to support participant recall. The validity of the TLFB has been extensively and favorably evaluated in several different formats for periods of up to 1 year (Searles et al., 2002; Sobell & Sobell, 2004). We have recently adapted the TLFB to a 90-day web-based format with optional memory cues including all holidays, Spring Break, major sporting events, important academic dates, homecoming, among others, and up to 10 personally significant events. Note that the TLFB will also yield a wealth of information for potential secondary analyses regarding variability in drinking over time and across specific days. The AUDIT consists of 10 items; three that assess for hazardous alcohol use, three that assess for dependence symptoms, and four that assess for harmful use. The ACI consists of 10 items; four of which are aimed at assessing heavy-episodic drinking, four items which are more general questions about number of drinks consumed in a given timeframe, and two items concentrating on perceptions of how one's drinking compares to that of others'. The Quantity-Frequency-Peak Alcohol Use Index is a five-item questionnaire that includes two items addressing the occasion where respondents drank the most during the previous three months, two items addressing typical weekend drinking in the previous three months, and one item addressing typical number of drinking days per week in the previous three months. Typical weekly drinking and typical drinks per occasion will be assessed with the DDQ. Participants fill in the average number of standard drinks they consumed and the time period of consumption for each day of the week over the previous three months. The TLFB will is anticipated to serve as a primary source for assessing drinking outcomes, and we will include the AUDIT, ACI, DDQ, and QF as alternative outcomes, which have all been validated in previous studies in this population.
- <u>4. Drinking Intentions</u> for quantity and frequency will be assessed by modifying the DDQ and QF. Response options will be identical to the DDQ and QF, but participants will be asked to indicate their intended drinking behaviors.
- <u>5. Alcohol-related Negative Consequences</u> will be assessed with the Rutgers Alcohol Problems Index (RAPI; White & Labouvie, 1989) and the Young Adult Alcohol Problems Screening Test (YAAPST; Hurlbut & Sher, 1992). The RAPI assesses how often participants experienced 23 alcohol-related consequences (e.g., "suddenly found yourself in a place that you could not remember getting to") over the past three months. Two items related to drinking and driving were added. Item responses range from 0 (never) to 4 (more than 10 times). Internal reliability for the RAPI in a previous sample was .86. The YAAPST (Hurlbut & Sher, 1992) will measure social and social problems related to drinking. Item responses will be modified from the past year to the past three months to prevent overlap in follow-up assessments and to mirror the timeframe for alcohol consumption. The YAAPST has good internal consistency and test-retest reliability (Hurlbut & Sher, 1992). Internal reliability for the YAAPST in a previous sample was .79. Both the RAPI and YAAPST have been modified to include items that assess for the degree to which the individual evaluates each consequence as negative or positive.
- 6. Psychological Well-being Outcomes will be assessed by anxiety, depression, mood, and satisfaction with life. Anxiety will be assessed by the Beck Anxiety Inventory (BAI; Beck, Brown, Epstein, & Steer, 1988), a 21-item measure of common symptoms of anxiety. Depression will be assessed by the Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977), a 20-item measure of depressive symptomatology in the general population. Mood will be assessed by the Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988), a 22-item measure of the degree to which one experiences positive and negative affective states on a regular basis. Satisfaction with life will be assessed by the Satisfaction with Life Scale (SWLS; Diener, Emmons, Larsen, & Griffin, 1985), a 5-item measure of general life satisfaction.

Mediators

7. Event-related Guilt will be measured in two ways. We will use a modified version of the self-report State Shame and Guilt Scale (SSGS; Marschall, Sanftner, & Tangney, 1994), a 15-item scale asking participants to

rate how guilty or ashamed they currently feel. This measure will be modified with the help of consultant Dr. Dearing. In addition we will also assess guilt using content coding from the LIWC.

<u>8. Change Talk/Thought</u> will be assessed through the narratives by the percentage of change talk/thought utterances or statements, as defined in the Manual for the Motivational Interviewing Skill Code (MISC 2.1; Miller, Moyers, Ernst, & Amrhein, 2008). Change talk/thought will be calculated as a percentage of the total number of words using the LIWC software.

Moderator

9. Guilt-proneness will be measured by the Test of Self-Conscious Affect-3 (TOSCA-3; Dearing, Stuewig, & Tangney, 2005), a 16-item, scenario-based scale that measures a propensity to experience guilt in given situations.

Perceived Descriptive Norms (PNF participants)

10. Perceived descriptive norms will be measured by a modified version of the Drinking Norms Rating Form (DNRF; Baer et al., 1991; Lewis & Neighbors, 2004). The gender-specific version (Lewis & Neighbors, 2004) assesses perceived typical number of drinks consumed per drinking occasion (e.g., "how many drinks on average do you think a typical male UH student consumes on a given occasion?"). In addition, this measure assesses perceived frequency of drinking occasions (e.g., "how often do you think a typical female UH student consumes alcohol?"). The DNRF assesses perceived typical weekly drinking in which participants fill in the average number of standard drinks they think the typical (male/female) UH student consumes for each day of the week over the previous month. The DNRF has been used in multiple studies of college drinking and has shown good concurrent and prospective validity (Neighbors, Dillard, Lewis, Bergstrom, & Neil, 2006).

Recruitment and Compensation. We will recruit a sample of 600 heavy-drinking UH students (n=100 for each cell), which will begin during the Fall semester of 2015 and will continue via rolling recruitment. To obtain our recruitment goal, we expect to recruit approximately 25 participants per month for a total of 24 months. During the recruitment phase, a random sample of 16,000 UH students, stratified by age and class standing, will be invited to complete a brief web-based screening survey via email. Based on our prior experience using similar methodology in multiple studies on this campus (e.g., A Randomized Controlled Trial of Personalized Normative Feedback for Problem Gambling College Students; R01AA014576), we anticipate 25% of invited students will complete the screen (n=4,000). Of these, we expect 30% to meet screening criteria (n=1,200) and 50% of these overall to complete the baseline assessment and intervention procedure (n=600). Participants will receive \$50 for coming into the lab to complete the baseline assessment and first narrative session. Participants will receive \$20 for each of the following two narrative sessions, plus a bonus of \$30 if they complete all three narrative sessions. Participants will also receive \$30 for each follow-up survey, which will occur 1, 3, 6, and 12 months later. Compensation will be provided with Amazon.com giftcards. Amazon.com giftcards have been successfully used in existing trials (R01AA014576). Amazon.com giftcards also allow participants to receive immediate reinforcement for their participation.

General Procedures. Screening. Screening and scheduling of baseline assessments (for those who meet screening criteria) will occur online in the same assessment session. All invited participants will be 18-26 years of age. Participants will be sent an invitation via email. Participants will be asked to complete a 5-minute confidential web-based survey to determine their eligibility to participate in the longitudinal trial. The screening survey will ask participants about their gender and drinking behaviors (i.e., the AUDIT). Students who complete the screening survey and who report at least a score of 8 on the AUDIT will be notified at the completion of the screening survey of their eligibility to participate. This AUDIT score threshold has been widely used as an indicator of risk and as a screening criterion in interventions.

Scheduling of Baseline Assessments/Intervention. Participants who meet screening criteria will be immediately routed to a screen to schedule an in-person session using an online scheduling module, which we have already programmed and used in multiple trials (e.g., R01AA016099, U01AA014742, R01AA014576).

Baseline Assessment, Intervention, and Post-Intervention Assessment. Prior to coming into the lab, participants will have been randomized to one of the six in-lab conditions. Upon entering the lab, students will be greeted by a research assistant and upon providing consent, directed to a private computer to complete the baseline assessment. The research assistant will enter a custom PIN, allowing the participant to enter the survey. Participants in the expressive writing conditions will receive instructions to complete the expressive writing prompt on the computer immediately after completing the baseline assessment. Participants will be instructed that they may be able to write about the same event or a different event across sessions, which is the standard procedure used in most expressive writing studies and reduces potential confusion of ambiguity among participants. Following the narrative intervention, participants will be asked to complete a short post-

intervention questionnaire (i.e., event-related guilt and drinking intentions). When finished, the participant will be asked to schedule their upcoming writing sessions. The scheduling options will be graduated, first providing a list of possible times in the next week. If students cannot attend a session within the next week they will be given a list of possible times for the following week, but no more than 10 days will elapse between writing sessions. A staff member will call to confirm the appointment when it is made and remind students of their appointment time and date one or two days before the scheduled appointment. Using urn randomization (Stout, Wirtz, Carbonari, & Del Boca, 1994), students will be stratified across conditions based on gender and typical drinking behavior to help ensure baseline equivalence in drinking across conditions. Research assistants collecting in-lab data will be blind to intervention conditions.

Follow-up Assessments. Follow-up assessments will be completed remotely online at one, three, six, and twelve months post-baseline. All follow-up assessments will be completed using web-assessment. Measures will be identical to those given at baseline.

Intervention Conditions and Narrative Prompts

Alcohol-No Guilt Condition. For the next three sessions, we would like for you to write about the following topic. Please tell us about an occasion when you drank alcohol heavily and had a bad time or experienced things you did not want to experience as a result of your drinking. We would like you to be as descriptive as possible in elaborating your very deepest thoughts and feelings. For example, what specific things made this event so negative for you? We would like you to really let go and explore your very deepest emotions and thoughts. You might consider the event or experience in terms of your relationships with others, including parents, lovers, friends, or relatives. You might also consider tying it to your past, your present, or your future; to who you have been, who you would like to be, or who you are now. You may write about the same event or experience on all days of writing or on different topics each session. Depending on your experience you may feel that you need to provide more detail. All of the information you tell us will remain confidential and will not be shared with anyone outside of the research study. Don't worry about spelling, sentence structure, or grammar. The only rule is that once you begin writing, continue to do so until your time is up.

Alcohol-Guilt Condition. For the next three sessions, we would like for you to write about the following topic. Please tell us about an occasion when you drank alcohol heavily and felt guilty as a result of your drinking. Think of an instance when you felt regretful for how you behaved or you felt like you disappointed people. For instance, afterwards you may have resolved to be better in the future or apologized for your actions. We would like you to be as descriptive as possible. For example, what specific things about this event made you feel guilty? We would like you to really let go and explore your very deepest emotions and thoughts. You might consider the event or experience in terms of your relationships with others, including parents, lovers, friends, or relatives. You might also consider tying it to your past, your present, or your future; to who you have been, who you would like to be, or who you are now. You may write about the same event or experience on all days of writing or on different topics each session. Depending on your experience you may feel that you need to provide more detail. All of the information you tell us will remain confidential and will not be shared with anyone outside of the research study. Don't worry about spelling, sentence structure, or grammar. The only rule is that once you begin writing, continue to do so until your time is up.

Distress-No Guilt Condition. For the next three sessions, we would like for you to write about the following topic. Please tell us about an upsetting experience that has affected you and your life. We would like you to be as descriptive as possible in elaborating your very deepest thoughts and feelings. For example, what specific things made this event so distressing for you? Please focus on an event that is unrelated to alcohol. We would like you to really let go and explore your very deepest emotions and thoughts. You might consider the event or experience in terms of your relationships with others, including parents, lovers, friends, or relatives. You might also consider tying it to your past, your present, or your future; to who you have been, who you would like to be, or who you are now. You may write about the same event or experience on all days of writing or on different topics each session. Depending on your experience you may feel that you need to provide more detail. All of the information you tell us will remain confidential and will not be shared with anyone outside of the research study. Don't worry about spelling, sentence structure, or grammar. The only rule is that once you begin writing, continue to do so until your time is up.

Distress-Guilt Condition. For the next three sessions, we would like for you to write about the following topic. Please tell us about an upsetting occasion when you felt guilty. Think of an instance when you felt regretful for how you behaved or you felt like you disappointed people. For instance, afterwards you may have resolved to be better in the future or apologized for your actions. We would like you to be as descriptive as possible. For example, what specific things about this event made you feel guilty? Please focus on an event that is unrelated to alcohol. We would like you to really let go and explore your very deepest emotions and

thoughts. You might consider the event or experience in terms of your relationships with others, including parents, lovers, friends, or relatives. You might also consider tying it to your past, your present, or your future; to who you have been, who you would like to be, or who you are now. You may write about the same event or experience on all days of writing or on different topics each session. Depending on your experience you may feel that you need to provide more detail. All of the information you tell us will remain confidential and will not be shared with anyone outside of the research study. Don't worry about spelling, sentence structure, or grammar. The only rule is that once you begin writing, continue to do so until your time is up.

Neutral Control Condition. For the next three sessions, we would like for you to write about the following topic. Please tell us about your first day of college. We would like you to be as descriptive as possible. For example, what specific things do you recall? We would like you to really let go and explore your very deepest emotions and thoughts. You might consider the event or experience in terms of your relationships with others, including parents, lovers, friends, or relatives. You might also consider tying it to your past, your present, or your future; to who you have been, who you would like to be, or who you are now. You may write about the same event or experience on all days of writing or on different topics each session. Depending on your experience you may feel that you need to provide more detail. All of the information you tell us will remain confidential and will not be shared with anyone outside of the research study. Don't worry about spelling, sentence structure, or grammar. The only rule is that once you begin writing, continue to do so until your time is up.

Personalized Normative Feedback (PNF) Condition. Participants in the PNF condition will be given gender-specific personalized feedback regarding their alcohol use, consistent with previous NIAAA-funded trials using PNF as a brief intervention (R01AA014576). Participants will be presented with the drinking estimates that they previously gave in addition to average gender-specific drinking estimates provided by 1124 students at the University of Houston (norms documentation study in R01AA014576). Feedback will be provided for drinking frequency (i.e., number of drinking days per week), and drinking quantity (i.e., the number of drinks consumed per week and number of drinks consumed per typical drinking occasion). Participants will also receive a printed a copy of the feedback for their records and to view again later. PNF participants will receive feedback immediately after the baseline assessment. A single administration of PNF was selected because this is how it has typically been administered. However, we also wanted to control for any differences that might be attributed to attention. Thus, like all other groups, PNF participants will be scheduled to come in to the lab for two additional sessions, during which time they will follow the same procedures as the neutral control group.

Analysis

Analysis Strategy. Aims will be evaluated using multi-level regression analyses, often referred to as Hierarchical Linear Modeling (HLM; Raudenbush & Bryk, 2002) or mixed-effects modeling. With respect to evaluating main effects of experimental conditions on drinking, each participant will provide baseline, post-intervention, 1-month, 3-month, 6-month, and 12-month follow-up data. Hypotheses will be tested using specific contrast vectors, using a general linear hypothesis framework (Fox, 2008). The study consists of a (2x2+1+1) design, represented as a factorial design with the addition of a control group that will write about their first day of school and a computer-based PNF comparison group.

Hypotheses will be tested with contrasts corresponding to the questions of interest. The first two hypotheses represent contrasts between the alcohol narrative conditions and the neutral control condition (H1a) and between the guilt narrative conditions and the neutral control condition (H1b). In examining these hypotheses, we will construct two dummy coded variables reflecting alcohol versus non-alcohol narratives conditions and between guilt and non-guilt narrative conditions with the reference group being the neutral control condition. Thus, the PNF group will not be included in the tests of these two hypotheses. Dependent variables will include alcohol outcomes for H1a and psychological well-being for H1b.

For these analyses each participant will provide up to 5 repeated measures (i.e., baseline, 1-month, 3-months, 6-months, and 12-months), yielding up to 3000 Level 1 cases (repeated-measures) across 600 Level 2 cases). The following model will be the basis for evaluating intervention effects:

Level 1:
$$DV_{ti} = \pi_{0i} + \pi_{1i}(Time)_{ti} + \varepsilon_{ti}$$
 $\varepsilon_{ti} \sim N(0, I\sigma_{\varepsilon}^{2})$
Level 2: $\pi_{0i} = \beta_{00} + \beta_{01}(Alcohol)_{i} + \beta_{02}(Guilt)_{i} + r_{00i}$
 $\pi_{1i} = \beta_{10} + \beta_{11}(Alcohol)_{i} + \beta_{12}(Guilt)_{i} + r_{10i}$

where t indexes repeated-measures and i indexes participants. Alcohol and Guilt represent the two contrasts. DV_{ti} represents the outcome vector for each individual from at each assessment point. $Time_{ti}$ measures weeks since baseline. Distributions of outcomes, which are count variables, are likely to be non-

normal (e.g., negative binomial) and we will adjust analysis to utilize appropriate distribution as we have done in previous work (e.g., Atkins, Baldwin, Zheng, Gallop, & Neighbors, 2013; Neighbors et al., 2010). The test of β_{11} where alcohol consumption and alcohol-related problems are specified as DVs will represent a test of H1a. The test of β_{12} where psychological well-being outcomes are specified as DVs will represent a test of H1b. The same approach will be used to test H1c where the neutral control will be replaced with the PNF comparison condition. H2a and H2b will follow a similar approach but will focus exclusively on the 2X2 factorial conditions where H2a will examine main effects of alcohol and guilt on drinking outcomes and H2b will test the interaction between alcohol and guilt, with the expecation that the alcohol+guil condition will be more effective in reducing drinking outcomes than the other three conditions. We will also evaluate this hypothesis more generally by examining the alcohol+guilt condition relative to the other five conditions.

Aim 3 will evaluate mediators of intervention effects. We will follow procedures described by MacKinnon and colleagues (e.g., MacKinnon et al., 2007) to assess mediation. Mediation will test indirect effects using the AB products method where A will represent effects of intervention contrasts by time interactions on mediators (expression of guilt and change thought). B will represent the associations of mediators on subsequent drinking outcomes. Both A and B paths will control for baseline outcomes. Evaluation of hypotheses regarding the moderation effect specified in Aim 4 will test whether individual differences in guilt-proneness interact with intervention contrasts. These will be tested by expanding the above model to add main effects and product terms of proposed moderators with intervention contrasts.

<u>Sample size and power calculations.</u> Power analyses focus on estimating a sample size large enough to detect "true" effects, thereby avoiding Type II errors. Sample size estimates were obtained for intervention contrasts. Necessary sample sizes were assessed via sample size and power equations for normally distributed outcomes as detailed in Raudenbush and Liu (2001). Effect-sizes and variance components were based on preliminary studies, and power was set at 0.80 for all estimates. Power was estimated using the Optimal Design software program. We anticipate intervention effects relative to the neutral control condition on drinking to be in the range of delta = .30-.40 (prelim studies and Young et al., 2013). Based on the proposed sample size of 500 (~PNF not included in H1a and H1b), given five assessment points, we anticipate the ability to detect main effects of intervention contrasts with power=.80. Considering maximum anticipated attrition rates of 20% we will have .80 power to detect effects sizes of delta = .28 and greater.

Timeline.

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Limitations and Conclusions. Careful consideration has been given to the ways in which the design of this research limits the generalizability and specificity of conclusions drawn from it. Where possible, steps have been taken to address these limitations. One limitation is the use of self-report measures of key dependent variables, and concern about validity of self-report. This concern is partially addressed by previous research supporting the validity of self-report measures of alcohol consumption (Babor et al., 1987, 2000; Chermack, Singer, & Beresford, 1998; Darke, 1998). Another limitation is the collection of data via the Internet and the potential confound of conducting baseline and intervention assessments in person and follow-up assessments remotely over the web. Based on previous research (Miller et al., 2002) we do not expect significant differences in responses to assessments as a function of location. We have carefully considered the scope of the proposal in the context of what we have previously achieved in similar time frames; in order to help ensure our ability to complete each of the study aims we will carefully monitor timelines and, where possible, complete formative tasks for each study early. We expect this research to inspire new theoretical directions in the applying expressive writing, change thought, and guilt to brief alcohol interventions. If expressive writing is found to be effective in reducing drinking outcomes, it will provide an alternative, innovative intervention approach which can be readily disseminated across the U.S. and which requires fewer resources than the gold standard personalized feedback approach.

PROTECTION OF HUMAN SUBJECTS

1. Risks to Human Subjects

a. Human Subjects Involvement and Characteristics:

The goals of the proposed research require participation from human subjects. This research consists of one study where participants will be assessed at screening, baseline, post-intervention, 1-, 3-, 6-, and 12-month follow-up. Participation is voluntary on the part of the participants. Undergraduates at the University of Houston will be invited to participate. This project will consist of two levels of participation: screening participation and longitudinal participation. Inclusion criteria for the screening survey include being at least 18 years of age and being a registered UH student. Exclusion criteria for the screening survey include not meeting inclusion criteria (i.e., younger than 18 years of age, not a registered UH student) or unwillingness to participate. Inclusion criteria for longitudinal participation include scoring an 8 or more on the AUDIT, being at least 18 years of age, being a registered UH student, and providing consent to participate in the study. Exclusion criteria include not meeting any of the inclusion criteria, unwillingness to participate, and failure to provide consent. No participants will be excluded on the bases of gender, race, or ethnicity. Following screening, students meeting the drinking criteria will be notified of their eligibility, and will be asked to schedule an in-lab session to complete the baseline and intervention procedures.

Heavy drinking students (N = 600) will be randomly assigned in a $2 \times 2 + 1 + 1$ factorial design. Prior to completing the baseline survey, participants will be randomly assigned to one of *six intervention* conditions based on the 2 (alcohol vs. distress) \times 2 (guilt vs. no guilt) + 1 (neutral control) + 1 (personalized normative feedback; PNF) design. The $2 \times 2 + 1$ writing conditions (all conditions except PNF) will consist of completing an expressive writing task on the computer based on previous studies (please see Preliminary Studies). The PNF intervention will consist of gender-specific norms taken from an ongoing study (R01AA014576) at UH. After completing the writing task or viewing PNF, participants will be asked to complete a 10-minute post-intervention survey. Participants will then be asked to come back two more times to complete additional writing tasks. Screening, one-month, three-month, six-month, and twelve-month follow-up assessments will be completed remotely by web. Participants will receive \$50 for the baseline assessment and first narrative/PNF session. Participants will receive \$20 for each of the following two narrative sessions, plus a bonus of \$30 if they complete all three narrative sessions (totaling \$120 for the three intervention sessions). Participants will also receive \$30 for each follow-up survey, which will occur 1, 3, 6, and 12 months later.

b. Sources of Materials:

All data will be collected using the DatStat Illume software. Measures include demographics, manipulation check items, typical alcohol consumption, drinking intentions, psychological well-being, perceived drinking norms, alcohol-related consequences, event-related guilt, guilt-proneness, and change talk/thought. All measures will be completed confidentially, using a secure web server with 128-bit encryption. Individual data will be identified by a unique PIN number generated for research purposes only, and will be collected for research purposes only.

c. Potential Risks:

Psychological risks posed by the research are primarily related to the sensitivity of some of the measures. Measure items may query for thoughts, feelings, personal difficulties, and personal behaviors (such as alcohol use) that are private. These questions may make subjects uncomfortable, or be perceived as an intrusion on their privacy. In addition, participants are asked to report on potentially illegal behaviors, such as underage drinking. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals. The risk of adverse or ineffective outcome is judged to be minimal.

2. Adequacy of Protection Against Risks

a. Recruitment, Informed Consent, and Compensation:

Recruitment. We will recruit a sample of 600 heavy-drinking UH students (n = 100 for each cell), which will begin during the Fall semester of 2015 and will continue via rolling recruitment. To reach our recruitment goal, we expect to recruit approximately 25 participants per month for a total of 24 months. During the recruitment phase, a random sample of 16,000 UH students, stratified by age and class standing, will be invited to complete a brief web-based screening survey. Based on our prior experience using similar methodology in multiple studies on this campus (e.g., A Randomized Controlled Trial of Personalized Normative Feedback for Problem Gambling College Students; R01AA014576), we anticipate 25% of invited students will complete the

screen (n = 4,000). Of these, we expect 30% to meet screening criteria (n = 1,200) and 50% of these overall to complete the baseline assessment and intervention procedure (n = 600). Screening, randomization, and scheduling of baseline assessments (for those who meet screening criteria) will occur online in the same assessment session. Participants will be sent an invitation via email, asking them to complete a 5-minute confidential web-based survey. Participants who complete the screening survey and who score at least an 8 on the AUDIT will be notified at the completion of the screening survey of their eligibility to participate. This AUDIT score threshold has been widely used as an indicator of risk and as a screening criterion in intervention studies targeting heavy drinking college students (e.g., Fleming, Barry, & MacDonald, 1991; Aertgeerts et al., 2000; Kokotailo, Egan, Gangnon, Brown, Mundt, & Fleming, 2004; Kypri, et al, 2004; Cook, Chung, Kelly, & Clark, 2005).

When participants log onto the website to complete screening, they will answer several questions, which will take no more than five minutes, to determine eligibility. If participants meet criteria, they will be asked to provide contact information, as well as schedule their baseline session. For the longitudinal portion of the study, eligible participants will be presented with an informed consent, addressing the voluntary nature of participation, participants' rights, the risks of participation, the availability or referral options outside the study for help with drinking, data retention and storage information, protections for and limits to confidentiality, and procedures for reporting complaints and/or adverse events to the investigators and to the University Institutional Review Board (IRB). Participants will have to indicate their agreement by clicking the appropriate box prior to being allowed access to the baseline survey. These procedures technically represent a waiver of written documentation of consent, as we will not use a formal electronic signature protocol. We intend to apply for a waiver of written documentation of consent through the UH IRB on the basis that the study involves no more than minimal risk, that all elements of informed consent are present, and that granting the waiver does not affect participants' rights as research subjects in any way.

Eligible participants will be randomized to either write about a specific drinking event or distressing event where they had a bad time or they did something they felt guilty about. Participants in the neutral control condition will be asked to write about their first day of college. Participants in the PNF condition will be instructed to view gender-specific feedback regarding their alcohol use and perceptions of other same-sex students' alcohol use. See Appendix 1 for all intervention writing prompts as well as a description of what participants in the PNF condition will receive.

Upon either completing the writing tasks or viewing PNF, participants will then be asked to complete a short post-intervention questionnaire, and will be compensated. Research assistants collecting in-lab data will be blind to intervention conditions. All follow-up assessments will be completed remotely online. Measures will be identical to those given at baseline and participants will be paid for each follow-up assessment. Please see Appendix 2 for all measures participants will be asked to complete.

Compensation. Participants will receive \$50 for coming into the lab to complete the baseline assessment and first narrative session/view PNF. Participants will receive \$20 for each of the following two narrative sessions, plus a bonus of \$30 if they complete all three narrative sessions. Participants will also receive \$30 for each follow-up survey, which will occur 1, 3, 6, and 12 months later. Compensation will be provided with Amazon.com giftcards. Amazon.com has been successfully used in existing trials (R01AA014576). Amazon.com giftcards also allow participants to receive immediate reinforcement for their participation.

b. Protection Against Risk:

We have taken steps to protect participants against potential risks posed by their participation in this research. Psychological risks of experienced invasion of privacy or increased awareness or concern about one's behavior as a result of completing the assessments will be addressed as a risk in the consent documents. Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Participants who report life-threatening levels of alcohol consumption (i.e., BAC greater than .35) or who express interest in seeking help for alcohol-related problems will be offered referral information. Participants will not be restricted from seeking other alcohol education, prevention, or treatment opportunities.

All data and other information in the proposed research will be maintained confidentially, but will not be anonymous due to the longitudinal nature of participation. In order to protect against risks posed by a potential loss of confidentiality, we will take the following steps: first, participants will be assured that they are free to refrain from answering any questions they do not wish to answer; second, all data will be identified only by a unique personal identifier (PIN), which will be randomly generated for study purposes. The list matching contact information and PIN numbers will be kept separate from the data under a password-protected file, so that names and other contact information will never be directly associated with data. This file will be available

only to research staff on this project. To maintain confidentiality of data submitted over the Internet, participants will be required to log into a secure server (site certificate provided by VeriSign) using a unique Personalized Identification Number (PIN) created for study purposes. Data transfer will be protected using a Secure Socket Layer with 128-bit encryption. This is the same level of encryption used for most banking transactions and offers the highest degree of protection available for data transfer. The server is physically located in a secure, commercially protected location facility with 24-hour locked and monitored key-card access, within a locked room, within a locked server rack, with a locking face-plate, protecting the server itself from physical access without authorization. Electronic protection is provided by a commercial-grade firewall, with continuous monitoring of the server for any attempts at electronic invasion. Finally, we will apply for a Federal Certificate of Confidentiality through the Department of Health and Human Services. This certificate offers the highest protection available by law for research data. We previously used these certificates in our work with college student gamblers, drinkers, and marijuana users. Participants will be informed of these risks and protections in the informed consent process.

All recruitment contacts will emphasize the voluntary nature of participation to reduce the risk that participants may feel coerced. Participants will also be notified of the potential risk that the information provided may not be helpful, and will be provided with information about where else they might seek information about alcohol use, or receive alcohol-related services if desired.

3. Potential Benefits of the Proposed Research to the Subjects and Others

There may be no direct benefit to individuals for their participation. However, participants may benefit if randomized to one of the intervention conditions, in that preliminary data already suggest that these interventions will reduce problem drinking. Further, this research has the potential for reducing the serious public health problem of heavy drinking college students. Given the high rates of problem drinking in college samples and the negative health and behavioral consequences related to excessive drinking, development and dissemination of increased knowledge has the potential for significant societal benefits in future development of brief prevention and intervention strategies. Given these potential individual and societal benefits, the risks of participation are outweighed.

4. Importance of Knowledge to be Gained

The present research proposes to evaluate expressive writing as an innovative intervention for heavy drinking students. The proposed research will evaluate theoretically and practically innovative critical questions regarding the impact of expressive writing on college alcohol use. The significance of this application is underscored by the novelty of the intervention in this context, and its potential to offer a new paradigm for college alcohol interventions that could be self-administered at low cost. Ultimately, the research findings will be translated and disseminated to health care providers, researchers, policymakers, and the public.

5. Data and Safety Monitoring Plan

The research proposed herein is not a NIH-defined phase III clinical trial. Thus, while a data and safety monitoring board is not a requirement, a data and safety monitoring plan is in place. As described above, all participants are encouraged to contact the Investigators and the UH IRB to report complaints or adverse events. Instructions for reporting adverse events and complaints, as well as for contacting the Investigators, will be included in the consent documents and on all contact letters provided to participants through the course of the study. Any significant adverse events will be reported to NIH within 48 hours, and all adverse events will be reported on the annual status report, in compliance with federal regulations. All data will be monitored by the research coordinator on a daily basis during each assessment period to screen for individuals who report life-threatening (i.e., BAC greater than .35) levels of alcohol consumption. These individuals will immediately be sent a letter from the investigator detailing the risks involved in drinking at their level and offering referral information.

INCLUSION OF WOMEN AND MINORITIES

Women will be included in the recruiting sample in proportion to their representation as students on the University of Houston campus. Demographic data from the population indicates 51% of students are female, and based on prior experience, we anticipate that baseline respondents will accurately mirror this gender breakdown.

Ethnic minority individuals will be included in the recruiting sample in proportion to their representation in the UH undergraduate population. The UH campus population provides an accurate estimation of the Houston-Galveston-Brazoria metropolitan area. Thus, we expect that the constitution of our longitudinal sample will be approximately 36.9% Caucasian, 34.6% Asian/Pacific Islander, 11.1% African American, .9% Native Hawaiian, 0.6% Native American, and 15.9% Other (please see Enrollment Table). Our prior experience suggests baseline respondents will be generally representative of the campus, as we have not encountered systematic response biases utilizing similar recruitment methods on several prior studies.

Contact PD/PI: Neighbors, Clayton

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Guilt and Expressive Writing for Reducing Alcohol Use in College Students

Domestic/Foreign: Domestic

Comments: N=600 for longitudinal intervention.

Parial Catagorias			ategories		
Racial Categories	Not Hispan	or Latino	Total		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	2	2	4
Asian	103	100	2	2	207
Native Hawaiian or Other Pacific Islander	3	3	0	0	6
Black or African American	33	31	1	1	66
White	75	72	38	36	221
More than One Race	15	15	34	32	96
Total	229	221	77	73	600

Study 1 of 1

INCLUSION OF CHILDREN

The majority of students participating in this research will be between 18 and 21 years of age. Thus, the majority of participants will be children by NIH definition at entry to the study. Some participants will be adults (over 21), or will become adults during their participation in the longitudinal portions of the research.

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The State University of New York

University at Buffalo

January 16, 2014

Ronda Dearing, PhD Senior Research Scientist Research Institute on Addictions University at Buffalo 1021 Main St. Buffalo, NY 14203-1016

Dear Clayton,

I am writing to offer my strongest endorsement for your proposal "Guilt and Expressive Writing for Reducing Alcohol Use in College Students," and I to agree to serve as a consultant to your project. This study is innovative in many ways and I believe that it will provide important new information about factors that influence high-risk drinking among a vulnerable population of emerging adults. In particular, the proposed research design will allow in-depth examination of potentially malleable characteristics that are essential to developing future prevention efforts within this group of young people. This emphasis fits in very well with my own research and expertise, which involves treatment of alcohol and substance use as well as links between shame, guilt, and problematic substance use (including alcohol).

I will contribute to all phases of the study and I am happy to dedicate 2 days each year during Years 1 and 5 for consultation (at a daily consulting rate of \$1000) on this important research project. In particular, I will contribute my expertise during the early phases to assist with measurement design and to refine the narrative prompts for guilt. I also will facilitate in crafting the event-related guilt items to be used as mechanisms underlying the intervention effect. In the final phases, I will gladly collaborate on the development and dissemination of the research findings, including manuscript preparation.

I look forward to working with you on this exciting project.

Sincerely,

Ronda L. Dearing, PhD