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A peer approach to suicide prevention and recovery: Study protocol for a feasibility and acceptability trial of Caring Cards for veterans

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ABSTRACT

Introduction: There is a need to develop, evaluate, and implement interventions that reduce Veteran suicide. Caring Cards (CC) is a novel intervention that integrates aspects of caring contacts and peers (i.e., persons with lived mental health experience). In CC, Veterans meet in a weekly group to create hope-filled cards that are sent to Veterans with mental health concerns. This study will examine feasibility and acceptability of CC with Veterans with a history of and current elevated suicide risk via in-person and virtual modalities and preliminarily evaluate pre/post changes on suicide-specific outcomes.

Methods: This 2-year open-trial study will employ a pre/post research design. Recruited Veterans with a history of suicide risk (n=30) will make up CC groups (card makers) and Veterans currently at high-risk for suicide (n=50) will be card recipients. Feasibility and acceptability (recruitment, retention, attendance, card receipt rates, and satisfaction questionnaire responses) and pre/post changes on suicide-specific outcomes (i.e., thwarted belonginess, perceived burdensomeness, social connectedness, suicidal ideation, and behavior) will be evaluated. Groups will meet weekly for 90–120 min for three to six months; card recipients will receive one card per month for six months.

Discussion: This study builds on preliminary data which indicate Veterans are interested in and find participating in CC highly meaningful. This study is innovative as it will target two new Veteran populations and use both inperson and virtual modalities. If feasible and acceptable, a large-scale efficacy trial will be conducted to further examine CC as a suicide prevention intervention for Veterans.

1. Introduction

Veteran suicide is a national problem, and, despite increased prevention efforts, rates are increasing [1]. Empirically supported interventions that reduce Veteran suicide are critically needed. Among those available to Veterans, is Caring Cards (CC) [2,3], a group-based intervention in which Veterans with a history of suicide risk create one-of-a-kind handmade cards during weekly groups that are sent to Veterans currently at high-risk for suicide. CC is similar to current evidence-based practices (EBPs) for Veteran suicide prevention (e.g., Cognitive Behavioral Therapy for Suicide Prevention, Project Life Force, Dialectical Behavior Therapy) in that it is delivered in a group format and centered on suicide prevention; however, it differs from these treatments in a few important ways. First, CC is low intensity (i.e., does not require a specialized or advanced therapist to facilitate), brief, and

has the potential to be highly scalable. Second, it simultaneously treats two distinct groups of Veterans at-risk for suicide. Third, CC is the only suicide-focused intervention that specifically targets two key social factors associated with risk: thwarted belongingness and perceived burdensomeness, collectively called social disconnectedness [4-6]. Thwarted belongingness (feeling socially disconnected) includes loneliness (a sense of inadequate connections) and the absence of reciprocally caring relationships [5]. Loneliness is closely associated with suicidal ideation (SI) among the general population [7,8] and Veterans [9]. Perceived burdensomeness is the perception of being profoundly useless that one's existence burdens others [10]. Purpose (responsibility to others) is central to perceived burdensomeness and perceptions of purposelessness are strongly associated with suicide risk [11,12]. As a lack of social connectedness predicts suicidal risk, social connection is a strong protective factor against suicide by facilitating purpose [13]. As noted above, despite their relevance, CC [2,3] is the only suicide-focused

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Abbreviations:

CC Caring Cards

EBPs Evidence-Based Practice
SI Suicidal Ideation
SB Suicidal Behavior
SA Suicide Attempt

NIH National Institutes of Health VASDHS VA San Diego Healthcare System

PI Principal Investigator VA Veterans Affairs

UBACC University of California San Diego Brief Assessment of

Capacity to Consent

C-SSRS Columbia-Suicide Severity Rating Scale SBOR Suicide Behavior and Overdose Report INQ-12 Interpersonal Needs Questionnaire BSS Beck Scale for Suicide Ideation

intervention that targets both thwarted belongingness and perceived burdensomeness (see Fig. 1).

CC uniquely combines aspects of caring contacts, an intervention in which staff longitudinally provide short, individualized letters with supportive messages to patients following psychiatric hospitalization [14], and the Recovery Model which heavily emphasizes peers (i.e., persons with lived mental health experience) and asserts recovery from a mental health condition is possible if mental healthcare is patient-directed [15]. Though caring contacts' ability to prevent suicide has shown mixed (statistically and non-statistically significant) results, its general efficacy is supported [16–18]. Studies of caring contacts have demonstrated outcomes such as reductions in suicide behavior (SB) [16] and suicide attempts (SA) [17,18], as well as lower odds of experiencing SI [18], whereas no significant differences between caring contacts and usual care across suicide-specific variables (i.e., suicidal ideation and behavior) and need for higher levels of care (i.e., emergency department visits and inpatient admissions) have also been observed [18].

Furthermore, when peers are integrated into mental health treatments, recipients of services have demonstrated reductions in relapse [19], isolation [20], and self-stigma [21], as well as increases in hope [22], empowerment [23,24], and involvement in and satisfaction with mental healthcare when integrated into it [25,26]. Using lived mental health experience, peers challenge stigmas, facilitate community integration, and empower individuals to be active in their care [27]. To date, only CC [2,3] and a non-clinical sample of Veteran peers [28] have used peers to create caring contacts. A recent pilot study established feasibility and acceptability of CC with outpatient Veterans with primary psychotic disorders [3]. All card makers recommended the group and the majority believed the group should be a permanent clinic offering. CC also had higher attendance rates compared to other groups in the same clinic [3]. All card recipients said receiving a card was a positive experience and recommended program continuance.

In contrast to the CC pilot study's sample of Veterans with psychotic disorders, this protocol (Stage 1B per the NIH Stage Model [29]) aims to establish feasibility and acceptability of CC in two new Veteran populations and preliminarily evaluate pre/post changes in suicide-specific (e.g., thwarted belongingness, perceived burdensomeness) and social

connectedness variables. We hypothesize that CC will be feasible and acceptable and participants will demonstrate significant pre/post reductions on suicide-specific and social connectedness outcomes.

2. Materials and methods

2.1. Study design

This study 2-year open-trial pilot study aims to establish the feasibility and acceptability of CC with Veterans with a history of and those with current risk of suicide. A pre/post design will be utilized to gather preliminary evidence of CC's ability to reduce thwarted belongingness, perceived burdensomeness, and suicide risk, as well as increase social connectedness among Veteran participants.

2.2. Participants

A total of N = 80 Veterans from the VA San Diego Healthcare System (VASDHS) will be recruited to participate. A total of n = 30 Veterans with a history of elevated suicide risk, as defined by having a history of a high-risk suicide flag (inactive flag), will be recruited to participate as card makers in weekly CC groups. A total of n = 50 Veterans with current high suicide risk, as defined by having a current high-risk suicide flag (active flag) will be recruited to receive cards. (Note. In the VA system, a high-risk flag serves as a marker in the Veteran's medical record to indicate this Veteran is currently at high risk for suicide. High-risk flags are activated based on new or worsening presentations of suicidal risk (e.g., recent suicide attempt, psychiatric hospitalization for suicidal ideation), which is determined by the local VA's Suicide Prevention Coordinator (SPC) Team and consultation with the Veteran's mental health treatment providers. Such flags are reviewed every 90 days and are either renewed or deactivated by the SPC team based on chart review and communication with the Veteran's providers.) Veteran card makers must: (1) be enrolled as a VASDHS Veteran with an inactive high-risk flag, (2) 18 years of age or older, (3) have access to transportation to attend the group in-person (if willing), or (4) have access to use a reliable computer, table, or smartphone with internet connection and a web-camera to participate if unable or unwilling to participate in an inperson group, and (5) have decisional capacity. Veteran card recipients must: (1) be enrolled as a VASDHS Veteran with an active high-risk flag, (2) 18 years of age or older, and (3) have decisional capacity. Exclusion criteria for both card makers and recipients are: (1) the absence of a mailing address or working phone number, (2) inability to read and write in English, (3) previous or current experience as either card maker or recipient (in previous CC pilot study), and (4) current VA employment.

2.3. Procedures

2.3.1. Recruitment and screening

Participants will be primarily recruited by the study coordinator. In some instances, clinical providers may refer Veterans directly to the study coordinator for screening. For card makers and recipients, utilizing VA records, the study coordinator will pre-screen Veterans (i.e., mailing address, living within San Diego County, telephone number, and VASDHS visit within last calendar year) and mail them an introductory letter. The coordinator will reach out via telephone two weeks after the letter has been sent. If Veterans are reached, they will be invited to be

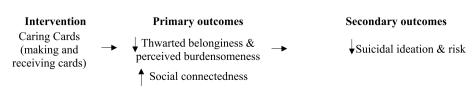


Fig. 1. Testing model.

screened for eligibility. If interested and eligible, Veterans will be consented, and baseline assessments will be collected. If uninterested or ineligible, Veterans will be offered a list of VA and community (local and national) mental health resources. Veterans will be called three times on separate days before follow-up is discontinued.

Eligible card makers will be invited to participate in either an inperson or virtual group; eligible card recipients will be consented and mailed their first card within one to two weeks following enrollment and baseline data collection (please see section 2.4.4 Sending Caring Cards for details). Consent and baseline assessments will be completed in-person or over telehealth using DocuSign. For inpatient prospects, the study coordinator will consult with the Principal Investigator (PI) and/or the Veteran's treating inpatient teams to determine the appropriate timing of approaching Veteran on the unit. If appropriate, the study coordinator will conduct screening on the unit, and, if agreeable and eligible, will enroll the Veteran prior to or following discharge.

All baseline and follow-up assessments will be collected individually, in-person or via telephone depending on the Veteran's preference. For card makers, follow-up data will be collected within one month of the last group meeting. If a card maker drops out prior to the group's end date, follow-up data will be collected within one month of the last meeting they attended. For card recipients, follow-up data will be collected within one month after the delivery of their sixth and final card. If a card recipient drops out prior to this, follow-up data will be collected within one month after the last card they received. Participants will be paid a total of \$120 to complete baseline and follow-up assessments (\$60 each).

2.4. Caring Cards intervention

CC is manualized [2] and consists of two main components— weekly groups that meet to create the cards and sending the cards. Fidelity of the CC group will be assessed by the PI. The audiotapes of treatment delivery will be measured via a fidelity rating scale, and feedback will be shared in weekly supervision. For specific information on fidelity assessment, monitoring, and enhancement, please see section 2.5.3 Fidelity.

2.4.1. Caring Cards groups (general)

Groups will consist of 5-10 Veterans and meet weekly. Virtual and in-person groups will be offered to accommodate for Veteran preference, transportation limitations, COVID-19 facility policies, and other personal barriers (health status, work/childcare schedules). All Veterans in the study will be offered both format options; they may select whichever format they would like to participate in. Virtual groups will meet for 90 min for three months and in-person groups will meet for 120 min for six months. The shortened time and duration for virtual groups attempts to increase accessibility for full-time working Veterans with limited free time during the workday. Groups will be run by two facilitators which may include a doctoral level psychology fellow, Master's level study therapist, and/or bachelor's level psychology technician supervised by a licensed clinician. To reduce bias, the PI will not facilitate or observe any of the groups. At the initial meeting, the Veterans will be introduced to the facilitators, supervisor, and peers; facilitators will review group rules (e.g., limits of confidentiality), format, purpose, and general guidelines for making cards (e.g., content neutral to military branch, age, religion, or political affiliation, no profanity, no personally identifying information should be included). Facilitators will also acknowledge at the outset that CC is not a group to discuss suicidal behavior; they will provide additional referrals (e.g., individual therapy) or alternative suggestions (e.g., stay after group to discuss with facilitators if there is a concern) if risk or inappropriate behavior concerns are indicated. Veterans will be instructed to focus on using their lived experience to communicate positive messages. To help elicit this, the facilitators may ask the Veterans to think of a difficult time they have experienced and what message they would have wanted to receive that would have been helpful during that time. Facilitators may also use reflection and supportive listening skills as needed to support the card makers in their process. Although facilitators will be present, CC is peer-run, and the Veteran group members are the creative decision-makers. Based on the previous CC pilot study [3], 10 Veteran-designed card covers will be used as materials for the present study. The statement "Designed and Created for a Veteran by a Veteran" appears the inside each card, and a list of local (VA and non-VA) resources for suicide prevention and mental health crises are printed on the back. Card makers design and create art and messages for the inside pages of each card. Participants will be encouraged to assist one another with ideas for various card content and artwork, as well as collaborate on card designs. The facilitators will be available to help. Each week, a Veteran will be selected to choose music for that day's group session.

2.4.2. Caring Cards groups (in-person)

In-person groups will meet for 120-min at the VASDHS. Blank cards and art supplies will be provided. Participants will be encouraged to collaborate on card designs and at the end of each session, Veterans will be asked to assist the facilitators with clean up, as well as collecting and organizing the cards.

2.4.3. Caring Cards groups (virtual)

Virtual groups will meet via WebEx for 90-min. The length of the virtual group will be shorter and more flexible than the in-person groups to prevent "virtual meeting fatigue" and accommodate full-time working Veterans with limited weekday availability. Prior to their first group, Veterans will be sent individual art supply kits, along with blank cards, and envelopes with pre-paid postage to return their completed cards. Veterans will be sent an email reminder each week the day before their group meeting; these emails will include the same WebEx link to join the session, as well as the date and time of the group and contact information for the facilitators.

2.4.4. Sending Caring Cards

A total of six cards, one per month, for six months will be mailed to Veteran card recipients. Consistent with Caring Contacts, ¹⁴ Veterans recruited from psychiatric inpatient care will be mailed a card within the week following their discharge; cards will be sent monthly thereafter. The study coordinator will contact Veterans via telephone two weeks after their initial card was sent to confirm the card was sent to the correct address. Once receipt has been confirmed, no additional calls will be made for the other five cards, unless a participant has indicated a potential address change. To assess fidelity for sending cards, quantity, timing, and receipt of the cards will be recorded. All cards will be screened by the study coordinator for appropriateness (e.g., no profanity) prior to being sent.

2.5. Measures

Study measures are outlined in Table 1.

2.5.1. Decisional capacity

The University of California San Diego Brief Assessment of Capacity to Consent (UBACC) [30] will be used to ensure decisional capacity. The UBACC is a 10-item questionnaire tailored to specific study procedures. It queries participants about the basic procedures, risks, benefits, and purpose of the study, along with participant rights. Each item on the UBACC is scored on a 0 (incapable) to 2 (capable) scale.

2.5.2. Feasibility and acceptability

Feasibility for card makers will be assessed by the proportion of enrolled Veterans who attend scheduled CC groups. Feasibility for card recipients will be assessed by the ratio of cards sent and received. For card makers and recipients, feasibility will also be measured by the proportion of Veterans: 1) referred for screening, 2) determined eligible,

Table 1 Study measures.

Timepoint	Measure	Construct Assessed
Screening	Chart review and eligibility screen;	
	University of California San Diego	
	Brief Assessment of Capacity to	
	Consent [30]	
Baseline Only	Columbia-Suicide Severity Rating	Suicidal ideation and
	Scale (C-SSRS) [31]	behavior
Baseline &	Interpersonal Needs Questionnaire	Thwarted belongingness &
Follow-Up	(INQ-12) [32]	perceived burdensomeness
	NIH Toolbox Adult Social	Social connectedness
	Relationship Scales [33]	
	Beck Scale for Suicide Ideation	Suicidal ideation severity
	(BSS) [34]	•
Follow-Up	C-SSRS "Since Last Contact" [31]	Suicidal ideation and
Only		behavior
	Intervention Satisfaction	Satisfaction with
	Questionnaire	intervention
CC Group	CC Rating Scale	Facilitator fidelity
Facilitation		

3) enrolled/completed baseline (benchmarks identified in Table 2), and 4) complete follow-up assessments. The Intervention Satisfaction Questionnaire, a measure developed by the research team, will primarily assess acceptability, personal experience, and overall satisfaction among study participants. The Intervention Satisfaction Questionnaire has either 34 items (CRs) or 43 items (CMs) and utilizes a combination of statements rated on a 7-point Likert scale (e.g., "As a result of this group, I helped Veterans in need of extra support"), yes/no questions, and openended qualitative feedback questions (e.g., "Why did you choose virtual/in-person format?").

2.5.3. Fidelity

Group facilitators will be trained on delivery of the CC groups by the PI. Centralized training will take place over one day. As this is a Stage 1B study, per the NIH Stage Model, we will be developing and validating a CC fidelity rating scale over the course of this study. The instrument will be developed by the PI and consist of items organized into domains that capture key components of CC. Group facilitators will be rated across all items using a 7-point Likert scale ranging from 0 (poor) to 6 (excellent), with 3 representing satisfactory performance. The PI will train a research assistant, who will not facilitate any CC groups, to use the rating scale. Once trained, the PI and research assistant will independently review and rate group sessions until Cohen's kappa of .8 has been reached. All group sessions will be rated until all facilitators have achieved initial adherence; thereafter, 20% of group sessions will spot-checked for any drift in CC adherence. If a facilitator falls below 80% adherence, they will undergo additional training by the PI.

2.5.4. Thwarted belongingness and perceived burdensomeness

Thwarted belongingness and perceived burdensomeness will be measured by the INQ-12 [32]. The INQ-12 consists of 12 statements (e. g., "These days, I feel like I belong") rated on a 7-point scale ranging from 1 (not at all true for me) to 7 (very true for me) [32]. The total score can be broken into two subscales (thwarted belongingness and perceived burdensomeness). Both have good psychometric properties, yielding

internal consistencies of $\alpha=0.85$ and $\alpha=0.89$, respectively [32]. The INQ-12 has been validated for use with U.S. Veterans [35].

2.5.5. Social connectedness

Social connectedness will be measured using three instruments from the NIH Toolbox Adult Social Relationship Scales [33]. The scales included in this study are the Emotional Support, Loneliness, and Perceived Rejection scales. Collectively, these scales assess current (past month) social connectedness, total 21 items, and are rated on a 5-point Likert scale. Moreover, these scales have good internal consistencies (Emotional Support [$\alpha=0.97$], Loneliness [$\alpha=0.94$], and Perceived Rejection [$\alpha=0.94$]) and have been validated for use with U.S. Veterans with depression and suicidality [36].

2.5.6. Suicide risk

Suicidal ideation and behaviors will be assessed by the BSS [34] and C-SSRS [31]. The BSS measures suicidal ideation severity over the past two weeks [34]; it has strong psychometric properties [37] and has been used with suicidal U.S. Veterans [38]. The C-SSRS has been implemented across the VA and is standard to VASDHS' risk assessment procedures. VASDHS uses an 8-item version of the C-SSRS, which assesses current (past 30 days) and lifetime suicide ideation and behaviors. Risk is considered present if a C-SSRS is "positive." A screen is positive if items 3, 4, 5, or 8 are answered "Yes." If a screen is positive, our assessor will adhere to local guidelines and a licensed independent practitioner (LIP) is notified to completes a comprehensive risk and needs assessment. A 6-item "Since Last Contact" version of the C-SSRS will be used to assess suicide risk at follow-up; the screen is positive if items 3, 4, or 5 are answered "Yes." If at either timepoint, a Veteran discloses any suicidal behavior, including an attempt, our assessor will adhere to local guidelines and a LIP will complete a VA-required Suicide Behavior and Overdose Report (SBOR). VA-issued criteria for generating a SBOR include any suicidal behavior reported as taking place within the past year that has not be previously reported by a local or other VA. Adverse event reporting may also take place if the behavior occurs while the Veteran is an active study participant.

2.6. Statistical analyses

2.6.1. Feasibility and acceptability

Point-estimates of feasibility and acceptability include 70% average attendance to weekly groups, >75% average satisfaction with group participation and card receipt, and 70% average follow-up response. These benchmarks are consistent with current VASDHS' standards, as well as data derived from the small CC pilot previously described. Descriptive analyses of facilitator fidelity will be assessed. Point-estimates of fidelity include a minimum of 80% average fidelity across all facilitators for at least 80% of group sessions reviewed. As previously noted, all group sessions will be rated until all facilitators have achieved initial adherence; thereafter, 20% of group sessions will spot-checked for any drift in CC adherence. If a facilitator falls below 80% adherence, they will undergo additional training by the PI.

2.6.2. Thwarted belongingness and perceived burdensomeness

To test the changes in thwarted belongingness and perceived

Table 2
Enrollment benchmarks.

Month	1	2	3	4	5	6	7	8	9	10	11	12
Y1 Screened: Card makers	0	10	10	10	10	10	10	0	0	0	0	0
Y1 Enrolled: Card makers	0	5	5	5	5	5	5	0	0	0	0	0
Y1 Screened: Card recipients	0	0	0	12	12	12	12	12	10	10	10	10
Y1 Enrolled: Card recipients	0	0	0	6	6	6	6	6	5	5	5	5
Total Enrolled: Card makers	0	5	10	15	20	25	30	30	30	30	30	30
Total Enrolled: Card recipients	0	0	0	6	12	18	24	30	35	40	45	50

burdensomeness before and after making and receiving cards, paired samples, two-tailed t tests with a p-value of .05 (95% CI) will be performed. For card makers with a sample size of 30 and an expected effect size of Cohen's d=0.5 (medium), the achieved power is .75. For card recipients with a sample size of 50 and an expected effect size of Cohen's d=0.5 (medium), the achieved power is .93.

2.6.3. Social connectedness and suicide risk

To test the changes in social connectedness, suicide risk, suicidal ideation and behaviors before and after making and receiving cards, paired samples, two-tailed t tests will be performed with a p-value of .05 (95% CI).

2.6.4. Considerations for multiple group formats

Provided that the CC groups will be delivered in varying formats (i. e., in-person, virtual), all abovementioned analyses related to the groups/card makers will also be examined separately based on their respective format. As such, feasibility, acceptability, and preliminary efficacy conclusions will be able to be understood based on both inperson and virtual designs.

3. Discussion

The integration of caring contacts and peers to facilitate social connection among Veterans at risk for suicide is an innovative approach to suicide prevention. CC is the first suicide-focused intervention to simultaneously target two important social risk factors for suicide risk – thwarted belongingness, and perceived burdensomeness. The present study aims to establish feasibility and acceptability of CC with two novel Veteran populations (those with a history of suicide risk and those with current elevated suicide risk) across in-person and virtual settings. This study will develop and pilot recruitment materials/strategies, assessment measures and protocols, including risk management procedures, as well as therapist training materials, and a fidelity measure. CC has the potential to benefit both Veterans who make and receive these cards; as such, preliminary pre/post changes across suicide-specific outcomes will be examined.

If found feasible and acceptable to these new Veteran populations and in both or either in-person and/or virtual formats, a large-scale efficacy trial will be conducted to further examine the impact of CC's ability to meaningfully reduce Veterans' suicide risk. Furthermore, testing the protocol in a virtual setting has the potential to improve access to care for Veterans unable to attend weekly in-person groups, such as those with limited mobility, lack of transportation, health restrictions, full-time work schedules, or childcare concerns. Despite these strengths, there are notable limitations. First, although we intend to evaluate preliminary efficacy of CC on the aforementioned variables, we will not be able to draw any conclusions about the efficacy of CC given this pilot study's lack of randomization, and small sample size. In addition, our limited range of assessment measures may restrict our ability to detect significant pre/post changes across our outcome variables. Although efficacy testing will require a larger, randomized trial, the results of the current study could inform if CC is worthy of further development/testing, as well as help identify potential outcomes for a future efficacy trial. While the assessments will be administered by a licensed clinician, we have not created additional safeguards to prevent bias or deviation from interview protocol. We also recognize the limitation in using a clinical determination (e.g., "high risk flag") for inclusion criterion rather than a specific measurement-based criterion. Finally, the COVID-19 pandemic shifted most of our CC groups to virtual format. While the in-person groups will be offered when safe, CC was developed before COVID-19 and facilitating the groups via telehealth was not part of its original design. As such, variability in group length and duration may impact the measurement of outcomes between inperson and virtual groups. The use of both in-person and virtual formats will also reduce the number of Veterans included in each. As noted

above, provided that feasibility and acceptability may differ between these two formats, we will conduct separate analyses based on format; however, to reduce the impact of smaller sample sizes split between both formats, we will also conduct combined sample (in-person and virtual) analyses.

3.1. Trial status

Study recruitment, assessment, and intervention delivery are currently underway. Follow-up data collection is anticipated to be completed by July 2022.

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Trial registration

ClinicalTrials.gov NCT04486677. Date of registration: July 24, 2020. This study was approved by the local Institutional Review Board (#H200125).

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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