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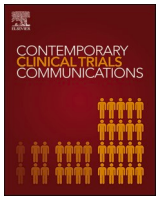

A randomized controlled trial protocol for a virtual, scalable suicide prevention gatekeeper training program for community pharmacy staff (Pharm-SAVES)

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ABSTRACT

Background: Suicide prevention gatekeeping is a skill that may support community (retail) pharmacists in managing patients who present with suicide warning signs. A brief, virtual, case-based training intervention was tailored to the retail setting (Pharm-SAVES). To test training effectiveness, a randomized controlled trial (RCT) protocol was developed for use in pharmacies across four states.
Objective: To introduce the trial protocol for assessing the effectiveness for increasing the proportion of staff who recognize patients displaying warning signs and self-report engaging in gatekeeping, including asking if the patient is considering suicide.
Methods: This study uses a parallel cluster-randomized controlled trial to recruit 150 pharmacy staff in community pharmacies in four states with two groups (intervention and control). The control group completes Pharm-SAVES online suicide prevention gatekeeper training and all assessment surveys at baseline after training and at 1-month follow-up. The experimental group completes all control group training and assessments plus interactive video role-play patient cases.
Conclusion: We hypothesize that compared to those in the control group, experimental group trainees exposed to the interactive video role play patient cases will be more likely to recognize warning signs in patient cases and self-report engaging in gatekeeping.

1. Introduction

Worldwide, more than 700,000 people die by suicide annually, and most suicides occur in low to middle-income countries where access to physicians and hospitals may be more limited than in high-income countries [1]. One person died by suicide every 11 min in the US in 2020 [1]. On average, suicide decedents had contact with health providers in the year (80%) and month (44%) before suicide [2–4]. Additionally, 74% of medical office visits end with a prescription, suggesting that some patients visit pharmacies for prescriptions before their deaths [5]. Studies in Canada, Australia, the Netherlands and Japan have illustrated the use of gatekeeper training and/or gatekeeper roles in pharmacy practice [6–15]. A scoping review of 13 articles that included studies from nine countries concluded that suicide prevention training positively impacted pharmacists' attitudes and preparedness to participate in suicide care, but that there was a clear lack of suicide prevention training for pharmacists [16]. Therefore, pharmacists trained in gatekeeping for suicide prevention may play an important role in identifying suicide warning signs and providing a warm hand-off to crisis lines or other emergency services [6,13].

Community (i.e., retail) pharmacies offer free walk-in access to a pharmacist, vaccination and other services. Some are staffed with a pharmacist 24-h per day, seven days per week. Community pharmacists are the most uniformly accessible healthcare professionals in the US [17–19] and pharmacy staff have reported interactions with patients at risk of suicide [20]. Among 501 North Carolina community pharmacists

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and pharmacy technicians, 22% knew a patient who had died by suicide, 22% had been asked for a lethal dose of medication, and 12% had interacted with a patient who expressed suicidal ideation [20]. Yet, few had been trained (7%) or provided resources (9%) to support suicide prevention, and most (90%) desired suicide prevention training [20]. Student pharmacists have also reported interacting with patients at risk [21].

Systematic reviews have identified 24 suicide prevention training resources used with pharmacists [12,22,23]. Of these, the Department of Veterans Affairs' (VA) SAVE gatekeeper training program shows promise for large-scale uptake by community pharmacies due to its short (20 min) time requirement and modeling of expert interactions with suicidal patients [13]. Short trainings are preferred by large chain pharmacies for the low cost associated with pharmacists' time to train. We used formative data from in-depth interviews with 19 community pharmacists and technicians to adapt VA SAVE training to community pharmacy settings. Periodic input from two advisory boards (community pharmacy staff, US military veterans) supported development of Pharm-SAVES [24]. This adapted training will be evaluated in this randomized controlled trial (RCT).

Knowledge is necessary to change behavior, and previous work has documented a lack of knowledge among community pharmacy staff about suicide warning signs, what constitutes an emergency, and how to counsel and refer at-risk patients [16,25–27]. Suicide prevention gatekeeper training programs consistently result in increased knowledge and more positive attitudes toward suicide prevention [6–15], however effects on behavior are less certain [25,26]. The purpose of this protocol is to describe a randomized controlled trial to test the effectiveness of Pharm-SAVES with and without interactive role-play videos. The RCT will: 1) deliver scalable, free, virtual, case-based, gatekeeper training for suicide prevention tailored to community pharmacies, and 2) assess the change in pharmacy staff (e.g., pharmacist, technician) behaviors with only Pharm-SAVES training (control group) versus Pharm-SAVES plus interactive virtual role-play cases (experimental group). We hypothesize that compared to those in the control group, a higher proportion of trainees in the experimental group will 1) recognize suicidal warning signs in a virtual patient case and respond with gatekeeping including asking about suicide specifically, and 2) demonstrate greater suicide prevention knowledge, higher gatekeeper self-efficacy, and higher gatekeeper preparedness.

2. Methods

2.1. Study design

This is a parallel cluster-randomized controlled trial of 150 pharmacy staff (e.g., pharmacists, technicians) in four states with two groups (intervention and control) (Fig. 1). This trial was reviewed and approved by the Institutional Review Board (IRB) at the University of North Carolina (UNC) at Chapel Hill (IRB approval #: 21–1062). Data collectors will complete the Collaborative IRB Training Initiative (CITI) web-based training course before data collection. In addition, this study was reviewed and approved by the Research Review Committee, Finger Lakes VISN 2 Department of Veterans Affairs. It is registered on Clinical Trials.gov (NCT05128227). Informed consent documentation is obtained via a Qualtrics baseline survey and data are stored on the secure Qualtrics server until transferred in a secure fashion to UNC servers with password-protected files.

2.2. Participants

All participants are pharmacists, pharmacy technicians, pharmacy interns or other pharmacy staff working in US community (retail) pharmacies. The recruitment target is 150 participants. Recruitment takes place at the individual level by advertising to pharmacy employees of a regional grocery store chain pharmacy, the Rural Research Alliance of Community Pharmacies Practice-Based Research Network (Rural-CP) and the North Carolina Association of Pharmacists (NCAP). Inclusion criteria are: age 18 or older, English-speaking, and employed full-time at a participating community pharmacy in North Carolina, South Carolina, Georgia, or Tennessee. Due to risk of loss to follow-up and contamination, temporary (e.g., floating) employees are excluded.

2.3. Description of comparators

2.3.1. Pharm-SAVES gatekeeper training: control and experimental groups

Both the control and experimental groups complete Pharm-SAVES gatekeeper training and assessments at baseline, post-training and at the approximately 1-month follow-up. All participants also may choose to complete a standardized patient assessment via Zoom at 1-month follow-up. Enrollment, Pharm-SAVES training and all assessments are completed on-line.

Pharm-SAVES is described in detail elsewhere [24]. In brief, the training website is divided into four modules: 1) Why me?, 2) What can I do? (Pharm-SAVES), 3) How does it work?, and 4) Resources. Module 1

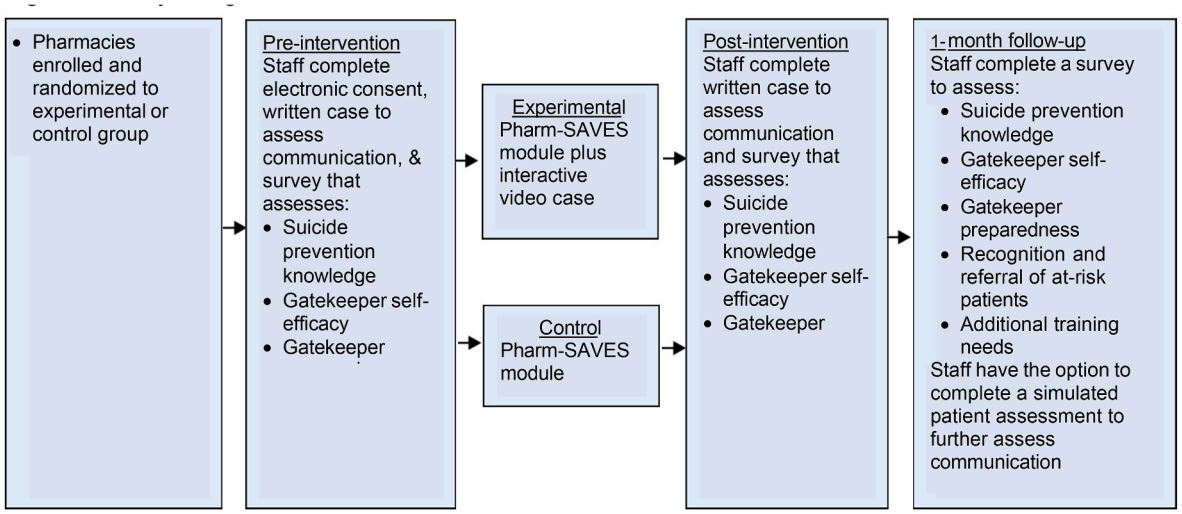

Fig. 1. Study design.

(Why me?) includes suicide statistics, the frequency of pharmacy staff interactions with individuals who have suicide warning signs, and medications that carry warning labels for suicidal behavior. Module 2 (What can I do?) defines SAVES as: 1) Recognize warning **S**igns of suicide, 2) **A**sk if someone is considering suicide, 3) **V**alidate feelings to encourage open communication, 4) **E**xpedite referral (e.g., call a crisis line), and 5) ***S***et a reminder to follow-up. Module 3 (How does it work?) has three videos of pharmacy staff performing Pharm-SAVES gatekeeping with three patients: a white, middle-aged male veteran presenting at a community pharmacy counter; a white male college student presenting in a drive-through; and the voice of a woman who calls the pharmacy. Finally, Module 4 (Resources) is a searchable local referral tool that also includes state and national resources.

Pharm-SAVES is based on Social Cognitive Theory (SCT) (Fig. 2). According to SCT, mastery experience and social modeling are key methods for improving self-efficacy [28]. Mastery experience supports trainee success in attainable but increasingly challenging goals related to Pharm-SAVES. Social modeling refers to showing realistic example interactions that take place within the constraints of a community pharmacy, including limited privacy and time.

2.3.2. Experimental group: Pharm-SAVES gatekeeper training plus interactive video case role-plays

In addition to Pharm-SAVES gatekeeper training and assessments completed by all participants, only the experimental group will complete two interactive role-play cases of approximately 10 min each. Interactive role-plays demonstrate a pharmacist implementing Pharm-SAVES gatekeeping at a community pharmacy retail counter. One scenario portrays a young black woman presenting at the counter feeling hopeless and exhausted on a Friday evening. Another portrays a white middle-aged US military veteran presenting with sleep problems and expressing a wish to never wake up. The same pharmacist in both scenarios is portrayed by a white, middle-aged woman. The pharmacist recognizes the warning signs, engages in conversation with the patient with open body language and validation, asks if the patient is considering suicide, and then initiates a warm hand-off to the US Suicide and Crisis Lifeline (dial 988). At each step in these case conversations, the patient presentation stops and the trainee is asked to type a response to the patient. The video then resumes and the trainee watches the pharmacist respond to the patient using Pharm-SAVES and views a list of key elements to a response for each step of Pharm-SAVES.

2.4. Randomization and allocation

To prevent contamination of the experimental and control groups within the same pharmacy, after enrollment participants are randomized by pharmacy using the county mean annual suicide rate, rurality, and proportion of residents older than age 65. The mean annual suicide rate is the primary matching variable for pairs, followed by location and age. Using computer-generated random numbers, one pharmacy is randomized to the experimental group and the other to the control group within each matched pair. Data are drawn from County Health Rankings [29] (mean annual age-adjusted suicide rate), US Department of Agriculture Rural-Urban Commuting Area Codes (rurality) [30] and the US Census (residents 65 years or older) [31].

2.5. Study procedures

2.5.1. Enrollment procedures

Recruitment via stores was approved by a regional grocery chain pharmacy, RURAL-CP, and NCAP. Initial email advertisements are sent by study staff to the contact person at each store (who is typically a supervising pharmacist). After the contact person at the store agrees that the study can be advertised to their pharmacy staff members, advertisements are sent via email to potential participants and posted as fliers in workspaces. This ends the involvement of the stores. Interested pharmacy staff (pharmacists, technicians, interns, etc.) will then respond to the advertisement to enroll with the study team. After confirming eligibility and verifying group assignment, study staff send an email that includes a link to the Qualtrics baseline survey. The consent form on the first page of the baseline survey describes the study pre-post training surveys, training, and follow-up assessments and advises participants that those who consent and complete the baseline survey are enrolled. The baseline survey includes demographics and prior suicide prevention training, pharmacy characteristics, and suicide prevention knowledge, gatekeeper self-efficacy, and preparedness (Table 1). Participants also respond to a written patient case to assess baseline gatekeeper skill and specifically whether or not the participant asks the patient if he or she is considering suicide. Participants are tracked by the project coordinator in an enrollment tracking Excel sheet using assigned study ID numbers. To receive gift card incentives and communications about assessments, participants provide contact information on the baseline survey.

2.5.2. Delivery of Pharm-SAVES training and assessments (control and experimental groups)

After participants complete the Qualtrics baseline survey, the completion page provides a link to the training website to which their pharmacy was randomized: Pharm-SAVES only (control group) or Pharm-SAVES + interactive video cases (experimental group). The last section of each website describes how to obtain continuing education credit and a link to the Qualtrics post-training survey. To ensure that the training websites are not used by the public during the trial, participants must log in. Those who complete the baseline survey but do not complete the training or post-training survey within one week of enrollment will receive an email reminder from the project coordinator with the website link and instructions for completing the training and receiving CE credit. After completing the post-training survey, participants receive a $20 Amazon eGift card.

The post-training survey includes suicide prevention knowledge,

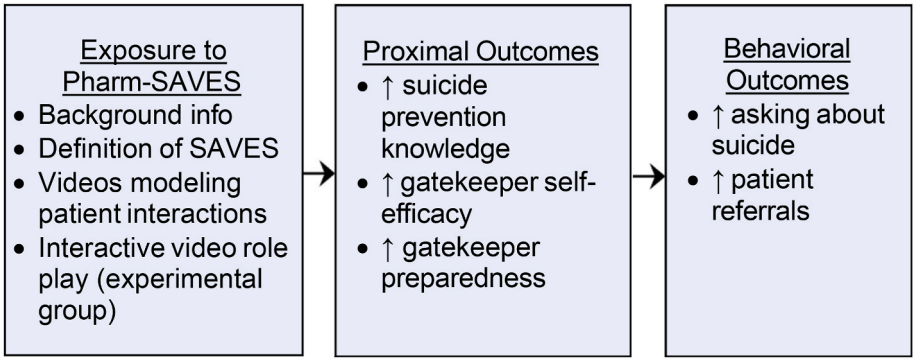

Fig. 2. Conceptual model for study.

Table 1
Data collection schedule.

Variable	Source	# of items	Baseline	Immediate post-intervention	1-month follow-up
Primary Outcome					
Asks patients about suicide	Written case response	4	X	X	
Secondary Outcomes					
Suicide prevention knowledge	Survey	10	X	X	X
Gatekeeper self-efficacy	Survey	6	X	X	X
Gatekeeper preparedness	Survey	6	X	X	X
Other Measures					
Demographic and pharmacy characteristics	Survey	10	X		
Other suicide prevention training	Survey	1	X		
Interactions with and referrals of patients exhibiting warning signs	Survey	5			X
How to improve SAVES module	Survey	2		X	X
Asks patients about suicide (optional)	SP assessments	2			X

[a]Experimental condition only.

gatekeeper self-efficacy, and preparedness (Table 1), plus a patient case. The case describes a patient presenting to a community pharmacist with warning signs of suicide and participants must type their responses to the patient.

2.5.3. One-month post-intervention follow-up: survey and optional standardized patient assessment

Approximately one month after completing the post-training survey, all participants are emailed a link to complete the one-month follow-up survey. This survey includes suicide prevention knowledge, gatekeeper self-efficacy and preparedness, plus questions about the use of Pharm-SAVES training or resources in the approximately 30 days since training. In addition, all participants may volunteer for an approximately 10-min standardized patient assessment via Zoom. The same email that contains the link to the follow-up survey also contains a link to a separate consent form for the standardized patient assessment. Those who consent are contacted by the project coordinator to schedule. During the standardized patient assessment, a young Black female standardized patient expresses suicide warning signs during a guided conversation with the participant (he standardized patient is not the same person as in the experimental condition interactive video case). Immediately afterwards, a second case is presented to the participant. This pre-recorded second case presents a young adult male exhibiting suicide warning signs. The order of live vs. pre-recorded scenarios is randomized. All interactions are recorded over Zoom.

2.5.4. Remuneration and participant reminders

Participants may receive Amazon eGift cards for completion of 1) the baseline survey, training, and post-training survey ($20); 2) the 1-month follow-up survey ($30); and 3) the optional follow-up standardized patient assessment ($50). Study staff may remind participants up to three times to complete each study component.

2.6. Outcomes and measures

2.6.1. Primary outcome

The primary outcome is the change in the number of trainees in the experimental and control groups who ask patients about suicide on the baseline versus post-training written case assessments (Table 1). We hypothesize that a higher proportion of participants in the experimental group (which trained with interactive video role-play cases) will ask about suicide on the post-training written assessment when compared to the control group (Pharm-SAVES only). Two independent blinded coders rate trainees' responses (asked/did not ask) using a rubric with examples of each coding category. During the trial, coders will meet to resolve discrepancies in coding and to update the codebook with additional examples.

For the optional, one-month standardized patient case assessments, two blinded coders will use an observation guide to independently code the Zoom recordings of each participant interacting with the live and pre-recorded standardized patients, respectively. The focus of this assessment is on whether or not the trainee (1) asked the patient a direct question about suicide and (2) referred the patient to the US Suicide Prevention and Crisis Lifeline (call 988). The observation guide was developed based on previous research [32,33] that provided detailed rules about how to code responses for whether a direct question about suicide was asked. Definitions and examples were included. Any coding discrepancies will be discussed during consensus meetings with both coders. Any remaining discrepancies will be decided by a senior psychologist with expertise in suicide prevention gatekeeper training and evaluation who is blinded to group assignment. Interrater reliability will be calculated.

Training of Standardized Patients (SPs) to Ensure Fidelity. Study staff will train the SPs to perform the patient scenarios using scripts. SPs will practice with staff until their presentations feel genuine. Weekly meetings with SPs will address any questions or concerns. For quality assurance during data collection, every third participant video interaction will be reviewed.

2.6.2. Secondary outcomes

Procedures for Measuring Behavioral Outcomes. Additional measures are included in the post-intervention survey (Table 1). Ten multiple-choice questions assess participants' Pharm-SAVES knowledge. A summary score (range 0–10) assesses the total number of correct answers, with higher scores reflecting greater knowledge. Gatekeeper efficacy is measured by a validated 5-item scale for how confident trainees are that they can perform suicide prevention tasks, including asking about suicide and making a referral [32,33]. An example reads, "ability to refer a patient with thoughts of suicide to other resources." Response options range from 1 = "not at all confident" to 5 = "extremely confident." Higher mean scores indicate greater gatekeeper self-efficacy. A validated 7-item scale is used to assess gatekeeper preparedness, or how well-prepared trainees feel to perform gatekeeping, including to "communicate with a patient at risk of suicide to help put them at ease." [21] Response options range from 1 = "not prepared" to 7 = "quite well-prepared." Higher mean scores indicate higher levels of gatekeeper preparedness.

2.6.3. Other measures

At baseline, other measures include prior suicide prevention training, participant and pharmacy characteristics (age, gender, race, ethnicity, how long they have worked in pharmacy practice, how long they have worked at their current pharmacy, role at their current pharmacy, military veteran status, and if they personally knew someone who died by suicide). At follow-up, the mean prescriptions filled per day and number of hours worked are elicited. Additionally, five questions assess participant encounters with patients exhibiting suicide warning signs since training and whether and where they referred the patient. Finally, immediately post-training and at follow-up, respondents are

asked two questions about how Pharm-SAVES can be improved and what additional information or resources are needed to help pharmacy staff implement Pharm-SAVES.

2.7. Analysis plan

All analyses will be performed in SAS (Version 9.4, Cary, NC). Characteristics of pharmacies and trainees will be presented by treatment group. Unadjusted statistical comparisons, using two sample t-tests and Pearson's chi-squared tests will be made between groups. Generalized estimating equations (i.e., the GEE method) [34] will be used to analyze the effects of the intervention on the primary and secondary outcome variables, while accounting for nesting of participants in pharmacies. The GEE method is an extension of the generalized linear model. It accounts for the intra-pharmacy correlation of data from multiple staff working in each pharmacy through its informative use in the computation of consistent estimates for model parameters and their corresponding covariance structure. Through calculation of the intra-class correlation coefficient (ICC), it will be determined whether trainees' communication behavior is highly correlated by pharmacy site, which will then be used to appropriately adjust the sample size for a future RCT. GEE also has the advantage of involving fewer

assumptions, including no assumption about the data distribution. GEE can handle both categorical and

continuous outcome variables and can support inferences across all trainees while at the same time correctly estimating variance to take into account the correlation within a given pharmacy. Model covariates can be at the pharmacy and trainee levels.

Data from the written cases will be used for the primary outcome analysis. The GEE method will be used to detect a significant difference in the primary outcome variable of asking the patient in the case whether or not they are considering suicide. Specifically, it will evaluate if trainees in the experimental group are more likely to ask about suicide than those in the control group. The multivariable model will be nested by pharmacy and will include several covariates, including treatment group, the county's average suicide rate, pharmacy location (urban/rural), and trainee and pharmacy characteristics. Alpha will be set at 0.05.

Similar GEE models as the one described above will be used to assess if the intervention improves the secondary outcomes of knowledge, gatekeeper self-efficacy, and gatekeeper preparedness. Interaction terms involving treatment group with gender and treatment group with pharmacy type will be added to each model and assessed.

2.8. Sample size and statistical power

Lack of robust data on how often pharmacy staff ask patients about suicidal intent mean that the RCT is not powered to detect a prespecified difference in frequency of asking about suicidal intent (the primary outcome). One goal of this RCT is to document how often pharmacy staff ask about suicidal intent and gather preliminary data on the effect size of the intervention on communication behavior in order to appropriately power a future large-scale RCT. A previous study found that only 3 of 501 (<1%) pharmacy staff members in North Carolina reported asking if a patient was thinking about killing him/herself after recognizing suicide warning signs [35]. Assuming that 5% of trainees at baseline will ask about suicide, randomizing 49 trainees per group would provide 80% power to detect a 20% or greater improvement in asking about suicidal ideation on the written case at the 0.05 significance level. Randomizing 75 per group allows for up to 35% (N = 52) attrition at the immediate post-training survey while maintaining 80% power to detect a significant difference in the primary outcome. With 95 pharmacies and 150 pharmacy staff there is 80% power at the 0.05 significance level to detect an effect size between 0.74 and 1 depending on the intraclass (within pharmacy) correlation.

3. Discussion

Suicide is a common cause of death globally. Both pharmacy staff [16,35,36] and student pharmacists [16] report interactions with patients expressing warning signs of suicide. Commonly dispensed and distributed medications are means of suicide [37] and labelled for suicidal behavior adverse effects, making pharmacies a logical intervention point for suicide prevention programs [37–40]. In rural areas, pharmacies may be particularly important sources of healthcare and referrals. Pharm-SAVES is, to the best of our knowledge, the first brief, online, video case-based suicide gatekeeper training program tailored to the retail pharmacy setting.

Joint development of Pharm-SAVES with pharmacy staff and veteran stakeholders ensures relevancy to community pharmacists. Realistic cases are designed to build pharmacists' confidence to implement Pharm- SAVES, including asking about suicide. Pharmacy staff and other health professionals have consistently expressed discomfort with asking about suicide with individuals exhibiting suicide warning signs even though it is recommended best practice. Pharm-SAVES models how to ask about suicide in a natural and confident way so at-risk individuals can be referred to appropriate resources when necessary. Given that many pharmacists report interacting with individuals with suicide warning signs, increasing the rate of asking about suicide could potentially increase referrals and reduce suicide attempts and/or suicide, especially in rural communities that lack non-pharmacist healthcare resources.

This RCT evaluates the first online community pharmacy suicide prevention gatekeeper training program designed for maximal scalability. The US Supreme Court ruled that employees do not need to be paid for *de minimus* time before or after work (typically at least 10 min). Pharm-SAVES' virtual, modular, brief, self-paced design supports training in 10-min segments and may significantly increase the likelihood of uptake to support pharmacy staff members' expressed needs for training. If Pharm-SAVES leads to improved pharmacist outcomes, its virtual design can be readily disseminated to pharmacy staff across the US or the world.

3.1. Strengths

This RCT applies innovative and inexpensive methods for assessing pharmacy staff learning using cases based on the actual experiences reported by surveyed pharmacists in practice settings [41,42]. The RCT design allows assessment of whether an active learning element (interactive video cases) improves community pharmacy staff learning outcomes. The randomization scheme is a strength in that it matches pharmacies on several important variables that could impact study outcomes. Inclusion of pharmacy staff in four states and three organizations increases generalizability. Validated and reliable measures are used, when possible, to assess study outcomes. Use of standardized patient cases ensures: 1) standardized presentation; 2) observations independent of potential interruptions or interference with the pharmacy's workflow; and 3) a safe environment for trainees to demonstrate their best possible performance in an emotionally charged and nuanced case.

3.2. Limitations

Generalizability of study results is limited due to the use of a convenience sample in four Southeastern states and potential selection bias, whereby pharmacy staff who are more interested in the topic of suicide prevention could be more likely to participate. Participants' actual communication skills and behaviors are not assessed with the written case data. To examine the potential impact of social desirability bias on post-intervention written case responses, we will compare written case data with SP data for those participants who opt to complete the SP encounters. We are unable to determine how much time trainees spent viewing the training, so this cannot be controlled in the analysis.

Disclaimer

This work does not represent the views or opinions of the Department of Veterans Affairs or the United States government.

CRediT authorship contribution statement

Jill E. Lavigne: Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing. **Amanda N. Stover:** Methodology, Writing – original draft. **Abigail Gamble:** Project administration, Writing – original draft, Writing – review & editing. **Gail Tudor:** Conceptualization, Writing – original draft, Writing – review & editing. **Wendi F. Cross:** Methodology, Writing – review & editing. **Delesha M. Carpenter:** Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing.

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.

Data availability

No data was used for the research described in the article.

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