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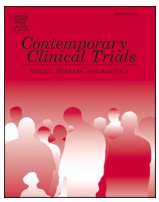

Examining the efficacy of a digital therapeutic to prevent suicidal ideation and behaviors in a primary care setting: Design and methodology of a randomized controlled trial with military service members

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ABSTRACT

Suicide is a leading cause of death among active-duty military personnel. Although specialty mental health services are readily available, primary care clinics represent the most frequently accessed clinical setting immediately preceding suicide deaths and suicide attempts among service members. Primary care clinics offer a critical and unique opportunity to implement interventions targeting suicide prevention. Effective engagement and response to servicemembers with elevated suicide risk requires scalable alternatives to traditional mental health care. The central focus of this study is to test the efficacy of Aviva, a scalable, digital adaptation of Brief Cognitive Behavioral Therapy for Suicide Prevention in three primary care clinics with active-duty military servicemembers in comparison to treatment as usual. This paper describes the design, methodology, and protocol of an active randomized controlled trial comparing Aviva to treatment as usual. The impact on subsequent suicidal ideation and behaviors during a year-long follow-up period will be evaluated.

Clinical Trial Registration: NCT06318962

1. Introduction

Over the past two decades, the suicide rate among U.S. servicemembers has continued to climb when compared to age and gender-adjusted rates in the general population and remains a serious and persistent problem [1–4]. Slightly less than half of servicemembers who die by suicide visit a specialty mental health clinic in the months leading up to their death [5]. Service members are more likely to seek help for psychosocial problems that elevate suicide risk in primary care clinics rather than in traditional mental health care settings, largely due to stigma associated with seeking mental health care [6]. As a result, primary care is the most frequently visited clinic type immediately prior to suicide deaths and suicide attempts by military personnel [5], with similar trends observed in non-military samples [7]. Recent research indicates that the largest percentage of those who die by suicide after entering the healthcare system pass through primary care settings, as opposed to specialty mental health care settings [8]. The importance of understanding how to effectively engage and respond to servicemembers with suicidal ideation or attempts who access primary care settings cannot be overstated. Neither can the need to develop and validate treatment alternatives that allow for meaningful scaling in order to meet the growing demand for empirically supported approaches to traditional mental health care.

Available evidence indicates that some treatments and clinical interventions are more effective than others at reducing suicide risk [9]. Meta-analyses support the efficacy of outpatient cognitive-behavioral therapies, in particular, for reducing suicide attempts, with larger effects for therapies that directly target processes that drive suicide risk. These processes include the thoughts, emotions, and behaviors that precipitate suicide attempts or suicidal behavior, in sharp contrast to therapies that indirectly target suicide risk by attempting to reduce symptoms of psychological disorders associated with suicide [10]. Two previous randomized clinical trials (RCT) with active-duty military personnel found that brief cognitive behavioral therapy (BCBT) for suicide prevention resulted in significant reductions in suicide attempts versus treatment as usual (TAU) among those reporting recent suicidal

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ideation and/or suicide attempts, even with safety planning being a common component of TAU [9,10]. The evidence supporting the efficacy of BCBT continues to grow, with subsequent adaptations and RCT showing reductions in suicide attempts in non-military populations, including adult psychiatric outpatients [11], and adult psychiatric inpatients [12]. Given these findings, expanding access to effective treatments such as BCBT is particularly critical for servicemembers who are unwilling to engage with or have limited access to specialty mental healthcare.

Efforts to broaden the reach of BCBT hold unique potential and promise in advancing suicide prevention efforts within military settings. Recent review studies have highlighted the potential of mobile applications to reduce suicidal ideation [13,14], however, evidence supporting their effectiveness in preventing suicidal behaviors remains remarkably limited [15]. Aligning with these findings, the 2024 VA/DoD Clinical Practice Guideline [16] acknowledges the potential short-term benefits of self-guided digital interventions for reducing suicidal ideation, while highlighting the lack of sufficient evidence to support their effectiveness in preventing suicide attempts. While specific apps such as iBobbly, Virtual Hope Box, BlueIce, and Therapeutic Evaluative Conditioning have shown some positive outcomes—such as reductions in depression, distress, and self-harm—their overall efficacy is modest, with none demonstrating a significant advantage over control conditions in reducing suicidal ideation [17]. Among these, the Virtual Hope Box is one of the most used applications in military populations; however, more research is needed, as only one randomized controlled trial has directly tested its effectiveness, and no trials to date have examined its impact on reducing suicidal behavior [17]. Building on these limitations and in line with efforts to expand access to Brief Cognitive Behavioral Therapy (BCBT), a digital adaptation of BCBT, Aviva, has been developed for use with individuals who have attempted suicide and/or are experiencing serious suicidal thoughts across the full spectrum of healthcare settings, including primary care. The smartphone app was developed as a platform for delivering BCBT with sufficient fidelity to the original treatment protocol to maximize therapeutic impact and reduce suicide risk. Aviva is easily accessible as it is deployed through Apple (iOS 11 or higher) and Android (OS 8.1 or higher) platforms and incorporates core treatment components of BCBT. An unpublished, open-label, single-group Phase I clinical trial of Aviva supported feasibility, usability, safety, and tolerability, with early indicators also suggesting good potential for clinical efficacy.

This paper describes the specific aims, hypotheses, design, methodology, and protocol of an ongoing randomized clinical trial (RCT; $N = 400$) examining the efficacy of the digital adaptation of BCBT (Aviva) as a treatment as usual (TAU) add-on in a primary care setting among service members reporting suicidal ideation and/or suicide attempts at a U.S. military facility in comparison to TAU.

2. Research aim and hypotheses

This study has two primary aims and four corresponding hypotheses, which will be examined in a sample of active-duty military servicemembers. Both the aims and hypotheses are straightforward and consistent with previous BCBT RCT outcomes and related findings summarized, including those specific to military settings [9–12].

1. Aim1: Evaluate the efficacy of the Aviva app in reducing suicidality among servicemembers. It is hypothesized that participants randomized to the Aviva app condition will show significantly larger reductions in severity of suicidal ideation and suicide attempts than participants randomized to the control TAU condition (Hypothesis 1). It is also hypothesized that greater app engagement will be negatively correlated with severity of suicidal ideation (Hypothesis 2).
2. Aim 2: Identify mediators of identified intervention effects. We expect that participants in the Aviva app condition will show significantly larger improvements in suicidal beliefs, wish to live, and impulsivity than participants in the control condition (Hypothesis 3). It is also hypothesized that reductions in suicidal ideation will be mediated by improvements in suicidal beliefs and wish to live (Hypothesis 4).

3. Materials and methods

This study is part of a collection of five studies within an umbrella project organized through The Ohio State University College of Medicine entitled *Augmenting Suicide Prevention Interventions for Service Members* (ASPIS), which includes a consortium of investigators focused on the assessment, treatment, and clinical interventions targeting the prevention of suicide. All five studies utilize centralized and collaborative administrative data and assessment cores.

3.1. Study design

This study is an RCT examining the efficacy of a digital therapeutic, Aviva, compared to TAU across three primary clinics at a U.S. military installation, Fort Carson, Colorado. The baseline assessment and intervention take place at three primary care clinics at Fort Carson. Follow-up assessments are conducted in-person, via phone, or through telehealth sessions, depending on the availability of participating servicemembers, and administered by trained, condition-blinded evaluators. The study design and CONSORT participant flow diagram are summarized in Fig. 1, including participants enrolled and randomized to date. (See Table 1.)

3.2. Participants

Participants will include 400 active-duty soldiers receiving routine medical care from a primary care clinic located at the Evans Army Community Hospital at Fort Carson, CO. The total enrollment to date is $N = 191$. Inclusion criteria are: (1) currently serving in the U.S. military; (2) at least 18 years old; (3) suicidal ideation within the past week and/or a suicide attempt within the past 30 days; (4) ability to complete the informed consent process; (5) ownership of either an Apple iPhone iOS 11 or higher or an Android smartphone OS 8.1 or higher. Exclusion criteria are: (1) an inability to complete informed consent procedures (e.g., secondary to intoxication, altered consciousness); (2) experiencing active psychosis or mania requiring hospitalization; (3) and inability to use a smartphone.

3.2.1. Ethical oversight

This study has been reviewed and approved by the relevant Institutional Review Boards (IRB), including the Ohio State University and The University of Memphis, with The University of Memphis serving as the IRB of record. The study has also been reviewed and approved by the U.S. Department of Defense's (DoD) Office of Human Research Oversight. The trial has been registered at ClinicalTrials.gov (Identifier NCT06318962).

3.3. Recruitment

Individuals seeking health services through primary care at the participating clinics routinely complete suicide risk screening, which includes the administration of the Patient Health Questionnaire-9 (PHQ-9) [18] and the Columbia Suicide Severity Rating Scale (CSSRS) [19] at every visit. Positive screens will be defined as a score of 1 or higher on the PHQ-9 suicide risk item, which assesses "thoughts that you would be better off dead or hurting yourself in some way" over the last two weeks, and/or a score of 1 or higher on the CSSRS Screener-Recent, which corresponds to "any thoughts of killing yourself." Patients who screen positive will be referred to a researcher, who will provide information about the study, answer patients' questions, clarify that they meet

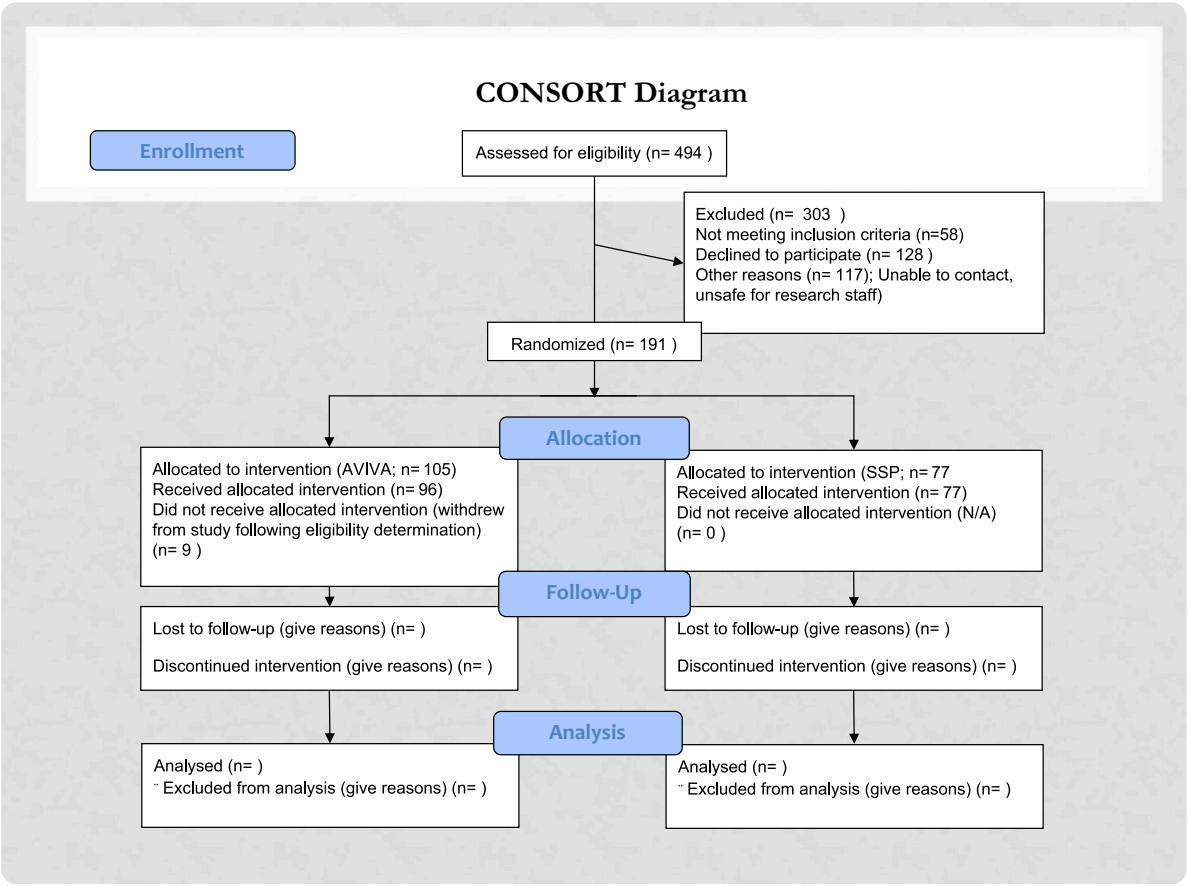

Fig. 1. CONSORT diagram and enrollment to date.

Table 1
Inclusion and exclusion criteria and rationale.

Inclusion Criteria	Rationale
(1) currently serving in the U.S. military, (2) at least 18 years old; (3) suicidal ideation within the past week and/or a suicide attempt within the past 30 days; (4) ability to complete the informed consent process; (5) ownership of either an Apple iPhone iOS 11 or higher or an Android smartphone OS 8.1 or higher.	Population under study
Ability to read, write, and speak English	Treatment confound

Exclusion Criteria	Rationale
Active psychosis or mania requiring hospitalization	Human subjects concern
Inability to use a smartphone	Treatment confound
Unable to provide informed consent[1]	Treatment confound

[1] Inability to provide informed consent may include instances such as other-directed violence or medical detoxification from substances such as alcohol. This information would be provided by the attending psychiatrist.

inclusion criteria, and complete informed consent procedures. The research clinician sees the patient within 48-h of referral and readministers the CSSRS to confirm the individual met the stated inclusion criteria at the point of referral, that is, "suicidal ideation within the past week and/or a suicide attempt within the past 30 days", with the window of ideation referenced as the original presentation at the primary care clinic. The patient does not have to be experiencing active ideation at the time of the second administration. Patients who meet inclusion criteria and consent to participate will complete the ASPIS baseline and will then be randomized to one of the two treatment conditions (see Fig. 1).

This study will be conducted in three primary care clinics at Fort Carson's Evans Army Community Hospital. We aim to enroll a total of $N = 400$ primary care patients during a two-year period. As indicated by active studies, current patient flow across the three clinics is large enough to accommodate our aims: approximately 20 clinicians work in each clinic (60 total clinicians), each of whom meet with an estimated 22 patients per day, of which approximately 50 % are active duty Servicemembers. Based on clinic records, results of a recently completed DoD-sponsored primary care suicide risk screening study that we have yet to publish, and previous work specific to DoD primary care clinics [7], we estimate that approximately 10 % of patients will screen positive for suicide risk, including 4 % with a history of suicide attempt. We therefore estimate that 66 patients per day will be eligible for participation. The overall patient flow rate and estimated participation rate indicate a total $N = 400$ is a reasonable goal.

3.4. Study-specific outcomes, measures, and assessment procedures

The primary outcome is severity of suicidal ideation over the 12-month follow-up, assessed using the Scale for Suicide Ideation (SSI) [20], and the secondary outcome is presence of a suicide attempt during the 12-month follow-up period, assessed using the Self-Injurious Thoughts and Behaviors Interview-Revised (SITBI-R) [21]. The study administrator schedules and coordinates all follow-up contacts to allow follow-up evaluators to remain blinded to randomized group assignment. All follow-up assessments will prioritize the collection of primary and secondary outcomes over other variables and outcomes that are less central to project aims. We have found that this approach mitigates

missing data for the most important outcome variables.

Additional secondary outcomes specific to this study include treatment satisfaction, treatment impact, app usability, and app engagement (see Table 2). Treatment satisfaction will be assessed using a single, modified item from the Youth Satisfaction Survey (YSS) [22], which uses a 5-point Likert scale ranging from strongly disagree to strongly agree. Treatment impact will be assessed using the 6-item functioning subscale of the YSS that addresses various domains of life (e.g., family relationships, occupational performance, coping). App usability will be assessed with the System Usability Scale (SUS) [23], a 10-item self-report scale that assesses a range of perceptions on the usability of digital systems. Item responses are summed and can be converted to a score ranging from 0 to 100, with scores above 68 indicating above-average usability. Scores can also be normalized to compare usability scores derived from hundreds of technologies and products. App engagement will be assessed using account-specific data that summarizes frequency of opening the app, duration of app use, and specific activities and features used within the app. Hypothesized mediators of treatment effects include suicidal beliefs, wish to live, and impulsivity. Suicidal beliefs will be assessed using the Brief Suicide Cognitions Scale (B-SCS) [24]. Wish to live will be assessed using item 1 from the SSI, and impulsivity will be assessed using the Monetary Choice Questionnaire (MCQ) [25]. Covariates will include the ASPIS common data elements (see Table 3) and the baseline assessment that is completed for all studies included in the ASPIS consortium. The various ASPIS measures are included in Table 3.

3.5. Medical record review

Electronic health records will be used to track hospitalizations and related emergency department presentations for suicide-related concerns and potential adverse events.

3.6. Randomization

As detailed in Fig. 1, servicemembers who meet inclusion criteria will be randomized to either Aviva or TAU using a stratified randomization algorithm designed to balance participants across both conditions based on the following variables of interest: gender, severity of suicidal ideation, and history of suicide attempt. A computerized randomization technique will be used to minimize human error or bias.

3.7. Treatment conditions

Participants will be randomly assigned to one of two treatment conditions: (1) Aviva, delivered as an add-on to TAU or (2) the TAU-only control, which routinely includes safety planning [26]. Because the Aviva app is intended as a supplement to standard mental healthcare (as opposed to a replacement for standard mental healthcare), all participants will continue to receive medical and mental healthcare as it is typically provided by the military healthcare system. Therefore, participants in both groups will receive suicide-focused interventions recommended by the VA/DoD Clinical Practice Guidelines [16].

Table 2
Study measures by assessment period.

	BL	3 Mos.	6 Mos.	9 Mos.	12 Mos.
Primary Outcome					
Suicidal ideation (SSI)	X	X	X	X	X
Secondary Outcomes					
Suicide attempts (SITBI-R)	X	X	X	X	X
Treatment satisfaction (YSS)		X	X	X	X
Treatment impact (YSS)		X	X	X	X
App usability (SUS)		X			
App engagement (metadata)		X	X	X	X
Mediators					
Suicidal beliefs (B-SCS)	X	X	X	X	X
Wish to live (SSI item 1)	X	X	X	X	X
Impulsivity (MCQ)	X	X	X	X	X
Covariates					
ASPIS CDEs	X	X	X	X	X

Notes: BL = Baseline, ASPIS CDEs = ASPIS Common Data Elements.

3.7.1. Aviva

Following the completion of informed consent procedures, participants assigned to the Aviva app group will download the app onto their smartphones and enter a unique one-time access code required to create a user account. This access code will be provided by the research therapist. Participants have the option of using a biometric feature such as face recognition and/or a fingerprint to quickly access Aviva. Participants will then complete the onboarding process and the first treatment module, which will help them to develop an individual conceptualization, a digital crisis response plan, and a plan for reducing or limiting access to potentially lethal methods of suicide. After completing all Module 1 tasks, participants will be scheduled for follow-up check-ins with a research clinician. Follow-up check-ins are described in detail below in section 3.9 (Safety Protocol). Participants will be informed that they can use and progress through the Aviva app at their preferred pace. Finally, participants will be referred for mental health care and suicide risk management procedures using local policies and procedures.

3.7.2. Treatment as Usual (TAU)

Following the completion of informed consent procedures, participants assigned to the TAU control condition will develop a safety plan [26] consistent with local procedures and policies. Participants will then be referred for standard mental health care treatment and suicide risk management procedures using local policies and procedures. To reduce performance bias, participants assigned to the control condition will download the Suicide Safety Plan app to their smartphones. The Suicide Safety Plan app is a digital version of the safety planning intervention routinely used in Fort Carson primary care clinics. Instead of creating a handwritten plan using a paper template, participants will develop a digital plan within this app, thereby mirroring the process used in the Aviva condition. The Suicide Safety Plan app includes the same components and steps used in the My Plan module of the Aviva app (warning signs, self-regulatory strategies, reasons for living, social support networks, and crisis and professional services), thereby providing balance across treatment groups.

3.8. Quality control

3.8.1. Training and supervision of research clinicians

All study research clinicians will hold either a master's or doctoral degree in psychology or counselling and have experience working with SITB-related concerns. Following completion of their initial training and familiarization with study procedures, therapists will receive 30- to 60-min weekly supervision or consultation with study investigators to monitor, identify, and address any potential problems. Once informed consent and randomization are completed, issues of fidelity of Aviva delivery will be addressed through the app itself.

3.8.2. Assessment of intervention fidelity

For participants randomized to the Aviva group, treatment fidelity will be maintained through the Aviva interface for delivery of BCBT, with no requirement for additional training or intervention fidelity checks, one of the significant advantages of Aviva that allows for substantial scaling of delivery. Prior to study launch, research clinicians will be trained to competence on the use of Aviva, follow-up check-in procedures, and the approved study protocol. Research clinicians will also be required to complete all local training and credentialing processes required for mental health professionals on boarding at the military installation, in the participating primary care clinics, and the military

Table 3
ASPIS common data elements.

Suicide-Related Outcomes
Suicide attempts SITBI-R [21]
Suicidal ideation SSI [20]
Theory-Specific Process/Mechanism Variables
Perceived burdensomeness INQ (Abbrev.) [33]
Thwarted belonging INQ (Abbrev.) [33]
Hopelessness BHS (Abbrev.) [34]
Suicidal cognitions B-SCS [24]
Emotion regulation DERS-SF [35]
Impulsivity MCQ [25]
Reward/punishment sensitivity BIS/BAS Scale [36]
Covariates
Demographics Demos Form
Mental health treatment history
Psychiatric symptoms PROMIS CAT [37]
Quality of life PROMIS CAT [37]

hospital facility. Research clinicians will also meet regularly with study investigators to review cases and to ensure that face-to-face interactions with participants are consistent with study procedures.

3.9. Safety protocol

The research and treatment team has extensive experience conducting treatment with individuals at high-risk for suicide, and we have well-established procedures for the effective management of emergency situations, including those that occur off-site. If a participant reports a moderate to severe level of suicide intent during an interview or on a self-report scale, research staff will conduct a more thorough assessment to evaluate the need for possible hospitalization or alternative clinical disposition. If the participant is off-site and the identification is made via phone or online, the staff member will immediately identify the location of the participant, clarify the nature of risk, and in accordance with DoD standards, provide a time constraint for the participant to voluntarily present at a hospital or mental health clinic. If the participant is unwilling, the appropriate military and/or civilian authorities will be notified to pursue mandatory evaluation/assessment. These procedures will be supplemented by high-risk management procedures tailored to the specific context and setting of each project. Safety policies and high-risk management procedures will be evaluated regularly by the ASPIS Administrative Core to ensure participant safety. Finally, we will track and document all safety-related interventions provided by research staff to control for these potential confounds in our data analyses.

In addition to the standardized procedures for managing high-risk situations outlined above, research clinicians will contact participants weekly for the first 12 weeks post-baseline to conduct routine check-ins. During these check-ins, clinicians will assess suicide risk, monitor safety, and assess for treatment adherence. Each check-in is expected to last 10–15 min and will provide a scheduled opportunity to briefly review treatment adherence, identify and address any logistical or operational issues, and respond to unexpected emergencies and/or participant safety concerns. This approach is not only consistent with the existing treatment adherence protocol for BCBT [9–12], it is also consistent with emerging evidence that such efforts can significantly improve treatment initiation and persistence over time, particularly with those evidencing elevated suicide risk [38,39]. To balance contact across treatment conditions, all participants will receive these same routine check-ins. Routine check-ins can be conducted in person, by phone, or virtually, depending on participant preference. All check-ins will be documented by staff members and reviewed on a weekly basis to quickly identify any emerging patterns and/or problems. Indicated safety-related interventions will be tracked and documented as potential confounds to be included in data analyses.

3.10. Data analytic strategy

3.10.1. General overview

To test differences in severity of suicidal ideation between conditions over time (hypothesis one), we will use general linear mixed models (GLMM) with treatment group, time, and the treatment-by-time interaction entered as the independent variables, and SSI total score entered as the dependent variable. Covariance structures and model distributions will be followed by planned mean comparisons of SSI scores at each time point. We will also examine differences in our secondary outcome (suicide attempts; hypothesis two) across treatment conditions using the log-rank and Wilcoxon statistics from the Kaplan-Meier method and the hazard ratio derived from the Cox regression, although we do not expect to have sufficient statistical power to identify statistically significant group differences, given that suicide attempts are relatively low frequency events. Despite low power, we will nonetheless examine suicide attempt rates.

Analyses of Aviva app engagement will be limited to participants in the Aviva condition. We will construct and test separate time-lagged GLMMs for each engagement metric (i.e., frequency of opening the app, duration of app use, specific activities and features used). Change in SSI score from time t to $t + 1$ will serve as the outcome. Independent variables will include each engagement metric and SSI score from time t. The original hypothesis will be supported if we obtain statistically significant negative coefficients for the engagement variables. The false discovery rate method will be used to mitigate Type I error with multiple comparisons. We will use the same GLMM approach described for hypothesis one to test hypothesis three. Separate models will be constructed for each outcome: suicidal beliefs (B-SCS score), wish to live (SSI item 1 score), and impulsive decision-making (MCQ score). Mediation effects will be tested as originally described by Baron and Kenny [27] and we will use regression parameters and their standard errors with 10,000 bootstrapped resamples as recommended by Preacher and Hayes [28] to conduct this analysis.

3.10.2. Missing data

All data available from all participants and all time points will be included in the analyses, consistent with the intent-to-treat principle. Across our previous clinical trials [9–11] and an in-progress RCT, attrition during the first 12 months postbaseline has been <30 %. Patterns of missingness will be inspected via a combination of Little's MCAR test and pattern mixture modeling to determine if they are ignorable. Based on our previous studies, we expect the assumptions of missing at random (MAR) to be met. We anticipate using multiple imputation and/or full information likelihood estimation for handling missing data, but other approaches may be explored if indicated.

The proposed likelihood-based analyses are valid when the assumption that data are missing at random (MAR) holds. We will examine whether data are MAR using several approaches. First, we will perform a test to determine whether the data are missing completely at random. Second, we will compare participants who are lost to outcome assessment with those available on baseline characteristics and response until dropout. If a statistical model predicting discontinuation can be developed, it can serve as the basis for inverse propensity weighting, a method that gives more weight to patients who are similar to those lost to follow-up [29].

3.10.3. Power analysis for sample size

Sample size estimates were computed using General Linear Mixed Model Power and Sample Size (GLIMMPSE) and were primarily focused on group differences in severity of suicidal ideation (hypothesis one). We estimated SSI mean scores and variance over time using the results of previous BCBT studies. Because this study will be conducted in primary care, not specialty mental health like previous work, we expect that participants may report less severe suicidal ideation. Therefore, we estimated the required sample size assuming a range of mean values and variances for SSI scores and an estimated 20 % attrition rate. Results indicated that a sample size of $N = 400$ (200 per treatment arm) provides 85.1 % power to detect a clinically meaningful reduction in SSI scores ($d > 0.3$) when assuming mean SSI scores are 20 % less severe than previous studies. With respect to our secondary outcome (suicide attempts), $N = 400$ provides only 42.3 % power to detect a 50 % reduction in suicide attempts (4 % vs. 2 %) and 67.0 % power to detect a 75 % (4 % vs. 1 %) reduction in suicide attempts. For this reason, suicide attempt will not serve as a primary outcome. Our previous BCBT-SP RCT's have consistently found post-intervention reductions in suicide attempts in the range of 40 %–60 %+, hence the conservative 50 % estimate in this trial [9–11]. As noted, the 4 % history of attempts reported during screening in primary care is based on observed rates during active and yet to be published studies [7]. We have also used the 4 % rate after screening as an estimate of attempts during follow-up but do not yet have other follow-up data in a primary care setting in the military available for an estimate. Regarding hypothesis two, which will only be conducted using participants from the Aviva condition, $n = 200$ provides 85.5 % power to detect a small regression effect ($R2 = 0.05$). Power for hypothesis three was calculated using the same procedures as for H1, and the analysis indicated we had >95 % power to detect moderate ($d > 0.4$) standardized mean differences between groups and > 85 % power to detect small ($d > 0.3$) mean differences. Finally, power for hypothesis four was estimated using published results of power simulations for mediation models.73 Based on those results, $N = 400$ exceeds the recommended minimum sample size needed to detect mediated effects when the *a* and *b* coefficients are small to medium (i.e., approximately 8 % of explained variance).

4. Discussion

This manuscript provided an overview of the research methodology and protocol of an RCT exploring the efficacy of Aviva, a digital application of BCBT, as a treatment as usual add-on compared to a treatment as usual control in primary care clinics at a U.S. Military installation. Given that primary care clinics are the most frequently visited clinic type immediately prior to suicide deaths and suicide attempts by military personnel, these settings offer a unique opportunity for interventions targeting suicide prevention. Aviva has potential as a scalable alternative to traditional mental health care to improve or supplement effective clinical engagement and response to servicemembers with elevated suicide risk. Although numerous mobile mental health applications are available, only a very limited number have undergone any empirical evaluation, leading to concerns regarding their evidence-based effectiveness [30]. Review studies have found that some suicide prevention apps enhanced users' ability to cope with unpleasant emotions and thoughts, leading to reductions in depression and psychological distress as well as increased coping self-efficacy, but they did not significantly reduce suicidal ideation compared to control conditions [17,30]. An important exception to this trend, our study aims to develop and rigorously test a mobile adaptation of BCBT as a treatment add-on and tailored for military service members, contributing to the limited pool of scientifically validated digital interventions in suicide prevention.

A major challenge in evaluating and scaling such interventions lies in their dissemination and implementation. Several studies have shown that very few individuals who might benefit from it have heard of or used the mobile apps [30]. Fortunately, targeted psychoeducational efforts directed at both patients and providers have demonstrated encouraging outcomes by increasing awareness and reducing barriers to use [31]. Another challenge is the consistently low adherence observed in digital intervention studies, with many participants failing to complete modules or disengaging during follow-up, posing a significant risk to the sustained effectiveness of mobile tools for suicide prevention [15].

4.1. Consideration of alternative study designs

The recently published White House interagency national strategy for preventing military service member and veteran suicide emphasized scalable interventions as a key priority [32]. This RCT will help determine if Aviva is a scalable alternative that can help reduce suicide risk in military servicemembers. The use of Aviva as a treatment as usual (TAU) add-on is ideal given the high-risk nature of care for those at elevated risk for suicide, as it would be unethical and clinically contraindicated to withhold TAU from participants, particularly since Aviva has yet to be tested as an independent treatment alternative and efficacious adaptation of BCBT. As far as we are aware, this is the first RCT of a digital adaptation of an empirically supported treatment for elevated suicide risk that has been conducted in a primary care setting.

Credit and authorship contribution statement

M. David Rudd: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Michelle Wine:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Investigation, Conceptualization. **Rhea Pedler:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Melissa Wright:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation. **Vivian L. Gleason:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Andrea Pérez-Muñoz:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Burak Tuna:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Jacob Tempchin:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Taylor A. Flowers:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Craig J. Bryan:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Disclaimer

Opinions, interpretations, conclusions and recommendations are those of the authors and do not reflect an endorsement by or the official policy or position of the Department of Defense, the Department of Veterans Affairs, or the U.S. Government.

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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 manuscript.

Data availability

Data will be made available on request.

References

[1] D.T. Chung, C.J. Ryan, D. Hadzi-Pavlovic, S.P. Singh, C. Stanton, M.M. Large, Suicide rates after discharge from psychiatric facilities: a systematic review and meta-analysis, JAMA Psychiatry 74 (7) (2017) 694–702, https://doi.org/10.1001/jamapsychiatry.2017.1044.

[2] D. Chung, D. Hadzi-Pavlovic, M. Wang, S. Swaraj, M. Olfson, M. Large, Meta-analysis of suicide rates in the first week and the first month after psychiatric hospitalisation, BMJ Open 9 (3) (2019) e023883, https://doi.org/10.1136/bmjopen-2018-023883.

[3] A. Forte, A. Buscajoni, A. Fiorillo, M. Pompili, R.J. Baldessarini, Suicidal risk following hospital discharge: a review, Harv. Rev. Psychiatry 27 (4) (2019) 209–216, https://doi.org/10.1111/j.1463-1318.2010.02477.x.

[4] D.D. Luxton, L. Trofimovich, L.L. Clark, Suicide risk among US Service members after psychiatric hospitalization, 2001–2011, Psychiatr. Serv. 64 (7) (2013) 626–629, https://doi.org/10.1176/appi.ps.201200413.

[5] L. Trofimovich, N.A. Skopp, D.D. Luxton, M.A. Reger, Health Care Experiences Prior to Suicide and Self-Inflicted Injury, Active Component, US Armed Forces, 2001–2010, Armed Forces Health Surveillance Center Silver Spring Md, 2012.

[6] C.W. Hoge, A. Terhakopian, C.A. Castro, S.C. Messer, C.C. Engel, Association of posttraumatic stress disorder with somatic symptoms, health care visits, and absenteeism among Iraq war veterans, Am. J. Psychiatry 164 (1) (2007) 150–153.

[7] J.B. Luoma, C.E. Martin, J.L. Pearson, Contact with mental health and primary care providers before suicide: a review of the evidence, Am. J. Psychiatry 159 (6) (2002) 909–916.

[8] National Action Alliance for Suicide Prevention, Transforming Health Systems Initiative Work Group. Recommended standard care for people with suicide risk: Making health care suicide safe, Washington, 2018.

[9] M.D. Rudd, C.J. Bryan, E.G. Wertenberger, et al., Brief cognitive-behavioral therapy effects on post-treatment suicide attempts in a military sample: results of a randomized clinical trial with 2-year follow-up, Am. J. Psychiatry 172 (5) (2015) 441–449.

[10] C.J. Bryan, J. Mintz, T.A. Clemans, et al., Effect of crisis response planning vs. contracts for safety on suicide risk in US Army soldiers: a randomized clinical trial, J. Affect. Disord. 212 (2017) 64–72.

[11] J.C. Baker, A. Starkey, E. Ammendola, et al., Telehealth brief cognitive behavioral therapy for suicide prevention: a randomized clinical trial, JAMA Netw. Open 7 (11) (2024) e2445913, https://doi.org/10.1001/jamanetworkopen.2024.45913.

[12] G.J. Diefenbach, K.A. Lord, J. Stubbing, et al., Brief cognitive behavioral therapy for suicidal inpatients: a randomized clinical trial, JAMA Psychiatry 81 (12) (2024) 1177–1186, https://doi.org/10.1001/jamapsychiatry.2024.2349.

[13] S.K. Burr, M. Yu, D. Clark, D. Alonzo, R.E. Gearing, Digital interventions for suicide prevention, Crisis 46 (3) (2025 May) 176–186, https://doi.org/10.1027/0227-5910/a000996 (Epub 2025 Apr 4. PMID: 40183238; PMCID: PMC12096958).

[14] M. Torok, J. Han, S. Baker, A. Werner-Seidler, I. Wong, M.E. Larsen, H. Christensen, Suicide prevention using self-guided digital interventions: a systematic review and meta-analysis of randomised controlled trials, Lancet Digit Health 2 (1) (2020 Jan) e25–e36, https://doi.org/10.1016/S2589-7500(19)30199-2. Epub 2019 Nov 29. PMID: 33328037.

[15] T.K. Witte, J.M. Holm-Denoma, K.L. Zuromski, J.M. Gauthier, J. Ruscio, Individuals at high risk for suicide are categorically distinct from those at low risk, Psychol. Assess. 29 (4) (2017) 382–393, https://doi.org/10.1037/pas0000349.

[16] L.A. Brenner, V. Capaldi, J. Constans, S. Dobscha, M. Fuller, B. Matarazzo, K. McGraw, K. Richter, J. Sall, D. Smolenski, S. Williams, S. Davis-Arnold, N. Bahraini, Assessment and Management of Patients at risk for suicide: synopsis of the 2024 U.S. Department of Veterans Affairs and U.S. Department of Defense clinical practice guidelines, Ann. Intern. Med. 178 (3) (2025 Mar) 416–425, https://doi.org/10.7326/ANNALS-24-01938.

[17] R. Melia, K. Francis, E. Hickey, J. Bogue, J. Duggan, M. O'Sullivan, K. Young, Mobile health technology interventions for suicide prevention: Systematic review, JMIR Mhealth Uhealth 8 (1) (2020) e12516, https://doi.org/10.2196/12516.

[18] K. Kroenke, R.L. Spitzer, J.B.W. Williams, *Patient health Questionnaire-9 (PHQ-9)* [database record], APA PsycTests (1999), https://doi.org/10.1037/t06165-000.

[19] K. Posner, *Columbia-suicide severity rating scale (C-SSRS)* [database record], APA PsycTests (2007), https://doi.org/10.1037/t52667-000.

[20] A.T. Beck, M. Kovacs, A. Weissman, *Scale for suicide ideation (SSI)* [database record], APA PsycTests (1979), https://doi.org/10.1037/t01299-000.

[21] K.R. Fox, J.A. Harris, S.B. Wang, A.J. Millner, C.A. Deming, M.K. Nock, Self-injurious thoughts and behaviors interview-revised: development, reliability, and validity, Psychol. Assess. 32 (7) (2020 Jul) 677–689, https://doi.org/10.1037/pas0000819.

[22] D. Stüntzner-Gibson, P.E. Koren, N. DeChillo, The youth satisfaction questionnaire: what kids think of services, Fam. Soc. 76 (10) (1995) 616–624.

[23] M. Hyzy, R. Bond, M. Mulvenna, L. Bai, A. Dix, S. Leigh, S. Hunt, System usability scale benchmarking for digital health apps: Meta-analysis, JMIR Mhealth Uhealth 10 (8) (2022 Aug 18) e37290, https://doi.org/10.2196/37290.

[24] M.D. Rudd, C.J. Bryan, The brief suicide cognitions scale: development and clinical application, Front. Psychol. 12 (2021 Sep 14) 737393, https://doi.org/10.3389/fpsyt.2021.737393.

[25] K.N. Kirby, N.M. Petry, W.K. Bickel, *Monetary Choice Questionnaire (MCQ)* [database record], APA PsycTests (1999), https://doi.org/10.1037/t10044-000.

[26] B. Stanley, G.K. Brown, Safety planning intervention: a brief intervention to mitigate suicide risk, Cogn. Behav. Pract. 19 (2) (2012) 256–264, https://doi.org/10.1016/j.cbpra.2011.01.001.

[27] R.M. Baron, D.A. Kenny, The moderator–mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations, J. Pers. Soc. Psychol. 51 (6) (1986) 1173–1182, https://doi.org/10.1037/0022-3514.51.6.1173.

[28] K.J. Preacher, A.F. Hayes, Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models, Behav. Res. Methods 40 (2008) 879–891, https://doi.org/10.3758/BRM.40.3.879.

[29] A.N. Glynn, K.M. Quinn, An introduction to the augmented inverse propensity weighted estimator, Polit. Anal. 18 (1) (2010) 36–56, https://doi.org/10.1093/pan/mpp036.

[30] S. Sarubbi, E. Rogante, D. Erbuto, M. Cifrodelli, G. Sarli, L. Polidori, D. Lester, I. Berardelli, M. Pompili, The effectiveness of Mobile apps for monitoring and Management of Suicide Crisis: a systematic review of the literature, J. Clin. Med. 11 (19) (2022 Sep 23) 5616, https://doi.org/10.3390/jcm11195616.

[31] M. Harned, M. Dhami, G.M. Reger, Evaluation of a psychoeducational group to expand Mobile application knowledge and use in a veteran residential treatment program, J. Technol. Behav. Sci. 8 (2023) 118–127, https://doi.org/10.1007/s41347-023-00299-1.

[32] White House, Reducing Military and Veteran Suicide: Advancing a Comprehensive, Cross-Sector, Evidence- informed Public Health Strategy [Accessed: May 5, 2022]. Available from: Military-and-Veteran-Suicide-Prevention-Strategy.pdf, whitehouse.gov, 2021.

[33] K.A. Van Orden, K.C. Cukrowicz, T.K. Witte, T.E. Joiner Jr., *Interpersonal Needs Questionnaire (INQ)* [database record], APA PsycTests. (2012), https://doi.org/10.1037/t10483-000.

[34] A.T. Beck, A. Weissman, D. Lester, L. Trexler, *Hopelessness Scale (HS)* [database record], APA PsycTests. (1974), https://doi.org/10.1037/t00966-000.

[35] E.A. Kaufman, M. Xia, G. Fosco, M. Yaptangco, C.R. Skidmore, S.E. Crowell, The difficulties in emotion regulation scale short form (DERS-SF): validation and replication in adolescent and adult samples, J. Psychopathol. Behav. Assess. 38 (3) (2016) 443–455, https://doi.org/10.1007/s10862-015-9529-3.

[36] C.S. Carver, T.L. White, Behavioral inhibition, behavioral activation, and affective responses to impending reward and punishment: the BIS/BAS scales, J. Pers. Soc. Psychol. 67 (2) (1994) 319–333, https://doi.org/10.1037/0022-3514.67.2.319.

[37] D. Cella, S.W. Choi, D.M. Condon, B. Schalet, R.D. Hays, N.E. Rothrock, S. Yount, K. F. Cook, R.C. Gershon, D. Amtmann, D.A. DeWalt, P.A. Pilkonis, A.A. Stone, K. Weinfurt, B.B. Reeve, PROMIS® adult health profiles: efficient short-form measures of seven health domains, Value Health 22 (5) (2019) 537–544.

[38] T. Stecker, M.P. McGovern, B. Herr, An intervention to increase alcohol treatment engagement: a pilot trial, J. Subst. Abus. Treat. 43 (2) (2012) 161–167.

[39] T. Stecker, G. McHugo, H. Xie, K. Whyman, M. Jones, A randomized controlled trial of a phone-based cognitive-behavioral intervention to improve PTSD treatment utilization among returning service members, Psychiatric Services (Washington, DC). 65 (10) (2014) 1232.