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Thomas O. Walton

Issac C. Rhew

Anna E. Jaffe

Adam R. Pierce

See next page for additional authors

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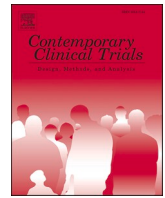


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Authors

Debra Kaysen, Thomas O. Walton, Issac C. Rhew, Anna E. Jaffe, Adam R. Pierce, and Denise D. Walker



Development of StressCheck: A telehealth motivational enhancement therapy to improve voluntary engagement for PTSD treatment among active-duty service members[☆]

Debra Kaysen^{a,b,*}, Thomas O. Walton^c, Isaac C. Rhew^d, Anna E. Jaffe^e, Adam R. Pierce^c, Denise D. Walker^c

^a Department of Psychiatry and Behavioral Sciences, School of Medicine, Stanford University, 401 Quarry Road, Palo Alto, CA 94305, USA

^b National Center for PTSD, Dissemination and Training Division, VA Palo Alto Health Care System, NCPSTSD – 334 795 Willow Rd, Menlo Park, CA 94025, USA

^c School of Social Work, University of Washington, 909 NE 43rd St. #304, Seattle, WA 98105, USA

^d Department of Psychiatry and Behavioral Sciences, School of Medicine, University of Washington, 1959 NE Pacific St., Box 357238, Seattle, WA 98195, USA

^e Department of Psychology, University of Nebraska-Lincoln, 238 Burnett Hall, Lincoln, NE 68588, USA

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ABSTRACT

Background: Rates of PTSD in active-duty military are high relative to the general population. Although efficacious treatments exist, they are underutilized. Many service members with PTSD do not present for treatment and, of those who do, many do not receive sufficient doses of the interventions to receive full benefits. Motivational Enhancement Therapy (MET) “check-ups”, are brief interventions designed to elicit treatment engagement for those who are not treatment-seeking.

Methods: StressCheck is an MET for nontreatment seeking Army and Air Force personnel. StressCheck aims to improve PTSD and increase treatment engagement, especially around evidence-based interventions, as well as to decrease stigma about seeking mental health services and improve knowledge about treatment options. This paper describes the intervention components and process of treatment development. The paper also describes next steps in testing the effectiveness of the intervention.

Conclusion: PTSD is associated with deleterious health, occupational, and psychological effects. If effective, this innovative intervention will bridge the gap between those who are not treatment seeking and existing services, thereby enhancing reach and impact of existing services.

ClinicalTrials.gov identifier: NCT03423394

1. Introduction

Current and former military service members are at high risk for posttraumatic stress disorder (PTSD) [1,2]. Studies have found post-deployment rates of PTSD ranging from 5 to 20% [3,4]. However, PTSD is relatively responsive to treatment. Across all PTSD psychotherapies 56% of those who entered treatment and 67% of completers no

longer met criteria for PTSD posttreatment [5]. Among military samples with PTSD, the majority who received evidence-based trauma-focused psychotherapy (60–72%) did retain their diagnosis; however, 49–70% experienced clinically meaningful gains, representing notable improvement in quality of life [6].

Despite availability of evidence-based therapies targeting PTSD, service members often do not access treatment. Nearly 70% of adults

Abbreviations: MI, Motivational interviewing; MET, Motivational enhancement therapy; PFR, Personalized feedback report.

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^{*} Corresponding author at: Department of Psychiatry and Behavioral Sciences, Stanford University, 401 Quarry Road, Palo Alto, CA 94305, USA.

E-mail addresses: dkaysen@stanford.edu (D. Kaysen), towalton@uw.edu (T.O. Walton), rhew@uw.edu (I.C. Rhew), ajaffe2@unl.edu (A.E. Jaffe), Adam.Pierce@va.gov (A.R. Pierce), ddwalker@uw.edu (D.D. Walker).

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with PTSD [7] and 63% of soldiers with mental health symptoms [8] did not seek help within the past year. Among service members with PTSD, less than half ask for help, and of those referred to specialty care, less than half complete the referral [3,9].

Motivational interviewing (MI) may be one way to strengthen treatment seeking and engagement. MI is a person-centered, directive approach aimed at helping individuals resolve ambivalence for behavior change. MI emphasizes a nonjudgmental counseling style that seeks to understand client perspectives and reasons for change. A widely applied, well-researched approach [10], MI has been evaluated as a prelude to treatment [11], an adjunct to existing treatment such as cognitive behavioral therapy [12], stand-alone treatment (Project MATCH) [13], and as an aftercare or maintenance intervention [14,15].

Research on application of MI to PTSD treatment is still relatively sparse. Among non-treatment-seeking Veterans with mental health concerns—58% of whom had PTSD, receiving four sessions of telephone-delivered MI increased treatment seeking and engagement relative to usual care [16]. Adding a four-session group MI-based intervention to a year-long group outpatient PTSD treatment increased attendance and treatment retention compared to an education control among veterans [17]. Thus, limited research on MI to enhance PTSD treatment shows promise but has not focused on connecting non-treatment seeking service members to care.

MI has been adapted to motivate change among individuals who are not treatment seeking—known as the Check-Up Model [18]. The Check-Up central premise is people experiencing difficulties but not engaged in treatment, do so because of ambivalence about treatment. Check-Up model interventions directly target individuals who are lower in readiness to change but also do attract, and include, a portion of individuals who are already motivated to change a behavior. The Check-Up includes an advertisement campaign to target individuals struggling with a problem behavior but not accessing care. The Check-Up model combines marketing with Motivational Enhancement Therapy (MET), an adaptation of MI, which includes individualized feedback based on standardized assessments and delivered in an MI style. The Check-Up model has been successfully applied to a variety of behaviors [18,19] including substance use among active-duty soldiers [20].

To fill these gaps, we developed a Check-Up MET intervention for PTSD (“StressCheck”). This paper describes the development of the intervention, components including the advertising and marketing campaign materials, and principles used to develop StressCheck. The randomized clinical trial protocol to test the intervention is also described.

2. Material and methods

2.1. Research design

The purpose of this two-phase study is to design and evaluate the StressCheck intervention. In Phase 1, we developed the novel MET intervention in collaboration with focus groups. In Phase 2, we will evaluate its efficacy in a randomized controlled trial. Both phases have been approved by the University of Washington Institutional Review Board and the DoD Human Research Protections Office, neither of which recommended the use of a Data and Safety Monitoring Board. Subjects in both phases will provide informed consent prior to their participation.

2.2. Target population

StressCheck is designed for active-duty service members with PTSD not currently engaged in evidence-based PTSD treatment. The goal is to increase treatment engagement, move participants toward treatment, and toward more effective treatment.

2.3. Phase 1: intervention development

2.3.1. Initial planning – delivery, structure, and content

Given high rates of treatment dropout and the role of avoidance in maintaining PTSD, we created a 1- to 3-session telephone-delivered intervention. Three sessions were selected to provide supports and sustain change in the face of ambivalence about treatment. StressCheck was framed as a chance to “check-in” rather than psychotherapy. Phone-based MI interventions have shown efficacy with military populations [16,20], and this mode of delivery maximizes dissemination potential and increases likelihood of engaging service members who are reluctant to seek counseling due to stigma, privacy worries, and logistical barriers [21].

The first component of a Check-Up intervention is a marketing campaign that attracts the target population and encourages engagement with the intervention. Marketing materials were developed utilizing McGuire’s [22] communication and persuasion matrix, which focuses on five communication components: audience, content, delivery modality, message source, and desired action. Thus, our marketing materials focused on military personnel’s potential concerns regarding PTSD symptoms, help-seeking, and messages that might prompt a response. Intended marketing messages also focused on symptoms rather than diagnostic labels, as this may be less stigmatizing and more engaging for non-treatment seekers or those higher in ambivalence to change. Lastly, we designed marketing materials to reach different types of personnel. Drafts of nine advertisements were created based on the research team’s prior MET “check-up” studies [23,24].

The second component is a Personalized Feedback Report (PFR) to guide conversations between counselor and participant to address ambivalence about seeking treatment while growing and sustaining change talk. The preliminary intervention content, including the PFR and accompanying treatment manual were developed by authors (DK, TW, DW) to target mechanisms theorized to be motivators of, or deterrents to, change. We included opportunities for participants to identify discrepancies between their goals and values, and current behavior. Lastly, we addressed stigma around treatment seeking, perceived practical barriers to care, and provided information about treatment options and effectiveness.

2.3.2. Focus group evaluation of draft intervention

Next, we convened focus groups with each of three stakeholder groups to gather feedback about the initial draft of recruitment and intervention materials. Stakeholder groups were: (1) active-duty personnel who had previously engaged in pharmacotherapy or any form of psychotherapy for the treatment of PTSD, (2) active-duty personnel with probable PTSD who had not received treatment, and (3) military service providers involved in PTSD treatment. Participants were recruited through printed advertisements posted at various locations throughout Joint Base Lewis-McChord (JBLM), such as gyms, recreation centers, libraries, and cafeterias.

Prospective participants were invited to complete a brief screening, delivered online or by phone. For service members, screening assessed demographics, mental health treatment history, and probable PTSD via the PTSD Checklist (PCL) [25]. A cut-score of 25 indicated probable PTSD. Service providers were asked about their role in treatment provision to ensure relevant experience. In total, 76 service members and providers completed screening, and the 42 who met criteria for one of the three groups were invited to participate. Final samples were determined by participants’ availability (treated, $n = 8$; non-treated, $n = 6$; provider, $n = 8$).

Focus groups were held at JBLM. After providing written informed consent, participants were asked to view draft recruitment posters, rate them as favorable or unfavorable, and participate in a discussion about reactions to those ads and possibilities for additional ads. The groups also reviewed each section of the draft PFR, discussing reactions to the content, presentation, and order of PFR sections. Each group was audio-

recorded and two note-takers recorded participants' feedback. Authors (DW, TW, DK) then conducted a content analysis to identify the strongest and most prevalent recommendations across groups.

2.3.3. Refinement of intervention component

One key recommendation was to mitigate stigma associated with PTSD treatment. Consistent with research on marketing Check-Up interventions with military populations [24], confidentiality is paramount. In addition to clearly stating confidentiality in ad copy, participants suggested including "Command NOT involved" to reassure viewers that the intervention is provided outside the military system. Another recommendation was to differentiate marketing materials from the military through design (e.g., deviate from military aesthetics, include university logo). As one member of the non-treated group stated, the ads looked "super civilian" – a positive attribute signaling that the military is not involved in the research.

Consistent with our draft marketing materials, participants also recommended that advertisements not directly name "PTSD" due to associated stigma. Additionally, many service members with PTSD are unaware of their diagnosis and may not relate to the label. Instead, ads address easily identifiable and less-stigmatized PTSD symptoms, such as nightmares, loss of interest in activities, or feeling isolated. Some symptoms of hyperarousal were recommended to include (irritability, difficulty concentrating, trouble sleeping) whereas hypervigilance and startle were not recommended as they were seen as part of situational awareness central to military training.

Treatment providers cautioned that avoiding painful memories is typically believed to be a useful coping strategy and therefore not a symptom to induce treatment seeking. However, avoidance of once-pleasurable activities (e.g., sporting events, restaurants) was suggested to be a relatable experience that the target population would be eager to overcome. With regard to mood-related symptoms, members of the treatment provider group expressed concern that images portraying service members in emotional distress or isolation may be off-putting or even "triggering". However, the two groups of service members expressed no such concern and found these images drew their interest. Sample final recruitment materials can be seen in Fig. 1.

Focus group participants emphasized the importance of variety with respect to ad placement. They explained that individual service members' on-post movement is fairly routine and largely dictated by job roles, so there are few locations that all service members will visit. As such, we will strive to place advertisements as widely as possible and in diverse locations, such as gyms, recreation centers (e.g., bowling alley, skating rink, gaming centers, etc.), movie theaters, administrative buildings, barracks, medical facilities, as well as in monthly printed periodicals with on-post circulation. Participants also suggested placement that allowed service members to read the material discretely given the stigma associated with mental health treatment. Accordingly, we will also print materials in a variety of sizes, for example 11- by 17-in. posters with large print posted on walls that can be read from across a room and stacks of small 3- by 5-in. cards that can be taken and read later. It was also suggested to post materials in places of privacy, such as bathroom stalls and locker rooms.

Focus groups suggested modifications to intervention structure that depart from prior Check-Up interventions. For example, service members recommended starting the PFR with a review of life goals – a positive component that typically concludes a PFR. One soldier commented "I am tired of being told I'm broken." When asked about motivations for treatment, a soldier who had completed PTSD treatment highlighted the goal orientation of her and her peers, stating "The reason we're in the military is because we want a career." Another followed up, explaining "There is a fear that PTS will affect transition into the civilian world; soldiers want to be productive after the military, and PTS treatment will help with that." Starting the PFR with goals roots the conversation in a strengths-based perspective and engages the participant in exploring PTSD symptoms within the context of their life and vision for the future.

Other recommended adaptations included omitting content on depression and suicide. Participants were wary of how such feedback might be (mis)used by the military. Some participating service members discussed negative personal experiences when disclosing suicidal ideation within the military and described how it might lead to distrust of the intervention. The research team decided that the clinical utility of feedback on suicide and depression was not sufficient to overcome participants' concerns about potential iatrogenic effects (i.e., concern about mandated reporting, privacy, or the military finding out about the information and using it to prevent promotion).

A final recommendation was to normalize responses to trauma. As one stated, "Traumatic events are all different, but we're all dealing with the same symptoms." Though this was originally an aspect of the clinical protocol, normalization became a more central theme of the intervention and was explicitly embedded in the review of PTSD symptoms and etiology, and discussion of treatment options.

2.4. Phase 2: randomized controlled trial

2.4.1. Design

The efficacy of StressCheck will be compared to treatment-as-usual (TAU) in a two-arm randomized trial. Participants ($N = 200$), recruited from JBLM via marketing materials developed in Phase 1, will be randomly assigned to receive MET or TAU. Both interventions will be preceded by a baseline assessment with follow-ups conducted 6-weeks, 3-, and 6-months post-baseline. Participants will complete all study activities by phone and will be compensated up to \$200 for completing assessments – \$25 for baseline and 6-weeks, \$50 for 3- and 6-months, and a \$50 bonus for completing all follow-ups. Hypotheses are: (1) Service members receiving MET will report more PTSD treatment engagement at follow-up relative to TAU. (2) Service members receiving MET will experience fewer PTSD symptoms at follow-up relative to TAU. (3) Intervention effects on PTSD symptoms will be mediated by PTSD treatment engagement. (4) Intervention effects on PTSD treatment engagement will be mediated by decreased perceived stigma and increased perceived effectiveness of PTSD treatment.

2.4.2. Assessment, enrollment and randomization

A small team of study assessors will be responsible for conducting screenings, enrolling participants, and conducting all follow-up interviews. Qualification for assessor positions will require a master's degree in a clinical discipline, such as psychology, social work, or marriage and family therapy, and applicants familiar with military populations will be preferred. Assessors will receive didactic training on military culture, PTSD, as well as suicide assessment and intervention. Assessors will practice administering assessments with other staff members serving as mock participants prior to engaging with service members. The study's project director will conduct randomization procedures, leaving assessors blind to treatment condition. When possible, participants will be matched with the assessor who conducted their baseline for subsequent follow-ups.

Inclusion criteria are current DSM-5 PTSD diagnosis and current active-duty status in the U.S. Army or Air Force. Exclusion criteria include current evidence-based treatment for PTSD, psychosis, pending deployment that would preclude completion of follow-ups, or non-fluency in English.

After obtaining informed consent for screening, prospective participants will complete a 15-min call to assess demographics, treatment history, and probable PTSD using the Primary Care PTSD Screen for DSM-5 (PC-PTSD) [26]. Soldiers and airmen with probable PTSD and no current PTSD treatment engagement will be scheduled for the full screen.

Determination of full eligibility will be made during the 90-min telephone-delivered full-screen, based on PTSD diagnosis, using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) [27]. Eligible participants will then provide informed consent, and choose confidential



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Memories of abuse keeping you up?
Call, check in, explore your options.



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Private
Confidential
All by phone
After duty hours
Earn up to \$200

W A University of Washington Study

(866) [REDACTED]
www.uwStressCheck.com

Fig. 1. Example recruitment print media. Note: Phone number obscured for publication.

or anonymous enrollment. When selected, anonymity will be maintained via pseudonyms, compensation through money orders, and contact via an anonymized phone number and a PO box.

Table 1 shows the purpose and administration timepoints of key measures. Three measures will assess primary outcomes. First, a measure of PTSD treatment engagement, developed for the purpose of this trial, will assess the type (e.g., talk therapy, medication, self-help, etc.), frequency, and focus of treatment utilized since the prior assessment timepoint. Lifetime and past 3-month engagement to be assessed at baseline/screening. Second, the gold standard for research-based assessment of PTSD, the CAPS-5 [27], will be used to provide a diagnosis and severity score for PTSD. Third, a version of the Treatment Reactions Scale [28] adapted to assess reactions to PTSD treatment generally (both medication and talk therapy) will be used for hypothesized mediators of stigma and perceptions of treatment efficacy. Other key measures will be used to generate the PFR and provide data for secondary outcomes. These include a two-item Readiness Ruler [29] assessing importance of and confidence in ability to address PTSD symptoms; the Alcohol Use Disorder Identification Test [30]; the Walter Reed Functional Impairment Scale [31]; the Patient Health Questionnaire (PHQ-9) [32] for depression; and the Daily Drinking Questionnaire [33].

While the majority of measures will ask participants for direct self-report of behaviors or opinions (e.g., Likert scale responses), the CAPS-5 requires clinical knowledge and judgment. Accordingly, assessors will first complete an online training in CAPS-5 administration provided by the US Department of Veterans Affairs and the National Center for PTSD [34]. Assessors will then conduct mock sessions with their peers as well as code audio-recorded CAPS-5 assessments conducted with participants. Such training will continue until reliable and accurate scoring is achieved. Throughout the study, assessors will continue to listen to the recording of roughly every fifth assessment conducted and independently code the CAPS-5. Discrepancies in scoring will be discussed as a team to maintain standards and consistency of measurement. Finally, upon study completion, 5–10% of recorded assessments will be independently coded by another member of the team and inter-rater reliability will be calculated.

A computerized restricted urn procedure will be used to stratify randomization on four factors to ensure equivalent distribution between conditions: gender (man/woman), PTSD severity (low/high), and service branch (Army/Air Force). High PTSD severity was defined as a cut score of 37 as at the time of study design there were not established cut-offs for the CAPS-5.

2.4.3. Study interventions

The MET consists of up to 3 phone sessions conducted by a study counselor. Session 1 is 45–90 min; Sessions 2 and 3 are each 30–60 min.

Table 1
Measures by purpose and administration timepoint.

| | Purpose | | | | | | Administration Timepoint | | | | |
|--|---------|----|----|----|----|-----|--------------------------|----|-----|-----|-----|
| | Elig | H1 | H2 | H3 | H4 | PFR | Scr | BL | 6wk | 3mo | 6mo |
| <i>Eligibility & Hypotheses</i> | | | | | | | | | | | |
| Demographics | X | | | | | | X | | | | |
| SCID – Psychosis | X | | | | | | | X | | | |
| Treatment Utilization | X | X | | X | X | | X | | X | X | X |
| Primary Care PTSD Screen | X | | | | | | X | | | | |
| Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) | X | | X | X | | | | X | | X | X |
| Treatment Reactions Scale | | | | | X | | | X | X | X | X |
| <i>PFR & Secondary Outcomes</i> | | | | | | | | | | | |
| Readiness Ruler | | | | | | X | | X | X | X | X |
| Alcohol Use Disorder Identification Test | | | | | | X | | X | | X | X |
| Walter Reed Functional Impairment Scale | | | | | | X | | X | | X | X |
| Patient Health Questionnaire (PHQ-9) | | | | | | X | | X | | X | X |
| Daily Drinking Questionnaire | | | | | | X | | X | | X | X |

Scr = Screening; BL = Baseline; 6wk = 6-week; 3mo = 3-month; 6mo = 6-month; Elig = Eligibility; H = Hypothesis; PFR = Personalized feedback report. H1- Treatment Engagement; H2- Decrease in PTSD Symptoms; H3- Mediation: Treatment Utilization; H4: Mediation: Stigma & Efficacy.

MI skills are used throughout each session, including use of open questions, reflective listening, affirmations, and selectively responding to the service member’s change talk to explore and resolve ambivalence around seeking help for PTSD.

As outlined in Table 2, Session 1 features the review of a personalized PFR based on their baseline assessment responses. The focus is to explore how PTSD is impacting the participant’s life, their treatment knowledge, and perceived barriers to care. Counselors are encouraged to follow the PFR’s general structure but focus on areas directly relevant to that participant. The session begins by discussing participant life goals. This segues into normative feedback about the degree of difficulty the participant is having with each PTSD symptom cluster. Avoiding diagnostic labels, symptoms are framed as “common responses to trauma.” The next section covers intersections between alcohol and tobacco use and PTSD. Then, the PFR presents feedback on the impact of PTSD on participant functioning in physical, social, occupational, and personal domains. This is intended as a means to begin exploring ambivalence about PTSD treatment engagement while highlighting the discrepancy between maintaining symptoms and functional costs of not changing. Goals are revisited to explore how addressing PTSD might affect achievement of those goals. Next, stigma about treatment seeking and practical barriers to seeking care are addressed. Lastly, the intervention provides psychoeducation about treatment efficacy and options, including evidence-based interventions, and a range of other treatments, self-help, and self-guided approaches and a discussion of next steps. Like other MI-based interventions, StressCheck presumes solutions rest within the service member, and the intervention goal is to help them identify their own solutions and strengths.

While Session 1 contains the primary clinical material, Sessions 2 and 3 are optional supports toward help-seeking. At the beginning of Sessions 2–3, the counselor asks about treatment engagement and PTSD symptoms since their last session. Using an MI style, the counselor elicits discussion of treatment seeking effort, or if plans were not acted upon, what got in the way. These sessions center on identifying and responding to risk factors for dropping out of treatment (increased ambivalence, avoidance, stigma, life chaos), barriers to treatment engagement, and identification of other therapeutic resources if necessary. For participants not yet engaged in treatment, these sessions are an opportunity to elicit their thinking about the pros and cons of doing so.

The comparison condition was selected to mirror the existing military process for identifying and encouraging treatment for personnel who screen positive for PTSD. TAU includes a written referral list of PTSD resources including information on in-person treatments, self-help, web-based, and bibliotherapy options for PTSD and comorbid disorders. Upon study completion, TAU participants are offered the MET intervention.

Table 2
Description of StressCheck MET sessions.

| Session | Content | Clinical Goals |
|---------|---|---|
| 1 | Participant life goals (reviewed at the beginning and then in the middle of the session) | <ul style="list-style-type: none"> Identify participant values and goals Examine potential discrepancy between current PTSD symptoms and life goals |
| | Common Reactions to Trauma | <ul style="list-style-type: none"> Identify consequences associated with PTSD to build motivation to change |
| | <ul style="list-style-type: none"> Review of severity of PTSD symptom clusters based on CAPS-5 Provide psychoeducation about PTSD Educate about relationships between PTSD, depression, and suicidality | <ul style="list-style-type: none"> Normalize trauma responses to reduce stigma Identify the role of depression and suicidality as reasons to build change <ul style="list-style-type: none"> Safety planning |
| | Feedback on substance use | <ul style="list-style-type: none"> Develop a discrepancy between perceived drinking and actual descriptive norms to create motivation to change Develop a discrepancy between personal goals and values and substance use (alcohol or tobacco) |
| | <ul style="list-style-type: none"> Information on standard drinks Branch and gender specific alcohol norms Information on monthly quantity and costs of tobacco Discuss functional relationships between substance use and PTSD | <ul style="list-style-type: none"> Explore specific ways substance use may be being used to self-medicate symptoms of PTSD Increase awareness of how substance use may maintain their PTSD symptoms or interfere with treatment |
| | Impact of symptoms on functional impairment | <ul style="list-style-type: none"> Provide opportunity to discuss consequences of symptoms on functioning Increase awareness of consequences to increase motivation to change |
| | Self-reported barriers to PTSD treatment | <ul style="list-style-type: none"> Provide an opportunity to explore what it would be like to pursue care Provide an opportunity to problem solve Provide an opportunity for reinforcing change talk Reduce stigma around treatment seeking Build self-efficacy around current and past help seeking behaviors |
| | PTSD treatment effectiveness information | <ul style="list-style-type: none"> Correct misperceptions regarding treatment efficacy Evoke conversation about treatment beliefs |
| | Description and discussion of treatment options | <ul style="list-style-type: none"> Increase self-efficacy around help-seeking Support autonomy |
| | Discussion about moving toward change | <ul style="list-style-type: none"> Review and problem solve with the counselor Identify next steps if any specific action was indicated |
| | <ul style="list-style-type: none"> Resource Booklets including treatment resources for PTSD, alcohol use, or tobacco use | |
| 2 & 3 | Assessment of PTSD symptoms since last session | <ul style="list-style-type: none"> Engage individual in a conversation about their PTSD Evoke change talk from discovering the consequences of PTSD Focus discussion (ie. this is what we are going to be talking about today) |
| | Assessment of help-seeking behaviors since last session. | <ul style="list-style-type: none"> Reinforce, maintain, and strengthen treatment or help seeking efforts or treatment completion Build and support self-efficacy |

Table 2 (continued)

| Session | Content | Clinical Goals |
|---------|--|--|
| | <ul style="list-style-type: none"> Trouble shoot and strategize barriers to treatment engagement and completion For those not seeking treatment, offer and discuss further resources | <ul style="list-style-type: none"> Strengthen motivation to persevere in help seeking or treatment completion |

2.4.4. Counselor training and supervision

Counselor training includes didactic review of MI/MET principles and the intervention manual, modeling of therapy techniques, and role-play of intervention strategies. Counselors will hold a graduate degree in psychology or social work and have clinical experience with PTSD. Counselor training consists of 20 h over 4–6 weeks with the PIs. Counselors will conduct “mock” MET sessions with other project staff which will be digitally recorded and reviewed in weekly supervision. Counselors will then be assigned at least one training case.

All training sessions will be coded (author DW) using an adapted version of the Motivational Interviewing Treatment Integrity (MITI) [35] system (see below) to measure treatment fidelity for MI. Individual supervision sessions are held weekly for the duration of the pilot cases, where counselors receive written and oral feedback on their performance and MITI counselor behavior counts. Group supervision will be 1 h weekly throughout the trial in which clinical case material will be presented, digital recordings of sessions reviewed, and problems of adherence to protocols discussed.

2.4.5. Intervention fidelity

A random sample of 20% of MET sessions will be rated for adherence and competence using the MITI [35] coding system, which has demonstrated reliability for evaluating adherence to MI interventions [36]. Four global scores (cultivating change talk, softening sustain talk, partnership, and empathy) are coded on a 7-point Likert scale ranging from “low” to “high” adherence. Behavior counts include: giving information, reflections (parsed by simple or complex), MI-adherent (examples include emphasizing service member’s control, affirmations, etc.) and MI non-adherent (examples include confronting, directing, advising without permission). Summary scores are calculated from the behavior counts and global scores as an index of counselor competence. Two independent coders, expert in the MITI will rate tapes allowing for analyses of therapeutic fidelity.

2.4.6. Analysis

The first two hypotheses address whether MET participants report more treatment engagement and fewer PTSD symptoms at follow-up than TAU participants. This study has 4 repeated measures from baseline to 6 months follow-up yielding up to 800 observations. Given the nesting of observations within service members, we will run linear mixed (a.k.a., hierarchical linear or multilevel) models [37]. Measures of treatment engagement and PTSD symptoms will be analyzed as outcomes in separate models. Fixed effects will include indicator variables for assessment timepoint (baseline as reference), condition (MET vs. TAU), and the time and condition interaction. Of particular interest are cross-level interactions between condition and time. We will consider inclusion of additional covariates such as gender, social support, and trauma severity to improve precision of estimates. Similar mixed effects models will be used to test intervention effects on stigma/barriers to treatment and treatment expectancies.

For Hypothesis 3, if effects of the interaction on the outcomes are observed, we will test whether effects of the intervention on treatment engagement are mediated through stigma and treatment expectancies. Using mixed effects models, we will evaluate the effect of the intervention on change in treatment engagement both before and after controlling for the putative mediators using the method described by

Krull and MacKinnon [38]. Reduction in the percentage of variance accounted for by the interaction effect after controlling for these proposed mediators will inform the degree to which the effect is mediated.

2.4.7. Statistical power

This study is primarily powered to detect differences in PTSD symptoms between conditions over time. We used a simulation-based approach to estimate power [39]. Two-hundred datasets were generated based on the linear mixed model described in the Analysis Plan where estimates for model parameters (e.g., baseline levels of PTSD symptoms, changes over time in the control condition, distributions of random effects) were guided by preliminary data from an earlier clinical trial and the extant literature. The model was fit for each dataset and specific outputs such as the regression coefficient and standard error. A number of simulation runs were conducted varying treatment effects size and the sample size. The percentage of datasets where the treatment-by-time interactions were statistically significant provides an estimate of power. We found that a sample size of 200 would allow for >0.80 power to detect effect sizes of 0.35 or greater at any given follow-up, which is at the lower end of the effect size range found in the extant literature on treatment for PTSD in military samples.

3. Discussion

There is limited evidence on interventions to attract and motivate those with untreated PTSD to engage with treatment. The present study protocol, a randomized comparison trial of a Check-Up intervention as compared to TAU, will help address that gap. Developing a Check-Up model to target self-referral of those suffering with PTSD involves both an advertisement campaign to elicit voluntary participation from those who are experiencing PTSD, but not accessing care and to decrease barriers to engaging in an intervention. This is in contrast to offering a MET session to service members identified in an opportunistic setting such as a clinic or through medical records because it has the ability to reach those who are not being identified by other institutions or services and could capitalize on inherent motivation of the service member to change their circumstances or how they feel.

Addressing PTSD in a MI or MET intervention may require a different approach than addressing health behaviors. One premise of MI is that the main obstacle to behavior change is ambivalence about change or lack of motivation – not a skills deficit. Thus, drawing out readiness to change sparks behavior modifications, rather than increased education or skill development. The focus is on changing behavior that is within the control of the service member. Counselors increase motivation by eliciting statements that are in favor of change. In contrast, PTSD recovery is thought to require more than resolving ambivalence. Thus, change talk for PTSD addresses categories such as why they want to change their PTSD and benefits of not having PTSD. Target behaviors for MI when addressing PTSD may include increased awareness of the costs of PTSD and increasing awareness of the benefits of resolving or improving PTSD, to increase motivation. However, counselors are also targeting behaviors adjacent to PTSD such as treatment entry and engagement. Therefore, areas of feedback include data on treatment effectiveness and didactic information related to treatments for PTSD that may be helpful in changing perceptions about the helpfulness of treatment and increase awareness of treatment options. MET is a flexible approach in terms of its relation to treatment; it can serve as a direct, standalone treatment, a precursor to treatment and facilitate treatment engagement, or it can occur after treatment to improve maintenance of treatment gains. Given our current focus on improving outcomes for non-treatment-seeking service members with PTSD, the primary aim of the current MET is to facilitate treatment seeking, broadly defined. That is, the intervention will be considered successful if it helps participants move toward seeking any form of PTSD treatment that they deem to be a good fit.

It is an open question regarding what proportion of service members

with PTSD who are not already in treatment will respond to a Check-Up intervention. It is possible that the intervention will predominantly be appealing to those who are already motivated to address their PTSD. If so, this could lead to challenges in seeing a treatment effect as participants may be primed to address their PTSD regardless of the intervention. In contrast, should we find that the intervention is missing the service members who are lower in motivation to change, this would argue for finding other ways to reach these service members, such as use of a Check-Up following a universal screening approach like in primary care settings where it could be implemented following a positive PTSD screen.

One strength of this study, and challenge, was the focus on creating an intervention that would be appealing to, and pull in, service members who are non-treatment seeking. This led to several design considerations including the type and messaging of the marketing campaign, the use of mass outreach to identify potential participants, and the incorporation of feedback from end users into development of study materials. Often treatment developers may develop interventions or recruitment materials without the voices of end-users being included in the process. It is important to highlight that provider and service member perspectives on outreach and on intervention content did not always align, which again suggests that interventions that are developed solely with input from other mental health professionals may not always appeal to the target audience. Moreover, by including both service members who had engaged in treatment, and those who had not, we were able to represent a broad array of reasons to address PTSD and barriers to doing so. What is appealing to someone who had completed treatment also could, and did, vary from what is appealing for someone who has not yet started that process. Overall, this approach has broader applicability for intervention development in appealing not just to those who deliver treatments and those who engage in the treatment but also those who could benefit from care, but never come in the door. If efficacious, this work has several implications for the military. PTSD is prevalent within service members. The Department of Defense has invested considerable resources into training and scaling up evidence-based treatments for PTSD but barriers still remain preventing affected service members from engaging with those resources. There are perceptions among service members that treatment is difficult and/or inefficacious, as well as that a diagnosis of PTSD will hamper one's career potential [21,40,41]. StressCheck is a potential means of addressing these issues. Moreover, the military has relatively unique opportunities for scaling up and sustaining a successful intervention. Behavioral health treatment is available within the military and covered under insurance benefits. A Check-Up, if successful, may be particularly suited for the military because specific practical barriers to treatment such as cost and access are reduced for those who decide to enter treatment. In addition, with an integrated behavioral health system, it is more feasible to incorporate a treatment program like a Check-Up into this type of system. Implementation of such a service might best be rolled out within military service providers who offer more opportunities for privacy such as chaplains or military and family life counselors. Military and family life counselors provide services without maintaining records to increase privacy and confidentiality, do not report to Command, and do not impact the security clearance of the service member, thus may be viewed as a trusted resource for conversations pertaining to PTSD. Future research could also investigate whether the Check-Up could be delivered by peers and what barriers and facilitators to engaging with these various implementation options might present.

The study, as developed, does have several limitations. One potential issue is that our measures of treatment engagement and subsequent PTSD improvement could be affected by access to care issues that we cannot control. For example, if service members are not able to get into effective treatments, regardless of how successful our MET intervention is, it will be difficult to show an effect. This is a potential confound that we can mitigate through measurement of treatment seeking efforts, not just treatment engagement per se. Another limitation is that we may

have a truncated range of readiness to change, which could obscure treatment effects. Thus, readiness to change will be measured, both as a potential confound and a potential moderator of treatment effects. In addition, participants will be compensated for research participation. Although they are not compensated for the treatment sessions they are for completion of assessments. This can create additional reasons to participate in a clinical trial and could lead to recruitment of service members with lower motivation to change. If so, this could create difficulties when rolling out an intervention in a standard clinical setting, as the financial incentives would not be sustainable. In sum, this study focused on testing an often-used approach (MI) for increasing PTSD treatment initiation within an at-risk population of service members with PTSD but unlikely to seek treatment. This study will also address whether decreasing perceived stigma and increased perceived effectiveness are important mediators of treatment effects, thereby identifying mechanisms of behavior change. If this trial of StressCheck demonstrates evidence of efficacy, the approach has potential for broad public health impact within the military.

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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