HHS Public Access

Author manuscript

J Psychiatr Res. Author manuscript; available in PMC 2023 April 24.

Published in final edited form as:

J Psychiatr Res. 2022 October ; 154: 242–251. doi:10.1016/j.jpsychires.2022.07.038.

Ethical and Methodological Challenges Slowing Progress in Primary Care-Based Suicide Prevention: Illustrations from a Randomized Controlled Trial and Guidance for Future Research

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Abstract

Introduction.—Despite the pressing need for primary care-based suicide prevention initiatives and growing acknowledgement of recruitment difficulties and Institutional Review Board (IRB) challenges in suicide research, we are aware of no illustrative examples describing how IRB decisions in the design of a primary care trial can compound recruitment challenges.

Methods.—The CDC-funded trial (NCT02986113) of Men and Providers Preventing Suicide aimed to examine the effects of a tailored computer program encourage men with suicidal thoughts (n=304, ages 35-64) to discuss suicide with a primary care clinician and accept treatment. Before a visit, participants viewed MAPS or a non-tailored control video. Post-visit, both arms were offered telephone collaborative care, as mandated by the institutional review board (IRB). We previously showed that exposure to MAPs led to improvements in communication about suicide

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in a primary care visit. In this paper, we report data on the study's primary outcome, suicide preparatory behaviors.

Results.—After screening nearly 4,100 men, 48 enrolled. Recruitment challenges, together with an IRB mandate narrowing post-intervention patient management differences between trial arms, limited detection of the effects of MAPS on suicide preparatory behaviors.

Conclusions.—While primary care settings are key sites for suicide prevention trials, recruitment difficulties and overly restrictive IRB requirements may limit their utility. Methodological innovation to improve recruitment and ethical guidance to inform IRB decision-making are needed.

Keywords

help-seeking behavior; institutional review board; men's health; patient activation; physician-patient relations; primary care; research ethics; suicide; tailored interventions

Almost 80% of the nearly 50,000 yearly suicide deaths in the United States occur in men. Suicide is particularly common among those aged 35-64 (hereafter, middle-aged men) representing the eighth leading cause of death among men in this age group, entailing tremendous human and economic costs (Centers for Disease Control and Prevention, 2016a, 2016b; Curtin et al., 2016; Shepard et al., 2016).

Half of all adults who die by suicide see a primary care clinician (PCC) in the month before death, whereas only about 20% seek specialty mental healthcare (Gordon et al., 2020; Luoma et al., 2002). Currently, however, nearly all clinical suicide prevention efforts are targeted to patients in non-primary care settings such as inpatient psychiatric facilities, outpatient mental health clinics, or emergency departments, typically following attempted suicide (Brown et al., 2005; du Roscoat & Beck, 2013; Linehan et al., 2006; Motto & Bostrom, 2001). Such approaches have value, but cannot prevent the two-thirds of male suicide deaths occurring on first attempt (Kessler et al., 1999; Mann, 2002), because men who die by suicide are less likely to come into contact with specialty mental health care in the days and weeks prior to the fatal attempt. These observations suggest the potential value of primary care-based suicide prevention interventions (National Action Alliance for Suicide Prevention, 2011; U.S. Department of Health and Human Services Office of the Surgeon General and National Action Alliance for Suicide Prevention, 2012).

Although the Surgeon General's 2012 National Strategy for Suicide Prevention promotes the adoption of zero suicide as an aspirational goal for healthcare systems, recruitment challenges and methodological challenges, including those arising in the context of IRB review prior to trial implementation, may compromise unbiased assessments of intervention effectiveness. Despite a growing literature on IRB review difficulties arising in the context of suicide prevention trials (Andriessen et al., 2019; Fisher et al., 2002; Hom et al., 2017; Lakeman & FitzGerald, 2009), we are aware of no illustrative examples of IRB decisions interfering with study design and outcome assessment. We provide an example in this paper, both to call attention to the problem and consider ways to mitigate or prevent such problems in the future. We note that although this paper provides one specific example, the situation described here is likely not uncommon and could potentially occur in any scenario where

an IRB's perceived mandate conflicts with the reality of conducting treatment research in real-world settings.

Even members of institutional research ethics committees themselves perceive these committees as potentially interfering with the scientific process by, for example, requiring researchers to modify research designs and procedures to avoid lawsuits and thus protect the institution (Guillemin et al., 2012). In addition, research ethics committee members may be biased to behave in an inappropriately paternalistic fashion (Coulter, 1999; Entwistle et al., 2010) when assessing applications that involve suicidal individuals (Fisher et al., 2002), particularly when reviewing intervention studies (Andriessen et al., 2019). For example, ethics committees have requested suicide intervention researchers to make major changes to the study design and offer additional resources for participants, even if there is no evidence to support the effectiveness of those additional resources, and even if such resources "might paradoxically reduce the demonstrable effect sizes of interventions" (Lakeman & FitzGerald, 2009, p. 18) and thereby slow the dissemination of effective interventions. Although there is evidence to suggest that this phenomenon is rare (Andriessen et al., 2019), it could be quite damaging to the scientific process, and thus merits debate and discussion in the scientific literature.

Rationale for the Men and Providers Preventing Suicide (MAPS) Trial

To be effective, primary care-based preventive interventions must address two tendencies among men with suicidal thoughts: reticence to discuss suicidal thoughts (or their mental health in general) with PCCs, and reluctance to accept treatment for suicide risk, depression, or other contributing factors. Suicide is rarely broached in primary care visits (Feldman et al., 2007; Nutting et al., 2005; Vannoy & Robins, 2011; Vannoy et al., 2011). This is true even among those preparing (e.g., attaining means) for suicide who have an established risk marker, such as financial problems, life event stressors, and depressive symptoms (Cavanagh et al., 2003; Conner et al., 2001; Hawton et al., 2003; Heikkinen et al., 1994; Kessler et al., 1999; McDowell et al., 2011; Milner et al., 2012; Nock et al., 2008; Olfson et al., 1996; Rudd et al., 2006; ten Have et al., 2009). Factors contributing to this "conspiracy of silence" include gender-linked norms, such as the need to appear tough (O'Loughlin et al., 2011; Rochlen et al., 2010); mental health stigma (Reynders et al., 2015); patients' beliefs that PCCs are not interested in suicide prevention or able to treat mental health concerns (Kravitz et al., 2011); fear of psychiatric hospitalization (Jerant et al., 2019); and the need for PCCs to attend to other medical concerns (Rost et al., 2000). While interventions targeted to PCCs can increase detection of suicidal patients, many at-risk patients go unrecognized (Almeida et al., 2012; Nutting et al., 2005).

Men are less likely than women to engage in treatment to address suicide (Bhar et al., 2013). This is unfortunate since the gold standard primary care treatment - collaborative care (Katon et al., 2010), implemented by social workers, nurses, or counselors working with a psychiatrist and PCC – is both highly effective and scalable. Telephonic collaborative care has been shown to be as effective as medication in treating depression and psychological distress and can reduce suicide thoughts (Choi et al., 2016; Comtois & Linehan, 2006; Gustavson et al., 2016; Stewart et al., 2009; Unutzer et al., 2006).

To summarize, primary care is an ideal setting to screen and begin to intervene on suicide risk given that far more people who die by suicide visit a primary care office than a therapist office prior to dying by suicide. Despite identifying an ideal setting, barriers to effective suicide prevention still remain, especially for men who are reluctant to disclose suicide risk and to engage in psychotherapy. Prior to the current trial, no interventions had sought to address men's reticence to discuss suicide thoughts by signaling PCC receptiveness to discussing suicide and activating men to disclose. Likewise, no interventions had sought to motivate suicidal men to engage in collaborative care

To fill these gaps, we developed the Men and Providers Preventing Suicide (MAPS) tailored interactive computer program. MAPS is focused on activating (Hibbard & Greene, 2013) middle-aged men with suicidal thoughts to discuss the thoughts with a PCC and engage in telephonic collaborative care. The computer program provides tailored multimedia content addressing user-endorsed barriers to suicide discussion and treatment. Prior to developing the MAPS computer program, we showed that a computer program focused on adult depression in primary care successfully increases PCC-patient discussion of depression, depression treatment and suicide and (Kravitz et al., 2013; Shah et al., 2014). Apart from having more suicide-related content, MAPS differed from the prior program in its focus on activating middle-aged men with suicide thoughts to both discuss and accept treatment to reduce the thoughts regardless of depression status, since many men who die by suicide are not clinically depressed (Nock et al., 2010).

We previously reported that in a randomized controlled trial (RCT), use of MAPS in the primary care office immediately before a visit was more effective than use of an active control in increasing discussion of suicide during the visit (Jerant et al., 2020). Here, we report the effects of MAPS on subsequent suicide preparatory behaviors (SPBs - planning, preparing, arranging, attaining means), the primary pre-specified trial outcome (NCT02986113), and suicide thoughts over three months follow-up. We hypothesized that compared with men viewing an active control, men viewing MAPS would be more likely to discuss suicide with their PCC; this was subsequently confirmed (Jerant et al., 2020). We further hypothesized that men exposed to MAPS would report fewer SPBs at 3-month follow-up.

Importantly, we also discuss ethical and methodological challenges encountered during trial implementation that may have undermined an accurate assessment of intervention outcomes. The key ethical challenge involved an institutional review board (IRB) requiring a significant protocol change in order to provide approval. The original hypothesis was premised on the supposition that men exposed to MAPS would be more likely to engage actively in telephonic collaborative care following PCC referral. However, the IRB mandated that telephonic collaborative care be offered *routinely* to all men in both trial arms by our study personnel (rather than by PCC referral). This diminished patient management differences between trial arms and compounded the key methodological challenge, slow patient recruitment, limiting statistical power.

Materials and Methods

Study activities were conducted from December 2016 through January 2020. The responsible Institutional Review Board (IRB) provided approval for the study. Figure 1 summarizes the IRB-approved trial design, with the changes to the original grant-funded design as specified above.

Study Setting, Recruitment, and Randomization

The unit of randomization was the PCC since patient-level randomization would have entailed risk of control arm contamination. We recruited clinicians from eight primary care offices in one university-affiliated network in California. The PCCs were told that the trial was comparing two office-based interventions for preventing suicide among middle-aged men but given no details of the interventions. Using a custom computer program, PCCs were randomly assigned to MAPS or control (both described subsequently – see Study Interventions) in blinded fashion, in varying blocks of 4 or 8 (Schulz & Grimes, 2002). Following randomization, PCCs in both arms were offered four online videos totaling 30 minutes in length and summarizing a patient-centered approach to suicide risk assessment (Pisani et al., 2012), to help ensure activated patients would visit appropriately prepared PCCs(Jerant et al., 2019). Of the 42 PCCs in the trial, 18 (43%) viewed at least some video content (mean percentage viewed 88% [SD = 18.9%]).

For patient enrollment, we initially used health system-generated reports to identify men aged 35-64 assigned to participating PCCs (NCT02986113). After encountering recruitment problems, the funder permitted us to expand eligibility to include men up to 74 years of age. In our prior studies of adult depression in primary care, we screened all adults who had upcoming appointments. Given that this trial focused on a narrower demographic (men in a specific age range) and a less prevalent symptom, thoughts of suicide, trained research assistants (RAs) telephoned and/or sent letters to solicit participants and men were subsequently screened if they expressed potential interest. Men were enrolled if they: were able to read and speak English; self-reported adequate vision, hearing, and hand function to use an interactive computer program on a touchscreen tablet device; had an appointment already set with their PCC within 2 weeks, scheduled previously by the patient for any indication or reason (i.e., not specifically earmarked to discuss suicide); and answered “yes” to the question, “In the last four weeks, have you had any (even brief) thoughts of killing yourself?” PCCs participating in the study were blinded to patient enrollment in the trial and were not notified of study visits made by enrolled patients, to avoid undue prompting that might have obscured detection of intervention effects on the specified outcomes. Men failing to meet any of the foregoing inclusion criteria were excluded from participation. Also excluded were men with any of the following: reported or apparent highly unstable medical or mental health status; presence of terminal illness with death anticipated within 3 months; or plan to transfer care from current primary care office within 3 months.

Eligible men agreeing to participate were asked to arrive at their primary care office one hour before their visit to meet with a research assistant to complete informed consent and the pre-intervention questionnaire. The questionnaire included an item reassessing the presence of suicide thoughts in the past four weeks. This was done since suicide thoughts may

have stopped since telephone eligibility screening (described previously), reducing potential benefit from trial participation. Men answering “no” to this item were excluded. Next, the study software presented each man with the intervention appropriate to his PCC’s random group assignment, based on his unique login number. After viewing the intervention, the man attended his PCC visit.

Study Interventions

MAPS Arm.—We employed personal tailoring in MAPS because a large body of research indicates tailored messages are often superior to non-tailored interventions in improving health behaviors and outcomes (Noar et al., 2007). We created MAPS using a previously described approach in the health communication literature (Kreuter & Wray, 2003), drawing on theory and research on patient activation (Hibbard & Greene, 2013; Sacks et al., 2014), suicide behavior (Cavanagh et al., 2003; Conner et al., 2001; Hawton et al., 2003; Heikkinen et al., 1994; Kessler et al., 1999; McDowell et al., 2011; Milner et al., 2012; Nock et al., 2008; Olfson et al., 1996; Rudd et al., 2006; ten Have et al., 2009), and male help-seeking (Kravitz et al., 2011; O'Loughlin et al., 2011; Rochlen et al., 2010). We included elements that prior research and stakeholder feedback suggested would be likely to enhance men’s knowledge, skills, and confidence to discuss suicide thoughts and willingness to accept telephonic collaborative care to address contributors to suicide thoughts. We anticipated that this would not only lead to greater PCC-patient discussion of suicide thoughts (Jerant et al., 2020), but also lead to greater enrollment and adherence to telephonic collaborative care. Online Appendix 1 provides a summary conceptual Figure specifying the key tailored aspects of the MAPS program (Jerant et al., 2019; Jerant et al., 2011; Noar et al., 2007; Shah et al., 2014).

The general structure of MAPS involved sequential empathic acknowledgement of, and encouragement to discuss, suicide thoughts with the PCC and to enroll and adhere to telephonic collaborative care (Figure 2). The key motivational elements were three sequential modules addressing: (1) why and how to talk with a PCC about suicide thoughts; (2) how to negotiate an individualized care plan with the PCC and collaborative care team to reduce suicide thoughts; and (3) how to monitor the impact of the plan and work with the collaborative care team to modify it when indicated. As indicated in Figure 2 multiple elements of the program incorporated personal tailoring of information, based on participants’ responses to questionnaire items embedded in the program. Consistent with research on tailored communication and personal control (Miller, 1995; Peterson & Stunkard, 1989), each module also allowed some user control over how much information to view by offering optional material. The program was designed for 15-20 minute usage time, commensurate with typical pre-visit wait times in primary care offices (Press-Ganey, 2009).

Control Arm.—Men assigned to the active non-tailored control viewed a three-minute sleep hygiene informational video (Epstein, 2011), followed by a text screen providing encouragement to discuss suicide thoughts with a PCC plus information about support resources (total usage time approximately five minutes).

Telephonic collaborative care

In the original study design, men would engage in collaborative care via the standard route, PCC referral. However, as noted previously, the IRB required that all study participants receive telephonic collaborative care. Per IRB mandate, men in both arms were routinely offered 3 months by a care manager (CM) within 72 hours following their study visit. The care managers, all blinded to enrollees' trial arm, were licensed marriage and family therapists (LMFTs) with extensive experience in suicide risk assessment, counseling, and crisis intervention. Men declining telephonic collaborative care remained in the trial to receive follow-up data collection calls. For those accepting telephonic collaborative care, a care manager completed a phone intake assessment using a standard process to assess factors relevant to suicide risk (e.g., suicide intent and planning, firearm access) (online Appendix 2). At this and all points of patient interaction, study personnel used safety protocols to identify and offer intervention to men at high immediate suicide risk (online Appendix 3).

After intake, the care manager discussed the man's case by telephone with a psychiatrist (also blinded to the man's trial arm), typically within 72 hours but immediately if acute intervention was indicated. Following the post-intake discussion, the psychiatrist generated care recommendations using a standard process (online Appendix 4), communicated to the patient via care manager call, and to the PCC via documentation in the electronic health record (plus urgent phone call for high acute risk patients). The study psychiatrists did not provide care directly to patient participants. Common recommendations included starting or adjusting medication, linkage with community services (e.g., substance treatment, employment assistance), and referral to behavioral counseling or psychiatry. The same process used to generate recommendations post- collaborative care intake was also employed to modify and generate new recommendations following weekly case conferences, which included discussion of all current enrollees.

Following intake, participants were offered 12 calls with a care manager over three months. Four collaborative care phone calls used the same standard assessments and approach employed at intake, while two others were brief check-ins; in all of these calls, care managers asked about status change since last contact, assessed whether prior care recommendations had been followed, and offered help in pursuing recommendations not yet implemented. In the remaining six collaborative care phone calls, care managers provided Problem Solving Therapy for Primary Care (PST-PC), an efficacious and frequently used manualized intervention designed for delivery in 30-45-minute sessions (Zhang et al., 2018). The care managers were trained and certified to provide PST-PC and underwent fidelity monitoring throughout the trial. Since PST-PC was developed originally for both men and women with depression, with or without suicide thoughts, three of the authors (AJ, PD, KVO) worked with one of the PST-PC developers to modify the manual to better fit our study focus and population.

Measures

Outcome measures were administered at baseline in the pre-visit computer questionnaire (prior to viewing the assigned intervention) and by telephone at 1, 2, and 3 months.

Participants were offered a $20 gift card to a popular retailer after completing each questionnaire.

The primary outcome was the suicide preparatory behaviors score, composed of four items from the Scale for Suicide Ideation (SSI) concerning planning, preparing, and arranging for suicide and attaining lethal means (Beck et al., 1988; Witte et al., 2006). For each item, the man was asked to select from three statements the one best describing their situation over the prior 2 weeks (e.g., I have no specific plan about how to kill myself – 0 points; I have considered ways of killing myself, but have not worked out the details – 1 point; or I have a specific plan for killing myself – 2 points). The possible score range was 0-8 (higher scores=more behaviors).

Secondarily, we examined the presence of active suicide thoughts within 4 weeks (single yes/no item) as well as the severity of suicide thoughts, reflected by the total SSI score (19 items)(Beck et al., 1988). Apart from the 4 preparatory behaviors items, the other SSI items assessed the nature of suicide thoughts and factors heightening or mitigating suicide risk (possible score range 0-38, higher scores=higher risk). We also asked participants whether suicide had been attempted since last contact (single yes/no item) (Linehan et al., 2006) and examined collaborative care enrollment (defined as completion of an intake call) and adherence to the phone calls.

Baseline measures to characterize the study sample included socio-demographics and health-related issues associated with suicide risk. The latter included counts of 8 common mental health conditions and 11 common medical conditions; the Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001); the Primary Care Posttraumatic Stress Disorder screen (Prins et al., 2016); the Alcohol Use Disorders Identification Test (Bush et al., 1998); and single items assessing recreational drug use and self-rated health (DeSalvo et al., 2006).

At trial end, we assessed men’s impressions of study participation and the assigned intervention with an 8-item scale (Kravitz et al., 2013). Also, analysts queried participant electronic health records for ICD-10 codes T14.91 and X60-X849 and ICD-9 codes E950-E959, indicative of potential suicide attempt or death.

Data Analysis

Data were analyzed using Stata 16.1 (Stata Corporation, College Station, TX). Descriptive and inferential statistics (means, standard deviations, percentages, chi-square, or t-tests) were used to describe patient characteristics and telephonic collaborative care enrollment and call adherence by trial arm (MAPS or control). A mixed model approach was used to examine key outcomes, adjusting for nesting of follow-up calls within patients, and patients within physicians; these analyses also adjusted for the baseline score (preparatory behaviors score or total SSI score) and follow-up timepoint. We employed Poisson regression to examine the relationship between trial arm and the SBPs scale score (highly skewed) at each follow-up call. We employed logistic regression to examine the relationship between trial arm and the dichotomous dependent variable, presence of active suicide thoughts in prior 4 weeks (yes/no) at each follow-up call, controlling for the previously mentioned

covariates. We employed linear regression to assess the relationship between total SSI score and trial arm at each follow-up call. Based on an a priori power calculation, we estimated that enrolling 304 eligible men would achieve 80% power to detect clinically significant effects of MAPS (d = .26; α=0.05, two-tailed) on the primary and secondary outcomes under conservative adjustments for loss to follow-up (20%) and design effects arising from longitudinal measurements of outcomes (Hsieh et al., 2003).

Results

Forty-two PCCs (all physicians) were enrolled and randomized, 20 (48%) to the MAPS arm and 22 (52%) to the active control arm. Of 32 PCCs who provided data at study entry, 21 (65%) were family physicians and 11 (35%) general internists. They had a mean of 8 years in practice (range 1-22) and mean age of 44 (range 29-61); 21 (65%) were female; and 19 (59%) were non-Hispanic White, 7 (22%) non-Hispanic Other race, and 5 (26%) Hispanic (any race).

Figure 3 depicts the flow of patients through the trial and indicates that we conducted telephone eligibility screening of more than 4000 men. The trial was terminated early by the funder because the pace of identifying potentially eligible men from telephone screening was far less than anticipated, leading to very slow patient accrual. Of the 42 PCCs randomized, 16 had no patients enroll. From the remaining 26 PCCs, 48 middle-aged male patients enrolled (MAPS 21, control 27), a mean of 1.8 (range 1-5) per PCC. Of these, 18 (86%) MAPS arm patients and 26 (96%) controls completed follow-up through 3 months. Table 1 shows the men's characteristics by trial arm. The men's characteristics, including history of prior suicide attempts and baseline SPB and total SSI scores, did not differ significantly between trial arms.

Table 2 shows unadjusted follow-up preparatory behavior scores, total SSI scores, and rates of recent active suicide thoughts by trial arm, as well as telephonic collaborative care enrollment and call adherence by arm. In analyses adjusted for nesting within visits and PCCs, baseline score, and follow-up point, there were no significant differences over 3 months for MAPS vs. control in the preparatory behaviors score (mean difference −0.5 [95% CI −1.5-0.4]; p=.30), the total SSI score (mean difference 0.4 [95% CI −2.0- 2.8]; p=.72), or recent active suicide thoughts (odds ratio 1.7 [95% CI 0.4-7.0]; p=.43).

Because of the limited sample size, we conducted an additional post-hoc analysis assessing the post-intervention suicide preparatory behavior score, averaged across the three post-intervention follow-up calls, using a mixed model Poisson regression (patients nested within physicians) adjusting for the baseline score. In this analysis, the intervention was associated with a lower adjusted post-intervention score (incidence rate ratio 0.73, 95% CI 0.54-0.98; p = .03), corresponding to a lower adjusted suicide preparatory behavior score of 0.46 (95% CI 0.05-0.88).

Men's impressions regarding their study participation and assigned intervention did not differ significantly between groups (data not shown, available from authors). Based on

follow-up questionnaire responses and an end of study electronic record query, no men in either arm attempted or died by suicide.

Discussion

To our knowledge, this was the first trial of a primary care suicide prevention intervention for at-risk middle-aged men. The tailored MAPS program was designed to encourage participants' discussion of suicide with their PCCs during a linked visit, and MAPS was successful in this regard (Jerant et al., 2020). MAPS was also designed to increase outcomes outside the linked primary care visit, including participants' enrollment and adherence to 3 months of telephonic collaborative care, creating the potential to reduce suicide thoughts as well as preparatory behaviors and thereby prevent suicide attempts and deaths. Unfortunately, the ability to examine the effects of MAPS on outcomes outside the linked visit was lessened when the IRB mandated that we offer telephonic collaborative care to all participants in both study arms, which compounded other issues associated with difficulties with recruitment. Ultimately, about two-thirds of men in each arm engaged in telephonic collaborative care, and we observed no significant differences in suicide thoughts and preparatory behaviors over three months follow-up in pre-specified analyses. Nonetheless, a post-hoc analysis suggested a possible signal of intervention effect on suicide preparatory behaviors ($p=.03$). Cautious interpretation of this finding is warranted given the analysis was not pre-specified.

One plausible interpretation of the nonsignificant findings of the pre-specified analyses is that the tailored content of MAPS encouraging men to engage in and adhere to telephonic collaborative care was no more effective in this regard than the non-tailored brief text encouragement in the active control intervention. While most research evidence suggests the general superiority of tailored interventions in improving targeted health outcomes, some studies found no significant advantage of tailoring (Noar et al., 2007).

Still, we believe aspects of our trial dictate a circumspect interpretation of the findings to avoid foreclosing prematurely on the potential promise of MAPS - particularly given the high prevalence and devastating impact of suicide and the dearth of other proven preventive approaches. As noted, trial enrollment was difficult, requiring calls and letters to over four thousand men to enroll only 48 (vs. target of 304), resulting in low power to examine outcomes and raising the possibility of Type II error. Other trials of interventions aimed at helping suicidal men have suffered similar recruitment challenges, reflecting the difficulty of identifying suicidal men and engaging them in such research (Bhar et al., 2013). Clearly, methodological innovation is needed to recruit at-risk men to primary care prevention trials in a more efficient manner. In retrospect, it might have been desirable not to restrict enrollment to men with active thoughts of suicide, as we needed to screen nearly 4100 patients to yield 32 participants. Moreover, although it is well-established that self-reported suicide ideation confers risk for suicide mortality (Brown et al., 2000), people who under-report or conceal suicide ideation are at elevated suicide risk as well (Duberstein, 2001; Heisel et al., 2006; Podlogar et al., 2017). Taken together, the requirement that participants endorse recent active suicide thoughts on a questionnaire appeared may be a key driver of the small sample. Outside of specialty mental health settings, under-reporting is

partially motivated by fear of hospitalization or intensive mental health treatment (Jerant et al., 2019). Thus, as others have suggested, clinicians should attend to suicide risk even in the absence of reported suicide ideation (Canadian Coalition for Seniors' Mental Health, 2008). Future primary care-based studies should consider expanding the inclusion criteria beyond self-report on an initial questionnaire of suicide risk, for example by screening for other risk factors, such as alcohol and substance abuse, depression, and anxiety (Lish et al., 1996).

Also, worth underscoring is that men in both trial arms were routinely offered telephonic collaborative care by a study are manager following their study visit, bypassing the usual process in primary care practices in which the PCC decides whether to offer telephonic collaborative care. By contrast, in typical primary care practice, it is of course unlikely that men not discussing suicide during a visit would be referred to telephonic collaborative care aimed at addressing factors contributing to suicide thoughts. Accordingly, having study care managers routinely offer telephonic collaborative care to all men in the trial was not a part of our originally proposed protocol. Rather the IRB required this change, reportedly driven by concerns about safeguarding individual participants. Unfortunately, this decision may have, in part, inadvertently created longer-term societal harms, such as slowing the dissemination of an effective intervention. Offering telephonic collaborative care to all participants in this manner may have obscured salutary effects of MAPS on telephonic collaborative care enrollment and adherence and, therefore, the outcomes.

Given evidence of variability across IRBs (Andriessen et al., 2019) it is plausible that a different IRB may not have demanded significant changes to our protocol. Unfortunately, our experience suggests that in the current regulatory climate obtaining ethical approval of a trial employing PCC referral of men (or other patients) with suicide thoughts to telephonic collaborative care (or other appropriate forms of follow-up care) would be difficult. Ethics committees' requests that researchers offer at-risk participants additional resources can obscure salutary effects of interventions, increase the costs of care, and also unintentionally subvert the scientific review process when investigators are asked to modify a peer-reviewed protocol for which they have received extramural funding. We believe there is a need for reconsideration of IRB requirements for handling control participants in suicide prevention trials, to avoid possible net societal harm due to potential spurious rejection of effective novel approaches. Others researching suicide prevention approaches have raised similar concerns (Hom et al., 2017), underscoring the need for more communication between researchers, patients, patient advocates, and IRB members. Research ethics is an ongoing negotiated process (Lakeman & FitzGerald, 2009). Just as there has been a movement away from medical paternalism toward shared decision making in the patient-physician relationship (Coulter, 1999; Entwistle et al., 2010), a similar shift in the relationship between researchers and IRBs could be fruitful, particularly for studies conducted in healthcare settings. It might be useful to develop and disseminate a sustainable, centralized consultation service that could be used by IRBs nationwide to guide their decision-making.

There are several other points worth considering that may have contributed to our difficulties with recruitment. First, that the research study itself, much like any other intervention study, required work on the part of the PCC staff. Studies like this likely require a small amount of protected/dedicated time completing study-related tasks. Researchers could negotiate

such carve out time with practice medical directors/administrators ahead of the study and could provide practices with funding to offset any resulting small losses in clinical revenue, as feasible within the confines of already tight research grant budgets. Second, staff and administrative buy-in of the project is likely crucial to its success. In future studies, it would be wise to work with staff to encourage staff to establish a culture of research participation in the practices. This was particularly difficult in this study, given that providers were located across multiple practices.

Apart from sample size and design issues, our trial had additional limitations. The patients (and PCCs) were drawn from primary care offices in a single health system in one region of California, and so generalizability to other settings is uncertain. Also, in recruiting and enrolling men to the study, we did not distinguish acute (new onset) from chronic, recurrent active suicide thoughts. While it seems plausible that the effects of MAPS might differ with the acuity of suicide thoughts, our small sample size precluded conducting stratified analyses to explore this issue.

Conclusion

The tailored MAPS program for middle-aged men with suicide thoughts, previously shown to increase engagement with PCCs around this taboo topic, was found to be no more effective than active control in reducing suicide thoughts and preparatory behaviors over 3 months in pre-specified outcome analyses. The current findings require cautious interpretation, given two key difficulties we faced in conducting the trial. One key difficulty was slow patient recruitment, resulting in a small sample size that fell well short of target, limiting statistical power in our pre-specified analyses. A post-hoc analysis examining the effects of MAPS on suicide preparatory behaviors had more promising findings, though cautious interpretation is indicated. A second key difficulty we faced was the IRB mandate that study personnel routinely offer collaborative care to all men in the trial, narrowing post-intervention management differences between trial arms. Employing the usual approach in primary care practices of relying on PCCs to refer patients to collaborative care may have more effectively isolated the potential benefits of MAPS. Such an approach would require relaxation of IRB expectations for risk reduction among patient participants in primary care-based suicide prevention trials.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

We have no conflicts of interest to disclose. The trial described in this paper was registered in ClinicalTrials.gov (identifier NCT02986113). This work was supported by cooperative agreement U01CE002664 from the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. Additional funding was provided by the UC Davis Behavioral Health Center of Excellence and Department of Family and Community Medicine. The CDC participated in the design and conduct of the study. Neither the CDC nor the other funders had a role in the collection, management, analysis, or interpretation of data, or in the decision to submit the manuscript for publication. The conclusions and findings in this report are those of the authors and do not necessarily represent the official position of the CDC. We are indebted to the primary care offices, PCCs, and patients who participated in the trial. We are also grateful to: Peach Dounias, BS, Sherry Hao, BA, Lauren Walker, MSW, and Zachary Weiss, BA, who facilitated patient recruitment and participation; Simon Dvorak, BA, Charles Turner, PhD, and Robert

Burnett, MA, who programmed the study interventions; the actors who performed in videos incorporated in MAPS, trained by Lynn Baker-Nauman, MA; John Linck, who produced the videos; Patricia Areán, PhD, co-developer of Problem Solving Therapy-Primary Care (PST-PC), for assisting us with modifying the manual to focus on middle-aged men with suicide thoughts; Grace Liu, PhD, who trained the care managers to provide PST-PC; and Anthony Pisani, PhD and Wendi Cross, PhD, for allowing us to offer the educational videos they created to PCCs in the trial.

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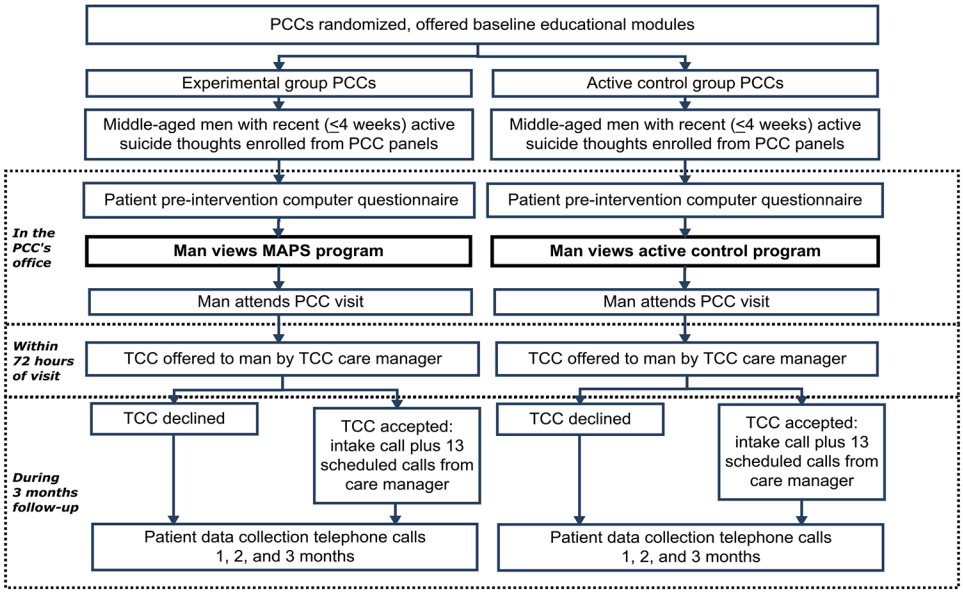

Figure 1. Overview of the randomized controlled trial design

Abbreviations: MAPS, Men and Providers Preventing Suicide; PCC, primary care clinician; TCC, telephone collaborative care

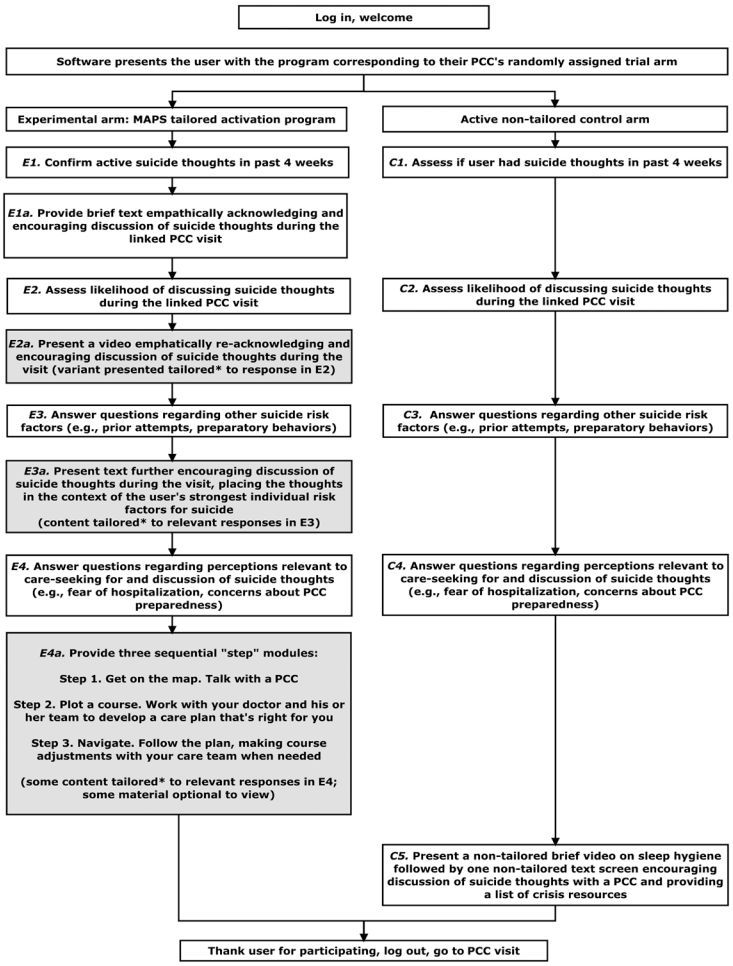

Figure 2. Overview of content and sequence of MAPS tailored program and nontailored control program

Abbreviations: MAPS, Men and Providers Preventing Suicide; PCC, primary care clinician

*Basic structure of tailoring in each module: (1) give all users brief feedback tailored to their response(s) to relevant question(s); (2) offer the option to view more-detailed information

Figure 3. Flow of participants through the trial

Abbreviations: PCC, primary care clinician; TCC, telephone collaborative care

Table 1

Characteristics of the Study Sample

Characteristic	Active non-tailored control arm (*N*=27)	MAPS (experimental) arm (*N*=21)	*p* value
Age, years, mean (*SD*)	55 (10)	56 (13)	0.82
Race/ethnicity, no. (%)			0.23
Hispanic (any race)	5 (19)	1 (5)	
Non-Hispanic White	19 (70)	18 (86)	
Non-Hispanic Black	2 (7)	0 (0)	
Non-Hispanic Other	1 (4)	2 (10)	
Education level, no. (%)			0.81
High-school graduate or less	1 (4)	0 (0)	
Some college	10 (37)	8 (38)	
College graduate	11 (41)	8 (38)	
Any graduate courses	5 (19)	5 (24)	
Annual household income, no. (%)			0.44
<$20,000	2 (7)	0 (0)	
$20,000-$34,999	2 (7)	2 (10)	
$35,000-$74,999	7 (26)	6 (29)	
$75,000-$124,999	4 (15)	6 (29)	
≥$125,000	12 (44)	6 (29)	
Decline to answer	0 (0)	1 (5)	
Sexual orientation, no. (%)			0.10
Heterosexual	26 (96)	16 (76)	
Gay	1 (4)	3 (14)	
Other	0 (0)	2 (10)	
Marital status, no. (%)			0.83
Married	20 (74)	14 (67)	
Widowed	1 (4)	1 (5)	
Divorced	2 (7)	2 (10)	
Separated	1 (4)	0 (0)	
Never married	3 (11)	4 (19)	
Living alone, no. (%)	5 (19)	5 (24)	0.65
Practice any religion/faith, no. (%)	6 (22)	6 (29)	0.61
Toughness score, standardized, mean (SD) [a]	0.1 (0.5)	−0.2 (0.8)	0.12
Self-rated health, no. (%)			0.38
Excellent	1 (4)	0 (0)	
Very good	8 (30)	2 (10)	
Good	7 (26)	9 (43)	
Fair	10 (37)	9 (43)	
Poor	1 (4)	1 (5)	
No. of medical conditions, mean (SD) [b]	3.3 (1.4)	3.1 (1.9)	0.75

Characteristic	Active non-tailored control arm (*N*=27)	MAPS (experimental) arm (*N*=21)	*p* value
No. of mental health conditions, mean (SD) [c]	2.7 (1.7)	3.3 (1.9)	0.23
AUDIT-C score, mean (SD)[d]	3.1 (2.6)	2.4 (2.1)	0.31
Recreational drug use past year, no. (%)			0.32
Never	19 (70)	10 (48)	
Less than monthly	4 (15)	3 (14)	
Monthly	0 (0)	1 (5)	
Weekly	0 (0)	1 (5)	
Daily or almost daily	4 (15)	6 (29)	
PHQ-9 score, mean (SD) [e]	13.2 (7.1)	14.1 (6.7)	0.65
PTSD-PC score, mean (SD) [f]	1.4 (1.3)	1.5 (1.4)	0.84
SSI scores, mean (SD)			
Total [g]	11.5 (6.7)	9.7 (6.9)	0.37
Suicide preparatory behaviors scale [h]	2.0 (1.7)	2.1 (2.1)	0.79
Suicide intent now, mean (SD) [i]	0.6 (1.0)	0.9 (1.5)	0.48
Any lifetime suicide attempt, no. (%)	5 (18.5)	4 (19.0)	0.96

Abbreviations: AUDIT-C, Alcohol Use Disorders Identification Test; MAPS, Men and Providers Preventing Suicide; PHQ-9, Patient Health Questionnaire; PTSD-PC, Primary Care Posttraumatic Stress Disorder screen; SSI, Scale for Suicide Ideation; SD, standard deviation

[a] 17-item scale, possible score range 17-85, higher scores=higher gender-linked toughness self-perceptions

[b] From a count of 11 conditions: arthritis/rheumatism, chronic or recurring painful condition, hearing or vision problem, neurological problem, hypertension, heart problem, human immunodeficiency virus infection/acquired immunodeficiency syndrome, diabetes, lung problem, cancer, or sleep problem

[c] From a count of 8 conditions: eating disorder, depression, anxiety disorder, bipolar disorder, posttraumatic stress disorder, psychosis, childhood sexual abuse, alcohol or drug problem

[d] 3 items, possible score range 0-12, scores of >4 considered optimal for identifying hazardous drinking or active alcohol use disorders in men

[e] 9 items, possible score range 0-27, scores of 10 or greater are suggestive of clinical depression

[f] 4 items, possible score range 0-4, scores of >2 are suggestive of posttraumatic stress disorder

[g] 19 items, possible score range 0-38, higher scores are suggestive of higher risk for suicide

[h] 4 items, possible score range 0-8, higher scores are suggestive of higher risk for suicide

[i] Single item, 11-point response scale, 0 (low suicide intent now) to 10 (high suicide intent now)

Table 2

Follow-up SSI Preparatory Behaviors Scale Scores, Total SSI Scores, Report of Active Suicide Thoughts, and TCC Utilization

Characteristic	Active non-tailored control arm (*N*=27)	MAPS (experimental) arm (*N*=21)
Outcome measures		
SSI Preparatory Behaviors Scale score, mean (SD) [a]		
1 month [c]	1.6 (1.7)	1.2 (1.4)
2 months [d]	1.7 (1.7)	1.2 (1.8)
3 months [d]	1.4 (1.7)	1.7 (1.7)
Total SSI score, mean (SD) [b]		
1 month [c]	7.1 (6.3)	5.6 (6.6)
2 months [d]	6.3 (5.8)	4.4 (5.0)
3 months [d]	4.3 (5.2)	7.3 (6.5)
Report of recent (≤4 wks) suicide thoughts, no. (%)		
1 month [c]	16 (76.1)	11 (68.8)
2 months [d]	12 (52.2)	9 (56.2)
3 months [d]	10 (47.6)	12 (66.7)
TCC utilization		
Attended intake call (enrolled), no. (%)	17 (63)	15 (71)
TCC calls attended (out of 12), mean no. (%)	6.9 (57)	7.8 (65)

Abbreviations: MAPS, Men and Providers Preventing Suicide; SSI, Scale for Suicide Ideation; SD, standard deviation; TCC, telephone collaborative care

[a] 4 items, possible score range 0-8, higher scores are suggestive of higher risk for suicide

[b] 19 items, possible score range 0-38, higher scores are suggestive of higher risk for suicide

[c] *N*=26 for control, 21 for MAPS

[d] *N*=26 for control, 18 for MAPS