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Mia Skytte O'Toole, Mikkel B. Arendt, Christian M. Pedersen

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Running title: APP-ASSISTED TREATMENT FOR SUICIDE PREVENTION

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Mia Skytte O'Toole

Aarhus University

Mikkel B. Arendt

Aarhus University Hospital, Risskov

Christian M. Pedersen

Aarhus University Hospital, Risskov

Author note

Mia Skytte O'Toole, MSc, Ph.D, Associate professor, Department of Psychology and Behavioral Sciences, Aarhus University, Denmark;

Mikkel B. Arendt, MSc, Ph.D, Department Q; Depression and Anxiety Disorders, Aarhus University Hospital, Risskov, Denmark

Christian M. Pedersen, MSc, Leading psychologist, Department Q; Depression and Anxiety Disorders, Aarhus University Hospital, Risskov, Denmark.

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Correspondence concerning this article should be addressed to Mia Skytte O'Toole, Bartholins Allé 9, 8000 Aarhus C, Denmark. Phone: +45 61703523. E-mail: mia@psy.au.dk

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APP-ASSISTED TREATMENT FOR SUICIDE PREVENTION

Abstract

Suicide is a global public health problem and effective psychological interventions are needed. The objective of the present study was to evaluate the effect of an app-assisted suicide prevention treatment on suicide risk and depression. 129 participants were randomized to treatment as usual (TAU), consisting of psychotherapy adhering to the framework of Collaborative Assessment and Management of Suicidality (CAMS), with (TAU+APP, N=60) or without (TAU, N=69) access to a mobile application (i.e., "LifeApp'tite"). Suicide risk and symptoms of depression were assessed pre and post therapy, and at 4-month follow-up. The TAU+APP group showed a smaller decrease on self-reported suicide risk at the end of treatment, corresponding to a medium between-group effect size (p=.008, d=.46). At the 4-month follow-up this was only the case at the trend level, where the effect size was also of a smaller magnitude (p=.057, d=.30). No differences between the treatment groups were observed on selfreported depressive symptoms, either immediately following treatment (p=.732, d=.05) or at follow-up (p=.467, d=.11). The unexpected negative effect concerning suicide risk points to crucial consideration of issues pertaining to timing, dosing, and content when adding new technology to existing treatments both in this and other populations.

Key words: suicide; depression; psychology; randomized controlled trial; internet therapy

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Highlights

- 129 participants were randomized to treatment with and without access to an app
- Access to the app resulted in poorer effects on self-reported suicide risk
- Much caution should be taken when adding new technology to existing treatments

Testing an app-assisted treatment for suicide prevention in a randomized controlled trial:

Effects on suicide risk and depression

Suicide is a global public health problem with close to one million individuals dying from suicide annually and 20 times more suicide attempts (Scott & Guo, 2012). Reducing suicidal ideation and preventing suicide attempts and suicide have thus been the primary aim of a growing number of psychosocial interventions (Comtois et al., 2011; Hawton et al., 2016; Scott & Guo, 2012; Turecki & Brent, 2016; Zalsman et al., 2016), demonstrating positive results across a variety of settings (e.g., outpatient care, inpatient units) and populations (e.g., youth and adults with and without other psychopathology). However, this body of literature is still relatively small and suffers from a number of methodological limitations including non-randomized designs, a failure to replicate studies, and concerns around the generalizability (Hawton et al., 2016; Turecki & Brent, 2016).

In recent years, psychotherapy research has seen a rapid growth in therapies incorporating web and mobile applications (i.e., 'apps'), and previous research indicates that such internet app services can be used effectively as both stand-alone treatments and supplements to more established treatments for a variety of psychiatric conditions, such as depression, anxiety, and stress (e.g., Andersson et al., 2014; Barak, Hen, Boniel-Nissim, & Shapira, 2008; Donker et al., 2013). A number of benefits to these web-/app-based treatments include the flexibility of use (e.g., at home), proximity of help, ability to repeat certain lessons/modules, potential of reaching populations that otherwise would not have access to mental health services, dissemination of highly specialized treatment methods, and cost-effectiveness (e.g., Andersson et al., 2014; Donker et al., 2013).

Treatments aimed at suicide prevention have also begun to explore the utility of web-/app-based or –assisted treatments (e.g., Donker et al., 2013; Lai, Maniam, Chan, Ravindran, & Res, 2014). A recent review showed preliminary evidence of the benefit of web-based interventions within this population (Lai et al., 2014), however, the review only included two randomized controlled trials (RCTs; Christensen et al., 2013; van Spijker, Majo, Smit, van Straten, & Kerkhof, 2012; van Spijker, van Straten, & Kerkhof, 2014), with only one of these primarily targeting suicide prevention. Another review (Menon, Rajan, & Sarkar, 2017) was able to locate an additional RCT, testing the effect of a mobile phone-based psychotherapy on individuals following hospitalization for suicide attempt (Marasinghe et al., 2012), finding no effect on suicidality or depressive symptoms. Finally, a study by Franklin and colleagues (2016) across three different studies tested the effect of a game-like app against a control app and found a significant effect of the game-like app on reductions in suicide plans and suicidal behaviors but not suicide ideation. The detected effects were not maintained at the 1-month follow-up.

Taken together, more studies are clearly needed before reaching any conclusions as to the effectiveness of web-/app-based and assisted suicide prevention treatments. As of now, only two RCTs exist, and the present study thus adds to this very young field. Our aim was to test the potential augmenting effect of a mobile application (i.e., *LifeApp'tite*), containing functionalities aligning with the content of therapy, ensuring fast access to a number of important tools (e.g., safety plan), and designed to serve as a supporting guide through additional psychoeducation and various therapeutic methods (e.g., problem-solving). Many individuals carry their smartphone most of the time, and a mobile application is therefore not only portable but also often readily available. As such, it provides great flexibility of use and holds the potential to improve adherence to treatment (e.g., Donker et al., 2013; Harrison et al., 2011). For individuals at risk of

death by suicide, the availability and portability may be of special value in case of suicidal impulses and acute suicidal thoughts.

Aim of the study

The primary objective of this study was to compare the effect between treatment as usual with (TAU + APP) and without (TAU) the assistance of the mobile application (i.e., LifeApp'tite) on individuals referred to out-patient suicide prevention treatment. We hypothesized that the TAU + APP group, compared with the TAU group, would show a larger decrease on the two primary outcomes, namely suicidal risk and symptoms of depression. This was hypothesized to be the case both following the acute treatment period and at 4-month follow-up. In addition, a number of moderation analyses were planned, where the aim was to investigate if a potential interaction effect was moderated by gender, age, and usage of the mobile application, measured as total number of clicks and total number of methods used, and evaluation of the mobile application.

Material and methods

Participants

The current study took place at a specialized outpatient suicide prevention clinic located at a psychiatric university hospital in Denmark from April 2014 through November 2016. The clinic provides psychosocial therapy for people at risk of suicide, typically presenting with adjustments disorders and mild to moderate depression. Inclusion criteria were: Referral to evaluation/treatment at the clinic due to current suicidal thoughts with or without a history of suicide attempt, age between 18 and 65, access to a personal smartphone supporting the mobile application, and presenting with symptoms where a brief psychotherapeutic out-patient intervention was deemed appropriate. Symptoms of mild to moderate anxiety, depression and

adjustment difficulties were allowed. Exclusion criteria were current severe psychopathology (e.g., severe depression, bipolar disorder, primary psychotic disorder), current substance abuse, need for inpatient treatment, and participation in other relevant psychotherapy. All participants were diagnostically screened, assessed with the Major Depression Inventory (MDI; Olsen et al., 2003), and discussed with a medical specialist in psychiatry at a weekly internal conference. All formal diagnoses were based on ICD-10 criteria (WHO, 1992).

Expecting a small effect size (d = 0.2), an a priori power calculation required a total number of 214 participants to be able to detect a significant between-group effect from pre to immediately post therapy with a 2 (time) x 2 (groups) analysis of variance. During the study period, fewer than expected participants were eligible for inclusion and the inclusion period was therefore terminated before reaching the target (N = 129).

Materials

Primary outcomes. Suicide risk was measured by the Suicide Status Form II-R (SSF; Conrad et al., 2009; Jobes, Jacoby, Cimbolic, & Hustead, 1997). The scale consists of six items rated on a 5-point Likert scale, including psychological pain, stress, agitation, hopelessness, self-hate, and overall risk of suicide. Cronbach's alpha for the first completed SSF was .74.

Depression was measured by MDI (Olsen et al., 2003). The scale consists of 10 items, however, 2 items are divided into two subitems (appetite and sleep rated as increased and decreased) where only the highest scores of those items are included in the total score. Cronbach's alpha for the first completed MDI was .80. Both primary outcomes exist in authorized and validated Danish versions.

Secondary outcomes and moderators. App evaluation was measured on a 6-point scale from -3 to +3 at the 4-month follow-up. Participants were asked to evaluate their perceived role

of the app in the psychotherapeutic intervention from negative to positive. <u>Total app activity</u> was calculated as the sum of all clicks regardless of the type of click. <u>Usage of methods library</u> was calculated as the mean number of methods used. There had to be at least one click inside a specific method's module to count as usage of that particular method. The total number of methods offered was 43. See description of methods below.

Intervention

Treatment as usual (TAU). The treatment provided at the out-patient clinic is an eclectic, supportive, problem-solving oriented psychotherapy, adhering to the framework of Collaborative Assessment and Management of Suicidality (CAMS; Erlangsen et al., 2015; Jobes, 2016). CAMS provides a therapeutic framework for suicide-specific assessment and treatment of a patient's suicidal risk, cutting across theoretical orientations and disciplines, ensuring a continuous focus on suicide prevention. Compared to no therapy, the treatment offered in this study has been found to be effective in lowering the risk of self-harm and death (Erlangsen et al., 2015). A typical intervention at the clinic runs over the course of 8 sessions, typically planned as weekly sessions, but the specific number of sessions is at the discretion of the therapist to decide. During the intervention period, six therapists provided treatment. Five were clinical psychologists and one was a social worker. All had more than 4 years of work experience, and all met for 3 hours of supervision per month. Supervision was led by the leading psychologist and/or a medical doctor and concerned diagnostic, medical, and treatment issues.

LifeApp'tite Mobile Application. The mobile application was designed to serve a number of functions. First, it provided psychoeducation for both patient and their loved ones concerning suicidal thoughts and ways to handle situations and reactions pertaining to such. Second, a number of self-rating scales were available, including MDI and SSF as described above, and the

mobile application sent out automated notifications as reminders of questionnaire completion during the active treatment period. In addition, users were asked to complete daily records of their sleep, appetite and stress levels. Third, a so-called safety plan (Stanley & Brown, 2012), describing specific actions to be taken in case of severe suicidal thoughts and impulses between the session, was developed in collaboration between therapist and patient. Fourth, users were asked to create a digital hope kit, containing positive memories and thoughts for times of overwhelming hopelessness. Fifth, quick access to an overview of places to seek help in case of severe suicidal thoughts. Sixth, a methods library divided into two sections of self-help exercises. One section consisted of methods targeting current issues, the other methods for planning and creating a better life. The specific methods included problem-solving, changing perspectives, distraction, mindfulness and acceptance, distraction, self-soothing, decreasing social isolation, planning pleasurable activities, and strengthening social competences. The mobile application notified the user daily to rate their mood after which it suggested the use of a method based on random generation.

The mobile application was developed designed and developed in collaboration between Christian Møller Pedersen (3rd author) from the Suicide Prevention Clinic and a local software company. This company was also in charge of technical support and data handling during the study period.

Statistical analyses

Mixed linear models (MLMs) were chosen to compare groups over time on the two dependent variables. All MLMs were based on the intent-to-treat sample, and participants appeared with their number of completed records without any data imputation or other handling

of missing records (cf. Chakraborty & Gu, 2009). Given the varying number of sessions completed, MLMs are especially suited for analyzing this type of data.

A 2-level model with time nested within individuals was specified. The time variable went from 1 to 25, corresponding to the maximum number of sessions. Fixed effects were specified for intercept, time, group (TAU or TAU+APP), and a time × group interaction. All models also included a random intercept and slope, as this improved the model fit evaluated by a significant change in the -2LL fit statistics (cf. Heck, Thomas, & Tabata, 2010). The time variable was entered as a log-transformation of the time points as this improved the model fit, which is sometimes the case in psychotherapy research, where the steepest change occurs at the beginning of therapy (cf. Tasca, Illing, Joyce, & Ogrodniczuk, 2009). A significant intervention effect is indicated by a 2-way interaction between treatment group and time.

A number of treatment moderators were then explored as either 2-way interaction terms (time * moderator), when measures were only available in the treatment group (i.e., total number of clicks, total number of methods used), or 3-way interaction terms (time * group * moderator), when measures were available in both groups (i.e., gender and age).

When detecting a significant between group difference on the primary outcomes, a reliable change index was calculated (cf. Jacobson & Truax, 1991).

Effect sizes were expressed as Cohen's d, where 0.2, 0.5, and 0.8 were considered a small, medium, and large effect size, respectively. Cohen's d was derived from the F-test calculated as $d = 2*\sqrt{(F/ddf)}$ (Verbeke & Molenberghs, 2009). All MLMs were estimated with the maximum likelihood method, and IBM SPSS statistics version 24 (IBM, 2016) was used for all analyses.

Mean substitution was chosen as the method to handle single missing items on the two dependent variables (cf. Schafer, Graham, & Psychol, 2002). If a case had more than 50% missing data on the scale, no mean substitution was performed.

Procedures

During the study period, all patients at the clinic were assessed for eligibility. Patients fulfilling the inclusion criteria were orally informed about the project during the first treatment session and also received written information. Upon signed consent, participants were randomized in an unrestricted manner to either the TAU+APP or TAU group. Sealed envelopes were prepared, each holding one of the two randomization results. An administrative assistant at the clinic, unaware of the content of the envelopes, would pick an envelope and open this in the presence of the participant, and all participants were thus aware of condition assignment. Participants randomized to the TAU+APP group were asked to download the mobile application before the second treatment session, where 30 extra minutes were allocated to the introduction of the mobile application. After that, it was at the discretion of the therapists and their clinical evaluation to decide how much and when to use the app. In both groups, the MDI and SSF were completed before each session. Participants randomized to the TAU+APP group were encouraged to complete the questionnaires via the mobile application, whereas participants in the TAU group completed the questionnaires in the beginning of each session. At the final session, participants were informed that they would receive a 4-month follow-up letter with an MDI and SSF to be completed along with a number of questions concerning treatment evaluation to be returned in a stamped envelope. All 4-month follow-up questionnaires were paper questionnaires. Participants were not compensated in any way for participation.

The study protocol and all study procedures were registered and approved by the national data protection agency and the regional ethics committee (#M-2012-630-12)¹.

Results

274 individuals were informed about the project and invited to participate. Of these, 145 declined participation, and the remaining 129 individuals were randomized to either TAU (N = 69) or TAU+APP (N = 60). Of the 129 individuals, 65 (50%) completed the 4-month follow-up measure. See participant flow in Figure 1. Participants were considered treatment drop-outs if they completed less than three sessions of therapy. No dropouts were due to serious adverse instances during treatment, but other specific reasons for dropout were not systematically collected.

There was no gender difference between non-participants (57% women) and participants (65% women), $\chi 2(1)=2.1$, p=.148. However, non-participants were significantly older (M=32.4, SD=12.8) than participants (M=28.7, SD=9.5), t(272)=2.7, p=.008. Due to the difference in age, main analyses were conducted with and without age as a covariate.

********Insert Figure 1 about here******

As for the included participants, the most prevalent psychiatric diagnosis (based on ICD-10) was adjustment disorder (F43.2). Ninety-six percent of participants in the TAU group, received a primary adjustment disorder diagnosis, compared with 93% in the TAU+APP group. Other diagnoses given were: Major depressive disorder, single moderate episode (F32.1), major depressive disorder, recurrent, moderate episode (F33.1), and mixed and other personality disorders (F61.1). The two groups did not differ on marital status, previous suicide attempt,

¹ The study protocol can be obtained by e-mailing third author Christian Møller Pedersen: christian.pedersen@ps.rm.dk

previous treatment, age, gender, completed number of sessions, or severity on the first MDI or SSF completed, and there was no difference in the distribution between the two groups of participants with and without a personality disorder ($\chi 2(1)=0.7$, p=.408). However, there was a trend toward more participants in the TAU+APP group being a student or employed (p=.052). See Table 1.

Participants had an average of 4.4 (SD = 4.0) missing SSF ratings and an average of 3.4 (SD = 3.7) missing MDI ratings. Neither baseline SSF, r < .01, p = .987, nor baseline MDI, r = .04, p = .703, was associated with the number of missing records, thus not violating the assumption of data missing at random (Snijders & Bosker, 2012).

Out of the 60 patients randomized to the TAU+APP group, 50 participants (83%) were active on the mobile application as measured by any number of clicks. Within the group that had been active on the mobile application as indicated by any clicks at all, the mean number of total clicks was 297.9 (SD=180.3). Twenty-three participants (38%) used the methods library. The mean number of methods used within the group that had used any method was 4.0 (SD=2.6). Participants used methods pertaining to six categories, including problem-solving, changing perspectives, decreasing social isolation, planning pleasurable activities, and strengthening social competences. Participants evaluated the mobile application to play a neutral role, with a mean score of .7 (SD=1.8) on a 6-point scale from -3 to +3.

*****Insert Table 1 about here****

Primary outcomes

Means and standard deviations at the different time points for the two primary outcomes are reported in Table 2. A significant main effect of time on SSF was found across the whole intervention period, where self-reported suicide risk decreased, F(1,173.1) = 104.4, p < .001, d = .001

1.55, corresponding to a large effect size. A significant between-group effect was found immediately following therapy, indicated by a significant *time x group* interaction term in predicting SSF, F(1,138.7) = 7.2, p = .008, d = 0.46, 95% CI [0.86 to 5.67], corresponding to a medium effect size. The TAU + APP group experienced a smaller decrease on the SFF, F(1,351.1) = 65.0, p < .001, d = 0.86 compared with the TAU group, F(1,333.0) = 133.7, p < .001, d = 1.27. The results remained significant (p = .010) when controlling for age. 31 participants (45%) in the TAU group and 20 participants (33%) in the TAU+APP experienced reliable change. This difference was not significant, $\chi 2(1) = 1.8$, p = .179. At the 4-month followup, the interaction effects was only borderline significant, F(1,168.2) = 3.7, p = .057, d = 0.30, 95% CI [-0.05 to 3.37], again favoring the TAU group and corresponding to a small effect size. The results remained borderline significant (p = .062) when controlling for age. At this follow-up point, 20 participants (30%) in the TAU group and 13 participants (22%) in the TAU+APP group experienced reliable change. This difference was not significant either, $\chi 2$ (1)=0.9, p = .342.

Concerning MDI, the main effect of time across the whole intervention period was significant, F(1,158.9) = 133.7, p < .001, d = 1.83, showing a large decrease across groups in depressive symptoms. No differences over time between the two groups were detected on the MDI either post therapy, F(1,140.3) = 0.1, p = .732, d = 0.05, 95% CI [-3.83 to 5.44], or at the 4-month follow-up, F(1,153.2) = 0.5, p = .467, d = 0.11, 95% CI [-2.36 to 5.13]. This was true also when controlling for age.

*****Insert Table 2 about here****

Moderation analyses

Given that an interaction effect was only found on SSF, moderation analyses were only conducted with SSF as the dependent variable. Gender did not moderate the effect, as indicated by a non-significant 3-way interaction term, F(1,132.6) = 0.1, p = .818, d = 0.04, nor did age, F(1,157.2) = 0.2, p = .678, d = 0.07, or number of sessions, F(1,111.6) = 0.2, p = .680, d = 0.08, post therapy. Similar results were obtained when including the follow-up time point.

Concerning the participants that had used the mobile application measured as any type of clicks (N = 50), the total number of clicks was not significant at either post treatment, F(1,46.3) = 1.5, p = .228, d = 0.36, of follow-up, F(1,50.0) = 0.3, p = .559, d = 0.15, although favoring the individuals with *more* clicks. Looking at the individuals that had used the methods library (N = 23), the total number of methods used was not significantly associated with the effect, F(1, 19.1) < 0.1, p = .997, d = 0.01, post treatment. However, at the 4-month follow-up, although the analysis remained non-significant, F(1,16.6) = 1.3, p = .278, d = 0.56, the effect size was of a medium magnitude, favoring participants that used *fewer* methods. There were no differences between individuals using any methods or not in their baseline SSF, t(52) = 1.2, p = .244, and there was no correlation between number of methods used and baseline SSF t(21) = -.1, t = .818.

The evaluation of the mobile application did not moderate the effect at either post therapy, F(1, 41.7) = 0.1, p = .780, d = 0.09, or 4-month follow-up, F(1, 50.0) = 0.1, p = .770, d = 0.10.

Discussion

This study was a randomized controlled trial testing a mobile application's potential augmenting effect of a suicide prevention program for out-patients with suicidal ideation with or without previous suicide attempts. Contrary to the hypothesis, results showed that the group receiving the mobile application in addition to the standard treatment showed a smaller decrease

on self-reported suicide risk at the end of treatment, corresponding to a medium effect size (d=.46), compared with the TAU group. At the 4-month follow-up this was only the case at the trend level, where the effect size was also of a smaller magnitude (d=.30). No differences between the treatment groups were observed on self-reported depressive symptoms, either immediately following treatment or at follow-up.

The negative result concerning suicide risk immediately following treatment is a surprising finding, although only few studies have evaluated the effect of mobile applications in RCTs (Bakker, Kazantzis, Rickwood, Rickard, & Health, 2016; Donker et al., 2013). Given the design of the present study, the effect of the mobile application as a stand-alone treatment cannot be evaluated, and the discussion below therefore cannot address the mobile application's potential usefulness or adverse effects as such. Keeping this in mind, a number of possibilities for the detected negative effect of the mobile application must be considered.

First, the two groups received the same number of sessions, however, the focus on and work with the mobile application throughout the therapy may have limited the TAU+APP group's dose of the face-to-face treatment, previously established to be effective (Erlangsen et al., 2015). Thus, the negative result may not point to adverse effects caused by the mobile application itself, but rather reflect a lower dose of an otherwise effective treatment. However, this is difficult to determine since no measure concerning time spent on the mobile application was obtained.

Second, adverse effects could be hypothesized, when considering the fact that a vulnerable population in distress and likely to exhibit neuropsychological difficulties (Keilp et al., 2013), is asked to learn and use a new technology or program. This may simply be overwhelming, possibly preventing reduction in the domains pertaining to the suicide risk, such

as hopelessness and stress. Along the same lines, the specific methods may have been too difficult to use, or the rationale behind them not explained with sufficient clarity, which is imperative when working with this population (Jobes, 2016). At the same time, it is recommended that mental health mobile applications explicitly recommend activities and coping skills training (Bakker et al., 2016), and much more needs to be learned about when, how, and which when it comes to specific methods. Unfortunately, no qualitative measures were obtained that could have addressed participants' experience of the mobile applications' methods. Rather, we simply know from a quantitative perspective that participants evaluated the mobile application to play a neutral role.

Third, there was no manual or guidelines as to *how* the mobile application should be introduced and used throughout treatment, and we therefore do not know how well incorporated the mobile application was in the face-to-face treatment, and if this led to a positive or negative effect. This may have been a problem for the patient that did not understand the rationale behind and role of the mobile application (Jobes, 2016). The perceived role of the mobile application by the therapists was not evaluated, and some therapists may have found the incorporation of the mobile application problematic, causing extra work and time away from the usual therapy. When it comes to the participants, the role of the mobile application was rated as neutral, however, this evaluation did not moderate the effect.

Fourth, a couple of issues related to timing should be considered. There is a potential timing issue concerning the daily notifications, asking the client to evaluate their mood. Such notification could be very helpful at times and at other times potentially turn the participant's focus inward where an external focus would be more adaptive (e.g., Aldao, Sheppes, & Gross, 2015). Another timing issue pertains to the time point of the introduction of the mobile

application itself. The mobile application may be better suited later in the treatment or following face-to-face treatment termination. However, the study by Marasinghe and colleagues (2012) did not detect an effect by adding a mobile treatment to the usual care as a follow-up.

Concerning clinical implications, this study points to important issues to consider when adding technology to face-to-face psychological interventions for this and other populations. Clinicians cannot rely on an assumption that addition of various technologies to existing treatments is unequivocally better, and more research is clearly needed when it comes to the question of timing, dosing, and content in order to understand if, when and how to integrate mobile application in psychotherapy. This study's findings on this particular population may point to self-reported suicide risk being more vulnerable to these issues.

The study suffers from a number of limitations. First, reasons for exclusion or decline of participation were not registered systematically. Second, individuals below the age of 18 were not included, and results may only generalize to the adult population. Third, inclusion of participants was terminated before the power calculated target, solely due to slower inclusion rate than expected within the available time frame for the study, and only half of the participants were retained through follow-up. Forth, although both modalities rely on self-report, it cannot be ruled out that the different assessment modalities (i.e., paper vs. app questionnaire) is a potential confound. Finally, therapists treated patients in both groups, and treatment fidelity was not evaluated. This also means that, although theoretically adhering to the same therapeutic framework (i.e., CAMS), specific interventions may have differed across the two groups.

Taken together, the potential augmenting effect of a mobile application on suicide prevention treatment was tested in a randomized controlled trial. Results showed that the group receiving TAU in combination with access to the mobile application experienced a smaller

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decrease in self-reported suicide risk immediately following treatment, but there was no between-group difference concerning symptom of depression. Adding technology to existing treatments can be problematic, and issues pertaining to timing, dosing, and content are crucial in researching both this and other populations.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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Aldao, A., Sheppes, G., & Gross, J. J. (2015). Emotion regulation flexibility. *Cognitive Therapy* and *Research*, 39(3), 263–278. https://doi.org/10.1007/s10608-014-9662-4

References

- Andersson, G., Cuijpers, P., Carlbring, P., Riper, H., Hedman, E., & World, P. (2014). Guided internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis. *World Psychiatry*, *13*(3), 288–295. https://doi.org/10.1002/wps.20151
- Bakker, D., Kazantzis, N., Rickwood, D., Rickard, N., & Health, J. M. (2016). Mental health smartphone apps: Review and evidence-based recommendations for future developments.

 **JMIR Mental Health*, 3(1), 1–31. https://doi.org/10.2196/mental.4984*
- Barak, A., Hen, L., Boniel-Nissim, M., & Shapira, N. (2008). A comprehensive review and a meta-enalysis of the effectiveness of internet-based psychotherapeutic interventions.
 Journal of Technology in Human Services, 26(2/4), 109–160.
 https://doi.org/10.1080/15228830802094429
- Chakraborty, H., & Gu, H. (2009). A mixed model approach for intent-to-treat analysis in longitudinal clinical trials with missing values. Research Triangle Park, NC.
- Christensen, H., Farrer, L., Batterham, P. J., Mackinnon, A., Griffiths, K. M., & Donker, T. (2013). The effect of a web-based depression intervention on suicide ideation: secondary outcome from a randomised controlled trial in a helpline. *British Medical Journal Open*, *3*(6), 1–9. https://doi.org/10.1136/bmjopen-2013-002886
- Comtois, K. A., Jobes, D. A., O' Connor, S. S., Atkins, D. C., Janis, K., Chessen, C. E., ...

 Yuodelis-Flores, C. (2011). Collaborative assessment and management of suicidality

 (CAMS): feasibility trial for next-day appointment services. *Depression and Anxiety*,

- 28(11), 963–972. https://doi.org/10.1002/da.20895
- Conrad, A. K., Jacoby, A. M., Jobes, D. A., Lineberry, T. W., Shea, C. E., Arnold Ewing, T. D., ... Kung, S. (2009). A psychometric investigation of the Suicide Status Form II with a psychiatric inpatient sample. *Suicide and Life-Threatening Behavior*, *39*(3), 307–320. https://doi.org/10.1521/suli.2009.39.3.307
- Donker, T., Petrie, K., Proudfoot, J., Clarke, J., Birch, M. R., Christensen, H., & Res, J. M. I. (2013). Smartphones for smarter delivery of mental health programs: a systematic review. *Journal of Medical Internet Research*, 15(11), 1–12. https://doi.org/10.2196/jmir.2791
- Erlangsen, A., Lind, B. D., Stuart, E. A., Qin, P., Stenager, E., Larsen, K. J., ... Nordentoft, M. (2015). Short-term and long-term effects of psychosocial therapy for people after deliberate self-harm: a register-based, nationwide multicentre study using propensity score matching.

 The Lancet Psychiatry, 2(1), 49–58. https://doi.org/10.1016/S2215-0366(14)00083-2
- Franklin, J. C., Fox, K. R., Franklin, C. R., Kleiman, E. M., Ribeiro, J. D., Jaroszewski, A. C., ...

 Nock, M. K. (2016). A brief mobile app reduces nonsuicidal and suicidal self-injury:

 Evidence from three randomized controlled trials. *Journal of Consulting and Clinical*Psychology, 84(6), 544–557. https://doi.org/10.1037/ccp0000093.supp
- Harrison, V., Proudfoot, J., Wee, P. P., Parker, G., Pavlovic, D. H., Manicavasagar, V., &
 Health, J. M. (2011). Mobile mental health: review of the emerging field and proof of concept study. *Journal of Mental Health*, 20(6), 509–524.
 https://doi.org/10.3109/09638237.2011.608746
- Hawton, K., Witt, K. G., Taylor Salisbury, T. L., Arensman, E., Gunnell, D., Hazell, P., ... van Heering, K. (2016). Psychosocial interventions for self-harm in adults. *Cochrane Database of Systematic Reviews*, *5*, CD012189. https://doi.org/DOI: 10.1002/14651858.CD012189

- Heck, R. H., Thomas, S. L., & Tabata, L. N. (2010). *Multilevel and longitudinal modeling with IBM SPSS. Quatative methodology series* (2nd ed.). New York: Taylor & Francis.
- IBM. (2016). IBM SPSS statistics. Armonk, NY: IBM Corp.
- Jacobson, N. S., & Truax, P. (1991). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology*, 59(1), 12–19.
- Jobes, D. A. (2016). *Managing Suicidal Risk. A Collaborative Approach* (2nd ed.). New York: Guilford Press.
- Jobes, D. A., Jacoby, A. M., Cimbolic, P., & Hustead, L. A. T. (1997). Assessment and treatment of suicidal clients in a university counseling center. *Journal of Counseling Psychology*, 44(4), 368–377.
- Keilp, J. G., Gorlyn, M., Russell, M., Oquendo, M. A., Burke, A. K., Harkavy-Friedman, J., & Mann, J. J. (2013). Neuropsychological function and suicidal behavior: attention control, memory and executive dysfunction in suicide attempt. *Psychological Medicine*, 43(3), 539–551. https://doi.org/10.1017/S0033291712001419
- Lai, M. H., Maniam, T., Chan, L. F., Ravindran, A. V, & Res, J. M. I. (2014). Caught in the web: a review of web-based suicide prevention. *Journal of Medical Internet Research*, *16*(1), 1–8. https://doi.org/10.2196/jmir.2973
- Marasinghe, R. B., Edirippulige, S., Kavanagh, D., Anthony, S., Mohamad, T. M. J., & Telecare, J. T. (2012). Effect of mobile phone-based psychotherapy in suicide prevention: a randomized controlled trial in Sri Lanka. *Journal of Telemedicine and Telecare*, *18*, 151–155. https://doi.org/10.1258/jtt.2012.SFT107
- Menon, V., Rajan, T., & Sarkar, S. (2017). Psychotherapeutic applications of mobile phone-

- based technologies: A systematic review of current research and trends. *Indian Journal of Psychological Medicine*, *39*(1), 4–11. https://doi.org/10.4103/0253-7176.198956
- Olsen, L. R., Jensen, D. V, Noerholm, V., Martiny, K., Bech, P., & Psychol, M. (2003). The internal and external validity of the Major Depression Inventory in measuring severity of depressive states. *Psychological Medicine*, *33*(2), 351–356.
- Schafer, J. L., Graham, J. W., & Psychol, M. (2002). Missing data: our view of the state of the art. *Psychological Methods*, 7(2), 147–177.
- Scott, A., & Guo, B. (2012). For which strategies of suicide prevention is there evidence of effectiveness? Copenhagen, Denmark: World Health Organization.
- Snijders, T. A. B., & Bosker, R. J. (2012). Multilevel Analysis: An Introduction to Basic and Advanced Multilevel Modeling. Comparative and General Pharmacology.
- Stanley, B., & Brown, G. K. (2012). Safety planning intervention: A brief intervention to mitigate suicide risk. *Cognitive and Behavioral Practice*, *19*(2), 256–264. https://doi.org/10.1016/j.cbpra.2011.01.001
- Tasca, G. A., Illing, V., Joyce, A. S., & Ogrodniczuk, J. S. (2009). Three-level multilevel growth models for nested change data: a guide for group treatment researchers. *Psychotherapy Research*, 19(4–5), 453–461. https://doi.org/10.1080/10503300902933188
- Turecki, G., & Brent, D. A. (2016). Suicide and suicidal behaviour. *Lancet*, 387(10013), 1227–1239. https://doi.org/10.1016/S0140-6736(15)00234-2
- van Spijker, B. A. J., Majo, M. C., Smit, F., van Straten, A., & Kerkhof, A. J. F. M. (2012).

 Reducing suicidal ideation: Cost-effectiveness analysis of a randomized controlled trial of unguided web-based self-help. *Journal of Medical Internet Research*, *14*(5), 1–14.

 https://doi.org/10.2196/jmir.1966

- van Spijker, B. A. J., van Straten, A., & Kerkhof, A. J. (2014). Effectiveness of online self-help for suicidal thoughts: results of a randomised controlled trial. *PLoS One*, *9*(2), 1–8. https://doi.org/10.1371/journal.pone.0090118
- Verbeke, G., & Molenberghs, G. (2009). *Linear mixed models for longitudinal data*. New York: Springer Science & Business Media.
- World Health Organization. (1992). The ICD-10 classification of mental and behavioural disorders: Clinical descriptions and diagnostic guidelines. Geneva: World Health Organization.
- Zalsman, G., Hawton, K., Wasserman, D., Van Heeringen, K., Arensman, E., Sarchiapone, M., ... Zohar, J. (2016). Suicide prevention strategies revisited: 10-year systematic review.
 Lancet Psychiatry, 3, 646–659. https://doi.org/10.1016/S2215-0366(16)30030-X

Figure 1. Participant flow diagram

Table 1

Participant descriptives

	TAU	TAU + APP	
	(<i>N</i> =69)	(N=60)	p
Percent married	40	49	.415
Percent employed/student	42	60	.052
Percent previous suicide	11	10	.832
attempt (in addition to current			
referral reason)			
Percent undergone previous	3	4	.801
treatment in the clinic	47		
Percent undergone any	21	22	.816
previous psychiatric treatment			
Age	29.3 (9.7)	28.1 (9.2)	.483
Percent women	44	40	.730
Suicide risk (SSF)	18.0 5.0)	18.7 (4.1)	.457
Depression (MDI)	32.9 (9.2)	34.5 (8.3)	.455
Number of sessions	10.4 (5.2)	9.4 (4.1)	.211



ACCEPTED MANUSCRIPT

APP-ASSISTED TREATMENT FOR SUICIDE PREVENTION

Table 2

Means and standard deviations at pre-therapy, post-therapy and follow-up

	Pre		Post		Follow-up	
	M (SD)		M (SD)		M (SD)	
	TAU	TAU+APP	TAU	TAU+APP	TAU	TAU+APP
Suicide risk (SSF)	18.0 5.0)	18.7 (4.1)	12.6 (5.6)	14.9 (5.7) 12	7 (5.8)	14.0 (5.2)
Depression (MDI)	32.9 (9.2)	34.5 (8.3)	21.1 (12.7)	22.6 (13.7) 18	3.1 (12.0)	20.5 (11.4)

Note. TAU=Treatment as usual without the mobile application; TAU+APP=Treatment as usual in addition to the mobile application.

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Highlights

- 129 participants were randomized to treatment with and without access to an app
- Access to the app resulted in poorer effects on self-reported suicide risk
- Much caution should be taken when adding new technology to existing treatments

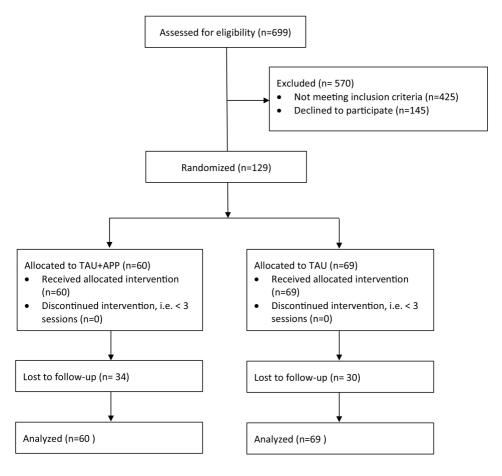


Figure 1