CHAPTER 6
DO PATIENTS BENEFIT FROM THE TRAINING OF MENTAL HEALTH PROFESSIONALS IN SUICIDE PRACTICE GUIDELINES? A CLUSTER-RANDOMIZED TRIAL

Background
Randomized studies examining the effect of suicide guideline implementation on patients are scarce.

Aims
To assess whether patients benefited from the structured implementation of suicide guidelines

Method
45 psychiatric departments were randomized. In the intervention condition, full staff of departments was trained with an e-learning supported Train-the-Trainer program. After the intervention, patients were assessed at intake and at three-months follow-up. Primary outcome was change in suicide ideation.

Results
For the total group of 566 suicidal patients, intention-to-treat analysis showed no effects of the intervention on patient outcomes at three-months follow-up. Suicidal patients with a DSM-IV diagnosis of depression (n = 154) did show a significant decrease in suicide ideation when treated in the intervention group. Also, patients in the intervention condition reported more often that suicidality was discussed during treatment.

Conclusion
Our findings demonstrate the potential of structured suicide guideline implementation on patients.

Declaration of interest
None
Introduction

Evidence-based practice guidelines should improve patient care. To strengthen suicide prevention in Dutch mental health care, the evidence-based multidisciplinary practice guideline for the assessment and treatment of suicidal behavior (PGSB) was issued in May 2012. The PGSB is based on various international guidelines on the assessment and treatment of suicidal behavior and two empirical reviews of the Scottish government and the Dutch health funding agency ZONMW funded a study on the implementation of psychiatric guidelines, and concluded that randomized controlled studies on the effect of implementation strategies on patients well-being and recovery are needed to adequately implement evidence and improve patient care.

Suicide prevention training has shown to improve knowledge, skills, and attitudes towards suicidal behavior of gatekeepers and mental health professionals. Also, professional and gatekeeper training in diagnosis and treatment of depressive disorder, likely results in a reduction of suicide rates. This might be explained by the strong association between a depressive disorder and suicide. However, the actual effects of a specific suicide practice guideline training on suicidality of patients has not yet been examined in a randomized controlled trial.

Considering the relevance for the PGSB for Dutch mental health care and the need for evidence on the effectiveness of guideline implementation, the Dutch health funding agency ZONMW funded a study on the implementation of the PGSB called PITSTOP suicide (Professionals in Training to STOP suicide). PITSTOP suicide is a cluster randomized controlled trial examining the effects of an e-learning supported Train-the-Trainer program (TtT-e) which content reflects the PGSB, delivered to multidisciplinary teams of mental health care departments. Departments were clustered in pairs on basis of patient characteristics to ensure comparability of experience with suicidal patients of professionals in both conditions. The Train-the-Trainer model is based on the Adult Learning Theory stating that the best resource for learning comes from peers, and on the Diffusion of Innovation Theory stating that people adopt new information better through their trusted social networks. TtT-e combines a one-day face-to-face training with an additional e-learning module. This form of blended learning is used extensively in medical education and has been found to be more effective when compared with traditional instructor-based training. We previously found that TtT-e resulted in approximately 10% improvement on confidence, knowledge and guideline adherence of mental health care professionals.

In the current study, we hypothesized that individual suicidal patients treated by professionals who were trained by the TtT-e program (intervention) would recover more quickly from suicidal ideation as compared with patients treated by professionals who were not trained via TtT-e (control) but received information on the release of the guideline via the usual methods (internet, conferences, workshops etc). Secondary outcomes were self-reported non-fatal suicide attempts and treatment satisfaction. As fostering a working relationship with the patient is the most important part of TtT-e, we hypothesized that all patients, whether they present suicide ideation at baseline or not, show more treatment satisfaction in the intervention condition than patients in the control condition.

Methods

Design and sample recruitment

The PITSTOP suicide trial has been described in detail elsewhere. In sum, PITSTOP suicide was a multicenter cluster randomized controlled trial. Clusters were care departments of Mental Health care Institutions throughout The Netherlands. Departments were considered eligible for participation if they treated patients of ≥18 years of age, if professionals felt a need for training in suicide prevention skills. Patients of included departments were eligible if they were ≥18 years of age and willing to provide a written informed consent. Whether a patient was able to enter the study was left to the discretion of the staff. Patients who were deemed emotionally and/or cognitively unable to complete questionnaires were excluded.

Matching and Randomization

Eligible departments were matched in pairs on basis of the main diagnostic DSM-IV category of patients treated in the department, and on comparable average length of treatment. Members of matched pairs were randomly
allocated to either implementation as usual IAU (control) or TtT-e + IAU (intervention). Binary randomization was performed by an independent researcher of the EMGO+ research institution who was not involved in the study. Patients were blind to the result, whereas professionals were not.

**Intervention**

In the intervention condition, complete multidisciplinary teams of mental health professionals were trained in the application of the guideline via a 1-day small interactive group program supported by e-learning modules (TtT-e) \(^4\). Personalized feedback was an important element of the training. The training was provided by peers, who were trained by experts/masters in the field of suicidology according to the PITSTOP training protocol. The PGSB recommendations served as the starting point to set the content of the TtT-e program. The PGSB recommends systematic investigation of the suicidal condition of patients by using the Chronological Assessment of Suicidal Events (CASE) interview \(^47\). Based on its outcome, risk and protection factors for suicide of individual patients are weighted. Subsequently, structured diagnosis, treatment strategy, and a safety protocol are determined. In the TtT-e program, the CASE interview was the overall framework for each of four role plays in which one trainee acted as a suicidal patient and the other trainee interviewed the ‘patient’ via the CASE interview.

**Data collection procedure**

If possible, patient data were collected via Routine Outcome Monitoring (ROM), an online assessment by which data on the effectiveness of treatment in everyday clinical practice are systematically collected \(^4\). In MHI’s not using ROM, data were collected by graduate students and/or research assistants using paper-and-pencil questionnaires. In the intervention condition, as soon as all staff was trained, newly admitted patients were assessed at admission or intake (T0) and subsequently three months after admission (T1). If a patient was discharged within three months, T1 was arranged just before discharge. In the control departments, T0 started at the time that the department was informed of the allocation outcome. At both T0 and T1, suicide ideation was measured with the first 19 items of the Beck Scale for Suicidal Ideation (BSS) \(^4\). Total score ranged from 0 to 38, a higher score reflects stronger suicide ideation. Frequency of self-reported non-fatal suicide attempts were assessed at admission (Did you ever do one or more suicide attempts?) and at T1 (Did you do one or more suicide attempts between now and the first questionnaire?). At T1, we also assessed treatment satisfaction with four items that had been established to measure the quality of therapeutic alliance. The first two items were: ‘How satisfied are you overall with your treatment?’ and ‘How would you evaluate your relationship with your care provider?’. These two items were rated from 0 to 10. The other two items were: ‘Was there any attention for your suicidal thoughts during treatment?’ and ‘How did your care provider deal with your suicidal thoughts?’. These two items were scored on a four-point scale ranging from 1= Yes/Good to 4= No/Poor. Finally, the main DSM-IV diagnosis of each patient was collected from their electronic health record.

**Ethics statement**

Written informed consent was obtained for all individual participants after the procedures had been fully explained. The study was approved by the Medical ethical commission of the VU Medical Center (2011/151) and was registered in the Netherlands Trial Register (NTR3092 www.trialregister.nl).

**Patient recruitment and follow-up**

The first patients were assessed at 20 January 2012. Last 3 months follow-up assessments were completed at 26 September 2013.

**Sample size**

For the primary outcome (change in suicide ideation) the number of patients that needed to be included was set to 423. This number is sufficient to find a small effect size (Cohen’s d) of 0.3, assuming an alpha of 0.05 and the statistical power of 1-Beta=0.80. A correction of 20% for clustering of effects within departments was applied.

**Statistical analyses**

Differences in baseline characteristics of patients who dropped out and those who did not were analyzed by using logistic regression.

**Suicide ideation and non-fatal suicide attempts**

For our primary analysis, change in suicide ideation, we selected only patients with suicide ideation at baseline (BSS > 0). Within this group of suicidal patients, baseline differences between the intervention and control group were described. Effects of the intervention on the BSS were analyzed on an intention-to-treat basis by using multiple imputation for missing values. We fitted a multilevel model with a random intercept at the department level. Score on the BSS at baseline was added as covariate and the randomization condition was the between subjects factor. A multilevel logistic
regression model was fitted to establish the effect of the intervention on self-reported non-fatal suicide attempt at T1. A subgroup analysis was done by repeating the same analysis for patients diagnosed with a depressive disorder and BSS > 0 at baseline. Results were presented using regression coefficients (b) or ORs, 95% confidence intervals and p-values. Cohen’s d’s represented the effect size of the TtT-e program.

Treatment satisfaction

The first two items on treatment satisfaction were analyzed by fitting linear multilevel models for all patients and, separately, for patients with baseline suicide ideation (BSS > 0). Data was analyzed on an intention-to-treat basis. Means, standard deviations and effect sizes were presented. Answers to the last two treatment satisfaction items were dichotomized by adding response option 1 and 2 into one response category (Yes/Good), and response 3 and 4 into another (No/Poor). All analysis were done with SPSS 21.

Results

CONSORT 2010 Flow Diagram

Figure 1 shows the flow of participants and departments through the trial, showing that 881 patients over 29 departments were included. Patients who were lost to follow-up were more likely allocated to the intervention condition (OR = 1.96 (95% CI 1.45-2.68), p < 0.01).
Table 1: Baseline characteristics of the total sample of patients. In % unless otherwise specified

<table>
<thead>
<tr>
<th>N(%)</th>
<th>Total group (n = 881)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention group</strong></td>
<td>484(55)</td>
</tr>
<tr>
<td><strong>Demographic</strong></td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>457(54)</td>
</tr>
<tr>
<td>Age (M,SD)</td>
<td>43(15)</td>
</tr>
<tr>
<td><strong>Education (n =540)</strong></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>72(13)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>363(67)</td>
</tr>
<tr>
<td>Higher</td>
<td>105(19)</td>
</tr>
<tr>
<td><strong>Living with partner</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>212(38)</td>
</tr>
<tr>
<td><strong>Born in the NL (n=434)</strong></td>
<td>409(93)</td>
</tr>
<tr>
<td><strong>Paid employment (n=550)</strong></td>
<td>80(14)</td>
</tr>
<tr>
<td><strong>Data collected with ROM</strong></td>
<td>287(32)</td>
</tr>
<tr>
<td><strong>Clinical characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Suicidal ideation (BSS &gt;0)</td>
<td>566(64%)</td>
</tr>
<tr>
<td>Attempted suicide (n=682)**</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>432(63)</td>
</tr>
<tr>
<td>Once</td>
<td>129(19)</td>
</tr>
<tr>
<td>More than once</td>
<td>121(18)</td>
</tr>
<tr>
<td><strong>Diagnosis (n=549)</strong></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>222(40)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>43(8)</td>
</tr>
<tr>
<td>Psychosis</td>
<td>51(9)</td>
</tr>
<tr>
<td>Personality disorder</td>
<td>77(14)</td>
</tr>
<tr>
<td>Substance dependence</td>
<td>89(16)</td>
</tr>
<tr>
<td>PTSS</td>
<td>22(4)</td>
</tr>
<tr>
<td>Eating disorder</td>
<td>45(8)</td>
</tr>
</tbody>
</table>

1 Data is missing for other patients

Table 1 shows baseline characteristics of all 881 included patients. 566 (64%) patients reported suicide ideation at baseline (BSS >0), and 250 (24%) patients reported a history of at least one suicide attempt.

Within this sample of 567 patients with suicide ideation at baseline, relatively more females were included in the intervention condition when compared to the control condition (Table 2). Also, the intervention condition contained more patients with a diagnosis of a personality disorder or an eating disorder, whereas the control condition contained more patients with a substance dependence disorder. Distribution of suicidal ideation and percentage of previous attempters within the suicidal sample were comparable between both conditions.
Suicide ideation results and non-fatal suicide attempts

Table 3: Mean changes in suicide ideation from baseline to follow up and effect sizes

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>B (CI 95%)</th>
<th>P</th>
<th>Effectsize</th>
</tr>
</thead>
<tbody>
<tr>
<td>total group suicidal</td>
<td>4.2 (13.4)</td>
<td>4.9 (10.5)</td>
<td>-0.68 (-0.26-1.21)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>patients N (intervention)=312 N (control)=254</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>suicidal patients with diagnoses of depression</td>
<td>8.4 (7.7)</td>
<td>4.8 (7.9)</td>
<td>3.41 (0.38-5.93)</td>
<td>0.008</td>
<td>0.4</td>
</tr>
<tr>
<td>N (intervention)=75 N (control)=79</td>
<td></td>
<td></td>
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</tbody>
</table>

Multilevel analysis showed no effect of the intervention on change in suicide ideation (b = -0.68, 95% CI -0.26-1.21, p > 0.05) or on frequency of self-reported attempted suicide between baseline and follow up (OR= 1.18, 95% CI 0.62-2.57, p > 0.05). However, in a subgroup of patients with a diagnosis of depression with presence of suicide ideation at baseline (n = 154, intervention = 75, control = 79), a significant effect on change in suicide ideation between conditions was found: suicidal ideation decreased 8.4 points between baseline and follow up in the intervention group, compared to a decrease of 4.8 in the control group (b = 3.41, 95% CI 0.38-5.93, p = .008, effect size = .4. (See Table 3). No effect of the intervention on self-reported attempted suicide was found within this subgroup (OR = 1.18, 95% CI 0.63-2.52). For any other subgroup (anxiety, personality, psychotic), numbers were too small or too unbalanced for any significant testing (Table 2).

Treatment satisfaction

Table 4: Mean treatment satisfaction at follow up for total group of patients

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>B (CI 95%)</th>
<th>P</th>
<th>Effectsize</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall satisfaction with therapy</td>
<td>6.8 (4.4)</td>
<td>6.8 (4.3)</td>
<td>-0.01 (-0.58-0.61)</td>
<td>n.s.</td>
<td></td>
</tr>
<tr>
<td>N = 484</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Satisfaction with relationship with therapist</td>
<td>6.9 (4.1)</td>
<td>7.4 (3.9)</td>
<td>0.61 (0.04-1.22)</td>
<td>0.01</td>
<td>0.4</td>
</tr>
<tr>
<td>N = 397</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

When analyzing the total group of patients, no significant effect on overall satisfaction with treatment was found (Table 4). The satisfaction with the relationship with the care giver was higher in the control condition when compared to the intervention condition (M (SD) intervention= 6.9 (4.1), M (SD) control = 7.4 (3.9), b = 0.61, 95% CI 0.04-1.22, p = 0.03, effect size = .4).

Since > 70% of the responses on the two items, “were suicidal thoughts addressed during treatment” and “how did your care giver deal with your suicidal thoughts”, were missing, we performed a complete case analysis only (Table 5). Suicidal thoughts were more likely to be discussed in the intervention condition when compared to the control condition (b = 1.78 CI 95% 1.12-2.93, p = 0.02, risk ratio = 1.3). No differences were found on the appraisal of the way the care giver dealt with suicidal ideations. When applying the same analysis for patients with suicidal ideation on baseline (BSS > 0), no significant effects of the intervention on any of the four items was found.

Sensitivity analysis

When comparing the analysis of the imputed data and the complete case data, all results were comparable, expect for “satisfaction with relationship with the therapist”. When using complete case analysis, no significant difference between intervention and control condition was found on that item (M (SD) intervention = 7.1(3.2), M (SD) control = 7.5 (3.6), b = 0.41, 95% CI -0.32-1.16, p = 0.2).

Discussion

This study examined the additional effects on patients of an e-learning supported Train-the-Trainer program (TtT-e) aimed at the structural implementation of the Dutch guideline on the assessment and treatment of suicidal behavior. TtT-e was found to result in a 10% improvement of confidence, knowledge and guideline adherence among professionals. We tested whether patients benefited from this 10% improvement of professionals.

For the total group of suicidal patients, no effect of the intervention was found on change in suicidal ideation or frequency of self-reported non-fatal suicide attempt(s) at 3 months follow up. As patients in the control group
also recovered significantly from suicidal ideation, any additional effect of TtT-e for the total group of suicidal patients was probably smaller than our sample size allowed us to detect. This is a common observation when implementing guidelines in psychiatry 12. We did find a significant effect of our intervention for the group of 154 patients diagnosed with a depression who were suicidal at baseline. This is in line with a multicenter trial that demonstrated the effectiveness of depression guideline training of general practitioners on decline of suicide ideation among depressed elderly patients 13. The effect of the intervention on only the group of depressed suicidal patients might be explained by the focus of TtT-e on making contact and discussing suicidality of the training program, which might be more appropriate for suicidal patients with a depressive disorder and less for suicidal patients with, for example, a borderline or psychotic disorder.

No effect of our intervention was found on overall satisfaction with the treatment. Patients in both conditions appeared to be quite satisfied with their treatment, making it difficult to achieve a significant increase in overall treatment satisfaction by training professionals in suicide guideline adherence. When analyzing the imputed data, patients in the control condition appeared to be more satisfied with their care giver. As no significant effect was found when analyzing completers only data, and a sensitivity analysis found no other discrepancies between imputed data and completers only, we argue that this found effect might be explained by the difficulty to impute data for a single item on subjective experience 10.

We have shown that patients reported more often that suicidality was discussed during treatment, which indicates that we were able to change behavior of professionals in individual treatment sessions. This is in line with another randomized study that found that general practitioners assessed more patients for suicide risk after a tailored depression guideline implementation 10.

Limitations and strengths

Patients who were lost to follow-up were more likely allocated to the intervention condition. This might be explained by the fact that departments in the intervention condition seemed to be more motivated and successful to start data collection, resulting in the inclusion of more patients at baseline. Some of these patients might have had more severe levels in pathology, and were therefore more likely to drop out at follow-up. Although MHI institutional boards agreed on collecting patient data using ROM, only 32% of the data was collected via ROM. For various reasons, mostly technical and organizational, most MHI’s were not able to add our questionnaires to their existing ROM. As data collecting via ROM is more systematically and on a larger scale when compared to data collection via paper-and-pencil questionnaires, we included less patients and had more missing values than we anticipated for. It was especially difficult for our research assistants to get access to the DSM-IV diagnosis of the patient. This resulted in a large amount of missing patient diagnoses (35%). Therefore, we were not able to test the effect of our intervention for other subgroups than patients with a diagnosis of depression. Also, the diagnoses were based on the registration in the electronic health records at admission. Next, we do not know if the diagnosis was changed during treatment.

Budget cuts in Dutch mental health care were introduced just after our randomization was completed. Various mental health care departments were shut down or did not have the resources anymore to fulfill the study requirements, resulting in a loss of 11 departments after randomization, leading to less power. Also, during our data-collection period, government retrenchment for mental health care made mental health care less accessible for patients. Patients suddenly were forced to pay a fair amount of money for the treatment in specialized mental health care, which resulted in a decrease in the numbers of new patients being admitted to the psychiatric departments resulting in less power.

An important focus of our intervention was making contact with suicidal patients, and paying more attention to suicidal ideation. Since most of the data (68%) was collected via paper-and-pencil instead of via the ROM, patients in both conditions might have experienced more attention being paid to their suicidal thoughts due to the assessment of suicidal ideation, making any effect of our intervention more difficult to detect. Finally, as part of our safety plan, when a patient showed increased suicidal ideation at baseline in either the control or the intervention condition, we reported this to their care giver. This monitoring and supervision has led to more attention for suicidal patients in both conditions, making it more difficult to find an effect of our intervention.

A strength of this study is its randomized controlled design, which is scarce in this field of research 12. Also, the included departments are a good representation of the psychiatric departments in the Netherlands 46 making the results generalizable to other institutions. Finally, given the difficulty in collecting data among suicidal patients admitted to mental health care, the difficulties with the ROM and the challenges of the ongoing budget cuts and reorganizations, the patient data collection in our trial can be regarded as quite successful. The large amount of patients included in our study makes our findings more reliable and generalizable.
Implications and further studies

This is the first randomized trial to examine the effect of training of professionals in adherence to the PGSB on patients. We found that the structural training of professionals resulted in more attention for suicidality during treatment. This indicates that suicide guideline implementation can have an impact on actual clinical practice. We found a significant effect on decrease in suicide ideation within suicidal patients with a diagnosis of depression. It appears that compared to implementation as usual, structured implementation of suicide guidelines has beneficial effects on depressed suicidal patients. Future studies should investigate whether a more tailored program, with special attention for the specific patient group of a department, would result in the same effect on for example suicidal patients with a personality disorder, as currently found on depressed suicidal patients. Also, the relative effectiveness of the different elements of TtT-e (the Train the-Trainer element, the face-to-face training, the e-learning module, the multidisciplinary training) has not been examined separately. Future studies may disentangle the effects of the different elements, so that more targeted programs can be developed. Finally, longitudinal studies should investigate the long term effect of suicide guideline implementation on patients.

Considering the methodological and diagnostic issues discussed earlier, our study needs replication. Ideally, data on suicidal ideation should be collected in a more systematic and less obtrusive manner via computerized outcome monitoring. However, implementation studies inevitably need to be done in a naturalistic sample, which has its limitations. In the current study, we managed to collect a large amount of data from multiple psychiatric departments among a heterogeneous sample of patients within a randomized design. Therefore, our findings offer the first evidence of effectiveness of suicide guideline training of professionals on the wellbeing of psychiatric patients, demonstrating the potential of structured guideline implementation.

Trial registration

Dutch trial register: NTR 3029

Financial support

This study is funded by The Dutch organization for health research and development (ZonMW)

Conflict of interest

None

Authors’ contributions

AK, MdG, en JdK obtained funding for this study. DdB carried out the study. DdB and MdG drafted the manuscript. AK, MdG, RdW, JdK, and EvD designed the training protocol and assisted in writing the manuscript. All authors contributed to the execution of the study, and to the manuscript writing.
References


46. de Beurs DP, de Groot MH, de Keijser J, Verwey B, Mokkenstorm J, Twisk JW, van Duijn E, van Hemert AM, Verlinde L, Spijker10 J: Improving the application of a practice guideline for the assessment and treatment of suicidal behavior by training the full staff of psychiatric departments via an e-learning supported Train-the-Trainer program: study protocol for a randomized controlled BMC trials 2013, 14(9).


