

Reductions in suicidality after internet cognitive behaviour therapy for depression.

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Reductions in suicidality after internet cognitive behaviour therapy for depression.

Sarah Watts¹

Jill M. Newby¹

Louise Mewton^{1,2}

Gavin Andrews¹

- 1. Clinical Research Unit for Anxiety and Depression, School of Psychiatry, University of New South Wales at St Vincent's Hospital, Darlinghurst, NSW, Australia.
- 2. Corresponding author.

Competing interests

None declared

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Abstract

Objectives: To examine reductions in both depressive symptomatology and suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression. Design: Effectiveness study within a quality assurance framework. Setting: Primary care. Participants: 299 patients who were prescribed an internet CBT course for depression by primary care clinicians. Intervention: 6 lesson, fully automated cognitive behaviour therapy course delivered over the internet. Primary outcome: suicidal ideation as measured by question 9 on the Patient Health Questionnaire (PHQ-9). Results: Suicidal ideation was common (54%) amongst primary care patients prescribed treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation was evident regardless of sex and age. Conclusions: The findings do not support the exclusion of patients with significant suicidal ideation.

Article summary

Article focus

• The reduction of suicidal ideation amongst patients treated for depression using internet cognitive behaviour therapy in clinical practice

Key messages

- Suicidal ideation is common amongst primary care patients prescribed internet CBT for depression
- After treatment with internet CBT, suicidal ideation decreased significantly
- The continued exclusion of these patients from research studies and internet CBT is no longer justified.

Strengths and limitations

• Evidence is needed to see if the changes in suicidal ideation is sustained over time

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Patients who say they feel they would be 'better off dead' worry clinicians and, for that matter, research ethics committees approving depression trials, especially trials over the internet. As a consequence, patients reporting suicidal ideas are often arbitrarily excluded from internet treatment trials (1-3). Given that suicidal thoughts are an integral part of depression we sought data to provide a rational basis for inclusion/exclusion of people with suicidal ideas.

Rates of suicide can be reduced through treatment of depression or reduction in access to the means for suicide (4-6). The efficacy of cognitive behavioural therapy (CBT) in treating depression has been established. Suicidal ideas and attempts decrease, commensurate with reductions in depressive symptomatology (7-15). These studies have all been conducted within a clinical trial framework amongst depressed patients selected for their high suicide risk. To our knowledge, there is currently no evidence regarding the effectiveness of CBT or internet CBT (iCBT) in reducing suicidal ideation in the depressed patient seeking treatment in primary care, and no data to inform inclusion/exclusion criteria in clinical trials.

The aim of the current quality assurance study is to therefore examine reductions in both depressive symptomatology and suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression by primary care clinicians.

Method

Sample: Primary care physicians prescribed the internet depression course for patients they deemed suitable (1). They were advised to exclude people who were 'actively suicidal'. As part of a routine quality assurance exercise we analysed the progress of the 299 primary care patients who completed the six lesson iCBT depression course between April 2009 and May 2011 (1). Data gathered was confined to measures used as a routine to inform practitioners about the progress of their patients. All patients agreed that their pooled data could be used for quality assurance purposes. This paper was written as part of the Quality Assurance activities of St Vincent's Hospital with whom the draft of the paper was lodged prior to submission.

Intervention: The iCBT depression course consists of six lessons covering psycho-education, behavioural activation, cognitive restructuring, problem solving, graded exposure and relapse prevention. Content is presented in the form of an illustrated story in which the character gains mastery over their depressive symptoms. At the end of each illustrated

lesson the patient downloads "homework," comprising a summary of the lesson content, and activities to be completed that translate the skills learnt in the lesson to their own lives. Automatic emails are also sent congratulating patients when they complete lessons. Clinicians are advised to contact patients at least twice during the course.

Outcome measures: The Patient Health Questionnaire (PHQ-9) is a brief 9-item measure of depression severity (16). The nine items assess DSM-IV Criterion A for major depressive disorder (MDD). Patients rate each item in terms of the frequency of symptoms over the past two weeks, on a 4-point scale (0= not at all, 1= several days, 2 = more than half of the days, 3= nearly every day). Scores can range from 0 to 27, with higher levels representing higher symptom severity. Cut points for MDD have been established as follows: 0-9 = well or sub-threshold, 10-14 = mild, 15-19 = moderate, and 20-27 = severe depression (17). Suicidal ideation was measured by question nine from the PHQ-9 which asks about the frequency of suicidal ideation ("thoughts that you would be better off dead, or of hurting yourself in some way") in the previous two weeks using the above 4 point scale.

Statistical Analysis: Changes in participants' PHQ-9 scores from pre- to post-treatment were analysed using a paired samples t-test. Multivariate linear regression controlling for baseline PHQ-9 scores was used to investigate the effect of sex and age on post-treatment PHQ-9 scores. A Wilcoxon signed-rank test was used to analyse differences in suicidal ideation in response to treatment. Multinomial logistic regression controlling for baseline suicidality investigated the effect of sex and age on post-treatment suicidal ideation. An alpha of .05 was used to test statistical significance.

Results

Baseline characteristics: The mean age of the 299 patients who completed the 6 lesson course was 43 years, 56% female. The mean baseline PHQ-9 score was 14.3 with 83 patients scoring 0-9 (well or subthreshold MDD), and 216 scoring 10-27 and likely to meet criteria for MDD (n= 72 mild, n= 70 moderate, and n= 74 severe MDD). Prior to commencing lesson 1, 54% of the patients (162/299) reported some level of suicidal ideation on question 9 of the PHQ-9: 30% (91/299) had thought about it for several days in the past two weeks, 15% (45/299) thought about it more than half the days and 9% (26/299) indicated that they thought about suicide nearly every day.

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Post-treatment outcomes: From pre- to post-treatment there was a significant reduction in PHQ-9 scores [t(298) = 18.1, p < .001], with PHQ-9 scores reducing by 6.2 points on average (d = 0.98). A multivariate linear regression controlling for baseline PHQ-9 scores indicated that age and gender were not statistically significant predictors of post-treatment PHQ-9 scores. The reduction in suicidal ideation was considerable and evident at all frequencies, with only 30% (90/299) reporting suicidal ideation at lesson 6 (see Figure). A Wilcoxin signed-rank test showed a statistically significant change in suicidal ideation (Z= -7.9, p < 0.001) as measured by question 9 on the PHQ-9, with median scores of 1 ("several days") pre-intervention and 0 ("not at all") post-intervention. A multinomial logistic regression controlling for baseline suicidal ideation scores indicated that age and gender were not statistically significant predictors of post-intervention suicidal ideation scores. Patient reported a median of 1 (range 0-2) clinician contacts during the course.

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Discussion

Suicidal ideation was common (54%) amongst primary care patients prescribed treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation was evident regardless of sex and age. To our knowledge, this is the first study to show that an internet CBT course for depression reduces suicidal ideation.

The benefits in reducing suicidal ideas are clear. Suicidal behaviour lies on a continuum from thoughts, through intent and planning, to attempt. In the general population it has been shown that 34% of people with ideas develop suicidal plans, and that these plans lead to suicide attempts in 72% of cases (15, 18). That is, 1 in 4 people who report suicidal ideation will transition to a suicide attempt, most within the first year of ideation onset (18). Suicide attempts are significant predictors of subsequent completed suicide. Suicidal ideas are distressing and dangerous, and therefore an important target for treatment.

We have conducted two randomised controlled trials of our iCBT program for depression (1, 2). In the first trial, 33% of applicants were excluded due to suicidal ideation. In the second, 23% were excluded due to suicidal ideation. Based on the current results it is now difficult to

justify excluding patients from clinical trials on the basis of their high suicidal ideation scores when internet CBT can reduce them quickly and effectively.

Limitations: Whilst the item from the PHQ-9 assessed the presence and frequency of suicidal ideation, it did not assess the intensity of the ideation, controllability, intention to act on thoughts, nor suicide plans or means. Evidence is also needed to understand whether the changes in suicidal ideation observed in this study are sustained over time.

Conclusion: Both suicidal ideation and depressive symptomatology were reduced considerably following completion of a six lesson iCBT course for depression. This is the first study to demonstrate these benefits in primary care. At present, it is routine to exclude patients with frequent suicidal ideation from participating in iCBT. This study provides evidence for change.

Contributors

SW drafted the initial manuscript, prepared and cleaned the data, and conducted initial data analysis. LM and JN conducted further statistical analysis. GA supervised the trial. All four authors contributed to revised paper drafts.

References

1. Perini S, Titov N, Andrews G. Clinician-assisted Internet-based treatment is effective for depression: randomized controlled trial. Australasian Psychiatry 2009;43:571-8.

2. Titov N, Andrews G, Davies M, et al. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. PloS one. 2010;5:e10939.

3. Andersson E, Walén C, Hallberg J, et al. A Randomized Controlled Trial of Guided Internet-delivered Cognitive Behavioral Therapy for Erectile Dysfunction. The Journal of Sexual Medicine 2011; 8:2800-9.

4. Kessler RC, Berglund P, Borges G, et al. Trends in suicide ideation, plans, gestures, and attempts in the United States, 1990-1992 to 2001-2003. JAMA: The Journal of the American Medical Association 2005;293:2487-95.

5. Goldsmith SK. Reducing suicide: A national imperative: Joseph Henry Pr; 2002.

6. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies. JAMA: The Journal of the American Medical Association 2005;294:2064-74.

7. Evans K, Tyrer P, Catalan J, et al. Manual-assisted cognitive-behavior therapy (MACT): A randomized controlled trial of a brief intervention with bibliotherapy in the treatment of recurrent deliberate self-harm. Psychological Medicine 1999;29:19-25.

8. Hawton K, Bancroft J, Catalan J, et al. Domiciliary and out-patient treatment of selfpoisoning patients by medical and non-medical staff. Psychological Medicine 1981;11:169-77.

9. Hawton K, Townsend E, Arensman E, et al. Psychosocial and pharmacological treatments for deliberate self harm. Cochrane Database of Systematic Reviews 1999;4.

10. Liberman RP, Eckman T. Behavior therapy vs insight-oriented therapy for repeated suicide attempters. Archives of General Psychiatry 1981;38:1126-30.

11. McLeavey BC, Daly RJ, Ludgate JW, et al. Interpersonal Problem-Solving Skills Training in the Treatment of Self-Poisoning Patients. Suicide and Life-Threatening Behavior 1994;24:382-94.

12. Patsiokas AT, Clum GA. Effects of psychotherapeutic strategies in the treatment of suicide attempters. Psychotherapy: Theory, Research, Practice, Training. 1985;22:281-290.

13. Salkovskis PM, Atha C, Storer D. Cognitive-behavioural problem solving in the treatment of patients who repeatedly attempt suicide. A controlled trial. The British Journal of Psychiatry 1990;157:871-6.

14. Sande R, Buskens E, Allart E, et al. Psychosocial intervention following suicide attempt: a systematic review of treatment interventions. Acta Psychiatrica Scandinavica 1997;96:43-50.

15. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior. Behavior Modification 2008;32:77-108.

16. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine 2001;16:606-13.

17. Kroenke K, Spitzer RL, Williams JBW, et al. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. General Hospital Psychiatry 2010;32:345-59.

18. Kessler RC, Borges G, Walters EE. Prevalence of and risk factors for lifetime suicide attempts in the National Comorbidity Survey. Archives of General Psychiatry. 1999;56:617-26.

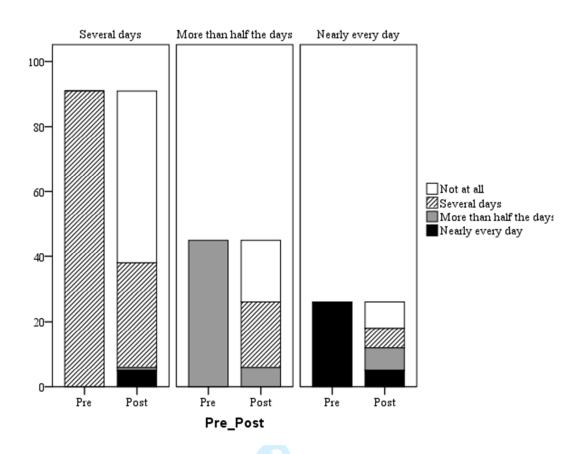


Figure. Frequency of suicidal thoughts (number of patients) before and after treatment for depression.

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- These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care.
- It may not be possible to include information about every numbered guideline item in reports of original formal studies, but authors should at least consider every item in writing their reports.
- Although each major section (i.e., Introduction, Methods, Results, and Discussion) of a published original study generally contains some information about the numbered items within that section, information about items from one section (for example, the Introduction) is often also needed in other sections (for example, the Discussion).

Text section; Item	Section or Item description
number and name	
Title and abstract	Did you provide clear and accurate information for finding, indexing, and
	scanning your paper?
1. Title	a. Indicates the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care)
	 b. States the specific aim of the intervention c. Specifies the study method used (for example, "A qualitative study," or "A randomized cluster trial")
2. Abstract	Summarizes precisely all key information from various sections of the text using the abstract format of the intended publication
Introduction	Why did you start?
3. Background Knowledge	Provides a brief, non-selective summary of current knowledge of the care problem being addressed, and characteristics of organizations in which it occurs
4. Local problem	Describes the nature and severity of the specific local problem or system dysfunction that was addressed
5. Intended	a. Describes the specific aim (changes/improvements in care processes and
improvement	patient outcomes) of the proposed intervention
	b. Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing)
6. Study question	States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer
Methods	What did you do?
7. Ethical issues	Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants' physical well-being, and potential author conflicts of interest, and how ethical concerns were addressed
8. Setting	Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized
9. Planning the	a. Describes the intervention and its component parts in sufficient detail
intervention	that others could reproduce it
	b. Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)

SQUIRE Publication Guidelines – Final revision – 4-29-08 Page 2

<i>Text section; Item number and name</i>	Section or Item description				
Planning the intervention (continued)	c. Outlines initial plans for how the intervention was to be implemented: e.g., <i>what</i> was to be done (initial steps; functions to be accomplished b those steps; how tests of change would be used to modify intervention) and <i>by whom</i> (intended roles, qualifications, and training of staff)				
10. Planning the study of the intervention	a. Outlines plans for assessing how well the intervention was implemented (dose or intensity of exposure)				
intervention	 b. Describes mechanisms by which intervention components were expected to cause changes, and plans for testing whether those mechanisms were effective a. Identifies the study design (for example, observational, quesi) 				
	c. Identifies the study design (for example, observational, quasi- experimental, experimental) chosen for measuring impact of the intervention on primary and secondary outcomes, if applicable				
	d. Explains plans for implementing essential aspects of the chosen study design, as described in publication guidelines for specific designs, if applicable (see, for example, www.equator-network.org)				
	e. Describes aspects of the study design that specifically concerned intern validity (integrity of the data) and external validity (generalizability)				
11. Methods of	a. Describes instruments and procedures (qualitative, quantitative, or				
evaluation	mixed) used to assess a) the effectiveness of implementation, b) the contributions of intervention components and context factors to				
	effectiveness of the intervention, and c) primary and secondary outcomb. Reports efforts to validate and test reliability of assessment instruments				
	c. Explains methods used to assure data quality and adequacy (for examp				
	blinding; repeating measurements and data extraction; training in data collection; collection of sufficient baseline measurements)				
12. Analysis	a. Provides details of qualitative and quantitative (statistical) methods use				
	to draw inferences from the data				
	b. Aligns unit of analysis with level at which the intervention was implemented, if applicable				
	c. Specifies degree of variability expected in implementation, change				
	expected in primary outcome (effect size), and ability of study design				
	(including size) to detect such effects				
	d. Describes analytic methods used to demonstrate effects of time as a				
Results	variable (for example, statistical process control) What did you find?				
13. Outcomes	a) Nature of setting and improvement intervention				
it outcomes	i. Characterizes relevant elements of setting or settings (for example,				
	geography, physical resources, organizational culture, history of chang				
	efforts), and structures and patterns of care (for example, staffing,				
	leadership) that provided context for the intervention				
	ii. Explains the actual course of the intervention (for example, sequence of				
	steps, events or phases; type and number of participants at key points), preferably using a time-line diagram or flow chart				
	iii.Documents degree of success in implementing intervention component				
	iv. Describes how and why the initial plan evolved, and the most important				
	lessons learned from that evolution, particularly the effects of internal				
	feedback from tests of change (reflexiveness)				
	b) Changes in processes of care and patient outcomes associated with the intervention				
	i. Presents data on changes observed in the care delivery process				
	ii. Presents data on changes observed in measures of patient outcome (for				
	example, morbidity, mortality, function, patient/staff satisfaction, servi utilization, cost, care disparities)				

SQUIRE Publication Guidelines – Final revision – 4-29-08 Page 3

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Text section; Item	Section or Item description				
number and name	iii Canaidam hanafita hamaa amamaatad maalta maahlama failama				
Outcomes	iii. Considers benefits, harms, unexpected results, problems, failures				
(continued)	iv. Presents evidence regarding the strength of association between observed				
	changes/improvements and intervention components/context factors				
	v. Includes summary of missing data for intervention and outcomes				
Discussion	What do the findings mean?				
14. Summary	a. Summarizes the most important successes and difficulties in				
	implementing intervention components, and main changes observed in				
	care delivery and clinical outcomes				
	b. Highlights the study's particular strengths				
15. Relation to	Compares and contrasts study results with relevant findings of others,				
other evidence	drawing on broad review of the literature; use of a summary table may				
	be helpful in building on existing evidence				
16. Limitations	a. Considers possible sources of confounding, bias, or imprecision in				
	design, measurement, and analysis that might have affected study				
	outcomes (internal validity)				
	b. Explores factors that could affect generalizability (external validity), for				
	example: representativeness of participants; effectiveness of				
	implementation; dose-response effects; features of local care setting				
	c. Addresses likelihood that observed gains may weaken over time, and				
	describes plans, if any, for monitoring and maintaining improvement;				
	explicitly states if such planning was not done				
	d. Reviews efforts made to minimize and adjust for study limitations				
	e. Assesses the effect of study limitations on interpretation and application				
	of results				
17. Interpretation					
17. Interpretation	a. Explores possible reasons for differences between observed and expected outcomes				
	b. Draws inferences consistent with the strength of the data about causal				
	mechanisms and size of observed changes, paying particular attention to				
	components of the intervention and context factors that helped determine the intervention's effectiveness (on lock thereof) and times of actings in				
	the intervention's effectiveness (or lack thereof), and types of settings in				
	which this intervention is most likely to be effective				
	c. Suggests steps that might be modified to improve future performance				
	d. Reviews issues of opportunity cost and actual financial cost of the				
	intervention				
18. Conclusions	a. Considers overall practical usefulness of the intervention				
	b. Suggests implications of this report for further studies of improvement				
0.1. 1.0.	interventions				
Other information	Were other factors relevant to conduct and interpretation of the study?				
19. Funding	Describes funding sources, if any, and role of funding organization in				
	design, implementation, interpretation, and publication of study				



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- 1. Clinical Research Unit for Anxiety and Depression, School of Psychiatry, University of New South Wales at St Vincent's Hospital, Darlinghurst, NSW, Australia.
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Objectives: To examine reductions in suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression. Design: Effectiveness study within a quality assurance framework. Setting: Primary care. Participants: 299 patients who were prescribed an internet CBT (iCBT) course for depression by primary care clinicians. Intervention: 6 lesson, fully automated cognitive behaviour therapy course delivered over the internet. Primary outcome: suicidal ideation as measured by question 9 on the Patient Health Questionnaire (PHQ-9). Results: Suicidal ideation was common (54%) amongst primary care patients prescribed iCBT treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation was evident regardless of sex and age. Conclusions: The findings do not support the exclusion of patients with significant suicidal ideation.

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Rates of suicide can be reduced through treatment of depression or reduction in access to the means for suicide (4-6). The efficacy of cognitive behavioural therapy (CBT) in treating depression has been established. Suicidal ideas and attempts decrease, commensurate with reductions in depressive symptomatology (7-15). These studies have all been conducted within a clinical trial framework amongst depressed patients selected for their high suicide risk. To our knowledge, there is currently no evidence regarding the effectiveness of CBT or internet CBT (iCBT) in reducing suicidal ideation in the depressed patient seeking treatment in primary care, and no data to inform inclusion/exclusion criteria in clinical trials.

We have previously reported from two randomized controlled trials that the progress of patients receiving the internet CBT course used in this study was significantly better than the progress of a waitlist control group (1, 2). We have also reported from quality assurance studies that when these courses were used routinely by primary care clinicians that effectiveness was comparable to the efficacy and that adherence rates of 60% could be achieved (16, 17). The aim of the current quality assurance study is to examine reductions in suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression by primary care clinicians.

Method

Sample: Primary care physicians prescribed the internet depression course for patients they deemed suitable (1). They were advised to exclude people who were 'actively suicidal'. As part of a routine quality assurance exercise we analysed the progress of the 299 primary care patients who completed the six lesson iCBT depression course between April 2009 and May 2011 (1). Data gathered was confined to measures used as a routine to inform practitioners about the progress of their patients. All patients agreed that their pooled data could be used for quality assurance purposes. This paper was written as part of the Quality Assurance activities of St Vincent's Hospital with whom the draft of the paper was lodged prior to submission.

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Statistical Analysis: Changes in participants' PHQ-9 scores from pre- to post-treatment were analysed using a paired samples t-test. Multivariate linear regression controlling for baseline PHQ-9 scores was used to investigate the effect of sex and age on post-treatment PHQ-9 scores. A Wilcoxon signed-rank test was used to analyse differences in suicidal ideation in response to treatment. Multinomial logistic regression controlling for baseline suicidality investigated the effect of sex and age on post-treatment suicidal ideation. An alpha of .05 was used to test statistical significance.

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patients scoring 0-9 (well or subthreshold MDD), and 216 scoring 10-27 and likely to meet criteria for MDD (n= 72 mild, n= 70 moderate, and n= 74 severe MDD). Prior to commencing lesson 1, 54% of the patients (162/299) reported some level of suicidal ideation on question 9 of the PHQ-9: 30% (91/299) had thought about it for several days in the past two weeks, 15% (45/299) thought about it more than half the days and 9% (26/299) indicated that they thought about suicide nearly every day.

Post-treatment outcomes: From pre- to post-treatment there was a significant reduction in PHQ-9 scores [t(298) = 18.1, p < .001], with PHQ-9 scores reducing by 6.2 points on average [S.D. = 5.9; d = 0.98 (95% CI:)]. A multivariate linear regression controlling for baseline PHQ-9 scores indicated that age and gender were not statistically significant predictors of post-treatment PHQ-9 scores. The reduction in suicidal ideation was considerable and evident at all frequencies, with only 30% (90/299) reporting suicidal ideation at lesson 6 (see Figure). A Wilcoxin signed-rank test showed a statistically significant change in suicidal ideation (Z=-7.9, p < 0.001, r = 0.5) as measured by question 9 on the PHQ-9, with median scores of 1 ("several days") pre-intervention and 0 ("not at all") post-intervention. A multinomial logistic regression controlling for baseline suicidal ideation scores indicated that age and gender were not statistically significant predictors of post-intervention. A multinomial logistic regression controlling for baseline suicidal ideation scores indicated that age and gender were not statistically significant predictors of post-intervention suicidal ideation scores. Patient reported a median of 1 (range 0-2) clinician contacts during the course.

<Insert Table and Figure here>

Discussion

Suicidal ideation was common (54%) amongst primary care patients prescribed treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation was evident regardless of sex and age. To our knowledge, this is the first study to show that an internet CBT course for depression reduces suicidal ideation.

The benefits in reducing suicidal ideas are clear. Suicidal behaviour lies on a continuum from thoughts, through intent and planning, to attempt. In the general population it has been shown that 34% of people with ideas develop suicidal plans, and that these plans lead to suicide attempts in 72% of cases (15, 21). That is, 1 in 4 people who report suicidal ideation

will transition to a suicide attempt, most within the first year of ideation onset (21). Suicide attempts are significant predictors of subsequent completed suicide. Suicidal ideas are distressing and dangerous, and therefore an important target for treatment.

We have conducted two randomised controlled trials of our iCBT program for depression (1, 2). In the first trial, 33% of applicants were excluded due to suicidal ideation. In the second, 23% were excluded due to suicidal ideation. Based on the current results it is now difficult to justify excluding patients from clinical trials on the basis of their high suicidal ideation scores when internet CBT can reduce them quickly and effectively.

Limitations: Whilst the item from the PHQ-9 assessed the presence and frequency of suicidal ideation, it did not assess the intensity of the ideation, controllability, intention to act on thoughts, nor suicide plans or means. Evidence is also needed to understand whether the changes in suicidal ideation observed in this study are sustained over time. In addition, there was no control sample, meaning that treatment effects could be attributable to regression to the mean, spontaneous remission or placebo effects, rather than the intervention *per se*. The fact that benefits were observed amongst patients at different levels of baseline risk indicates that regression to the mean may not underlie treatment effects. However, it is not possible to fully examine the influence of these alternative factors on the outcomes of interest. It was also not possible to establish whether treatment effects were sustained over time due to the lack of follow up data. Finally, the lack of formal exclusion criteria means that patients may have been using adjunctive treatments which contributed to the magnitude of treatment effects. Whilst the limitations outlined above may be critical within the context of an efficacy trial, they are endemic to effectiveness research.

Conclusion: Both suicidal ideation and depressive symptomatology were reduced considerably following completion of a six lesson iCBT course for depression. This is the first study to demonstrate these benefits in primary care. At present, it is routine to exclude patients with frequent suicidal ideation from participating in iCBT. This study provides evidence for change.

Contributors

SW drafted the initial manuscript, prepared and cleaned the data, and conducted initial data analysis. LM and JN conducted further statistical analysis. GA supervised and took responsibility for the data. All four authors contributed to revised drafts.

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References

 Perini S, Titov N, Andrews G. Clinician-assisted Internet-based treatment is effective for depression: randomized controlled trial. Australasian Psychiatry. 2009;43(6):571-8.
 Titov N, Andrews G, Davies M, et al. Internet treatment for depression: a randomized

controlled trial comparing clinician vs. technician assistance. PloS one. 2010;5(6):e10939.

3. Johansson R, Sjöberg E, Sjögren M, et al. Tailored vs. Standardized Internet-Based Cognitive Behavior Therapy for Depression and Comorbid Symptoms: A Randomized Controlled Trial. PloS one. 2012;7(5):e36905.

4. Kessler RC, Berglund P, Borges G, et al. Trends in suicide ideation, plans, gestures, and attempts in the United States, 1990-1992 to 2001-2003. JAMA: The Journal of the American Medical Association. 2005;293(20):2487-95.

5. Goldsmith SK. Reducing suicide: A national imperative: Joseph Henry Pr; 2002.

6. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies. JAMA: The Journal of the American Medical Association. 2005;294(16):2064-74.

7. Evans K, Tyrer P, Catalan J, et al. Manual-assisted cognitive-behavior therapy (MACT): A randomized controlled trial of a brief intervention with bibliotherapy in the treatment of recurrent deliberate self-harm. Psychological Medicine. 1999;29(19-25).

8. Hawton K, Bancroft J, Catalan J, et al. Domiciliary and out-patient treatment of selfpoisoning patients by medical and non-medical staff. Psychological medicine. 1981;11(01):169-77.

9. Hawton K, Townsend E, Arensman E, et al. Psychosocial and pharmacological treatments for deliberate self harm. Cochrane Database of Systematic Reviews. 1999;4.

10. Liberman RP, Eckman T. Behavior therapy vs insight-oriented therapy for repeated suicide attempters. Archives of general psychiatry. 1981;38(10):1126.

11. McLeavey BC, Daly RJ, Ludgate JW, et al. Interpersonal Problem-Solving Skills Training in the Treatment of Self-Poisoning Patients. Suicide and Life-Threatening Behavior. 1994;24(4):382-94.

12. Patsiokas AT, Clum GA. Effects of psychotherapeutic strategies in the treatment of suicide attempters. Psychotherapy: Theory, Research, Practice, Training. 1985;22(2):281.

13. Salkovskis PM, Atha C, Storer D. Cognitive-behavioural problem solving in the treatment of patients who repeatedly attempt suicide. A controlled trial. The British Journal of Psychiatry. 1990;157(6):871-6.

14. Sande R, Buskens E, Allart E, et al. Psychosocial intervention following suicide attempt: a systematic review of treatment interventions. Acta psychiatrica scandinavica. 1997;96(1):43-50.

15. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior. Behavior Modification. 2008;32(1):77-108.

16. Sunderland M, Wong N, Hilvert-Bruce Z, et al. Investigating trajectories of change in psychological distress amongst patients with depression and generalised anxiety disorder treated with internet cognitive behavioural therapy. Behaviour Research and Therapy. 2012.

17. Hilvert-Bruce Z, Rossouw PJ, Wong N, et al. Adherence as a determinant of effectiveness of internet cognitive behavioural therapy for anxiety and depressive disorders. Behaviour Research and Therapy. 2012.

18. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. 2001;16(9):606-13.

19. Kroenke K, Spitzer RL, Williams JBW, et al. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. General Hospital Psychiatry. 2010;32(4):345-59.

20. Titov N, Dear BF, McMillan D, et al. Psychometric Comparison of the PHQ-9 and BDI-II for Measuring Response during Treatment of Depression. Cognitive Behaviour Therapy. 2011;40(2):126-36.

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Text 1226 words; abstract 116 words

Reductions in suicidality after internet cognitive behaviour therapy for depression.

Sarah Watts¹

Jill M. Newby¹

Louise Mewton^{1,2}

Gavin Andrews¹

- 1. Clinical Research Unit for Anxiety and Depression, School of Psychiatry, University of New South Wales at St Vincent's Hospital, Darlinghurst, NSW, Australia.
- 2. Corresponding author.

Competing interests

None declared

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Abstract

Objectives: To examine reductions in suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression. Design: Effectiveness study within a quality assurance framework. Setting: Primary care. Participants: 299 patients who were prescribed an internet CBT (iCBT) course for depression by primary care clinicians. Intervention: 6 lesson, fully automated cognitive behaviour therapy course delivered over the internet. Primary outcome: suicidal ideation as measured by question 9 on the Patient Health Questionnaire (PHQ-9). Results: Suicidal ideation was common (54%) amongst primary care patients prescribed iCBT treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation was evident regardless of sex and age. Conclusions: The findings do not support the exclusion of patients with significant suicidal ideation.

Article summary

Article focus

• The reduction of suicidal ideation amongst patients treated for depression using internet cognitive behaviour therapy in clinical practice

Key messages

- Suicidal ideation is common amongst primary care patients prescribed internet CBT for depression
- After treatment with internet CBT, suicidal ideation decreased significantly
- The continued exclusion of these patients from research studies and internet CBT is no longer justified.

Strengths and limitations

• Evidence is needed to see if the changes in suicidal ideation is sustained over time

Patients who say they feel they would be 'better off dead' worry clinicians and, for that matter, research ethics committees approving depression trials, especially trials over the internet. As a consequence, patients reporting suicidal ideas are often arbitrarily excluded from internet treatment trials (1-3). Given that suicidal thoughts are an integral part of depression we sought data to provide a rational basis for inclusion/exclusion of people with suicidal ideas.

Rates of suicide can be reduced through treatment of depression or reduction in access to the means for suicide (4-6). The efficacy of cognitive behavioural therapy (CBT) in treating depression has been established. Suicidal ideas and attempts decrease, commensurate with reductions in depressive symptomatology (7-15). These studies have all been conducted within a clinical trial framework amongst depressed patients selected for their high suicide risk. To our knowledge, there is currently no evidence regarding the effectiveness of CBT or internet CBT (iCBT) in reducing suicidal ideation in the depressed patient seeking treatment in primary care, and no data to inform inclusion/exclusion criteria in clinical trials.

We have previously reported from two randomized controlled trials that the progress of patients receiving the internet CBT course used in this study was significantly better than the progress of a waitlist control group (1, 2). We have also reported from quality assurance studies that when these courses were used routinely by primary care clinicians that effectiveness was comparable to the efficacy and that adherence rates of 60% could be achieved (16, 17). The aim of the current quality assurance study is to therefore examine reductions in suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression by primary care clinicians.

Method

Sample: Primary care physicians prescribed the internet depression course for patients they deemed suitable (1). They were advised to exclude people who were 'actively suicidal'. As part of a routine quality assurance exercise we analysed the progress of the 299 primary care patients who completed the six lesson iCBT depression course between April 2009 and May 2011 (1). Data gathered was confined to measures used as a routine to inform practitioners about the progress of their patients. All patients agreed that their pooled data could be used for quality assurance purposes. This paper was written as part of the Quality Assurance

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activities of St Vincent's Hospital with whom the draft of the paper was lodged prior to submission.

Intervention: The iCBT depression course consists of six lessons covering psycho-education, behavioural activation, cognitive restructuring, problem solving, graded exposure and relapse prevention_(1, 2). Content is presented in the form of an illustrated story in which the character gains mastery over their depressive symptoms. At the end of each illustrated lesson the patient downloads "homework," comprising a summary of the lesson content, and activities to be completed that translate the skills learnt in the lesson to their own lives. Automatic emails are also sent congratulating patients when they complete lessons. Clinicians are advised to contact patients at least twice during the course.

Outcome measures: The Patient Health Questionnaire (PHQ-9) is a brief 9-item measure of depression severity (18). The nine items assess DSM-IV Criterion A for major depressive disorder (MDD). Patients rate each item in terms of the frequency of symptoms over the past two weeks, on a 4-point scale (0= not at all, 1= several days, 2 = more than half of the days, 3= nearly every day). Scores can range from 0 to 27, with higher levels representing higher symptom severity. Cut points for MDD have been established as follows: 0-9 = well or sub-threshold, 10-14 = mild, 15-19 = moderate, and 20-27 = severe depression (19). Suicidal ideation was measured by question nine from the PHQ-9 which asks about the frequency of suicidal ideation ("thoughts that you would be better off dead, or of hurting yourself in some way") in the previous two weeks using the above 4 point scale. The PHQ-9 has been shown to demonstrate adequate reliability, convergent/discriminant validity, and responsiveness to change in previous studies of iCBT (20), with a Cronbach's alpha of 0.89 in the current sample.

Statistical Analysis: Changes in participants' PHQ-9 scores from pre- to post-treatment were analysed using a paired samples t-test. Multivariate linear regression controlling for baseline PHQ-9 scores was used to investigate the effect of sex and age on post-treatment PHQ-9 scores. A Wilcoxon signed-rank test was used to analyse differences in suicidal ideation in response to treatment. Multinomial logistic regression controlling for baseline suicidality investigated the effect of sex and age on post-treatment suicidal ideation. An alpha of .05 was used to test statistical significance.

Results

Baseline characteristics: The mean age of the 299 patients who completed the 6 lesson course was 43 years, 56% female. The mean baseline PHQ-9 score was 14.3 with 83 patients scoring 0-9 (well or subthreshold MDD), and 216 scoring 10-27 and likely to meet criteria for MDD (n= 72 mild, n= 70 moderate, and n= 74 severe MDD). Prior to commencing lesson 1, 54% of the patients (162/299) reported some level of suicidal ideation on question 9 of the PHQ-9: 30% (91/299) had thought about it for several days in the past two weeks, 15% (45/299) thought about it more than half the days and 9% (26/299) indicated that they thought about suicide nearly every day.

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Contributors

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 Perini S, Titov N, Andrews G. Clinician-assisted Internet-based treatment is effective for depression: randomized controlled trial. Australasian Psychiatry. 2009;43(6):571-8.
 Titov N, Andrews G, Davies M, et al. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. PloS one. 2010;5(6):e10939.

 Johansson R, Sjöberg E, Sjögren M, et al. Tailored vs. Standardized Internet-Based Cognitive Behavior Therapy for Depression and Comorbid Symptoms: A Randomized Controlled Trial. PloS one. 2012;7(5):e36905.

4. Kessler RC, Berglund P, Borges G, et al. Trends in suicide ideation, plans, gestures, and attempts in the United States, 1990-1992 to 2001-2003. JAMA: The Journal of the American Medical Association. 2005;293(20):2487-95.

5. Goldsmith SK. Reducing suicide: A national imperative: Joseph Henry Pr; 2002.

6. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies. JAMA: The Journal of the American Medical Association. 2005;294(16):2064-74.

7. Evans K, Tyrer P, Catalan J, et al. Manual-assisted cognitive-behavior therapy (MACT): A randomized controlled trial of a brief intervention with bibliotherapy in the treatment of recurrent deliberate self-harm. Psychological Medicine. 1999;29(19-25).

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9. Hawton K, Townsend E, Arensman E, et al. Psychosocial and pharmacological treatments for deliberate self harm. Cochrane Database of Systematic Reviews. 1999;4.

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12. Patsiokas AT, Clum GA. Effects of psychotherapeutic strategies in the treatment of suicide attempters. Psychotherapy: Theory, Research, Practice, Training. 1985;22(2):281.

13. Salkovskis PM, Atha C, Storer D. Cognitive-behavioural problem solving in the treatment of patients who repeatedly attempt suicide. A controlled trial. The British Journal of Psychiatry. 1990;157(6):871-6.

14. Sande R, Buskens E, Allart E, et al. Psychosocial intervention following suicide attempt: a systematic review of treatment interventions. Acta psychiatrica scandinavica. 1997;96(1):43-50.

15. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior. Behavior Modification. 2008;32(1):77-108.

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18. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. 2001;16(9):606-13.

19. Kroenke K, Spitzer RL, Williams JBW, et al. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. General Hospital Psychiatry. 2010;32(4):345-59.

20. Titov N, Dear BF, McMillan D, et al. Psychometric Comparison of the PHQ-9 and BDI-II for Measuring Response during Treatment of Depression. Cognitive Behaviour Therapy. 2011;40(2):126-36.

Kessler RC, Borges G, Walters EE. Prevalence of and risk factors for lifetime suicide 21. attempts in the National Comorbidity Survey. Archives of general psychiatry. 1999;56(7):617.

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	Not at all	Several days	More than half the days	Nearly every day
Pre-intervention PHQ-9 score	137 (45.8%)	91 (30.4%)	45 (15.15%)	26 (8.7%)
Post-intervention PHQ-9 score	209 (69.9%)	66 (22.1%)	14 (4.7%)	10 (3.3%)

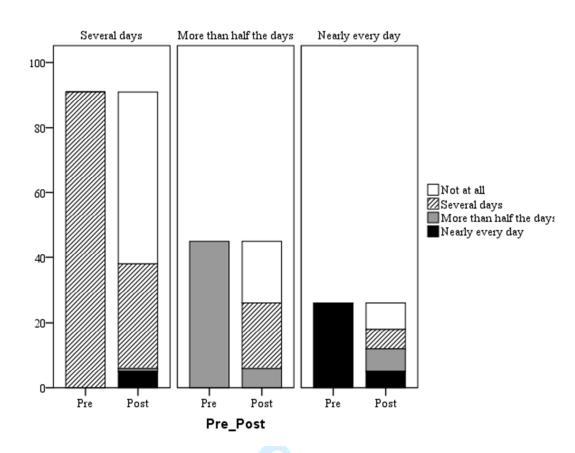


Figure. Frequency of suicidal thoughts (number of patients) before and after treatment for depression.

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SQUIRE Guidelines (<u>Standards for QU</u>ality <u>Improvement Reporting Excellence</u>) Final revision – 4-29-08

- These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care.
- It may not be possible to include information about every numbered guideline item in reports of original formal studies, but authors should at least consider every item in writing their reports.
- Although each major section (i.e., Introduction, Methods, Results, and Discussion) of a published original study generally contains some information about the numbered items within that section, information about items from one section (for example, the Introduction) is often also needed in other sections (for example, the Discussion).

Text section; Item	Section or Item description				
number and name					
Title and abstract	Did you provide clear and accurate information for finding, indexing, and				
	scanning your paper?				
1. Title	a. Indicates the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care)				
	 b. States the specific aim of the intervention c. Specifies the study method used (for example, "A qualitative study," or "A randomized cluster trial") 				
2. Abstract	Summarizes precisely all key information from various sections of the text using the abstract format of the intended publication				
Introduction	Why did you start?				
3. Background Knowledge	Provides a brief, non-selective summary of current knowledge of the care problem being addressed, and characteristics of organizations in which it occurs				
4. Local problem	Describes the nature and severity of the specific local problem or system dysfunction that was addressed				
5. Intended	a. Describes the specific aim (changes/improvements in care processes and				
improvement	patient outcomes) of the proposed intervention				
	b. Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing)				
6. Study question	States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer				
Methods	What did you do?				
7. Ethical issues	Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants' physical well-being, and potential author conflicts of interest, and how ethical concerns were addressed				
8. Setting	Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterized				
9. Planning the	a. Describes the intervention and its component parts in sufficient detail				
intervention	that others could reproduce it				
	b. Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)				

SQUIRE Publication Guidelines – Final revision – 4-29-08 Page 2

Text section; Item number and name	Section or Item description
Planning the	c. Outlines initial plans for how the intervention was to be implemented:
intervention	e.g., what was to be done (initial steps; functions to be accomplished by
(continued)	those steps; how tests of change would be used to modify intervention),
	and by whom (intended roles, qualifications, and training of staff)
10. Planning the	a. Outlines plans for assessing how well the intervention was implemented
study of the	(dose or intensity of exposure)
intervention	b. Describes mechanisms by which intervention components were expected
	to cause changes, and plans for testing whether those mechanisms were effective
	c. Identifies the study design (for example, observational, quasi-
	experimental, experimental) chosen for measuring impact of the
	intervention on primary and secondary outcomes, if applicable
	d. Explains plans for implementing essential aspects of the chosen study
	design, as described in publication guidelines for specific designs, if
	applicable (see, for example, www.equator-network.org)
	e. Describes aspects of the study design that specifically concerned international design that specifically concerned international design and the study design that specifically concerned international design and the study design and the st
	validity (integrity of the data) and external validity (generalizability)
11. Methods of	a. Describes instruments and procedures (qualitative, quantitative, or
evaluation	mixed) used to assess a) the effectiveness of implementation, b) the
	contributions of intervention components and context factors to
	effectiveness of the intervention, and c) primary and secondary outcomb. Reports efforts to validate and test reliability of assessment instruments
	c. Explains methods used to assure data quality and adequacy (for example
	blinding; repeating measurements and data extraction; training in data
	collection; collection of sufficient baseline measurements)
12. Analysis	a. Provides details of qualitative and quantitative (statistical) methods use
·	to draw inferences from the data
	b. Aligns unit of analysis with level at which the intervention was
	implemented, if applicable
	c. Specifies degree of variability expected in implementation, change
	expected in primary outcome (effect size), and ability of study design
	(including size) to detect such effects
	d. Describes analytic methods used to demonstrate effects of time as a unrichle (for example, statistical process control)
Results	variable (for example, statistical process control) What did you find?
13. Outcomes	a) Nature of setting and improvement intervention
15. Outcomes	i. Characterizes relevant elements of settings (for example,
	geography, physical resources, organizational culture, history of change
	efforts), and structures and patterns of care (for example, staffing,
	leadership) that provided context for the intervention
	ii. Explains the actual course of the intervention (for example, sequence o
	steps, events or phases; type and number of participants at key points),
	preferably using a time-line diagram or flow chart
	iii.Documents degree of success in implementing intervention component
	iv. Describes how and why the initial plan evolved, and the most importan
	lessons learned from that evolution, particularly the effects of internal
	feedback from tests of change (reflexiveness)
	b) Changes in processes of care and patient outcomes associated with the
	intervention i. Presents data on changes observed in the care delivery process
	ii. Presents data on changes observed in the care derivery process iii. Presents data on changes observed in measures of patient outcome (for
	example, morbidity, mortality, function, patient/staff satisfaction, service
	utilization, cost, care disparities)
	autorite aspurates)

SQUIRE Publication Guidelines – Final revision – 4-29-08 Page 3

Text section; Item	Section or Item description					
number and name	Section of Rem description					
Outcomes	iii. Considers benefits, harms, unexpected results, problems, failures					
(continued)	iv. Presents evidence regarding the strength of association between observe					
	changes/improvements and intervention components/context factors					
	v. Includes summary of missing data for intervention and outcomes					
Discussion	What do the findings mean?					
14. Summary	a. Summarizes the most important successes and difficulties in					
	implementing intervention components, and main changes observed in					
	care delivery and clinical outcomes					
	b. Highlights the study's particular strengths					
15. Relation to	Compares and contrasts study results with relevant findings of others,					
other evidence	drawing on broad review of the literature; use of a summary table may					
	be helpful in building on existing evidence					
16. Limitations 🥄	a. Considers possible sources of confounding, bias, or imprecision in					
	design, measurement, and analysis that might have affected study					
	outcomes (internal validity)					
	b. Explores factors that could affect generalizability (external validity), for					
	example: representativeness of participants; effectiveness of					
	implementation; dose-response effects; features of local care setting					
	c. Addresses likelihood that observed gains may weaken over time, and					
	describes plans, if any, for monitoring and maintaining improvement;					
	explicitly states if such planning was not done					
	d. Reviews efforts made to minimize and adjust for study limitations					
	e. Assesses the effect of study limitations on interpretation and application					
	of results					
17. Interpretation	a. Explores possible reasons for differences between observed and expected					
	outcomes					
	b. Draws inferences consistent with the strength of the data about causal					
	mechanisms and size of observed changes, paying particular attention to					
	components of the intervention and context factors that helped determine					
	the intervention's effectiveness (or lack thereof), and types of settings in					
	which this intervention is most likely to be effective					
	c. Suggests steps that might be modified to improve future performance					
	d. Reviews issues of opportunity cost and actual financial cost of the					
	intervention					
18. Conclusions	a. Considers overall practical usefulness of the intervention					
	b. Suggests implications of this report for further studies of improvement					
	interventions					
Other information	Were other factors relevant to conduct and interpretation of the study?					
19. Funding	Describes funding sources, if any, and role of funding organization in					
	design, implementation, interpretation, and publication of study					



A clinical audit of changes in suicide ideas with internet treatment for depression.

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A clinical audit of changes in suicide ideas with internet treatment for depression.

Sarah Watts¹

Jill M. Newby¹

Louise Mewton^{1,2}

Gavin Andrews¹

- 1. Clinical Research Unit for Anxiety and Depression, School of Psychiatry, University of New South Wales at St Vincent's Hospital, Darlinghurst, NSW, Australia.
- 2. Corresponding author.

Competing interests

None declared

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Abstract

Objectives: To examine reductions in suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression. **Design**: Effectiveness study within a quality assurance framework. **Setting**: Primary care. **Participants**: 299 patients who were prescribed an internet CBT (iCBT) course for depression by primary care clinicians. **Intervention**: 6 lesson, fully automated cognitive behaviour therapy course delivered over the internet. Primary outcome: suicidal ideation as measured by question 9 on the Patient Health Questionnaire (PHQ-9). **Results**: Suicidal ideation was common (54%) amongst primary care patients prescribed iCBT treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation was evident regardless of sex and age. **Conclusions**: The findings do not support the exclusion of patients with significant suicidal ideation.

Article summary

Article focus

• The reduction of suicidal ideation amongst patients treated for depression using internet cognitive behaviour therapy in clinical practice

Key messages

- Suicidal ideation is common amongst primary care patients prescribed internet CBT for depression
- After treatment with internet CBT, suicidal ideation decreased significantly
- The continued exclusion of these patients from research studies and internet CBT is no longer justified.

Strengths and limitations

• Evidence is needed to see if the changes in suicidal ideation is sustained over time

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Patients who say they feel they would be 'better off dead' worry clinicians and, for that matter, research ethics committees approving depression trials, especially trials over the internet. As a consequence, patients reporting suicidal ideas are often excluded from internet treatment trials (1-3). Given that suicidal thoughts are an integral part of depression we sought data to provide a rational basis for inclusion/exclusion of people with suicidal ideas.

Rates of suicide can be reduced through treatment of depression or reduction in access to the means for suicide (4-6). The efficacy of cognitive behavioural therapy (CBT) in treating depression has been established. Suicidal ideas and attempts decrease, commensurate with reductions in depressive symptomatology (7-15). These studies have all been conducted within a clinical trial framework amongst depressed patients selected for their high suicide risk. To our knowledge, there is currently no evidence regarding the effectiveness of CBT or internet CBT (iCBT) in reducing suicidal ideation in the depressed patient seeking treatment in primary care, and no data to inform inclusion/exclusion criteria in clinical trials.

We have previously reported from two randomized controlled trials that the progress of patients receiving the internet CBT course used in this study was significantly better than the progress of a waitlist control group (1, 2). We have also reported from quality assurance studies that when these courses were used routinely by primary care clinicians that effectiveness was comparable to the efficacy and that adherence rates of 60% could be achieved (16, 17). The aim of the current quality assurance study is to examine reductions in suicidal ideation amongst a sample of patients who were prescribed an internet CBT course for depression by primary care clinicians.

Method

Sample: Primary care physicians prescribed the internet depression course for patients they deemed suitable (1). They were advised to exclude people who were 'actively suicidal'. As part of a routine quality assurance exercise we analysed the progress of the 299 primary care patients who completed the six lesson iCBT depression course between April 2009 and May 2011 (1). Data gathered was confined to measures used as a routine to inform practitioners about the progress of their patients. All patients agreed that their pooled data could be used for quality assurance purposes. This paper was written as part of the Quality Assurance activities of St Vincent's Hospital with whom the draft of the paper was lodged prior to submission.

Intervention: The iCBT depression course consists of six lessons covering psycho-education, behavioural activation, cognitive restructuring, problem solving, graded exposure and relapse prevention (1, 2). Content is presented in the form of an illustrated story in which the character gains mastery over their depressive symptoms. At the end of each illustrated lesson the patient downloads "homework," comprising a summary of the lesson content, and activities to be completed that translate the skills learnt in the lesson to their own lives. Automatic emails are also sent congratulating patients when they complete lessons. Clinicians are advised to contact patients at least twice during the course.

Outcome measures: The Patient Health Questionnaire (PHQ-9) is a brief 9-item measure of depression severity (18). The nine items assess DSM-IV Criterion A for major depressive disorder (MDD). Patients rate each item in terms of the frequency of symptoms over the past two weeks, on a 4-point scale (0= not at all, 1= several days, 2 = more than half of the days, 3= nearly every day). Scores can range from 0 to 27, with higher levels representing higher symptom severity. Cut points for MDD have been established as follows: 0-9 = well or sub-threshold, 10-14 = mild, 15-19 = moderate, and 20-27 = severe depression (19). Suicidal ideation was measured by question nine from the PHQ-9 which asks about the frequency of suicidal ideation ("thoughts that you would be better off dead, or of hurting yourself in some way") in the previous two weeks using the above 4 point scale. The PHQ-9 has been shown to demonstrate adequate reliability, convergent/discriminant validity, and responsiveness to change in previous studies of iCBT (20), with a Cronbach's alpha of 0.89 in the current sample.

Statistical Analysis: Changes in participants' PHQ-9 scores from pre- to post-treatment were analysed using a paired samples t-test. Multivariate linear regression controlling for baseline PHQ-9 scores was used to investigate the effect of sex and age on post-treatment PHQ-9 scores. A Wilcoxon signed-rank test was used to analyse differences in suicidal ideation in response to treatment. Multinomial logistic regression controlling for baseline suicidality investigated the effect of sex and age on post-treatment suicidal ideation. An alpha of .05 was used to test statistical significance.

Results

Baseline characteristics: The mean age of the 299 patients who completed the 6 lesson course was 43 years, 56% female. The mean baseline PHQ-9 score was 14.3 with 83

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patients scoring 0-9 (well or subthreshold MDD), and 216 scoring 10-27 and likely to meet criteria for MDD (n=72 mild, n=70 moderate, and n=74 severe MDD). Prior to commencing lesson 1, 54% of the patients (162/299) reported some level of suicidal ideation on question 9 of the PHQ-9: 30% (91/299) had thought about it for several days in the past two weeks, 15% (45/299) thought about it more than half the days and 9% (26/299) indicated that they thought about suicide nearly every day.

Post-treatment outcomes: From pre- to post-treatment there was a significant reduction in PHQ-9 scores [t(298) = 18.1, p < .001], with PHQ-9 scores reducing by 6.2 points on average [S.D. = 5.9; d = 0.98 (95% CI:)]. A multivariate linear regression controlling for baseline PHQ-9 scores indicated that age and gender were not statistically significant predictors of post-treatment PHQ-9 scores. The reduction in suicidal ideation was considerable and evident at all frequencies, with only 30% (90/299) reporting suicidal ideation at lesson 6 (see Figure). A Wilcoxin signed-rank test showed a statistically significant change in suicidal ideation (Z=-7.9, p < 0.001, r = 0.5) as measured by question 9 on the PHQ-9, with median scores of 1 ("several days") pre-intervention and 0 ("not at all") post-intervention. A multinomial logistic regression controlling for baseline suicidal ideation scores indicated that age and gender were not statistically significant predictors of post-intervention. A multinomial logistic regression controlling for baseline suicidal ideation scores indicated that age and gender were not statistically significant predictors of post-intervention suicidal ideation scores. Patient reported a median of 1 (range 0-2) clinician contacts during the course.

Table 1

	Not at all	Several days	More than half	Nearly every
			the days	day
Pre-intervention PHQ-9 score	137 (45.8%)	91 (30.4%)	45 (15.15%)	26 (8.7%)
Post-intervention PHQ-9 score	209 (69.9%)	66 (22.1%)	14 (4.7%)	10 (3.3%)

Discussion

Suicidal ideation was common (54%) amongst primary care patients prescribed treatment for depression but dropped to 30% post treatment despite minimal clinician contact and the absence of an intervention focused on suicidal ideation. This reduction in suicidal ideation

was evident regardless of sex and age. To our knowledge, this is the first study to document an association between iCBT for depression and reductions in suicidal ideation.

The benefits in reducing suicidal ideas are clear. Suicidal behaviour lies on a continuum from thoughts, through intent and planning, to attempt. In the general population it has been shown that 34% of people with ideas develop suicidal plans, and that these plans lead to suicide attempts in 72% of cases (15, 21). That is, 1 in 4 people who report suicidal ideation will transition to a suicide attempt, most within the first year of ideation onset (21). Suicide attempts are significant predictors of subsequent completed suicide. Suicidal ideas are distressing and dangerous, and therefore an important target for treatment.

We have conducted two randomised controlled trials of our iCBT program for depression (1, 2). In the first trial, 33% of applicants were excluded due to suicidal ideation. In the second, 23% were excluded due to suicidal ideation. Based on the current results it is now difficult to justify excluding patients from clinical trials on the basis of their high suicidal ideation scores when internet CBT can reduce them quickly and effectively.

Limitations: Whilst the item from the PHQ-9 assessed the presence and frequency of suicidal ideation, it did not assess the intensity of the ideation, controllability, intention to act on thoughts, nor suicide plans or means. Evidence is also needed to understand whether the changes in suicidal ideation observed in this study are sustained over time. In addition, there was no control sample, meaning that treatment effects could be attributable to regression to the mean, spontaneous remission or placebo effects, rather than the intervention *per se*. The fact that benefits were observed amongst patients at different levels of baseline risk indicates that regression to the mean may not underlie treatment effects. However, it is not possible to fully examine the influence of these alternative factors on the outcomes of interest. It was also not possible to establish whether treatment effects were sustained over time due to the lack of follow up data. Finally, the lack of formal exclusion criteria means that patients may have been using adjunctive treatments which contributed to the magnitude of treatment effects. Whilst the limitations outlined above may be critical within the context of an efficacy trial, they are endemic to effectiveness research.

Conclusion: Both suicidal ideation and depressive symptomatology were reduced considerably following completion of a six lesson iCBT course for depression. This is the

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first study to demonstrate this association in primary care. At present, it is routine to exclude patients with frequent suicidal ideation from participating in iCBT. This study provides evidence for change.

Contributors

SW drafted the initial manuscript, prepared and cleaned the data, and conducted initial data analysis. LM and JN conducted further statistical analysis. GA supervised and took responsibility for the data. All four authors contributed to revised drafts.

Data Sharing Statement

vailable No additional data available

References

1. Perini S, Titov N, Andrews G. Clinician-assisted Internet-based treatment is effective for depression: randomized controlled trial. Australasian Psychiatry. 2009;43(6):571-8.

2. Titov N, Andrews G, Davies M, et al. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. PloS one. 2010;5(6):e10939.

3. Johansson R, Sjöberg E, Sjögren M, et al. Tailored vs. Standardized Internet-Based Cognitive Behavior Therapy for Depression and Comorbid Symptoms: A Randomized Controlled Trial. PloS one. 2012;7(5):e36905.

4. Kessler RC, Berglund P, Borges G, et al. Trends in suicide ideation, plans, gestures, and attempts in the United States, 1990-1992 to 2001-2003. JAMA: The Journal of the American Medical Association. 2005;293(20):2487-95.

5. Goldsmith SK. Reducing suicide: A national imperative: Joseph Henry Pr; 2002.

6. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies. JAMA: The Journal of the American Medical Association. 2005;294(16):2064-74.

7. Evans K, Tyrer P, Catalan J, et al. Manual-assisted cognitive-behavior therapy (MACT): A randomized controlled trial of a brief intervention with bibliotherapy in the treatment of recurrent deliberate self-harm. Psychological Medicine. 1999;29(19-25).

8. Hawton K, Bancroft J, Catalan J, et al. Domiciliary and out-patient treatment of selfpoisoning patients by medical and non-medical staff. Psychological medicine. 1981;11(01):169-77.

9. Hawton K, Townsend E, Arensman E, et al. Psychosocial and pharmacological treatments for deliberate self harm. Cochrane Database of Systematic Reviews. 1999;4.

10. Liberman RP, Eckman T. Behavior therapy vs insight-oriented therapy for repeated suicide attempters. Archives of general psychiatry. 1981;38(10):1126.

11. McLeavey BC, Daly RJ, Ludgate JW, et al. Interpersonal Problem-Solving Skills Training in the Treatment of Self-Poisoning Patients. Suicide and Life-Threatening Behavior. 1994;24(4):382-94.

12. Patsiokas AT, Clum GA. Effects of psychotherapeutic strategies in the treatment of suicide attempters. Psychotherapy: Theory, Research, Practice, Training. 1985;22(2):281.

13. Salkovskis PM, Atha C, Storer D. Cognitive-behavioural problem solving in the treatment of patients who repeatedly attempt suicide. A controlled trial. The British Journal of Psychiatry. 1990;157(6):871-6.

14. Sande R, Buskens E, Allart E, et al. Psychosocial intervention following suicide attempt: a systematic review of treatment interventions. Acta psychiatrica scandinavica. 1997;96(1):43-50.

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15. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior. Behavior Modification. 2008;32(1):77-108.

16. Sunderland M, Wong N, Hilvert-Bruce Z, et al. Investigating trajectories of change in psychological distress amongst patients with depression and generalised anxiety disorder treated with internet cognitive behavioural therapy. Behaviour Research and Therapy. 2012.

17. Hilvert-Bruce Z, Rossouw PJ, Wong N, et al. Adherence as a determinant of effectiveness of internet cognitive behavioural therapy for anxiety and depressive disorders. Behaviour Research and Therapy. 2012.

18. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. 2001;16(9):606-13.

19. Kroenke K, Spitzer RL, Williams JBW, et al. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. General Hospital Psychiatry. 2010;32(4):345-59.

20. Titov N, Dear BF, McMillan D, et al. Psychometric Comparison of the PHQ-9 and BDI-II for Measuring Response during Treatment of Depression. Cognitive Behaviour Therapy. 2011;40(2):126-36.

21. Kessler RC, Borges G, Walters EE. Prevalence of and risk factors for lifetime suicide attempts in the National Comorbidity Survey. Archives of general psychiatry. 1999;56(7):617.

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<u>A clinical audit of changes in suicide ideas with internet treatment for depression.</u> Reductions in suicidality after internet cognitive behaviour therapy for depression.

Sarah Watts¹

Jill M. Newby¹

Louise Mewton^{1,2}

Gavin Andrews¹

- 1. Clinical Research Unit for Anxiety and Depression, School of Psychiatry, University of New South Wales at St Vincent's Hospital, Darlinghurst, NSW, Australia.
- 2. Corresponding author.

Competing interests

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Article summary

Article focus

• The reduction of suicidal ideation amongst patients treated for depression using internet cognitive behaviour therapy in clinical practice

Key messages

- Suicidal ideation is common amongst primary care patients prescribed internet CBT for depression
- After treatment with internet CBT, suicidal ideation decreased significantly
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Strengths and limitations

• Evidence is needed to see if the changes in suicidal ideation is sustained over time

Patients who say they feel they would be 'better off dead' worry clinicians and, for that matter, research ethics committees approving depression trials, especially trials over the internet. As a consequence, patients reporting suicidal ideas are often excluded from internet treatment trials (1-3). Given that suicidal thoughts are an integral part of depression we sought data to provide a rational basis for inclusion/exclusion of people with suicidal ideas.

Rates of suicide can be reduced through treatment of depression or reduction in access to the means for suicide (4-6). The efficacy of cognitive behavioural therapy (CBT) in treating depression has been established. Suicidal ideas and attempts decrease, commensurate with reductions in depressive symptomatology (7-15). These studies have all been conducted within a clinical trial framework amongst depressed patients selected for their high suicide risk. To our knowledge, there is currently no evidence regarding the effectiveness of CBT or internet CBT (iCBT) in reducing suicidal ideation in the depressed patient seeking treatment in primary care, and no data to inform inclusion/exclusion criteria in clinical trials.

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<Insert Table and Figure here>

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Contributors

SW drafted the initial manuscript, prepared and cleaned the data, and conducted initial data analysis. LM and JN conducted further statistical analysis. GA supervised and took responsibility for the data. All four authors contributed to revised drafts.

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References

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 Titov N, Andrews G, Davies M, et al. Internet treatment for depression: a randomized

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12. Patsiokas AT, Clum GA. Effects of psychotherapeutic strategies in the treatment of suicide attempters. Psychotherapy: Theory, Research, Practice, Training. 1985;22(2):281.

13. Salkovskis PM, Atha C, Storer D. Cognitive-behavioural problem solving in the treatment of patients who repeatedly attempt suicide. A controlled trial. The British Journal of Psychiatry. 1990;157(6):871-6.

14. Sande R, Buskens E, Allart E, et al. Psychosocial intervention following suicide attempt: a systematic review of treatment interventions. Acta psychiatrica scandinavica. 1997;96(1):43-50.

15. Tarrier N, Taylor K, Gooding P. Cognitive-behavioral interventions to reduce suicide behavior. Behavior Modification. 2008;32(1):77-108.

16. Sunderland M, Wong N, Hilvert-Bruce Z, et al. Investigating trajectories of change in psychological distress amongst patients with depression and generalised anxiety disorder treated with internet cognitive behavioural therapy. Behaviour Research and Therapy. 2012.

17. Hilvert-Bruce Z, Rossouw PJ, Wong N, et al. Adherence as a determinant of effectiveness of internet cognitive behavioural therapy for anxiety and depressive disorders. Behaviour Research and Therapy. 2012.

18. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. 2001;16(9):606-13.

19. Kroenke K, Spitzer RL, Williams JBW, et al. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. General Hospital Psychiatry. 2010;32(4):345-59.

20. Titov N, Dear BF, McMillan D, et al. Psychometric Comparison of the PHQ-9 and BDI-II for Measuring Response during Treatment of Depression. Cognitive Behaviour Therapy. 2011;40(2):126-36.

Kessler RC, Borges G, Walters EE. Prevalence of and risk factors for lifetime suicide 21. attempts in the National Comorbidity Survey. Archives of general psychiatry. 1999;56(7):617.

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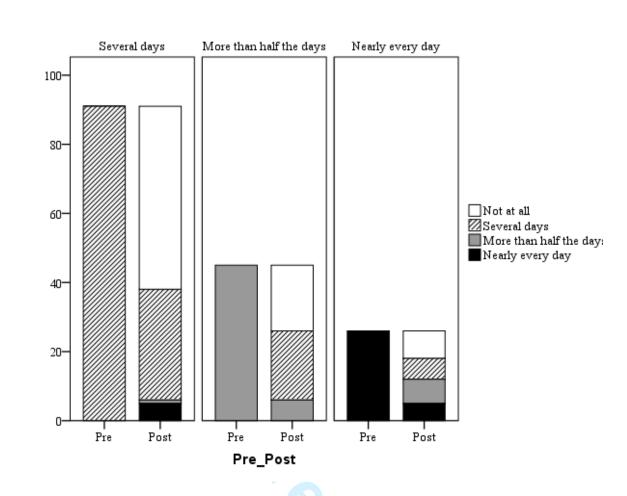


Figure. Frequency of suicidal thoughts (number of patients) before and after treatment for depression.