BMJ open

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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-002886
Article Type:	Research
Date Submitted by the Author:	15-Mar-2013
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Primary Subject Heading:	Public health
Secondary Subject Heading:	Mental health
Keywords:	Suicide & self-harm < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Internet, Telephone

The effect of a web based depression intervention on suicide ideation. Secondary outcome from a randomised controlled trial.

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Key words: Suicide, Depression, Telephone, Internet

Word count: 4,076

Abstract

Objectives: The effect of web-based interventions for depression on suicide ideation in call centres is not known. The aim of this study was to determine if web-based Cognitive Behaviour Therapy (CBT) with and without telephone support is effective in reducing suicide ideation compared to treatment as usual in a helpline. A secondary aim was to examine the factors that predict change in suicide ideation. Putative predictors included level of baseline depression, suicide behaviour, baseline anxiety and type of intervention.

Design: Randomised Controlled Trial

Setting: Lifeline, Australia's 24-hour telephone counselling service Participants: 155 callers to a national helpline service with moderate to high psychological distress.

Interventions: participants were recruited and randomised to receive either 6 weeks of Internet CBT plus weekly telephone follow-up; Internet CBT only; weekly telephone follow-up only; or a wait-list treatment as usual (TAU) control group.

Primary and secondary outcome measures: Suicidal ideation was measured using four items from the 28-item General Health Questionnaire (GHQ-28; [1]. Predictors of change in ideation were tested using logistic regression analysis.

Results: Regardless of intervention condition, participants showed significant reductions in suicidal ideation over twelve months ($p < 0.001$). Higher baseline suicidal behaviour decreased the odds of remission of suicidal ideation at post-intervention (OR: 0.409 ($p < 0.001$). However, change in depression over the course of the interventions was associated with improvement in suicide ideation (OR: 1.165, $p < 0.001$).

Conclusions: Suicide ideation declines with and without proactive intervention. Improvements in depression are associated with the resolution of suicide ideation. Specific interventions focussing on suicide ideation should be further investigated.

TRIAL REGISTRATION: Controlled-Trials.com ISRCTN93903959.

ARTICLE SUMMARY

Article focus:

- To evaluate the effectiveness of a web-based Cognitive Behaviour Therapy intervention on suicide ideation in a helpline.
- To examine predictors of suicide ideation resolution

Key messages:

- Irrespective of intervention condition, participants' suicidal ideation declined over time at post-test, and six months. Declines in suicidal ideation remained significant at 12 month follow-up
- Suicide ideation reduces significantly more in those individuals who also had resolving depression.
- While CBT internet interventions are significantly more effective in resolving depression symptoms compared to control conditions, these operate no more successfully than current call centre practice in resolving suicide ideation.
- Our findings demonstrate the importance of not excluding suicidal participants from interventions designed to target depression.

Strengths and limitations of this study:

- The study used a Randomised Controlled Trial.

- The addition of the TAU control condition is a significant improvement over previous trials.
- Because all scores were initially high at baseline, the lower scores on the second occasion of measurement may have been due to reversion to the mean.

INTRODUCTION

Suicide prevention interventions are delivered every day through crisis intervention lines and through chat in call centres. In Australia, Lifeline reports that over 50 high risk telephone calls are answered daily [2]. However, despite the load taken by suicide prevention crisis lines in responding to callers at risk, there has been little investigation of the role of crisis lines in reducing suicide risk, or in reducing risk factors associated with suicide risk, such as depression.

To date, the research evidence from suicide call centres has largely focussed on evaluating interventions using the telephone, and to our knowledge, only one randomised controlled trial (RCT) has been conducted. This study [3] evaluated the effects of two brief telephone psychotherapies in reducing general distress [Solution Focussed Brief Therapy (SFBT) and Common Factors Therapy (CFT)] compared to a waitlist control condition using 85 individuals recruited via a suicide hotline. Outcome measures included the Brief Psychiatric Rating Scale, and the Beck Depression Inventory. Drop out was high in the SFBT condition (50%) compared to the CFT condition (37%) and across both conditions drop out occurred before the first session. Relative to the waitlist control, significant reductions in several measures of depression and anxiety symptoms were found in participants who completed the interventions, with effect sizes estimated in the range of .67 and .93. However, outcomes on suicide specific measures were not reported. A highly cited, although uncontrolled study, used a follow-up design (pre-post outcomes) to evaluate the effectiveness of a crisis line for non-suicidal crisis callers (n=1617, of whom 801 provided follow-up data) [4]. Callers' levels of crisis and hopelessness were rated during the calls and found to decrease during the course of the call. In a second study, focussing on 1,085 participants who

were suicidal Gould et al. [5] found that levels of intent to die over the course of a call decreased and that there were continuing falls in hopelessness and psychological pain over the continuing weeks.

Web-based interventions are now more frequently used in call centres, and research of their usefulness is emerging in community settings. Two studies of online e-health applications targeting either risk factors for suicide (depression) or suicide ideation were published in 2012. The first was an uncontrolled service evaluation which found a 30% reduction in suicide ideas [6] over the course of a depression web program. The second was a randomised controlled trial of an online intervention which examined the effectiveness and cost effectiveness of an automated six module, six week, intervention specifically targeting suicide ideation for individuals with mild to moderate suicidal thoughts. The intervention was based on Cognitive Behaviour Therapy (CBT), with Dialectical Behaviour Therapy, Problem Solving Therapy and Mindfulness Cognitive Behaviour Therapy included. Significant reductions in suicidal thoughts were found relative to Control condition. The mean incremental cost-effectiveness ratio (ICER) was estimated to be €34,727 (US $41,325) for an additional treatment response, indicating annual cost savings per treatment responder [7].

In 2012, we published the results of a randomised controlled trial investigating the effects of a web application in reducing depression and anxiety in a large call centre [8, 9]. This trial compared four conditions: a treatment as usual condition (TAU), where the participant could call the crisis line at any time; a telephone support service where the participant was contacted for 10 minutes once a week for six weeks; a CBT internet

program for depression combined with a evidence-based depression information website, and a combined condition which incorporated telephone call back and the web programs. Both the web programs alone, and the web programs in combination with the telephone call back, were effective at 12 months in reducing depression symptoms, relative to TAU. This study also measured suicide ideation, and in this paper, we report the results using this outcome measure.

Suicide ideation is a substantial risk factor for suicide attempt. Theories of suicide causation point to the importance of depression and hopelessness in leading to increased levels of suicide ideation and attempts (see [10]). We hypothesised that suicide ideation would be reduced over time in those conditions which successfully reduced depression. Accordingly, we first examined the effect of the four interventions conditions on suicide ideation. For suicide ideation, we hypothesised that the web CBT intervention focussing on reducing depression—with or without the telephone call back— would result in significantly greater reduction of suicide ideation than the other two conditions, which did not include interventions specifically aiming to reduce depression. We then used logistic regression to explore which factors, in addition to any effect of the intervention, predicted changes in suicide ideation at post-test. These factors were baseline suicidality, baseline depression, baseline anxiety, age, gender, education, workforce participation, and changes in depression and anxiety over the course of the intervention (pre to post-test).

METHOD

Data for this study were collected as part of a randomized controlled trial of the impact of a Web-based CBT and psychoeducation intervention on depression symptoms

[9]. The trial comprised four arms: (i) a Web-based CBT intervention; (ii) a Web-based CBT intervention delivered in conjunction with a telephone support line; (iii) the telephone support line alone, and (iv) TAU, which consisted of the opportunity to contact the support line if needed.

Participants

Participants were 155 callers to Lifeline, Australia's 24-hour telephone counselling service, recruited between July 2007 and January 2009. A total of 910 callers agreed to be screened by telephone. Of these, 142 (15.6%) were subsequently unable to be contacted, 61 (7%) were later unwilling to participate, and 337 (37%) did not meet eligibility criteria. Respondents were not eligible for inclusion in the trial if they (1) scored less than 22 on the Kessler Psychological Distress Scale [11] (138/337, 41%), (2) had, by self-report, a diagnosis of schizophrenia or bipolar disorder (89, 26%), or (3) did not have Internet access (67, 20.0%). Ineligible participants were offered brochures sent by mail containing information about the Web intervention used in the trial. Of the 370 people eligible for inclusion in the trial, 155 completed informed consent procedures and pre-intervention assessments, and were randomly assigned to the trial conditions.

Procedure

Following screening and informed consent procedures, pre-intervention data were obtained through a self-report questionnaire mailed to participants. A block randomization procedure was used, with stratification based on site of recruitment and severity of psychological distress at screening. Allocation of participants to trial conditions was conducted independently by a research assistant not involved in the day-

to-day running of the trial. Following randomization, all participants were contacted by telephone and were mailed the relevant materials for their allocated condition.

Intervention and Trial Conditions

The Web-only intervention consisted of Web-based psychoeducation (in week 1 provided by BluePages: bluepages.anu.edu.au) combined with Web-based CBT (in weeks 2–6 provided by MoodGYM: moodgym.anu.edu.au). Both of these Web programs have been shown to reduce depression symptoms in community users [12]. A printed manual containing week-by-week instructions for accessing the Web programs (via a login) was mailed to participants at the start of the trial.

In the Web with telephone support condition, participants completed the Web intervention and also received a weekly 10-minute telephone call from a Lifeline telephone counsellor. The purpose of these calls was to address any issues associated with the participants' use of the intervention.

In the telephone call back only condition, participants received a weekly 10-minute telephone call from a telephone counsellor. These scripted calls focused on various environmental and lifestyle factors associated with depression.

In the TAU condition, participants received neither the call back nor Web interventions, but were free to use the Lifeline counselling service as needed. Participants in this condition were wait-listed to receive the Web-only intervention following completion of the 6-month follow-up.

Participants in all 4 conditions were able to use the Lifeline telephone counselling service as needed, which provided usual emergency or support services. Any use of this service during the intervention period was additional to the 10-minute telephone calls offered as part of the Web with telephone support and telephone support-only intervention conditions. The 10-minute intervention calls were scripted and not intended to provide any form of psychological or supportive counselling.

Measures

Suicidal ideation

Suicidal ideation was measured using four items from the 28-item General Health Questionnaire (GHQ-28; [1]. The four questions measure suicidal ideation, asking respondents to indicate how they have felt over the last few weeks. The first two items: 'Have you recently felt that life is not worth living' and 'Have you recently found yourself wishing you were dead and away from it all' were scored on the 4-point scale: 'Not at all', 'No more than usual', 'Rather more than usual' or 'Much more than usual'. The remaining two items: 'Have you recently had thoughts of the possibility that you might do away with yourself' and 'Have you recently found that the idea of taking your own life kept coming into your mind' were scored on the 4-point scale: 'Definitely not', 'I don't think so', 'Has crossed my mind' or 'Definitely has'. Responses were then categorised in a binary manner, with the negatively-worded response categories (Not at all, No more than usual, definitely not, and I don't think so) scored with a 0, and the positively-worded response categories scored with a 1. Binary scores for each item were summed to provide a total scale score ranging from 0 to 4, with a higher score indicating higher suicidal ideation. This scoring system is that used for all items and sub

scores of the GHQ-28, which has been validated in Australian populations [13]. The four suicide items from the GHQ-28 have been used extensively by Goldney and colleagues to assess suicidal ideation in a number of Australian samples [14-16]. These items have been validated relative to other well established measures of suicidal intent and hopelessness [17, 18].

Predictor variables

Depression symptoms were measured by the Center for Epidemiologic Studies Depression Scale (CES-D)[19], a widely used, 20 item scale with strong reliability and validity [19, 20], with scores ranging from 0 to 60. Anxiety symptoms were assessed using the 14-item anxiety scale from the Depression, Anxiety and Stress Scales (DASS-A;[21]. Each of these items is rated on a four-point scale from 0 ("did not apply to me at all") to 4 ("applied to me most of the time"), with total scores ranging from 0 to 42. The reliability and validity of the DASS-A scale has been demonstrated previously ([22, 23]).

Demographic variables including age, gender, educational attainment and workforce participation were assessed by self-report in the pre-test survey. Educational attainment was based on two items assessing highest level of education, which were used to form an estimate of total number of years of education. Workforce participation was based on an item assessing employment status, with "unemployed" and "not in the labour force" categorised as non-participation, and employed "full-time" or "part-time" categorised as participation.

Statistical analyses

Differential changes in suicide ideation across the four conditions were assessed using mixed model repeated measures analysis of variance. Within-person variation was modeled using an unstructured covariance matrix and degrees of freedom were estimated using Satterthwaite's approximation. This model included the fixed effects of condition, time (pre, post, 6 month, 12 month) and the interaction between condition and time. The presence of a significant interaction between an active intervention and the TAU condition over time would indicate a significant reduction in suicidal ideation for that condition relative to control. Within-condition change in suicidal ideation was also examined using this model. Mixed models yield an intention-to-treat analysis, using all available measurement points for each participant under the assumption that withdrawal data are missing at random. Two participants with missing suicidal ideation scores at baseline were omitted from analyses. To evaluate whether the scoring of the suicidal ideation scale influenced the findings, the models were re-estimated using a continuous score of suicidal ideation, assessed at each time point as the sum of responses to the four ideation items (range 0-12).

Logistic regression was then used to examine predictors of suicidal ideation at post-intervention, defined as a suicidal ideation score of 0. In particular, the hypothesis was assessed that reduction in depression symptoms from pre- to post-intervention predicted remission of ideation. Only completers of the post-test assessment were included in this analysis. A depression symptom change score from pre- to post-intervention was calculated by subtracting post-intervention CES-D scores from pre-intervention scores, with positive scores indicating a reduction/improvement in symptoms. The effect of anxiety symptoms and changes in anxiety were assessed in the same way. Suicidal ideation scores (ranging from 0 to 4) were coded categorically as

"0" (score >= 1, indicating some suicidal ideation) or "1" (score = 0, no ideation). To control for baseline depression, baseline anxiety, baseline suicidality and intervention condition, these variables were included in the regression simultaneously with the depression change score. In addition, age, gender, education and workforce participation were included in the models due to their potential associations with suicidal ideation.

RESULTS

Descriptives and changes in suicide ideation

Table 1 shows the characteristics of the sample at baseline, with mental health measures for post-intervention also presented. The age range was 19-72, with a median age of 42 years. The majority of participants (57%) had graduated from high school. Most of the participants were female and approximately half were in the work force. Depression and anxiety scores were considerably higher than the cut points for the scales used at both time points, although there were decreases from pre- to post-intervention. Likewise, high rates of suicidality were observed, with 62.7% and 41.5% reporting suicidal ideation at pre- and post-intervention respectively.

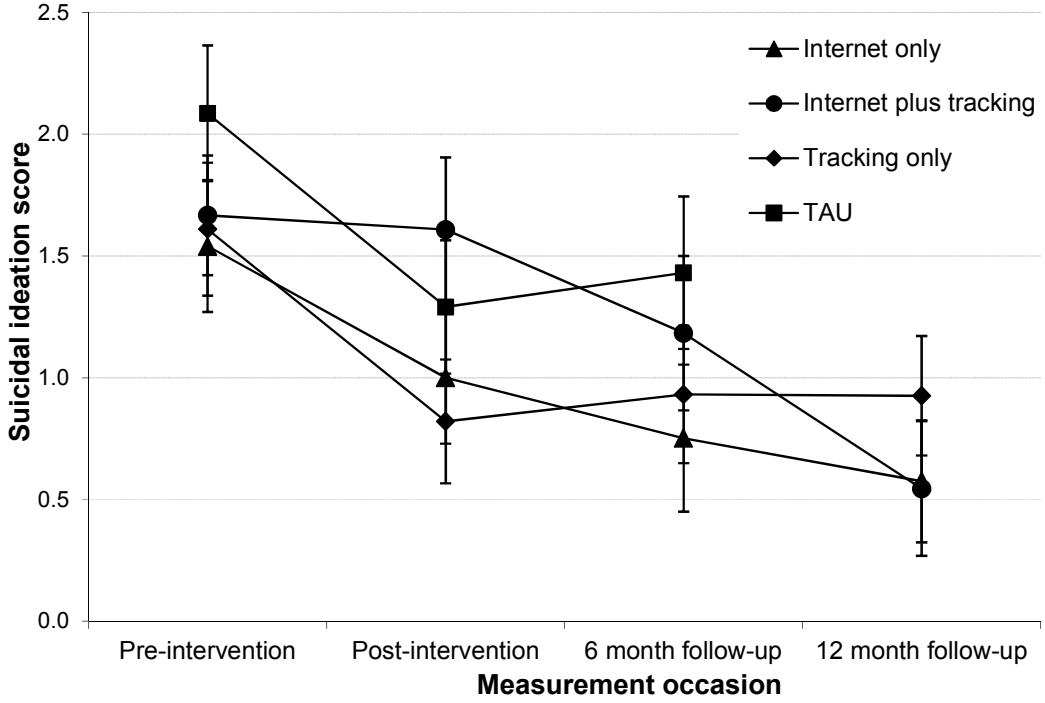
Table 1. Characteristics of participants

	N	Mean	SD
Age	155	41.49	12.35
Years of education	150	13.47	2.67
CES-D depression score, pre-intervention	152	36.25	10.22
CES-D depression score, post-intervention	107	28.68	14.40
DASS anxiety score, pre-intervention	154	13.34	8.03
DASS anxiety score, post-intervention	107	11.45	10.16
GHQ suicidal ideation score - pre-intervention	153	1.73	1.64
GHQ suicidal ideation score - post-intervention	106	1.00	1.45
	N	Count	%
Gender	155		
Female		127	81.9%
Male		28	18.1%
Workforce participation	155		
Participation		72	46.5%
Non-participation		83	53.5%
Treatment condition	155		
Internet only		38	24.5%
Internet plus telephone support		45	29.0%
Telephone support only		37	23.9%
Treatment as usual		35	22.6%

Mixed models: Effect of intervention type on suicidal ideation

Suicide ideation declined significantly over the 12 month period ($F_{3,95.4} = 15.06$, $p < 0.001$). However, differences in change over time between conditions were not significant ($F(8,115.8) = 1.13$, $p = .352$). Figure 1 shows the estimated marginal means for suicidal ideation across measurement occasions.

Figure 1: Estimated marginal means for suicidal ideation across measurement occasions.



Within group contrasts

As can be seen in Table 2, planned contrasts revealed that participants in the call back only and TAU conditions showed significant declines in suicidal ideation from pre- to post-intervention and from pre-intervention to 6 month follow-up. Declines in suicidal ideation from pre-intervention to 12 month follow-up were significant for participants in all conditions in which the difference could be assessed.

Table 2. Within group contrast estimates and significance tests for suicidal ideation

		Contrast		
		Pre-intervention to post- intervention	**Pre-intervention to 6 month follow-up**	**Pre-intervention to 12 month follow-up**
Condition	**Statistic**			
Internet only	Contrast estimate	-.54	-.79	-.97
	Test value	$t(109.8) = -1.98$	$t(101.5) = -2.50$	$t(73.2) = -3.65$
	p value	.050	.016	<.001
Internet + telephone support	Contrast estimate	-.06	-.48	-1.12
	Test value	$t(121.3) = -.20$	$t(106.2) = -1.45$	$t(80.8) = -3.91$
	p value	.85	.15	<.001
Telephone support only	Contrast estimate	-.79	-.68	-.68
	Test value	$t(105.6) = -3.05$	$t(100.0) = -2.22$	$t(78.0) = -2.61$
	p value	.003	.029	.011
Treatment as usual	Contrast estimate	-.80	-.66	
	Test value	$t(108.0) = -2.89$	$t(103.1) = -1.96$	
	p value	.005	.053	

Between group contrasts

No significant differences were found between conditions at post-intervention, 6 month follow-up, or 12 month follow-up: Internet only vs. TAU (post-test: Contrast estimate = .26; $p = .51$; 6-month follow-up: Contrast estimate = -.14, $p = .77$); Internet only vs. Telephone support only (post-test: Contrast estimate = .25; $p = .51$; 6-month follow-up: Contrast estimate = -.11, $p = .80$; 12-month follow-up: Contrast estimate = -.28; $p = .45$); Internet + telephone support vs. TAU (post-test: Contrast estimate = .74; $p = .07$; 6-month follow-up: Contrast estimate = .17, $p = .72$); Internet + telephone support vs Telephone support only (post-test: Contrast estimate = .73; $p = .07$; 6-month follow-up:

Contrast estimate = .19, p = .67; 12-month follow-up: Contrast estimate = -.44; p = .26); Telephone support only vs TAU (post-test: Contrast estimate = .01; p = .99; 6-month follow-up: Contrast estimate = -.02, p = .96); Internet only vs Internet + telephone support (post-test: Contrast estimate = -.48; p = .24; 6-month follow-up: Contrast estimate = -.31, p = .51; 12-month follow-up: Contrast estimate = .16; p = .69).

To test whether the lack of between-group effects were related to scaling effects of the suicidal ideation measure, the models were re-estimated using a continuous score for suicidal ideation. As with the original analysis, there was significant reduction over time in suicidal ideation scores ($F_{3,94.5}$ = 14.08, p < 0.001). Again, there was no significant interaction between condition and time ($F_{8,89.9}$ = 0.81, p = 0.598), indicating no significant difference in change of suicidal ideation scores between the intervention groups across the study period.

Effect sizes for suicidal ideation

At post-intervention, effect sizes were 0.10 (95% CI: -0.43 to 0.64) for the Internet only condition and 0.04 (95% CI: -0.54 to 0.62) for the Internet plus call back condition, compared to the TAU condition. Compared to call back only, effect sizes were 0.28 (95% CI: -0.24 to 0.79) for the Internet only condition and 0.41 (95% CI: -0.15 to 0.98) for the Internet plus call back condition. At 6 month follow-up, effect sizes were 0.36 (95% CI: -0.24 to 0.96) for the Internet only condition and 0.20 (95% CI: -0.42 to 0.81) for the Internet plus telephone support condition, compared to the TAU condition. Compared to telephone support only, effect sizes were 0.08 (95% CI: -0.48 to 0.63) for the Internet only condition and 0.07 (95% CI: -0.51 to 0.65) for the Internet

plus telephone support condition. At 12 month follow-up, effect sizes were 0.28 (95% CI: -0.33 to 0.89) for the Internet only condition and 0.45 (95% CI: -0.24 to 1.13) for the Internet plus telephone support condition, compared with the call back only condition.

Predictors of suicide ideation

A logistic regression analysis was designed to measure predictors of suicide ideation change taking account of intervention condition. Consistent with findings reported above, compared to baseline (M:1.73; SD: 1.64; N=153) suicidal ideation significantly decreased in the whole sample at post-test (M:1.00; SD:1.45; N=106), 6-month (M:0.99; SD:1.54; N=91) and 12-month follow-up (M:0.66; SD:1.27; N=56). However, as there was no significant interaction effect between condition and time on suicidal ideation, this interaction was not retained in the model. Table 3 shows the results for the model with interactions excluded. As would be expected, higher levels of suicide ideation at baseline were associated with significantly reduced odds of absence of suicide ideation at post-test. Neither baseline depression nor anxiety was significantly associated with no suicide ideation at post-test. There were also no significant effects of any of the demographic characteristics. However, a greater improvement in depression symptoms from pre- to post-intervention was associated with increased odds of no suicidal ideation at post-intervention. At baseline, the majority of participants (n=93; 62.0%) reported both depressive symptoms and suicidal ideation. This proportion decreased at all time-points following the interventions [post-test: 44 (41.5%); 6-months follow-up: 30 (33.0%); 12-months follow-up: 13 (23.2%)]. Based on McNemar's tests using completers of each assessment, these decreases were significant at all three time

points ($P = 0.005$, $P < 0.001$ and $P = 0.002$ at post, 6-months and 12-months respectively). There was no significant difference in the proportion of participants with depression but no suicidal ideation, except at 12-month follow-up [baseline: n=53 (35.3%); post-test: n=42 (39.6%), 6-months follow-up: n=28 (30.8%); 12-months follow-up: 18 (32.1%); $P = 1.00$; $P = 0.15$ and $P = 0.019$ at post, 6-months and 12-months respectively).

Table 3. Logistic regression analyses of remission of suicidal ideations (completers only)

			95% CI	
	OR	p	Lower	Upper
Suicidality score at baseline	0.409	**<0.001**	0.249	0.671
Condition	--	0.239		
TAU	1.000	--		
Internet only	1.408	0.699	0.248	8.001
Internet + telephone support	0.323	0.234	0.050	2.082
Telephone support only	2.442	0.284	0.476	12.512
Baseline depression score	0.926	0.081	0.849	1.010
Depression change score	1.165	**<0.001**	1.070	1.267
Baseline anxiety score	1.066	0.256	0.955	1.190
Anxiety change score	0.986	0.836	0.859	1.130
Gender: F vs M	0.992	0.993	0.174	5.646
Age	1.051	0.054	0.999	1.106
Years of education	0.897	0.438	0.681	1.181
Not in labour force vs. employed	0.915	0.899	0.233	3.592

*only main effects included.

DISCUSSION

This was the first study to examine the effect of online interventions on suicide ideation in a call centre using a randomised controlled trial design. In contrast to our hypothesis, results from our study indicated that irrespective of intervention condition, participants' suicidal ideation declined over time at post test, and six months. Declines in suicidal ideation remained significant at 12 month follow-up. Although there were small effects at post-test and medium effect sizes at follow-up among the intervention conditions, there were no consistent overall effects for condition. Participants having higher baseline suicide scores were more likely to continue experiencing suicidal ideation at post-intervention, while those with greater improvements in depression symptoms were less likely to experience suicide ideation at post-intervention.

Several studies have shown reductions of suicide ideation in uncontrolled pre post trials of counselling or internet CBT (e.g.,[5, 6]). This is, to our knowledge the first randomised controlled trial of an intervention in a call line centre, comparing a number of active interventions to treatment as usual. The study is also unique in that it examined predictors of ideation change, taking account of the effect of intervention. As previously reported for this study [9], web based CBT, and web CBT with counsellor call back significantly reduced depression symptoms relative to TAU. These findings indicate that suicide ideation did not follow the same pattern as depression in response to the intervention, and, more generally, that suicide ideation was not strictly tethered to depression. Nevertheless, the regression analysis found that taking account of intervention type, changes in depression did predict later lower levels of ideation, suggesting that depression change is an important albeit not necessarily the only factor in reducing ideation. We interpret these findings to suggest that change in depression, in

what ever way it is brought about, is a contributing variable to reduction in suicide ideation. A second explanation for the findings is that changes in suicide ideation and changes in depression follow different time trajectories, with ideation resolving faster than depression. The two constructs are likely to be interactive, with ideation reduction assisting in lowering depression symptoms over time. Hopelessness may mediate both depression and ideation but may influence each within different time frames [24]. Interestingly, a recent meta-analysis [25] has examined the effects of face-to-face psychotherapy for adult depression on suicidality. It found a non-significant effect of psychotherapy in the reduction of suicidality but a significant effect for depression, consistent with concept that depression and suicidality are not strictly tethered.

Suicide ideation resolved in our TAU condition, consistent with the notion that ideation is responsive to the passage of time. This finding, however, does not rule out the possibility that specific psychological or support interventions will support faster resolution of suicide ideation symptoms. Indeed the intervention developed by Van Spijker et al. [7] may be one of these specific interventions.

Limitations of the study

One explanation of the failure to find an effect of intervention type on suicide ideation outcomes is that these findings are due to regression to the mean. Because all scores were initially high at baseline, scores would be expected to revert to the mean on the second occasion of measurement. Intervention completion rates were lower in our study relative to some other trials of web-based treatments for depression [26] but not of other telephone-based services [3]. The reasons for this are unclear. The current trial

was a true effectiveness trial employing a volunteer workforce for recruitment and call back, and hence might be expected to be associated with greater recruitment and adherence problems relative to the more controlled environment of an efficacy study [27]. Also, the interventions were short, delivered by non-health professionals, and may have constituted the only service received. The measure used to assess suicidality used items that categorised outcomes dichotomously, and then summed responses, as per scale score recommendations. Moreover, these scores were then further dichotomised in the regression analysis. This is essentially a conservative treatment of data. We did investigate whether other continuous scoring methods might reveal intervention effects. These data did not yield any relationships. Finally, we were not able to analyse the influence of other psychological characteristics on treatment outcome, such as hopelessness, or support from family, which might affect both depression and suicidal ideation levels. These measures were not included in our study.

Future research

Replications of this trial need to be performed to check consistency of research findings. Furthermore, examination of mediators of change such as hopelessness in larger samples would add significantly to our knowledge of which components of therapy are necessary for reduction of suicide ideation. Given the absence of differences between conditions, it may be that one or more components present in each treatment arm (e.g., giving hope, or participating in research) are responsible for change in outcome. Identifying these components and altering their presence by intensifying or omitting them in a new intervention trial would add to our current knowledge

mechanisms of change. Investigation of the causes of reductions in suicide ideation is warranted.

Clinical implications

Despite the limitations, the current study clearly demonstrated that suicide ideation declined irrespective of intervention, telephone counsellor contact or wait-list. The addition of the TAU control condition is a significant improvement over previous trials. The study demonstrated that, while CBT internet interventions are significantly more effective in resolving depression symptoms than control conditions, these operate no more successfully than current call centre practice in resolving suicide ideation. Suicide ideation reduces significantly more effectively in those individuals who also have resolving depression. The majority of people experiencing suicidal ideation do not receive mental health treatment [28]. Internet-based or telephone based interventions have the ability advantage that they can be easily accessed by large numbers of people, on an anonymous basis. In line with Watts et al. [6], our findings demonstrate the importance of not excluding suicidal participants from interventions designed to target depression.

ACKNOWLEDGEMENTS

Nicole Burgess coordinated and conducted data collection for the trial. Dawn O'Neil was involved in obtaining funding for the trial and coordinating Lifeline Australia's collaboration with the ANU. Assoc Prof Richard O'Kearney was a member of LF's PhD supervisory panel. Trevor Carlyon was also involved in coordinating Lifeline staff and

volunteer involvement in the trial and supported Nicole in her role. The e hub team supported the trial implementation. We acknowledge the contributions of the Lifeline counselors who participated in this trial.

COMPETING INTERESTS

None.

FUNDING

Australian Research Council Linkage Grant (LP0667970), 2006, 3 years, $279,325 (Christensen, Griffiths, Mackinnon, Smith), Internet technologies, health informatics, and statistical models, and new delivery platforms in call centres (CIA).
HC and PB were supported by NHMRC 525411 and NHMRC Early Career Fellowship 1035262. KMG is supported by NHMRC Fellowship No. 525413.

CONTRIBUTORSHIP

HC, KG, AJM conceived the study, LF, HC, KG, AJM designed the study, HC, TD drafted the initial manuscript, LF, PB, AJM prepared and cleaned the data and conducted initial data analysis. All authors contributed to revised drafts.

DATA SHARING

The data from this study are available through email to Dr Philip Batterham p.batterhan@anu.edu.au

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	6 (ref 8-9)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6 (ref 8-9)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8 (and ref 8-9)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	Ref 8-9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Ref 8-9
	14b	Why the trial ended or was stopped	Ref 8-9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17-19
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20-22
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ open

The effect of a web based depression intervention on suicide ideation. Secondary outcome from a randomised controlled trial in a helpline.

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-002886.R1
Article Type:	Research
Date Submitted by the Author:	26-Apr-2013
Complete List of Authors:	Christensen, Helen; Black Dog Institute, University of New South Wales, School of Medicine Farrer, Lou; Australian National University, Centre for Mental Health Research Batterham, Philip; Australian National University, Centre for Mental Health Research Mackinnon, Andrew; University of Melbourne, Orygen Youth Health Griffiths, Kathleen; Australian National University, Centre for Mental Health Research Donker, Tara; Black Dog Institute, University of New South Wales, School of Medicine
Primary Subject Heading:	Public health
Secondary Subject Heading:	Mental health
Keywords:	Suicide & self-harm < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Internet, Telephone

The effect of a web based depression intervention on suicide ideation. Secondary outcome from a randomised controlled trial in a helpline.

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Key words: Suicide, Depression, Telephone, Internet

Word count: 4,076

ABSTRACT

Objectives: The effect of web-based interventions for depression on suicide ideation in callers to helplines is not known. The aim of this study was to determine if web-based Cognitive Behaviour Therapy (CBT) with and without telephone support is effective in reducing suicide ideation in callers to a helpline compared to treatment as usual. A secondary aim was to examine the factors that predict change in suicide ideation. Putative predictors included level of baseline depression, suicide behaviour, baseline anxiety and type of intervention.

Design: Randomised Controlled Trial

Setting: Lifeline, Australia's 24-hour telephone counselling service Participants: 155 callers to a national helpline service with moderate to high psychological distress.

Interventions: participants were recruited and randomised to receive either 6 weeks of Internet CBT plus weekly telephone follow-up; Internet CBT only; weekly telephone follow-up only; or a wait-list treatment as usual (TAU) control group.

Primary and secondary outcome measures: Suicidal ideation was measured using four items from the 28-item General Health Questionnaire (GHQ-28; [1]. Predictors of change in ideation were tested using logistic regression analysis.

Results*:* Regardless of intervention condition, participants showed significant reductions in suicidal ideation over twelve months ($p < 0.001$). Higher baseline suicidal behaviour decreased the odds of remission of suicidal ideation at post-intervention (OR: 0.409 ($p < 0.001$). However, change in depression over the course of the interventions was associated with improvement in suicide ideation (OR: 1.165, $p < 0.001$).

Conclusions*:* Suicide ideation declines with and without proactive intervention. Improvements in depression are associated with the resolution of suicide ideation. Specific interventions focussing on suicide ideation should be further investigated.

TRIAL REGISTRATION: Controlled-Trials.com ISRCTN93903959.

ARTICLE SUMMARY

Article focus:

- To evaluate the effectiveness of a web-based Cognitive Behaviour Therapy intervention on suicide ideation in a helpline.
- To examine predictors of suicide ideation resolution

Key messages:

- Irrespective of intervention condition, participants' suicidal ideation declined over time at post-test, and six months. Declines in suicidal ideation remained significant at 12 month follow-up
- Suicide ideation reduces significantly more in those individuals who also had resolving depression.
- While CBT internet interventions are significantly more effective in resolving depression symptoms compared to control conditions, these operate no more successfully than current call centre practice in resolving suicide ideation.
- Our findings demonstrate the importance of not excluding suicidal participants from interventions designed to target depression.

Strengths and limitations of this study:

- The study used a Randomised Controlled Trial.

- The addition of the TAU control condition is a significant improvement over previous trials.
- Because all scores were initially high at baseline, the lower scores on the second occasion of measurement may have been due to reversion to the mean.

INTRODUCTION

Suicide prevention interventions are delivered every day through helplines and through chat in call centres. In Australia, Lifeline reports that over 50 high risk telephone calls are answered daily [2]. However, despite the load taken by helplines in responding to callers at risk, there has been little investigation of the role of these services in reducing suicide risk, or in reducing risk factors associated with suicide risk, such as depression.

To date, the research evidence from suicide helplines has largely focussed on evaluating interventions using the telephone, and to our knowledge, only one randomised controlled trial (RCT) has been conducted. This study [3] evaluated the effects of two brief telephone psychotherapies in reducing general distress [Solution Focussed Brief Therapy (SFBT) and Common Factors Therapy (CFT)] compared to a waitlist control condition using 85 individuals recruited via a suicide hotline. Outcome measures included the Brief Psychiatric Rating Scale, and the Beck Depression Inventory. Drop out was high in the SFBT condition (50%) compared to the CFT condition (37%) and across both conditions drop out occurred before the first session. Relative to the waitlist control, significant reductions in several measures of depression and anxiety symptoms were found in participants who completed the interventions, with effect sizes estimated in the range of .67 and .93. However, outcomes on suicide specific measures were not reported. A highly cited, although uncontrolled study, used a follow-up design (pre-post outcomes) to evaluate the effectiveness of a helpline for non-suicidal crisis callers (n=1617, of whom 801 provided follow-up data) [4]. Callers' levels of crisis and hopelessness were rated during the calls and found to decrease

during the course of the call. In a second study, focussing on 1,085 participants who were suicidal Gould et al. [5] found that levels of intent to die over the course of a call decreased and that there were continuing falls in hopelessness and psychological pain over the continuing weeks.

Web-based interventions are now more frequently used in helpline services, and research of their usefulness is emerging in community settings. Two studies of online e-health applications targeting either risk factors for suicide (depression) or suicide ideation were published in 2012. The first was an uncontrolled service evaluation which found a 30% reduction in suicide ideas [6] over the course of a depression web program. The second was a randomised controlled trial of an online intervention which examined the effectiveness and cost effectiveness of an automated six module, six week, intervention specifically targeting suicide ideation for individuals with mild to moderate suicidal thoughts. The intervention was based on Cognitive Behaviour Therapy (CBT), with Dialectical Behaviour Therapy, Problem Solving Therapy and Mindfulness-Based Cognitive Therapy included. Significant reductions in suicidal thoughts were found relative to Control condition. The mean incremental cost-effectiveness ratio (ICER) was estimated to be €34,727 (US $41,325) for an additional treatment response, indicating annual cost savings per treatment responder [7].

In 2012, we published the results of a randomised controlled trial investigating the effects of a web application in reducing depression and anxiety in a large helpline [8, 9]. This trial compared four conditions: a treatment as usual condition (TAU), where the participant could call the crisis line at any time; a telephone call back service where the participant was contacted for 10 minutes systematically once a week for six weeks; a

CBT internet program for depression combined with a evidence-based depression information website, and a combined condition which incorporated telephone call back and the web programs. Both the web programs alone, and the web programs in combination with the telephone call back, were effective at 12 months in reducing depression symptoms, relative to TAU. This study also measured suicide ideation, and in this paper, we report the results using this outcome measure.

Suicide ideation is a substantial risk factor for suicide attempt. Theories of suicide causation point to the importance of depression and hopelessness in leading to increased levels of suicide ideation and attempts (see [10]). We hypothesised that suicide ideation would be reduced over time in those conditions which successfully reduced depression. Accordingly, we first examined the effect of the four interventions conditions on suicide ideation. For suicide ideation, we hypothesised that the web CBT intervention focussing on reducing depression—with or without the telephone call back— would result in significantly greater reduction of suicide ideation than the other two conditions, which did not include interventions specifically aiming to reduce depression. We then used logistic regression to explore which factors, in addition to any effect of the intervention, predicted changes in suicide ideation at post-test. These factors were baseline suicidality, baseline depression, baseline anxiety, age, gender, education, workforce participation, and changes in depression and anxiety over the course of the intervention (pre to post-test).

METHOD

Data for this study were collected as part of a randomized controlled trial of the impact of a Web-based CBT and psychoeducation intervention on depression symptoms

[9]. The trial comprised four arms: (i) a Web-based CBT intervention; (ii) a Web-based CBT intervention delivered in conjunction with a telephone call back; (iii) the proactive call back telephone line alone, and (iv) TAU, which consisted of the opportunity for the participant to contact the helpline if needed.

Ethics statement

Ethics approval for the trial was granted by the Australian National University Human Research Ethics Committee (Protocol no. 2007/12).

Participants

Participants were 155 callers to Lifeline, Australia's 24-hour telephone counselling service, recruited between July 2007 and January 2009. High distress or acutely suicidal participants were excluded. A total of 910 callers agreed to be screened by telephone. Of these, 142 (15.6%) were subsequently unable to be contacted, 61 (7%) were later unwilling to participate, and 337 (37%) did not meet eligibility criteria. Respondents were not eligible for inclusion in the trial if they (1) scored less than 22 on the Kessler Psychological Distress Scale [11] (138/337, 41%), a brief screening scale used clinically and epidemiologically, (2) had, by self-report, a diagnosis of schizophrenia or bipolar disorder (89, 26%), or (3) did not have Internet access (67, 20.0%). Ineligible participants were offered brochures sent by mail containing information about the Web intervention used in the trial. Of the 370 people eligible for inclusion in the trial, 155 completed informed consent procedures and pre-intervention assessments, and were randomly assigned to the trial conditions. The trial flow is illustrated in Figure 1.

Procedure

Following screening and informed consent procedures, pre-intervention data were obtained through a self-report questionnaire mailed to participants. A block randomization procedure was used, with stratification based on site of recruitment and severity of psychological distress at screening. Allocation of participants to trial conditions was conducted independently by a research assistant not involved in the day-to-day running of the trial. Following randomization, all participants were contacted by telephone and were mailed the relevant materials for their allocated condition.

Intervention and Trial Conditions

The Web-only intervention consisted of Web-based psychoeducation (in week 1 provided by BluePages: bluepages.anu.edu.au) combined with Web-based CBT (in weeks 2–6 provided by MoodGYM: moodgym.anu.edu.au). BluePages is an educational site that provides information on evidence-based interventions for depression. MoodGYM is a first generation, interactive web application which delivers cognitive behaviour therapy through a series of 5 modules, captures user behaviour and self-report symptoms on validated scales, and offers an online CBT workbook. Both of these Web programs have been shown to reduce depression symptoms in community users [12]. A printed manual containing week-by-week instructions for accessing the Web programs (via a login) was mailed to participants at the start of the trial.

In the Web with telephone call back condition, participants completed the Web intervention and also received a weekly 10-minute telephone call from a Lifeline

telephone counsellor. The purpose of these calls was to address any issues associated with the participants' use of the intervention.

In the telephone call back only condition, participants received a weekly 10-minute telephone call initiated from a telephone counsellor. These scripted calls focused on various environmental and lifestyle factors associated with depression.

In the TAU condition, participants received neither the call back nor Web interventions, but were free to use the helpline service as needed. Participants in this condition were wait-listed to receive the Web-only intervention following completion of the 6-month follow-up.

As in the TAU condition, participants in all 3 other conditions were also able to use the helpline service as needed, which provided usual emergency or support services. Self-reported contacts with the service were taken at each follow-up occasion for each of the 4 conditions. Any use of this service during the intervention period was additional to the 10-minute telephone calls offered proactively as part of the call back component of the Telephone call back condition and the Internet plus call back condition.

Measures

Suicidal ideation

Suicidal ideation was measured using four items from the 28-item General Health Questionnaire (GHQ-28; [1]. The four questions measure suicidal ideation, asking respondents to indicate how they have felt over the last few weeks. The first two items: 'Have you recently felt that life is not worth living' and 'Have you recently found yourself wishing you were dead and away from it all' were scored on the 4-point scale:

'Not at all', 'No more than usual', 'Rather more than usual' or 'Much more than usual'. The remaining two items: 'Have you recently had thoughts of the possibility that you might do away with yourself' and 'Have you recently found that the idea of taking your own life kept coming into your mind' were scored on the 4-point scale: 'Definitely not', 'I don't think so', 'Has crossed my mind' or 'Definitely has'. Responses were then categorised in a binary manner, with the negatively-worded response categories (Not at all, No more than usual, definitely not, and I don't think so) scored with a 0, and the positively-worded response categories scored with a 1. Binary scores for each item were summed to provide a total scale score ranging from 0 to 4, with a higher score indicating higher suicidal ideation. This scoring system is that used for all items and sub scores of the GHQ-28, which has been validated in Australian populations [13]. The four suicide items from the GHQ-28 have been used extensively by Goldney and colleagues to assess suicidal ideation in a number of Australian samples [14-16]. These items have been validated relative to other well established measures of suicidal intent and hopelessness [17, 18]. Cronbach Alpha for the 4 items at baseline in the present sample was 0.90.

Predictor variables

Depression symptoms were measured by the Center for Epidemiologic Studies Depression Scale (CES-D)[19], a widely used, 20 item scale with strong reliability and validity [19, 20], with scores ranging from 0 to 60. Anxiety symptoms were assessed using the 14-item anxiety scale from the Depression, Anxiety and Stress Scales (DASS-A;[21]. Each of these items is rated on a four-point scale from 0 ("did not apply to me at all") to 4 ("applied to me most of the time"), with total scores ranging from 0 to 42. The

reliability and validity of the DASS-A scale has been demonstrated previously ([22, 23]).

Demographic variables including age, gender, educational attainment and workforce participation were assessed by self-report in the pre-test survey. Educational attainment was based on two items assessing highest level of education, which were used to form an estimate of total number of years of education. Workforce participation was based on an item assessing employment status, with "unemployed" and "not in the labour force" categorised as non-participation, and employed "full-time" or "part-time" categorised as participation.

Statistical analyses

Differential changes in suicide ideation across the four conditions were assessed using mixed model repeated measures analysis of variance. Within-person variation was modeled using an unstructured covariance matrix and degrees of freedom were estimated using Satterthwaite's approximation. This model included the fixed effects of condition, time (pre, post, 6 month, 12 month) and the interaction between condition and time. The presence of a significant interaction between an active intervention and the TAU condition over time would indicate a significant reduction in suicidal ideation for that condition relative to control. Within-condition change in suicidal ideation was also examined using this model. Mixed models yield an intention-to-treat analysis, using all available measurement points for each participant under the assumption that withdrawal data are missing at random. Two participants with missing suicidal ideation scores at baseline were omitted from analyses. To evaluate whether the scoring of the suicidal ideation scale influenced the findings, the models were re-estimated using a

continuous score of suicidal ideation, assessed at each time point as the sum of responses to the four ideation items (range 0-12).

Logistic regression was then used to examine predictors of suicidal ideation at post-intervention, defined as a suicidal ideation score of 0. In particular, the hypothesis was assessed that reduction in depression symptoms from pre- to post-intervention predicted remission of ideation. Only completers of the post-test assessment were included in this analysis. A depression symptom change score from pre- to post-intervention was calculated by subtracting post-intervention CES-D scores from pre-intervention scores, with positive scores indicating a reduction/improvement in symptoms. The effect of anxiety symptoms and changes in anxiety were assessed in the same way. Suicidal ideation scores (ranging from 0 to 4) were coded categorically as "0" (score >= 1, indicating some suicidal ideation) or "1" (score = 0, no ideation). To control for baseline depression, baseline anxiety, baseline suicidality and intervention condition, these variables were included in the regression simultaneously with the depression change score. In addition, age, gender, education and workforce participation were included in the models due to their potential associations with suicidal ideation.

RESULTS

Descriptives and changes in suicide ideation

Table 1 shows the characteristics of the sample at baseline, with mental health measures for post-intervention also presented. The age range was 19-72, with a median age of 42 years. The majority of participants (57%) had graduated from high school. Most of the participants were female and approximately half were in the work force. Depression and anxiety scores were considerably higher than the cut points for the scales used at both time points, although there were decreases from pre- to post-intervention. Likewise, high rates of suicidality were observed, with 62.7% and 41.5% reporting suicidal ideation at pre- and post-intervention respectively.

Table 1. Characteristics of participants

	N	Mean	SD
Age	155	41.49	12.35
Years of education	150	13.47	2.67
CES-D depression score, pre-intervention	152	36.25	10.22
CES-D depression score, post-intervention	107	28.68	14.40
DASS anxiety score, pre-intervention	154	13.34	8.03
DASS anxiety score, post-intervention	107	11.45	10.16
GHQ suicidal ideation score - pre-intervention	153	1.73	1.64
GHQ suicidal ideation score - post-intervention	106	1.00	1.45
	N	Count	%
Gender	155		
Female		127	81.9%
Male		28	18.1%
Workforce participation	155		
Participation		72	46.5%
Non-participation		83	53.5%
Treatment condition	155		
Internet only		38	24.5%
Internet plus call back		45	29.0%
Telephone call back only		37	23.9%

Treatment as usual	35	22.6%

Mixed models: Effect of intervention type on suicidal ideation

Suicide ideation declined significantly over the 12 month period (F (3, 95.4) = 15.06, $p < 0.001$). However, differences in change over time between conditions were not significant (F (8,115.8) = 1.13, p = .352). Figure 2 shows the estimated marginal means for suicidal ideation across measurement occasions.

Within group contrasts

As can be seen in Table 2, planned contrasts revealed that participants in the call back only and TAU conditions showed significant declines in suicidal ideation from pre- to post-intervention and from pre-intervention to 6 month follow-up. Declines in suicidal ideation from pre-intervention to 12 month follow-up were significant for participants in all conditions in which the difference could be assessed.

Table 2. Within group contrast estimates and significance tests for suicidal ideation

		Contrast		
		Pre-intervention to post- intervention	**Pre-intervention to 6 month follow-up**	**Pre-intervention to 12 month follow-up**
Condition	**Statistic**			
Internet only	Contrast estimate	-.54	-.79	-.97
	Test value	t(109.8) = -1.98	t(101.5) = -2.50	t(73.2) = -3.65
	p value	.050	.016	<.001
Internet + telephone call back	Contrast estimate	-.06	-.48	-1.12
	Test value	t(121.3) = -.20	t(106.2) = -1.45	t(80.8) = -3.91
	p value	.85	.15	<.001
Telephone callback only	Contrast estimate	-.79	-.68	-.68
	Test value	t(105.6) = -3.05	t(100.0) = -2.22	t(78.0) = -2.61

	p value	.003	.029	.011
Treatment as usual	Contrast estimate	-.80	-.66	
	Test value	*t*(108.0) = -2.89	*t*(103.1) = -1.96	
	p value	.005	.053	

Between group contrasts

No significant differences were found between conditions at post-intervention, 6 month follow-up, or 12 month follow-up: Internet only vs. TAU (post-test: Contrast estimate = .26; $p = .51$; 6-month follow-up: Contrast estimate = -.14, $p = .77$); Internet only vs. Telephone call back only (post-test: Contrast estimate = .25; $p = .51$; 6-month follow-up: Contrast estimate = -.11, $p = .80$; 12-month follow-up: Contrast estimate = -.28; $p = .45$); Internet + telephone call back vs. TAU (post-test: Contrast estimate = .74; $p = .07$; 6-month follow-up: Contrast estimate = .17, $p = .72$); Internet + telephone call back vs Telephone call back only (post-test: Contrast estimate = .73; $p = .07$; 6-month follow-up: Contrast estimate = .19, $p = .67$; 12-month follow-up: Contrast estimate = -.44; $p = .26$); Telephone call back only vs TAU (post-test: Contrast estimate = .01; $p = .99$; 6-month follow-up: Contrast estimate = -.02, $p = .96$); Internet only vs Internet + telephone call back (post-test: Contrast estimate = -.48; $p = .24$; 6-month follow-up: Contrast estimate = -.31, $p = .51$; 12-month follow-up: Contrast estimate = .16; $p = .69$). To test whether the lack of between-group effects were related to scaling effects of the suicidal ideation measure, the models were re-estimated using a continuous score for suicidal ideation. As with the original analysis, there was significant reduction over time in suicidal ideation scores ($F(3, 94.5) = 14.08$, $p < 0.001$). Again, there was no significant interaction between condition and time ($F(8, 89.9) = 0.81$, $p = 0.598$),

indicating no significant difference in change of suicidal ideation scores between the intervention groups across the study period.

Effect sizes for suicidal ideation

At post-intervention, effect sizes were 0.10 (95% CI: -0.43 to 0.64) for the Internet only condition and 0.04 (95% CI: -0.54 to 0.62) for the Internet plus call back condition, compared to the TAU condition. Compared to call back only, effect sizes were 0.28 (95% CI: -0.24 to 0.79) for the Internet only condition and 0.41 (95% CI: -0.15 to 0.98) for the Internet plus call back condition. At 6 month follow-up, effect sizes were 0.36 (95% CI: -0.24 to 0.96) for the Internet only condition and 0.20 (95% CI: -0.42 to 0.81) for the Internet plus call back condition, compared to the TAU condition. Compared to telephone call back only, effect sizes were 0.08 (95% CI: -0.48 to 0.63) for the Internet only condition and 0.07 (95% CI: -0.51 to 0.65) for the Internet plus telephone call back condition. At 12 month follow-up, effect sizes were 0.28 (95% CI: -0.33 to 0.89) for the Internet only condition and 0.45 (95% CI: -0.24 to 1.13) for the Internet plus call back condition, compared with the call back only condition.

Predictors of suicide ideation

A logistic regression analysis was designed to measure predictors of suicide ideation change taking account of intervention condition. Consistent with findings reported above, compared to baseline (M:1.73; SD: 1.64; N=153) suicidal ideation significantly decreased in the whole sample at post-test (M:1.00; SD:1.45; N=106), 6-month (M:0.99; SD:1.54; N=91) and 12-month follow-up (M:0.66; SD:1.27; N=56).

However, as there was no significant interaction effect between condition and time on suicidal ideation, this interaction was not retained in the model. Table 3 shows the results for the model with interactions excluded. As would be expected, higher levels of suicide ideation at baseline were associated with significantly reduced odds of absence of suicide ideation at post-test. Neither baseline depression nor anxiety was significantly associated with no suicide ideation at post-test. There were also no significant effects of any of the demographic characteristics. However, a greater improvement in depression symptoms from pre- to post-intervention was associated with increased odds of no suicidal ideation at post-intervention. At baseline, the majority of participants (n=93; 62.0%) reported both depressive symptoms and suicidal ideation. This proportion decreased at all time-points following the interventions [post-test: 44 (41.5%); 6-months follow-up: 30 (33.0%); 12-months follow-up: 13 (23.2%)]. Based on McNemar's tests using completers of each assessment, these decreases were significant at all three time points ($P = 0.005$, $P < 0.001$ and $P = 0.002$ at post, 6-months and 12-months respectively). There was no significant difference in the proportion of participants with depression but no suicidal ideation, except at 12-month follow-up [baseline: n=53 (35.3%); post-test: n=42 (39.6%), 6-months follow-up: n=28 (30.8%); 12-months follow-up: 18 (32.1%); $P = 1.00$; $P = 0.15$ and $P = 0.019$ at post, 6-months and 12-months respectively).

Table 3. Logistic regression analyses of remission of suicidal ideations (completers only)

			95% CI	
	OR	p	Lower	Upper

Suicidality score at baseline	0.409	**<0.001**	0.249	0.671
Condition	--	0.239		
TAU	1.000	--		
Internet only	1.408	0.699	0.248	8.001
Internet + telephone call back	0.323	0.234	0.050	2.082
Telephone call back only	2.442	0.284	0.476	12.512
Baseline depression score	0.926	0.081	0.849	1.010
Depression change score	1.165	**<0.001**	1.070	1.267
Baseline anxiety score	1.066	0.256	0.955	1.190
Anxiety change score	0.986	0.836	0.859	1.130
Gender: F vs M	0.992	0.993	0.174	5.646
Age	1.051	0.054	0.999	1.106
Years of education	0.897	0.438	0.681	1.181
Not in labour force vs. employed	0.915	0.899	0.233	3.592

*only main effects included.

DISCUSSION

This was the first study to examine the effect of online interventions on suicide ideation in a helpline using a randomised controlled trial design. In contrast to our hypothesis, results from our study indicated that irrespective of intervention condition, participants' suicidal ideation declined over time at post-test, and six months. Declines were slower to become significant for those randomised to the Internet plus call back condition. For all groups, declines in suicidal ideation remained significant at 12 month follow-up. Although there were small effects at post-test and medium effect sizes at follow-up among the intervention conditions, there were no consistent overall effects

for condition. Participants having higher baseline suicide scores were more likely to continue experiencing suicidal ideation at post-intervention, while those with greater improvements in depression symptoms were less likely to experience suicide ideation at post-intervention.

Several studies have shown reductions of suicide ideation in uncontrolled pre post trials of counselling or internet CBT (e.g.,[5, 6]). This is, to our knowledge the first randomised controlled trial of an intervention in a helpline, comparing a number of active interventions to treatment as usual. The study is also unique in that it examined predictors of ideation change, taking account of the effect of intervention. As previously reported for this study [9], web based CBT, and web CBT with counsellor call back significantly reduced depression symptoms relative to TAU. These findings indicate that suicide ideation did not follow the same pattern as depression in response to the intervention, and, more generally, that suicide ideation was not strictly tethered to depression. Nevertheless, the regression analysis found that taking account of intervention type, changes in depression did predict later lower levels of ideation, suggesting that depression change is an important albeit not necessarily the only factor in reducing ideation. We interpret these findings to suggest that change in depression, in whatever way it is brought about, is a contributing variable to reduction in suicide ideation. A second explanation for the findings is that changes in suicide ideation and changes in depression follow different time trajectories, with ideation resolving faster than depression. The two constructs are likely to be interactive, with ideation reduction assisting in lowering depression symptoms over time. Hopelessness may mediate both depression and ideation but may influence each within different time frames [24]. Interestingly, a recent meta-analysis [25] has examined the effects of face-to-face

psychotherapy for adult depression on suicidality. It found a non-significant effect of psychotherapy in the reduction of suicidality but a significant effect for depression, consistent with concept that depression and suicidality are not strictly tethered.

Suicide ideation resolved in our TAU condition, consistent with the notion that ideation is responsive to events or processes that occurred with the passage of time for participants with access to "usual services". We do know that at 6 weeks TAU participants were more likely to make more calls to the helpline service compared to participants in the Internet alone condition, but not to the other conditions. Eighty one percent of TAU participants reported that they made at least one call, and approximately 55% had made 3 or more calls. These calls may have contributed to the suicide resolution in this and the other two conditions. However, these spontaneous calls were unlikely to be responsible for the differences in depression resolution, given that the Internet alone group also showed drops in depression levels.

The finding that all groups showed suicide resolution, however, does not rule out the possibility that specific psychological or proactive interventions will support faster resolution of suicide ideation symptoms than the interventions reported here. Indeed the intervention developed by Van Spijker et al. [7] may be one of these specific interventions.

Limitations of the study

One explanation of the failure to find an effect of intervention type on suicide ideation outcomes is that these findings are due to regression to the mean. Because all scores were initially high at baseline, scores would be expected to revert to the mean on

the second occasion of measurement. Intervention completion rates were lower in our study relative to some other trials of web-based treatments for depression [26] but not of other telephone-based services [3]. The reasons for this are unclear. The current trial was a true effectiveness trial employing a volunteer workforce for recruitment and call back, and hence might be expected to be associated with greater recruitment and adherence problems relative to the more controlled environment of an efficacy study [27]. Also, the interventions were short, delivered by non-health professionals, and may have constituted the only service received. The measure used to assess suicidality used items that categorised outcomes dichotomously, and then summed responses, as per scale score recommendations. Moreover, these scores were then further dichotomised in the regression analysis. This is essentially a conservative treatment of data. We did investigate whether other continuous scoring methods might reveal intervention effects. These data did not yield any relationships. The generalisability of the findings to severely suicidal individuals is also limited, given acutely suicidal or highly distressed callers were specifically not invited to participate. We had relatively low success in recruiting participants to the trial, a finding that reflects the nature of effectiveness trials using targeted samples such as ours [27] and where a mismatch occurs between the expectation of phoning a crisis centre and being 'diverted' to another program. Finally, we were not able to analyse the influence of other psychological characteristics on treatment outcome, such as hopelessness, or support from family, which might affect both depression and suicidal ideation levels. These measures were not included in our study.

Future research

Replications of this trial need to be performed to establish consistency of research findings. Furthermore, examination of mediators of change such as hopelessness in larger samples would add significantly to our knowledge of which components of therapy are necessary for reduction of suicide ideation. Given the absence of differences between conditions, it may be that one or more components present in each treatment arm (e.g., giving hope, or participating in research) are responsible for change in outcome. Identifying these components and altering their presence by intensifying or omitting them in a new intervention trial would add to our current knowledge mechanisms of change. Investigation of the causes of reductions in suicide ideation is warranted.

Clinical implications

Despite the limitations, the current study clearly demonstrated that suicide ideation declined irrespective of intervention, telephone counsellor contact or wait-list. The addition of the TAU control condition is a significant improvement over previous trials. The study demonstrated that, while CBT internet interventions are significantly more effective in resolving depression symptoms than control conditions, these operate no more successfully than current call centre practice in resolving suicide ideation. Suicide ideation reduces significantly more effectively in those individuals who also have resolving depression. The majority of people experiencing suicidal ideation do not receive mental health treatment [28]. Internet-based or telephone based interventions have the advantage that they can be easily accessed by large numbers of people, on an anonymous basis. In line with Watts et al. [6], our findings demonstrate the importance of not excluding suicidal participants from interventions designed to target depression.

Figure legends:

Figure 1: Trial Flow Diagram

Figure 2: Estimated marginal means for suicidal ideation across measurement occasions.

ACKNOWLEDGEMENTS

Nicole Burgess coordinated and conducted data collection for the trial. Dawn O'Neil was involved in obtaining funding for the trial and coordinating Lifeline Australia's collaboration with the ANU. Assoc Prof Richard O'Kearney was a member of LF's PhD supervisory panel. Trevor Carlyon was also involved in coordinating Lifeline staff and volunteer involvement in the trial and supported Nicole in her role. The e hub team supported the trial implementation. We acknowledge the contributions of the Lifeline counselors who participated in this trial.

COMPETING INTERESTS

None.

FUNDING

Australian Research Council Linkage Grant (LP0667970), 2006, 3 years, $279,325 (Christensen, Griffiths, Mackinnon, Smith), Internet technologies, health informatics, and statistical models, and new delivery platforms in call centres (CIA).

HC and PB were supported by NHMRC 525411 and NHMRC Early Career Fellowship 1035262. KMG is supported by NHMRC Fellowship No. 525413.

CONTRIBUTORSHIP

HC, KG, AJM conceived the study, LF, HC, KG, AJM designed the study, HC, TD drafted the initial manuscript, LF, PB, AJM prepared and cleaned the data and conducted initial data analysis. All authors contributed to revised drafts.

DATA SHARING

The data from this study are available through email to Dr Philip Batterham p.batterhan@anu.edu.au

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	na
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	na
Sample size	7a	How sample size was determined	6 (ref 8-9)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6 (ref 8-9)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8 (and ref 8-9)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	Ref 8-9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Ref 8-9
	14b	Why the trial ended or was stopped	Ref 8-9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	17-19
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20-22
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

The effect of a web based depression intervention on suicide ideation. Secondary outcome from a randomised controlled trial in a helpline.

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Key words: Suicide, Depression, Telephone, Internet

Word count: 4,076

ABSTRACT

Objectives: The effect of web-based interventions for depression on suicide ideation in callers to helplines is not known. The aim of this study was to determine if web-based Cognitive Behaviour Therapy (CBT) with and without telephone support is effective in reducing suicide ideation in callers to a helpline compared to treatment as usual. A secondary aim was to examine the factors that predict change in suicide ideation. Putative predictors included level of baseline depression, suicide behaviour, baseline anxiety and type of intervention.

Design: Randomised Controlled Trial

Setting: Lifeline, Australia's 24-hour telephone counselling service Participants: 155 callers to a national helpline service with moderate to high psychological distress.

Interventions: participants were recruited and randomised to receive either 6 weeks of Internet CBT plus weekly telephone follow-up; Internet CBT only; weekly telephone follow-up only; or a wait-list treatment as usual (TAU) control group.

Primary and secondary outcome measures: Suicidal ideation was measured using four items from the 28-item General Health Questionnaire (GHQ-28; [1]. Predictors of change in ideation were tested using logistic regression analysis.

Results*:* Regardless of intervention condition, participants showed significant reductions in suicidal ideation over twelve months ($p < 0.001$). Higher baseline suicidal behaviour decreased the odds of remission of suicidal ideation at post-intervention (OR: 0.409 ($p < 0.001$). However, change in depression over the course of the interventions was associated with improvement in suicide ideation (OR: 1.165, $p < 0.001$).

Conclusions*:* Suicide ideation declines with and without proactive intervention. Improvements in depression are associated with the resolution of suicide ideation. Specific interventions focussing on suicide ideation should be further investigated.

TRIAL REGISTRATION: Controlled-Trials.com ISRCTN93903959.

ARTICLE SUMMARY

Article focus:

- To evaluate the effectiveness of a web-based Cognitive Behaviour Therapy intervention on suicide ideation in a helpline.
- To examine predictors of suicide ideation resolution

Key messages:

- Irrespective of intervention condition, participants' suicidal ideation declined over time at post-test, and six months. Declines in suicidal ideation remained significant at 12 month follow-up
- Suicide ideation reduces significantly more in those individuals who also had resolving depression.
- While CBT internet interventions are significantly more effective in resolving depression symptoms compared to control conditions, these operate no more successfully than current call centre practice in resolving suicide ideation.
- Our findings demonstrate the importance of not excluding suicidal participants from interventions designed to target depression.

Strengths and limitations of this study:

- The study used a Randomised Controlled Trial.

- The addition of the TAU control condition is a significant improvement over previous trials.
- Because all scores were initially high at baseline, the lower scores on the second occasion of measurement may have been due to reversion to the mean.

INTRODUCTION

Suicide prevention interventions are delivered every day through helplines and through chat in call centres. In Australia, Lifeline reports that over 50 high risk telephone calls are answered daily [2]. However, despite the load taken by helplines in responding to callers at risk, there has been little investigation of the role of these services in reducing suicide risk, or in reducing risk factors associated with suicide risk, such as depression.

To date, the research evidence from suicide helplines has largely focussed on evaluating interventions using the telephone, and to our knowledge, only one randomised controlled trial (RCT) has been conducted. This study [3] evaluated the effects of two brief telephone psychotherapies in reducing general distress [Solution Focussed Brief Therapy (SFBT) and Common Factors Therapy (CFT)] compared to a waitlist control condition using 85 individuals recruited via a suicide hotline. Outcome measures included the Brief Psychiatric Rating Scale, and the Beck Depression Inventory. Drop out was high in the SFBT condition (50%) compared to the CFT condition (37%) and across both conditions drop out occurred before the first session. Relative to the waitlist control, significant reductions in several measures of depression and anxiety symptoms were found in participants who completed the interventions, with effect sizes estimated in the range of .67 and .93. However, outcomes on suicide specific measures were not reported. A highly cited, although uncontrolled study, used a follow-up design (pre-post outcomes) to evaluate the effectiveness of a helpline for non-suicidal crisis callers (n=1617, of whom 801 provided follow-up data) [4]. Callers' levels of crisis and hopelessness were rated during the calls and found to decrease during the course of the call. In a second study, focussing on 1,085 participants who

were suicidal Gould et al. [5] found that levels of intent to die over the course of a call decreased and that there were continuing falls in hopelessness and psychological pain over the continuing weeks.

Web-based interventions are now more frequently used in helpline services, and research of their usefulness is emerging in community settings. Two studies of online e-health applications targeting either risk factors for suicide (depression) or suicide ideation were published in 2012. The first was an uncontrolled service evaluation which found a 30% reduction in suicide ideas [6] over the course of a depression web program. The second was a randomised controlled trial of an online intervention which examined the effectiveness and cost effectiveness of an automated six module, six week, intervention specifically targeting suicide ideation for individuals with mild to moderate suicidal thoughts. The intervention was based on Cognitive Behaviour Therapy (CBT), with Dialectical Behaviour Therapy, Problem Solving Therapy and Mindfulness-Based Cognitive Therapy included. Significant reductions in suicidal thoughts were found relative to Control condition. The mean incremental cost-effectiveness ratio (ICER) was estimated to be €34,727 (US $41,325) for an additional treatment response, indicating annual cost savings per treatment responder [7].

In 2012, we published the results of a randomised controlled trial investigating the effects of a web application in reducing depression and anxiety in a large helpline [8, 9]. This trial compared four conditions: a treatment as usual condition (TAU), where the participant could call the crisis line at any time; a telephone call back service where the participant was contacted for 10 minutes systematically once a week for six weeks; a CBT internet program for depression combined with a evidence-based depression

information website, and a combined condition which incorporated telephone call back and the web programs. Both the web programs alone, and the web programs in combination with the telephone call back, were effective at 12 months in reducing depression symptoms, relative to TAU. This study also measured suicide ideation, and in this paper, we report the results using this outcome measure.

Suicide ideation is a substantial risk factor for suicide attempt. Theories of suicide causation point to the importance of depression and hopelessness in leading to increased levels of suicide ideation and attempts (see [10]). We hypothesised that suicide ideation would be reduced over time in those conditions which successfully reduced depression. Accordingly, we first examined the effect of the four interventions conditions on suicide ideation. For suicide ideation, we hypothesised that the web CBT intervention focussing on reducing depression—with or without the telephone call back— would result in significantly greater reduction of suicide ideation than the other two conditions, which did not include interventions specifically aiming to reduce depression. We then used logistic regression to explore which factors, in addition to any effect of the intervention, predicted changes in suicide ideation at post-test. These factors were baseline suicidality, baseline depression, baseline anxiety, age, gender, education, workforce participation, and changes in depression and anxiety over the course of the intervention (pre to post-test).

METHOD

Data for this study were collected as part of a randomized controlled trial of the impact of a Web-based CBT and psychoeducation intervention on depression symptoms [9]. The trial comprised four arms: (i) a Web-based CBT intervention; (ii) a Web-based

CBT intervention delivered in conjunction with a telephone call back; (iii) the proactive call back telephone line alone, and (iv) TAU, which consisted of the opportunity for the participant to contact the helpline if needed.

Ethics statement

Ethics approval for the trial was granted by the Australian National University Human Research Ethics Committee (Protocol no. 2007/12).

Participants

Participants were 155 callers to Lifeline, Australia's 24-hour telephone counselling service, recruited between July 2007 and January 2009. High distress or acutely suicidal participants were excluded. A total of 910 callers agreed to be screened by telephone. Of these, 142 (15.6%) were subsequently unable to be contacted, 61 (7%) were later unwilling to participate, and 337 (37%) did not meet eligibility criteria. Respondents were not eligible for inclusion in the trial if they (1) scored less than 22 on the Kessler Psychological Distress Scale [11] (138/337, 41%), a brief screening scale used clinically and epidemiologically, (2) had, by self-report, a diagnosis of schizophrenia or bipolar disorder (89, 26%), or (3) did not have Internet access (67, 20.0%). Ineligible participants were offered brochures sent by mail containing information about the Web intervention used in the trial. Of the 370 people eligible for inclusion in the trial, 155 completed informed consent procedures and pre-intervention assessments, and were randomly assigned to the trial conditions. The trial flow is illustrated in Figure 1.

Procedure

Following screening and informed consent procedures, pre-intervention data were obtained through a self-report questionnaire mailed to participants. A block randomization procedure was used, with stratification based on site of recruitment and severity of psychological distress at screening. Allocation of participants to trial conditions was conducted independently by a research assistant not involved in the day-to-day running of the trial. Following randomization, all participants were contacted by telephone and were mailed the relevant materials for their allocated condition.

Intervention and Trial Conditions

The Web-only intervention consisted of Web-based psychoeducation (in week 1 provided by BluePages: bluepages.anu.edu.au) combined with Web-based CBT (in weeks 2–6 provided by MoodGYM: moodgym.anu.edu.au). BluePages is an educational site that provides information on evidence-based interventions for depression. MoodGYM is a first generation, interactive web application which delivers cognitive behaviour therapy through a series of 5 modules, captures user behaviour and self-report symptoms on validated scales, and offers an online CBT workbook. Both of these Web programs have been shown to reduce depression symptoms in community users [12]. A printed manual containing week-by-week instructions for accessing the Web programs (via a login) was mailed to participants at the start of the trial.

In the Web with telephone call back condition, participants completed the Web intervention and also received a weekly 10-minute telephone call from a Lifeline telephone counsellor. The purpose of these calls was to address any issues associated with the participants' use of the intervention.

In the telephone call back only condition, participants received a weekly 10-minute telephone call initiated from a telephone counsellor. These scripted calls focused on various environmental and lifestyle factors associated with depression.

In the TAU condition, participants received neither the call back nor Web interventions, but were free to use the helpline service as needed. Participants in this condition were wait-listed to receive the Web-only intervention following completion of the 6-month follow-up.

As in the TAU condition, participants in all 3 other conditions were also able to use the helpline service as needed, which provided usual emergency or support services. Self-reported contacts with the service were taken at each follow-up occasion for each of the 4 conditions. Any use of this service during the intervention period was additional to the 10-minute telephone calls offered proactively as part of the call back component of the Telephone call back condition and the Internet plus call back condition.

Measures

Suicidal ideation

Suicidal ideation was measured using four items from the 28-item General Health Questionnaire (GHQ-28; [1]. The four questions measure suicidal ideation, asking respondents to indicate how they have felt over the last few weeks. The first two items: 'Have you recently felt that life is not worth living' and 'Have you recently found yourself wishing you were dead and away from it all' were scored on the 4-point scale: 'Not at all', 'No more than usual', 'Rather more than usual' or 'Much more than usual'. The remaining two items: 'Have you recently had thoughts of the possibility that you

might do away with yourself' and 'Have you recently found that the idea of taking your own life kept coming into your mind' were scored on the 4-point scale: 'Definitely not', 'I don't think so', 'Has crossed my mind' or 'Definitely has'. Responses were then categorised in a binary manner, with the negatively-worded response categories (Not at all, No more than usual, definitely not, and I don't think so) scored with a 0, and the positively-worded response categories scored with a 1. Binary scores for each item were summed to provide a total scale score ranging from 0 to 4, with a higher score indicating higher suicidal ideation. This scoring system is that used for all items and sub scores of the GHQ-28, which has been validated in Australian populations [13]. The four suicide items from the GHQ-28 have been used extensively by Goldney and colleagues to assess suicidal ideation in a number of Australian samples [14-16]. These items have been validated relative to other well established measures of suicidal intent and hopelessness [17, 18]. Cronbach Alpha for the 4 items at baseline in the present sample was 0.90.

Predictor variables

Depression symptoms were measured by the Center for Epidemiologic Studies Depression Scale (CES-D)[19], a widely used, 20 item scale with strong reliability and validity [19, 20], with scores ranging from 0 to 60. Anxiety symptoms were assessed using the 14-item anxiety scale from the Depression, Anxiety and Stress Scales (DASS-A;[21]. Each of these items is rated on a four-point scale from 0 ("did not apply to me at all") to 4 ("applied to me most of the time"), with total scores ranging from 0 to 42. The reliability and validity of the DASS-A scale has been demonstrated previously ([22, 23]).

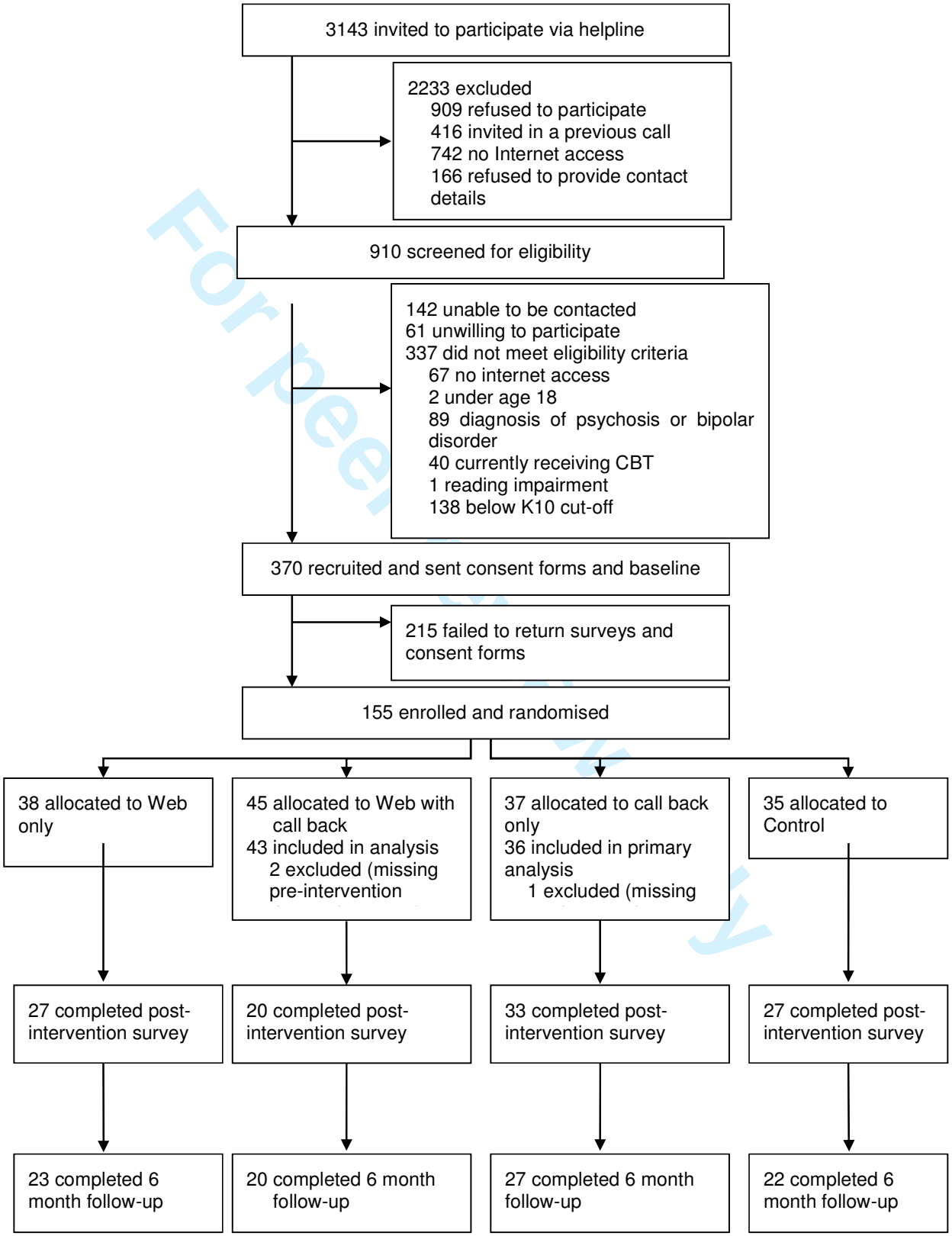
Demographic variables including age, gender, educational attainment and workforce participation were assessed by self-report in the pre-test survey. Educational attainment was based on two items assessing highest level of education, which were used to form an estimate of total number of years of education. Workforce participation was based on an item assessing employment status, with "unemployed" and "not in the labour force" categorised as non-participation, and employed "full-time" or "part-time" categorised as participation.

Statistical analyses

Differential changes in suicide ideation across the four conditions were assessed using mixed model repeated measures analysis of variance. Within-person variation was modeled using an unstructured covariance matrix and degrees of freedom were estimated using Satterthwaite's approximation. This model included the fixed effects of condition, time (pre, post, 6 month, 12 month) and the interaction between condition and time. The presence of a significant interaction between an active intervention and the TAU condition over time would indicate a significant reduction in suicidal ideation for that condition relative to control. Within-condition change in suicidal ideation was also examined using this model. Mixed models yield an intention-to-treat analysis, using all available measurement points for each participant under the assumption that withdrawal data are missing at random. Two participants with missing suicidal ideation scores at baseline were omitted from analyses. To evaluate whether the scoring of the suicidal ideation scale influenced the findings, the models were re-estimated using a continuous score of suicidal ideation, assessed at each time point as the sum of responses to the four ideation items (range 0-12).

Logistic regression was then used to examine predictors of suicidal ideation at post-intervention, defined as a suicidal ideation score of 0. In particular, the hypothesis was assessed that reduction in depression symptoms from pre- to post-intervention predicted remission of ideation. Only completers of the post-test assessment were included in this analysis. A depression symptom change score from pre- to post-intervention was calculated by subtracting post-intervention CES-D scores from pre-intervention scores, with positive scores indicating a reduction/improvement in symptoms. The effect of anxiety symptoms and changes in anxiety were assessed in the same way. Suicidal ideation scores (ranging from 0 to 4) were coded categorically as "0" (score >= 1, indicating some suicidal ideation) or "1" (score = 0, no ideation). To control for baseline depression, baseline anxiety, baseline suicidality and intervention condition, these variables were included in the regression simultaneously with the depression change score. In addition, age, gender, education and workforce participation were included in the models due to their potential associations with suicidal ideation.

Figure 1: Trial Flow Diagram



RESULTS

Descriptives and changes in suicide ideation

Table 1 shows the characteristics of the sample at baseline, with mental health measures for post-intervention also presented. The age range was 19-72, with a median age of 42 years. The majority of participants (57%) had graduated from high school. Most of the participants were female and approximately half were in the work force. Depression and anxiety scores were considerably higher than the cut points for the scales used at both time points, although there were decreases from pre- to post-intervention. Likewise, high rates of suicidality were observed, with 62.7% and 41.5% reporting suicidal ideation at pre- and post-intervention respectively.

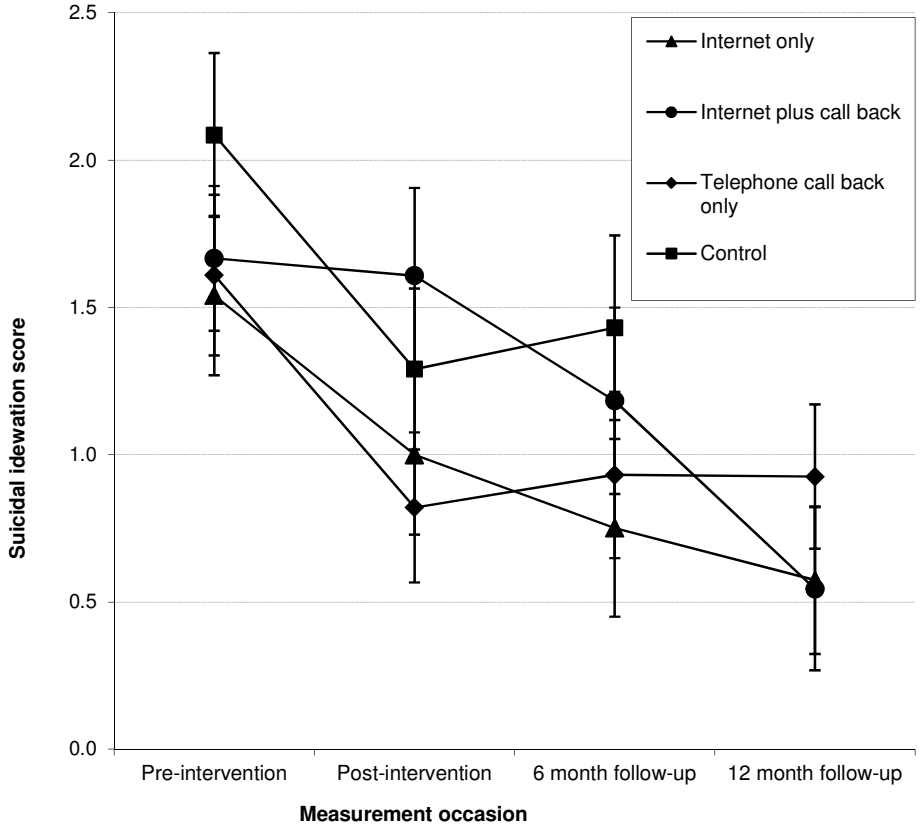
Table 1. Characteristics of participants

	N	Mean	SD
Age	155	41.49	12.35
Years of education	150	13.47	2.67
CES-D depression score, pre-intervention	152	36.25	10.22
CES-D depression score, post-intervention	107	28.68	14.40
DASS anxiety score, pre-intervention	154	13.34	8.03
DASS anxiety score, post-intervention	107	11.45	10.16
GHQ suicidal ideation score - pre-intervention	153	1.73	1.64
GHQ suicidal ideation score - post-intervention	106	1.00	1.45
	N	Count	%
Gender	155		
Female		127	81.9%
Male		28	18.1%
Workforce participation	155		
Participation		72	46.5%
Non-participation		83	53.5%
Treatment condition	155		
Internet only		38	24.5%
Internet plus call back		45	29.0%
Telephone call back only		37	23.9%
Treatment as usual		35	22.6%

Mixed models: Effect of intervention type on suicidal ideation

Suicide ideation declined significantly over the 12 month period (F (3, 95.4) = 15.06, $p < 0.001$). However, differences in change over time between conditions were not significant (F (8,115.8) = 1.13, p = .352). Figure 2 shows the estimated marginal means for suicidal ideation across measurement occasions.

Figure 2: Estimated marginal means for suicidal ideation across measurement occasions.



Within group contrasts

As can be seen in Table 2, planned contrasts revealed that participants in the call back only and TAU conditions showed significant declines in suicidal ideation from pre- to post-intervention and from pre-intervention to 6 month follow-up. Declines in

suicidal ideation from pre-intervention to 12 month follow-up were significant for participants in all conditions in which the difference could be assessed.

Table 2. Within group contrast estimates and significance tests for suicidal ideation

		Contrast		
		Pre-intervention to post- intervention	**Pre-intervention to 6 month follow-up**	**Pre-intervention to 12 month follow-up**
Condition	**Statistic**			
Internet only	Contrast estimate	-.54	-.79	-.97
	Test value	$t(109.8) = -1.98$	$t(101.5) = -2.50$	$t(73.2) = -3.65$
	p value	.050	.016	<.001
Internet + telephone call back	Contrast estimate	-.06	-.48	-1.12
	Test value	$t(121.3) = -.20$	$t(106.2) = -1.45$	$t(80.8) = -3.91$
	p value	.85	.15	<.001
Telephone callback only	Contrast estimate	-.79	-.68	-.68
	Test value	$t(105.6) = -3.05$	$t(100.0) = -2.22$	$t(78.0) = -2.61$
	p value	.003	.029	.011
Treatment as usual	Contrast estimate	-.80	-.66	
	Test value	$t(108.0) = -2.89$	$t(103.1) = -1.96$	
	p value	.005	.053	

Between group contrasts

No significant differences were found between conditions at post-intervention, 6 month follow-up, or 12 month follow-up: Internet only vs. TAU (post-test: Contrast estimate = .26; $p = .51$; 6-month follow-up: Contrast estimate = -.14, $p = .77$); Internet only vs. Telephone call back only (post-test: Contrast estimate = .25; $p = .51$; 6-month follow-up: Contrast estimate = -.11, $p = .80$; 12-month follow-up: Contrast estimate = -.28; $p = .45$); Internet + telephone call back vs. TAU (post-test: Contrast estimate = .74;

p = .07; 6-month follow-up: Contrast estimate = .17, p = .72); Internet + telephone call back vs Telephone call back only (post-test: Contrast estimate = .73; p = .07; 6-month follow-up: Contrast estimate = .19, p = .67; 12-month follow-up: Contrast estimate = -.44; p = .26); Telephone call back only vs TAU (post-test: Contrast estimate = .01; p = .99; 6-month follow-up: Contrast estimate = -.02, p = .96); Internet only vs Internet + telephone call back (post-test: Contrast estimate = -.48; p = .24; 6-month follow-up: Contrast estimate = -.31, p = .51; 12-month follow-up: Contrast estimate = .16; p = .69). To test whether the lack of between-group effects were related to scaling effects of the suicidal ideation measure, the models were re-estimated using a continuous score for suicidal ideation. As with the original analysis, there was significant reduction over time in suicidal ideation scores ($F(3, 94.5)$ = 14.08, $p < 0.001$). Again, there was no significant interaction between condition and time ($F(8, 89.9)$ = 0.81, p = 0.598), indicating no significant difference in change of suicidal ideation scores between the intervention groups across the study period.

Effect sizes for suicidal ideation

At post-intervention, effect sizes were 0.10 (95% CI: -0.43 to 0.64) for the Internet only condition and 0.04 (95% CI: -0.54 to 0.62) for the Internet plus call back condition, compared to the TAU condition. Compared to call back only, effect sizes were 0.28 (95% CI: -0.24 to 0.79) for the Internet only condition and 0.41 (95% CI: -0.15 to 0.98) for the Internet plus call back condition. At 6 month follow-up, effect sizes were 0.36 (95% CI: -0.24 to 0.96) for the Internet only condition and 0.20 (95% CI: -0.42 to 0.81) for the Internet plus call back condition, compared to the TAU condition.

Compared to telephone call back only, effect sizes were 0.08 (95% CI: -0.48 to 0.63) for the Internet only condition and 0.07 (95% CI: -0.51 to 0.65) for the Internet plus telephone call back condition. At 12 month follow-up, effect sizes were 0.28 (95% CI: -0.33 to 0.89) for the Internet only condition and 0.45 (95% CI: -0.24 to 1.13) for the Internet plus call back condition, compared with the call back only condition.

Predictors of suicide ideation

A logistic regression analysis was designed to measure predictors of suicide ideation change taking account of intervention condition. Consistent with findings reported above, compared to baseline (M:1.73; SD: 1.64; N=153) suicidal ideation significantly decreased in the whole sample at post-test (M:1.00; SD:1.45; N=106), 6-month (M:0.99; SD:1.54; N=91) and 12-month follow-up (M:0.66; SD:1.27; N=56). However, as there was no significant interaction effect between condition and time on suicidal ideation, this interaction was not retained in the model. Table 3 shows the results for the model with interactions excluded. As would be expected, higher levels of suicide ideation at baseline were associated with significantly reduced odds of absence of suicide ideation at post-test. Neither baseline depression nor anxiety was significantly associated with no suicide ideation at post-test. There were also no significant effects of any of the demographic characteristics. However, a greater improvement in depression symptoms from pre- to post-intervention was associated with increased odds of no suicidal ideation at post-intervention. At baseline, the majority of participants (n=93; 62.0%) reported both depressive symptoms and suicidal ideation. This proportion decreased at all time-points following the interventions [post-test: 44 (41.5%); 6-months follow-up: 30 (33.0%); 12-months follow-up: 13 (23.2%)]. Based on McNemar's tests

using completers of each assessment, these decreases were significant at all three time points ($P = 0.005$, $P < 0.001$ and $P = 0.002$ at post, 6-months and 12-months respectively). There was no significant difference in the proportion of participants with depression but no suicidal ideation, except at 12-month follow-up [baseline: n=53 (35.3%); post-test: n=42 (39.6%), 6-months follow-up: n=28 (30.8%); 12-months follow-up: 18 (32.1%); $P = 1.00$; $P = 0.15$ and $P = 0.019$ at post, 6-months and 12-months respectively).

Table 3. Logistic regression analyses of remission of suicidal ideations (completers only)

			95% CI	
	OR	p	Lower	Upper
Suicidality score at baseline	0.409	**<0.001**	0.249	0.671
Condition	--	0.239		
TAU	1.000	--		
Internet only	1.408	0.699	0.248	8.001
Internet + telephone call back	0.323	0.234	0.050	2.082
Telephone call back only	2.442	0.284	0.476	12.512
Baseline depression score	0.926	0.081	0.849	1.010
Depression change score	1.165	**<0.001**	1.070	1.267
Baseline anxiety score	1.066	0.256	0.955	1.190
Anxiety change score	0.986	0.836	0.859	1.130
Gender: F vs M	0.992	0.993	0.174	5.646
Age	1.051	0.054	0.999	1.106
Years of education	0.897	0.438	0.681	1.181
Not in labour force vs. employed	0.915	0.899	0.233	3.592

*only main effects included.

DISCUSSION

This was the first study to examine the effect of online interventions on suicide ideation in a helpline using a randomised controlled trial design. In contrast to our hypothesis, results from our study indicated that irrespective of intervention condition, participants' suicidal ideation declined over time at post-test, and six months. Declines were slower to become significant for those randomised to the Internet plus call back condition. For all groups, declines in suicidal ideation remained significant at 12 month follow-up. Although there were small effects at post-test and medium effect sizes at follow-up among the intervention conditions, there were no consistent overall effects for condition. Participants having higher baseline suicide scores were more likely to continue experiencing suicidal ideation at post-intervention, while those with greater improvements in depression symptoms were less likely to experience suicide ideation at post-intervention.

Several studies have shown reductions of suicide ideation in uncontrolled pre post trials of counselling or internet CBT (e.g.,[5, 6]). This is, to our knowledge the first randomised controlled trial of an intervention in a helpline, comparing a number of active interventions to treatment as usual. The study is also unique in that it examined predictors of ideation change, taking account of the effect of intervention. As previously reported for this study [9], web based CBT, and web CBT with counsellor call back significantly reduced depression symptoms relative to TAU. These findings indicate that suicide ideation did not follow the same pattern as depression in response to the intervention, and, more generally, that suicide ideation was not strictly tethered to

depression. Nevertheless, the regression analysis found that taking account of intervention type, changes in depression did predict later lower levels of ideation, suggesting that depression change is an important albeit not necessarily the only factor in reducing ideation. We interpret these findings to suggest that change in depression, in whatever way it is brought about, is a contributing variable to reduction in suicide ideation. A second explanation for the findings is that changes in suicide ideation and changes in depression follow different time trajectories, with ideation resolving faster than depression. The two constructs are likely to be interactive, with ideation reduction assisting in lowering depression symptoms over time. Hopelessness may mediate both depression and ideation but may influence each within different time frames [24]. Interestingly, a recent meta-analysis [25] has examined the effects of face-to-face psychotherapy for adult depression on suicidality. It found a non-significant effect of psychotherapy in the reduction of suicidality but a significant effect for depression, consistent with concept that depression and suicidality are not strictly tethered.

Suicide ideation resolved in our TAU condition, consistent with the notion that ideation is responsive to events or processes that occurred with the passage of time for participants with access to "usual services". We do know that at 6 weeks TAU participants were more likely to make more calls to the helpline service compared to participants in the Internet alone condition, but not to the other conditions. Eighty one percent of TAU participants reported that they made at least one call, and approximately 55% had made 3 or more calls. These calls may have contributed to the suicide resolution in this and the other two conditions. However, these spontaneous calls were unlikely to be responsible for the differences in depression resolution, given that the Internet alone group also showed drops in depression levels.

The finding that all groups showed suicide resolution, however, does not rule out the possibility that specific psychological or proactive interventions will support faster resolution of suicide ideation symptoms than the interventions reported here. Indeed the intervention developed by Van Spijker et al. [7] may be one of these specific interventions.

Limitations of the study

One explanation of the failure to find an effect of intervention type on suicide ideation outcomes is that these findings are due to regression to the mean. Because all scores were initially high at baseline, scores would be expected to revert to the mean on the second occasion of measurement. Intervention completion rates were lower in our study relative to some other trials of web-based treatments for depression [26] but not of other telephone-based services [3]. The reasons for this are unclear. The current trial was a true effectiveness trial employing a volunteer workforce for recruitment and call back, and hence might be expected to be associated with greater recruitment and adherence problems relative to the more controlled environment of an efficacy study [27]. Also, the interventions were short, delivered by non-health professionals, and may have constituted the only service received. The measure used to assess suicidality used items that categorised outcomes dichotomously, and then summed responses, as per scale score recommendations. Moreover, these scores were then further dichotomised in the regression analysis. This is essentially a conservative treatment of data. We did investigate whether other continuous scoring methods might reveal intervention effects. These data did not yield any relationships. The generalisability of the findings to

severely suicidal individuals is also limited, given acutely suicidal or highly distressed callers were specifically not invited to participate. We had relatively low success in recruiting participants to the trial, a finding that reflects the nature of effectiveness trials using targeted samples such as ours [27] and where a mismatch occurs between the expectation of phoning a crisis centre and being 'diverted' to another program. Finally, we were not able to analyse the influence of other psychological characteristics on treatment outcome, such as hopelessness, or support from family, which might affect both depression and suicidal ideation levels. These measures were not included in our study.

Future research

Replications of this trial need to be performed to establish consistency of research findings. Furthermore, examination of mediators of change such as hopelessness in larger samples would add significantly to our knowledge of which components of therapy are necessary for reduction of suicide ideation. Given the absence of differences between conditions, it may be that one or more components present in each treatment arm (e.g., giving hope, or participating in research) are responsible for change in outcome. Identifying these components and altering their presence by intensifying or omitting them in a new intervention trial would add to our current knowledge mechanisms of change. Investigation of the causes of reductions in suicide ideation is warranted.

Clinical implications

Despite the limitations, the current study clearly demonstrated that suicide ideation declined irrespective of intervention, telephone counsellor contact or wait-list. The addition of the TAU control condition is a significant improvement over previous trials. The study demonstrated that, while CBT internet interventions are significantly more effective in resolving depression symptoms than control conditions, these operate no more successfully than current call centre practice in resolving suicide ideation. Suicide ideation reduces significantly more effectively in those individuals who also have resolving depression. The majority of people experiencing suicidal ideation do not receive mental health treatment [28]. Internet-based or telephone based interventions have the advantage that they can be easily accessed by large numbers of people, on an anonymous basis. In line with Watts et al. [6], our findings demonstrate the importance of not excluding suicidal participants from interventions designed to target depression.

ACKNOWLEDGEMENTS

Nicole Burgess coordinated and conducted data collection for the trial. Dawn O'Neil was involved in obtaining funding for the trial and coordinating Lifeline Australia's collaboration with the ANU. Assoc Prof Richard O'Kearney was a member of LF's PhD supervisory panel. Trevor Carlyon was also involved in coordinating Lifeline staff and volunteer involvement in the trial and supported Nicole in her role. The e hub team supported the trial implementation. We acknowledge the contributions of the Lifeline counselors who participated in this trial.

COMPETING INTERESTS

None.

FUNDING

Australian Research Council Linkage Grant (LP0667970), 2006, 3 years, $279,325 (Christensen, Griffiths, Mackinnon, Smith), Internet technologies, health informatics, and statistical models, and new delivery platforms in call centres (CIA).

HC and PB were supported by NHMRC 525411 and NHMRC Early Career Fellowship 1035262. KMG is supported by NHMRC Fellowship No. 525413.

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Figure 1: Trial Flow Diagram

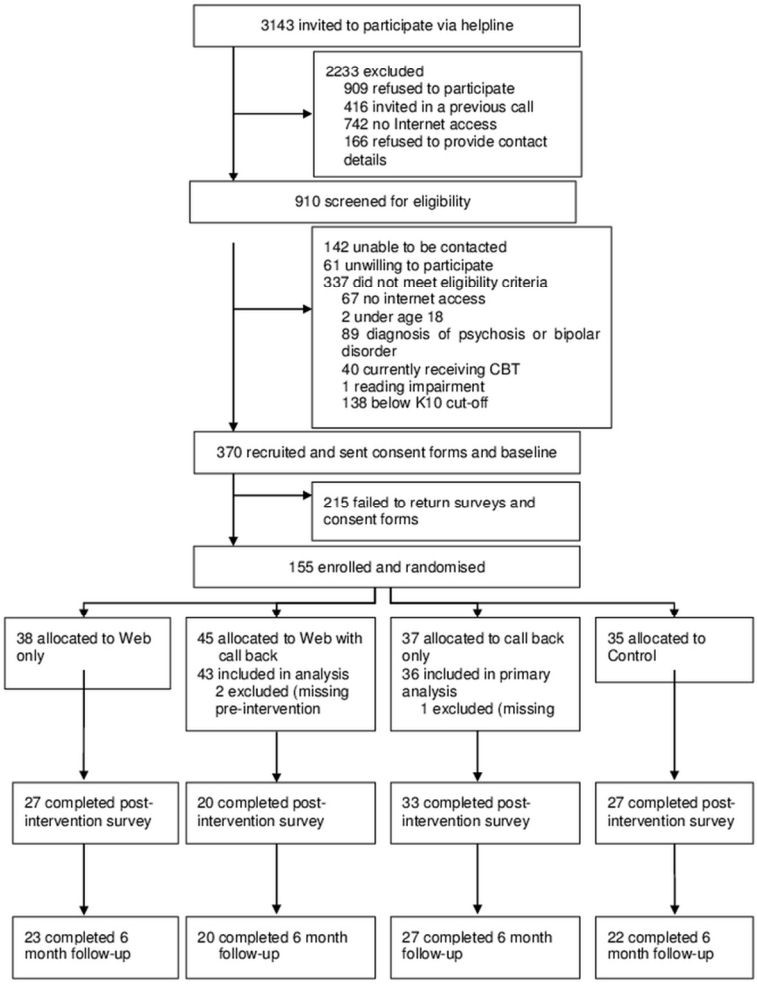

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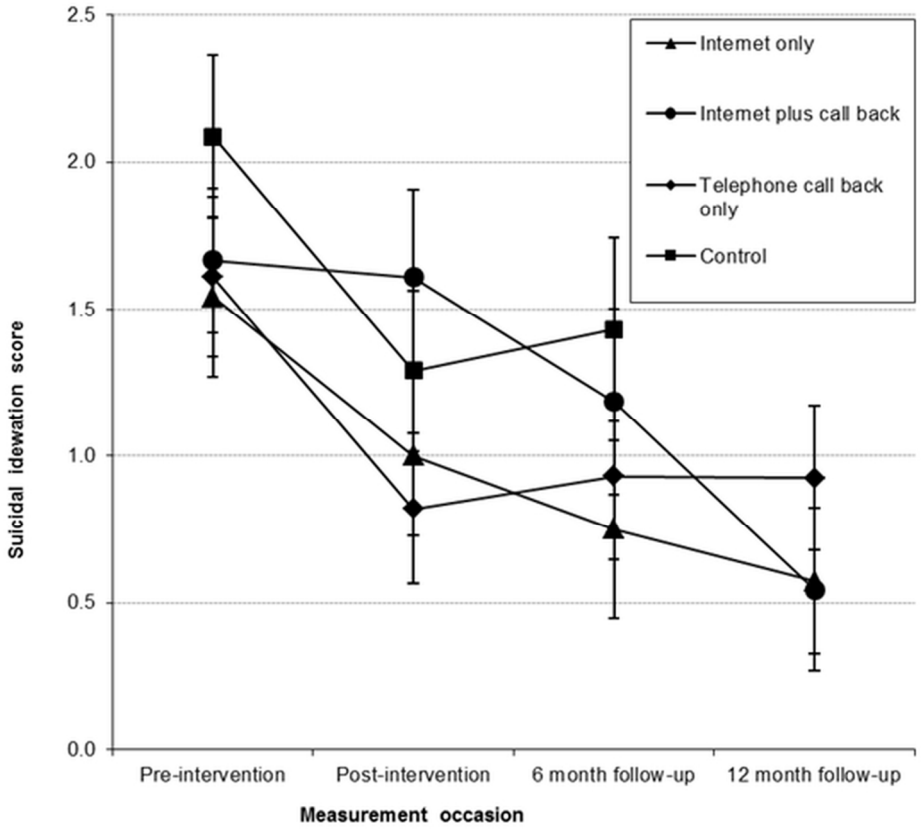
Figure 2: Estimated marginal means for suicidal ideation across measurement occasions.



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