PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The effect of a web based depression intervention on suicide ideation. Secondary outcome from a randomised controlled trial in a helpline.
AUTHORS	Donker, Tara; Christensen, Helen; Farrer, Lou; Batterham, Philip; Mackinnon, Andrew; Griffiths, Kathleen

VERSION 1 - REVIEW

REVIEWER	Emeritus Professor Robert D Goldney Discipline of Psychiatry University of Adelaide
REVIEW RETURNED	20-Mar-2013

THE STUDY	No other issues need to be addressed.
GENERAL COMMENTS	An excellent focused study , sorely needed in this specific area.

REVIEWER	Gerhard Andersson Linköping University, Sweden I have no competing interests.
REVIEW RETURNED	24-Mar-2013

THE STUDY	I wonder about exclusion as mentioned in the original trial.
GENERAL COMMENTS	I read this ms with great interest. The findings are important and it was not clear to me from the previous report how much suicidal ideation there was in the included sample. This paper adds important information. I have a number of concerns that need not be included. For example, I suspect that callers may inflate their reports to get advice and treatment and that we see a regression to the mean here. Second, it would be interesting to hear the authors views on how the treatment could be improved as it to my knowledge does not deal with suicidal ideation at all. Hence it is not suprising that it adds little. My main and only concern is this: In the original report this is stated: "Callers who were considered by the telephone counsellor to be suicidal or experiencing high levels of distress were excluded from receiving a recruitment invitation.". This is not mentioned in this report which is a strange omission. Please explain. Perhaps I have missed something, but if this is the case it calls for a rewrite of the ms. Overall, I liked this paper and think it is crucial to report data even when they do not show what we may have hoped for. It is an important trial.

REVIEWER	Adele S. Krusche DPhil Psychiatry Student & Research Assistant Oxford Mindfulness Centre Department of Psychiatry University of Oxford England No competing interests.
REVIEW RETURNED	28-Mar-2013

THE STUDY	The beginning of the Abstract could be clarified; initially it was unclear that the participants themselves were not workers in the call centre, but their callers. It would be interesting to establish why out of 370 eligible people only 115 completed informed consent and the pre-interventions, if this data is available. It seems a large number of people to drop-out having already agreed to participate. The Kessler Psychological Distress Scale is used for screening. It would be useful to include a description of the measure in the Method section. Although the General Health Questionnaire has been validated in Australian populations there is no mention of reliability or internal consistency, this would be useful. It would be interesting to include a brief description of the web-based interventions being used. The names of the interventions are reported but there is no explanation and this would be a useful addition. On page 14, it is stated that 62.7% of the sample reported suicidal ideation pre-intervention. It is unclear whether all participants were included in all analyses and why people with no ideation were included.
RESULTS & CONCLUSIONS	The paper would benefit from more explanation of missing data and outlining exactly who was in the sample and at which time point (e.g. it is unclear why the sample included people with no ideation). The table on page 16 would benefit from the inclusion of the sample sizes.
GENERAL COMMENTS	The manuscript presents an innovative way of looking at the use of web-based interventions for depression examining the change in suicidal ideation in a group of callers to a suicide support call centre. The results are interesting and this topic warrants further investigation. The study is one of the first RCTs examining the effects of a web-based intervention compared to a control group. The authors were careful to note limitations in the Discussion. Throughout the paper the group receiving waitlist TAU seems a little confusing. Initially, TAU is described as calling the support line when needed, which is designed to deliver support to those in distress. Later the calls are described as having no psychotherapeutic or supportive properties. It is also not reported whether people in the TAU group did use the support line or not. This may be important because calling (especially frequently) may be similar to receiving an intervention.

	The terms ‘intervention lines’, ‘call centres’ and ‘crisis lines’ are used throughout the introduction. It is unclear whether these are these being used interchangeably or if there a difference between them. It would be useful to include a brief explanation of the types of support offered already via call centres in the introduction. Mindfulness Cognitive Behaviour Therapy is mentioned on page 6. I think ‘Mindfulness-Based Cognitive Therapy’ was intended. The sample randomised to TAU seems to have higher suicide ideation pre-intervention. The sample was not stratified by ideation, probably because this is a secondary outcome paper, but there is no discussion about this and this seems important. The lack of a significant result for Internet & Phone support is not mentioned in the text. It would be an interesting discussion point. The manuscript would benefit from proof reading as there are a couple of extra spaces between paragraphs (p 6, 17), small font size used for some of the degrees of freedom reported, but not all (p 16, 18) and a typo on page 23, where the line reads “ability advantage”. Otherwise very well written and easy to follow. A really nice contribution to the literature.

REVIEWER	Jo Robinson Research Fellow Orygen Youth Health Research Centre University of Melbourne I have no competing interests.
REVIEW RETURNED	03-Apr-2013

THE STUDY	Overall this study appears to have been well conducted and is well reported. However there are one or two aspects of the study that would benefit from further clarification. Firstly, were there any inclusion criteria around suicidal ideation? Secondly, more information regarding the intervention would be helpful. More specifically, the authors could clearly set out the duration of the intervention phase of the study. In addition, more detail about the web-based programs would be helpful. I realise that these have been reported elsewhere but a brief summary of the content, delivery, duration would be useful to the reader, as would information as to whether or not they are moderated at all. Were the telephone calls made to people randomised to the web-based programs standardised and / or monitored? Were any additional telephone calls that were made to Lifeline by participants monitored and accounted for in the analysis? Were there any safety protocols in place? Was treatment (over and above the intervention) assessed at all?
RESULTS & CONCLUSIONS	I found the results somewhat confusing to read. The lack of adherence and attrition data is also problematic, and it is hard to extrapolate how many participants completed the web-based interventions. Whilst this is referred to in the CONSORT checklist, and in the limitations section, a participant flow chart would be beneficial. In addition, the lack of actual numbers presented in the results

	makes them hard to interpret, in particular given the above point. It would be of interest to know whether any form of dose-response effect was in operation.
REPORTING & ETHICS	Information regarding ethical approval being obtained should be included, plus information regarding any safety protocols in place. A participant flow chart is required. I note that this is referred to in the CONSORT checklist as having been provided in a previous publication, but in my view it would also be helpful here.

VERSION 1 – AUTHOR RESPONSE

Emeritus Professor Robert D Goldney Discipline of Psychiatry University of Adelaide
No required changes

Gerhard Andersson
Linköping University, Sweden

In the original report this is stated: "Callers who were considered by the telephone counsellor to be suicidal or experiencing high levels of distress were excluded from receiving a recruitment invitation." This is not mentioned in this report which is a strange omission. Please explain. Perhaps I have missed something, but if this is the case it calls for a rewrite of the ms.

We did not intend that this be omitted from the manuscript. Our main purpose was to report the secondary suicide data as concisely as possible. We have now added a sentence to the methods and added a note in the discussion. High distress or acutely suicidal participants were excluded. (P.8.) We have added the following sentence to the Discussion. 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 (P. 23).

Adele S. Krusche
DPhil Psychiatry Student & Research Assistant Oxford Mindfulness Centre Department of Psychiatry University of Oxford England

The beginning of the Abstract could be clarified; initially it was unclear that the participants themselves were not workers in the call centre, but their callers.

This has been amended accordingly. The title of the manuscript has also been amended.

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. (Abstract, p.2)

It would be interesting to establish why out of 370 eligible people Only 115 completed informed consent and the pre-interventions, if this data is available. It seems a large number of people to drop-out having already agreed to participate.

The target audience for the study differs radically from individuals presenting to clinical services. Helpline callers are on the “fringe of services”, may be less likely to enrol in traditional health services, less likely to engage with mental health services, and more adverse to “signing up” to a trial where contact would no longer be anonymous. We note this in the Primary Outcome Trial paper: “The current trial was a true effectiveness trial employing a volunteer workforce for recruitment and

tracking, and hence would be expected to be associated with recruitment and adherence issues relative to the more controlled environment of an efficacy study".
We now add 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 (Reference added here: Flay BR (1986) Efficacy and effectiveness trials (and other phases of research) in the development of health promotion programs. Prev Med 15: 451-474) and where a mismatch occurs between the expectation of phoning a crisis centre and being 'diverted' to another program.

The Kessler Psychological Distress Scale is used for screening. It would be useful to include a description of the measure in the Method section.

We have added Kessler Psychological Distress Scale [11] (138/337, 41%), a brief screening scale used clinically and epidemiologically. This scale is well known and identified by reference in the paper. (p.8)

Although the General Health Questionnaire has been validated in Australian populations there is no mention of reliability or internal consistency, this would be useful.

Although data on consistency and reliability is reported for the GHQ 28 (as a full scale), it is rarely reported for the 4 suicide questions alone. As an alternative to published data, we now report Cronbach's Alpha for the 4 suicidal ideation items at baseline for the present study. Cronbach's Alpha was 0.90 (Page 11). Retest reliability was approximately .53. However, given the retest period was contemporaneous with the intervention conditions, this is not a reasonable measure of re-test reliability.

It would be interesting to include a brief description of the web-based interventions being used. The names of the interventions are reported but there is no explanation and this would be a useful addition.

See above. These have been provided above. (Page 9)

On page 14, it is stated that 62.7% of the sample reported suicidal ideation pre-intervention. It is unclear whether all participants were included in all analyses and why people with no ideation were included.

Suicide ideation is a secondary measure in this study. Intention to treat analyses require that all participants are included in secondary analyses.

We believe that retention in analyses of people who were not experiencing suicidal ideation at baseline is required within the intention to treat framework of the trial. Suicidal ideation was not an inclusion criteria, and so did not define the population at which the intervention was directed (the intent-to-treat sample). To exclude individuals who might develop ideation in the period during which the intervention was running could bias the conclusions reached.

The paper would benefit from more explanation of missing data and outlining exactly who was in the sample and at which time point (e.g. it is unclear why the sample included people with no ideation).

A consort flow diagram is included which outlines this information.

The table on page 16 would benefit from the inclusion of the sample sizes.

The samples contributed to each condition are now provided in the consort flow diagram. The

contrasts shown in Table 2 are based on the estimates obtained within the mixed model. These models included all participants with a baseline depression scores, and are estimated under the missing at random assumption, consistent with the ITT analysis.

Throughout the paper the group receiving waitlist TAU seems a little confusing. Initially, TAU is described as calling the support line when needed, which is designed to deliver support to those in distress. Later the calls are described as having no psychotherapeutic or supportive properties.
We have now strengthened our description of the conditions to avoid confusion. These changes are in green highlight to improve our description of the conditions. Changes have been made on pages: We have taken out the sentence: “The 10-minute intervention calls were scripted and not intended to provide any form of psychological or supportive counselling” as this refers to the proactive call back provided and not to the services offered via the helpline service itself (which may offer supportive properties, as noted by the reviewer). We have made changes to p 6,8,10, 17,18, and 19, and to Tables 1 and 2.
We now report whether the participants took up the opportunity to contact the Lifeline service. This may be important because calling (especially frequently) may be similar to receiving an intervention.

This is an important point. Although we did not report these data in this study, we did analyze differences in rates of use of Lifeline services. Logistic regression analyses were used to examine the association between treatment condition and Lifeline use at post-intervention. Lifeline use data were dichotomised into the following categories: ‘minimal Lifeline use’ (No calls or 1-2 calls) and ‘frequent Lifeline use’ (3 or more calls). Analyses revealed that at post-intervention, participants in the Internet only condition were less likely than participants in the control condition to be a ‘frequent’ user of Lifeline (odd ratio .23, 95% CI: .07 to .75, p = .014). We have added relevant comment in the discussion.

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. (p22)

The terms Œintervention lines¹, Œcall centres¹ and Œcrisis lines¹ are used throughout the introduction. It is unclear whether these are these being used interchangeably or if there a difference between them. It would be useful to include a brief explanation of the types of support offered already via call centres in the introduction.

We have now used the generic term helpline or helpline services. Part of the problem is that there is little consistency in the use of these terms. Many services are identified as targeting suicide via their branding, eg. Lifeline. Moreover, because of technology advances lines are often delivered on internet platforms with associated “chat”.

Mindfulness Cognitive Behaviour Therapy is mentioned on page 6. I think ŒMindfulness-Based Cognitive Therapy¹ was intended.

This is corrected.

The sample randomised to TAU seems to have higher suicide ideation pre intervention. The sample

was not stratified by ideation, probably because this is a secondary outcome paper, but there is no discussion about this and this seems important.

Pre-intervention, TAU participants did not have significantly higher levels of suicidal ideation compared with participants in any of the other conditions ($F(3,149) = .77$, $p = .52$).

The lack of a significant result for Internet & Phone support is not mentioned in the text. It would be an interesting discussion point.

We have now mentioned this in the text
....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.p. 21.

The manuscript would benefit from proof reading as there are a couple of extra spaces between paragraphs (p 6, 17), small font size used for some of the degrees of freedom reported, but not all (p 16, 18) and a typo on page 23, where the line reads ³ability advantage².

These have been corrected.

Reviewer: Jo Robinson
Research Fellow
Orygen Youth Health Research Centre
University of Melbourne

Overall this study appears to have been well conducted and is well reported. However there are one or two aspects of the study that would benefit from further clarification.

Firstly, were there any inclusion criteria around suicidal ideation?

This has been addressed above.

Secondly, more information regarding the intervention would be helpful. More specifically, the authors could clearly set out the duration of the intervention phase of the study. In addition, more detail about the web-based programs would be helpful. I realise that these have been reported elsewhere but a brief summary of the content, delivery, duration would be useful to the reader, as would information as to whether or not they are moderated at all.

This is now provided (see above)

Were the telephone calls made to people randomised to the web-based programs standardised and / or monitored?

These scripted calls focused on various environmental and lifestyle factors associated with depression (page 10).
Were any additional telephone calls that were made to Lifeline by participants monitored and accounted for in the analysis?

This has been responded to above and within the research paper (see Page 22) .

Were there any safety protocols in place?

Yes, all participants had access to Lifeline services. Duty of care was provided as per Lifeline

protocols, which included emergency and police rescue.

Was treatment (over and above the intervention) assessed at all?

We have data available on General Practitioner services sought by participants, as measured by self-report. We did not analyze this data systematically or formally. However, reported GP service use appeared to decline from rates (62-80% at baseline) to 44-68% at six months, and there appeared to be no group differences.

The lack of adherence and attrition data is also problematic, and it is hard to extrapolate how many participants completed the web-based interventions. Whilst this is referred to in the CONSORT checklist, and in the limitations section, a participant flow chart would be beneficial. This is now included. A separate paper on Adherence has been sent for review and is in revision.

In addition, the lack of actual numbers presented in the results makes them hard to interpret, in particular given the above point.

Data on numbers of participants is now included.

It would be of interest to know whether any form of dose-response effect was in operation.

A separate paper on adherence has been in revision.

Information regarding ethical approval being obtained should be included, plus information regarding any safety protocols in place.

An Ethics Statement is now included.

A participant flow chart is required. I note that this is referred to in the CONSORT checklist as having been provided in a previous publication, but in my view it would also be helpful here.

As above, this has now been included.

VERSION 2 – REVIEW

REVIEWER	Andersson, Gerhard Linkoping University
REVIEW RETURNED	20-May-2013

GENERAL COMMENTS	I have now checked the revised ms and am happy with the corrections and clarifications made.

REVIEWER	Adele S. Krusche DPhil Student & Researcher University of Oxford England No competing interests.
REVIEW RETURNED	09-May-2013

THE STUDY	CONSORT supplied & clearly presented.
GENERAL COMMENTS	Minor point-There are a few occasions where brackets need

	checking (either missing close bracket or too many, p10, p12, p14). The clarity of the ms is very much improved, particularly with the inclusion of the CONSORT diagram. The Methods section is clear and the interventions are described and defined throughout. An interesting study and a really nice contribution to the literature.