Title: The safety and acceptability of delivering an online intervention to secondary students at risk of suicide: findings from a pilot study

Running head: Iatrogenic effects of an online intervention

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Abstract

Background

Suicide-related behaviour is a major problem among adolescents. Yet relatively few studies have tested the efficacy, acceptability and safety of interventions for this population. We developed and pilot tested an online intervention for at-risk school students, which has led to reduced suicidal ideation, hopelessness and depressive symptoms. The aims of this study were to examine the safety and acceptability of the program, and to determine which components were found to be most helpful and enjoyable.

Methods

This pilot study employed a pre-test/post-test design, with an 8-week intervention phase. Participants were assessed immediately before, and immediately after the intervention. Participants were also asked to complete a weekly questionnaire immediately after the intervention, and again two days later assessing suicidal ideation and distress.

Results

Twenty-one young people completed the intervention. Overall the intervention did not lead to increases in suicidal ideation or distress. Participants reported enjoying the program, in particular watching the video diaries and completing the activities, and said they would recommend the program to a friend. Overall the cognitive components of the program were found to be most helpful.

Conclusions

Overall the program appeared to be a safe and acceptable intervention for at-risk adolescents. This was a small, pilot study so we need to interpret the results with caution. However, the findings are promising and suggest that young people at risk of suicide can safely be included in trials as long as adequate safety procedures are in place. The program is now being tested in a randomised controlled trial.

Key words: Suicidal ideation; Adolescents; Internet; Cognitive behavioural therapy; Iatrogenic

Word count: 3,603

Background

Suicide, and suicide-related behaviours are a significant problem among young people (1, 2). Despite this, there is a lack of research, in particular randomised-controlled trials (RCTs), testing either the effectiveness, or the acceptability, of interventions designed to reduce risk among this population (3-5).

Of the interventions tested with suicidal young people, cognitive behavioural therapy (CBT) appears to show promise (3, 6), and in response to the growing popularity of electronic means of communication, in particular among youth, CBT interventions for depression and anxiety are now routinely delivered via the Internet (7-9). However, whilst one study has examined the effects of an online intervention among suicidal adults (10, 11), to our knowledge none have done so with suicidal youth.

Indeed, it is not uncommon for studies, even in the depression literature, to actively exclude people who are suicidal from trials testing the effects of either face-to-face therapy (12), or Internet-based interventions (13), despite the relationship between depression and suicide risk (14-16). Whilst one possible explanation for this may relate to pragmatic or methodological issues (5), another may relate safety concerns. In particular, concerns exist around the safety of using media such as the Internet to talk about suicide, largely due to the potential effects of contagion, or copycat suicide, whereby one person's suicide influences another person to either attempt or to complete suicide (17-19).

However, in addition to the possible risks, there may also be potential benefits to delivering interventions to suicidal youth online, as long as it is done so safely. For example, research has shown that young people find the Internet a useful vehicle for the expression of suicidal feelings, for discussing one's feelings in relation to the suicides of others, for seeking

support, and in terms of being able to support others (20-22). Further, whilst questions have been raised as to its potential utility in terms of suicide prevention (23), to our knowledge no studies have tested this empirically. Therefore studies are needed that can examine the efficacy, acceptability and safety of online interventions among suicidal young people.

In response to this we have developed an Internet-based program (*Reframe IT*) that is specifically designed for secondary school students at risk of suicide. The program has been piloted in secondary schools around Melbourne, Australia, and participants reported lower levels of suicidal ideation, depressive symptoms and hopelessness at the end of the program (24). The aims of this study were to report on the safety and acceptability of the program.

Methods

Aims and hypotheses

The aims of this study were threefold. 1) The primary aim was to examine whether or not a specifically designed Internet-based program (*Reframe IT*) has any iatrogenic effects. 2) Secondly we set out to examine which components of the program, and which of the skills taught, were found to be the most helpful and the most enjoyable. 3) Finally we assessed the acceptability of the program.

Study design

This was a small pilot study that employed a pre-test/post-test design with an 8-week intervention phase. Participants were assessed immediately before beginning the intervention (baseline), and immediately after the intervention was complete (post-

intervention). Participants were also asked to complete a brief questionnaire each week immediately after the intervention and again two days later over the telephone that assessed suicidal ideation and levels of distress.

Study team

The study was conducted by researchers at Orygen Youth Health Research Centre (OYHRC). The research team comprised two researchers who conducted the assessments and delivered each module (JR and GC) and two researchers who provided clinical supervision and moderated the website (SH and SB).

Sample

Secondary schools from the OYHRC catchment area, and a nearby **headspace** centre were invited to participate. In total 11 schools agreed to participate in the study. Students were eligible for the study if they were between 14 and 18 years old, and if they had presented to a member of their school wellbeing team and reported experiencing suicidal ideation during the past month. Exclusion criteria were any intellectual disability, the presence of psychotic symptoms and/or an inability to speak English.

Students who met the inclusion criteria were asked by the school wellbeing team if they were interested in participating in the study. If they said 'yes', a plain language statement and consent form was given to them to be signed by both the student and their parent/guardian. Once the consent form was returned to the school, the school wellbeing staff member contacted the study team and an appointment was made for the baseline assessment to be conducted. All research questionnaires were administered face-to-face, by a trained researcher (JR and GC), in a quiet room at the participant's school. The exception

to this was the two-day follow up questionnaire, which was administered over the telephone.

Intervention

The *Reframe IT* intervention was developed by the research team and comprises eight modules, each of which takes around 15-20 minutes to complete. Each student completed one module a week. This was done in a quiet room at school in the presence of one of the research team. However, each participant also had access to his or her own personalized webpage accessed via a secure login, and they were able to access the modules again in their own time once they had been completed with the researcher. Only the participant and the research team could access the page. There was no social networking function.

The site comprised an adult ‘host’ character who delivered the therapy verbally, and a series of video diaries made by young people (actors), that told a different ‘story’ each week.

There were also two activities to be completed per week that related to the issues raised in the module. The site also included a message board, a series of factsheets covering a range of related topics, downloadable MP3s and a list of local and national helplines and services that participants could access if they wished. As individual participants progressed through the weekly modules, items associated with those modules were added to the site, (e.g., an activity diary).

The eight modules incorporated standard CBT approaches commonly used with young people (25). These were: engagement and agenda setting; emotional recognition and distress tolerance; identification of negative automatic thinking; behavioural activation - help-seeking and activity scheduling (including relaxation techniques); problem solving, with a specific focus on managing suicidal ideation; detecting and challenging problematic

thinking, and cognitive restructuring.

Researcher involvement was two-fold. Firstly, two researchers (JR and GC) facilitated delivery of the program, this included setting up appointments; managing Internet issues; and remaining in the vicinity while the participant viewed the program. Secondly, there was involvement from a researcher-therapist (SH) who checked the responses to a weekly 'distress-check' which was completed online at the end of each module. If scores on this were high, this information was fed-back to the school staff. She also checked completed activities and responded with personalised but standardised messages and checked the message board daily responding as appropriate.

Outcomes

Overall participants were assessed on a range of outcomes, including suicidal ideation, depressive symptoms and hopelessness the data for which is reported elsewhere (24). However, the primary aim of the current paper is to examine any possible iatrogenic effects of the intervention. This was assessed as follows; firstly, weekly suicidal ideation and distress scores were measured using a specifically designed questionnaire administered on paper immediately after the program, and again two days later over the telephone. Participants were asked to rate their current level of suicidal ideation on a scale of zero to three with zero indicating 'no thoughts of suicide'; one indicating 'mild thoughts of suicide but without intent or a specific plan'; two indicating 'moderate suicidal thoughts, with some level of intent and a rough plan' and three indicating 'severe thoughts of suicide with a clear plan and the intent to act'. Distress was also measured on a scale of zero to three, with zero indicating 'not at all distressed'; one indicating 'mildly distressed'; two indicating 'moderately distressed' and three indicating 'very distressed'.

A second aim of the study was to examine which components and skills taught as part of the program were found to be most enjoyable and most helpful. This was measured using a specifically designed questionnaire administered on paper at the end of the program.

Participants were asked to rate their opinions using a series of Likert scales, which broke down the various components of the website into the following and assessed how enjoyable and how helpful they were considered to be: watching the video diaries; listening to the host; completing the activities; hearing from the site moderator and receiving text messages. Participants were then asked to rate how helpful and how much they used the following skills: emotional recognition; identifying ‘problem situations’; identifying tipping points; recognizing unhelpful thoughts; learning who to go to for help; pleasurable activity scheduling; problem solving and replacing unhelpful thoughts with helpful thoughts.

Acceptability was also measured at the end of the program using a series of specifically designed Likert scales. The first three questions asked participants to rate the overall ‘look and feel’ of the website; overall enjoyment; and overall helpfulness. Participants were also asked to rate whether or not they found the intervention to be distressing in an overall sense, and whether or not they considered any distress to be worthwhile if it led to receipt of appropriate help or support. Finally they were asked whether or not they would recommend the program to a friend.

Data analysis

All data were entered into SPSS. Changes in suicidal ideation and distress were measured by examining whether or not people reported greater or less suicidal ideation and distress pre to post intervention and post intervention to follow up on the four-item scale described

above. The percentage of participants who reported either no change, increased, or decreased suicidal ideation and distress scores is reported.

In order to assess how enjoyable and how helpful each component of the intervention was considered to be, simple frequencies were calculated and percentages are reported.

An independent samples t-test was conducted in order to examine whether or not there were any differences in suicidal ideation between those who did and did not report finding the program in any way distressing.

Ethics and safety

Several safety measures were in place. Firstly, immediately following the baseline assessment a detailed safety plan was conducted with each participant. This included a number of strategies that the participant could use if they felt suicidal. It also contained contact details for informal and formal sources of help, nominated by the participant.

Secondly, all assessments and modules were completed at school. Psychological distress was measured weekly immediately following the module, using the ten-item version of the Kessler Psychological Distress Scale (K10) (26, 27) and a specifically designed questionnaire assessing feelings of distress and suicidal ideation. The outcomes of both of these measures was fed back immediately to the school wellbeing staff member who responded appropriately.

Fortnightly clinical supervision meetings were held, attended by the researchers responsible for participant assessments (JR and GC) and two additional members of the research team (SH and SB), both of whom are registered clinical psychologists and provided the supervision. Any concerns regarding the wellbeing of participants were discussed, and where necessary referrals were made to specialist services.

Ethical approval was obtained from the University of Melbourne Human Research Ethics Committee and the Victorian Department of Education and Early Childhood Development Ethics Committee. Written consent was required from all students and their parents/guardian.

Results

Participants

Over the recruitment period 34 students were referred to the study, from nine schools. Of these 34 students, baseline assessments were conducted with 32, and 27 students began the intervention. Twenty-one students completed all eight modules and a post-intervention assessment, and constitute the observed case sample used for the analysis.

Demographic and baseline characteristics of the sample

The demographic characteristics of those students for whom baseline data are available, including both those who did (n=21) and did not complete the program (n=11), are presented in Table 1. Reasons given for dropping out of the program were not always given, however when they were provided they included feeling better, changing school, and having too much schoolwork. One participant reported feeling too unwell to continue. As can be seen in Table 1, the majority of participants were female, ages ranged from 14-18 (mean age 15.6), lived with a family member and identified as Australian. No participants identified as Aboriginal or Torres Strait Islander.

= Insert Table 1 about here =

There were no differences in suicidal ideation at baseline between those students who provided follow up data and those who did not. The number of weeks over which the

intervention was delivered ranged from 5 to 25 weeks, with a mean of 9.6 and a median of 6.6 weeks.

Iatrogenic effects

Weekly changes in suicidal ideation and distress

As noted above, each week participants were asked to record their levels of suicidal ideation and distress immediately before, immediately after the intervention, and again approximately two days later. Tables two and three detail the changes seen in these scores between each of the different time points for each of the eight modules.

[Please insert Tables 2 and 3 about here]

As can be seen in the majority of cases both suicidal ideation and distress either remained the same, or decreased, over the course of each module. Whilst there were some cases where suicidal ideation increased slightly over the two-day follow-up period, there were no instances of suicidal ideation increasing immediately post-intervention. With regard to distress, whilst some increases were seen immediately after modules two and three, from module four onwards there was relatively little change.

Overall distress

At the end of the study participants were also asked to report how distressing (if at all) they found the program overall. Of the twenty-one young people that completed the intervention and filled in a final evaluation questionnaire, one reported finding the program moderately distressing (4.8%), four found it mildly distressing (19.0%), and sixteen reported that they did not find the intervention in any way distressing (76.2%).

None of the participants reported finding the program ‘very distressing’.

Finally, participants were also asked to report how worthwhile they thought any distress

might be if it meant that young people could then receive the help that they needed. One participant reported that it was ‘not at all worthwhile’ (4.8%); 2 participants reported that it was ‘somewhat worthwhile’ (9.5%) and 18 participants reported that it was ‘quite or very worthwhile’ (85.7%).

The young person who did not find the program to be at all worthwhile also reported it to be ‘moderately distressing’. In contrast, participants who found the program to be either mildly or moderately distressing also reported finding it to be ‘quite worthwhile’.

Program components

We then asked their opinions of the different components of the program. Watching the video diaries and completing the activities were rated as the most helpful components of the program, with 71.4% of students rating them as either somewhat or very helpful. This was followed by listening to the host (57.1%). Hearing from the website moderator and receiving text messages were rated as the least helpful aspects of the program, with both rated as somewhat or very helpful by 38.1% of participants.

With regard to enjoyment, watching the video diaries was reported to be the most enjoyable component of the program (71.4%). This was followed by completing the activities (47.6%), and then listening to the host (38.1%). Receiving text messages and hearing from the website moderator were rated as the least enjoyable aspects of the program, with both rated as somewhat or very enjoyable by 33.3% and 28.5% of participants respectively.

Participants also rated the different skills taught during the program. Cognitive restructuring was rated as the most helpful skill taught during the program, with 90.5% of participants rating it as either somewhat or very helpful. This was followed by recognising

one's 'tipping point' and problem solving, rated as somewhat or very helpful by 71.5% and 71.4% of participants respectively. Learning to recognise one's emotions and scheduling pleasurable activities were the skills that were rated as somewhat or very helpful least frequently (by 52.4% and 57.2% respectively). The only skills that participants reported as not being helpful at all were learning who to go to for help and scheduling pleasurable activities, each rated as not at all helpful by 4.8% of participants (n=1).

Finally participants were asked how frequently they used the skills taught in the program. This is summarised in Table 4.

[Please insert Table 4 about here]

Nine participants used the program outside of their session with the researchers. Of them one person used the fact sheets, two used the message board, two used the mood diary, two used the relaxation MP3 and three used the safety plan. There were no crisis messages written on the message board throughout the study.

Acceptability

At the end of the program, the twenty-one participants who completed the program were asked a number of questions designed to assess their overall opinion of the intervention. Regarding the look and style of the *Reframe-IT* website, the majority of participants liked the website (76.1%; n=16) and only one participant reported not liking it. Overall almost all of the participants reported finding the program enjoyable (80.9%; n=17), and the majority reported finding it helpful (90.5%; n=19). Ninety-five per cent of participants (n=20) reported that they would recommend the program to a friend.

Discussion

Key findings and implications

The primary aim of this study was to examine whether or not participating in an online suicide prevention program had any iatrogenic effects. As can be seen from the results reported above, in no instances did suicidal ideation increase immediately following delivery of the program. There were a couple of instances where suicidal ideation did increase slightly over the two-day follow-up period but it is unlikely that this would be attributed to the intervention itself.

In addition to suicidal ideation, we also examined levels of distress following completion of each module, and although some increases were seen immediately after modules two and three, from module four onwards there was relatively little change, suggesting a degree of stabilisation in terms of emotion from this point onwards. Again the key message being that participation in the program did not, for the most part, lead to an increase in levels of distress.

With regard to overall distress, measured at the end of the intervention only one person found the program to be moderately distressing, whilst the majority did not find it in any way distressing. In addition to this, the majority reported that any distress experienced would be worthwhile if it meant that young people could then receive the help that they needed. Participants also reported finding the program enjoyable, and acceptable, and most said that they would recommend it to a friend.

Taken together these findings suggest that, despite the concerns that have been expressed regarding talking about suicide online (17, 18), the Internet, when used carefully, has the potential to be a safe and acceptable medium for delivering suicide prevention activities.

This is not to say that care should not be taken and examples do exist whereby the Internet has lead to concerns, for example regarding the accessibility of information regarding suicide methods or the ability to befriend others who may serve to reinforce suicidal feelings rather than alleviate them (28, 29). Indeed, this was a carefully administered, highly structured program with detailed safety and supervision procedures in place and administered by highly trained staff, however, the findings support others that have concluded that the Internet does hold potential for good, as well as bad, when it comes to suicide prevention (30).

With regard to the different components of the program, participants reported finding the more interactive components to the program, namely watching the video diaries, completing the activities and listening to the host, as the most helpful and the most enjoyable components of the program. This is of interest; unlike other online CBT programs (31, 32) *Reframe-IT* was not heavily text-based, rather participants in *Reframe-IT* were simply required to watch a series of short video diaries made by other youngsters. This was deliberate. Previous criticisms of online programs have included that they have not necessarily been designed with young people in mind (33), and it is possible that this has contributed to the relatively low rates of adherence reported (34). Thus, in developing this program the researchers spent a significant amount of time observing, and talking with young people, about the ways in which they communicate about suicide online, and it is hoped that by designing a specifically youth friendly program, improved rates of adherence and better outcomes will be observed.

Finally, we note that young people reported that they found the cognitive skills (e.g. cognitive restructuring) that were taught within the program to be more helpful than the

more behavioural-focused components. This contradicts previous research that has suggested that it is the behavioural activation, social skills and problem solving components of CBT that are more likely to produce positive treatment effects with depressed young people, than the cognitive components (35-37). This could be due to the fact that suicidal ideation is primarily a cognitive process (i.e. thinking about suicide) whereas depression is more multi-faceted with cognitive, affective and behavioural components. It is possible that cognitive restructuring, that directly targets suicidal thinking is most effective at changing it than other, less direct strategies. This is a valuable area for future investigation.

Limitations

Before we consider the implication of this study it is important to note some limitations. Firstly, this was a small pilot study with no control group. Secondly, rates of attrition were relatively high with 13 students dropping out of the study. Whilst this is not unusual in studies testing Internet-based interventions (38), it did reduce our sample size by approximately one third and introduced the potential for a degree of bias in the sample. With regard to delivery of the intervention, the program was designed to be delivered over an eight-week period, however the length of time taken to deliver the program ranged from 5 to 25 weeks. This we took to be an indication of the feasibility of delivering programs such as these in schools. The reality is schools are busy places and there are many reasons that students couldn't attend each week, for example exams, school camp, illness and so on. The upper end of the range was 25 weeks. This is because we had one student who dropped out of the program, but later re-approached us wanting to finish it. Similarly some students completed the program in less than eight weeks in order that they could finish it before the end of the school term or before exams began. Thus some flexibility is required if programs such as this are to be successfully delivered in a school setting.

Additionally, the study relies entirely on self-report measures so may be susceptible to elements of recall bias, in particular when asking students to recall past suicidal ideation or distress.

Finally, we cannot be certain that changes in distress or suicidal ideation were not mediated by overall levels suicidal ideation. However given the small sample size, the study was not sufficiently powered to examine this.

Conclusions

Overall the *Reframe IT* program appeared to be a safe and acceptable intervention to deliver to at-risk young people. However, as noted above, this was a small, uncontrolled study so we need to interpret the results with caution. That said the findings are promising and suggest that young people at risk of suicide can safely be included in trials as long as adequate safety procedures are in place. The program is now being tested in a randomised controlled trial.

Acknowledgements

This study received funding from the American Foundation for Suicide Prevention and from an NHMRC Program Grant. JP is on a National Health and Medical Research Council Senior Research Fellowship. SH and SB are both on a National Health and Medical Research Council Early Career Fellowship. OYHRC is affiliated with Melbourne Health and the University of Melbourne and receives funding from the Colonial Foundation.

Conflict of interest

The authors report no conflict of interest.

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Title:

The safety and acceptability of delivering an online intervention to secondary students at risk of suicide: findings from a pilot study

Date:

2015-12-01

Citation:

Robinson, J., Hetrick, S., Cox, G., Bendall, S., Yung, A. & Pirkis, J. (2015). The safety and acceptability of delivering an online intervention to secondary students at risk of suicide: findings from a pilot study. *EARLY INTERVENTION IN PSYCHIATRY*, 9 (6), pp.498-506.
<https://doi.org/10.1111/eip.12136>.

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