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The online treatment of suicidal ideation: A randomised controlled trial of an unguided web-based intervention



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ABSTRACT

Suicide is a major public health issue, and treatment of suicidal thoughts may contribute to its prevention. Provision of online treatment of suicidal ideation may reduce barriers that suicidal individuals experience in face-to-face treatment. We therefore aimed at evaluating the effectiveness of a web-based intervention targeting a reduction of suicidal ideation. We carried out a two-arm, parallel-design, randomised controlled trial in the general population in Flanders (Belgium) (registered as NCT03209544). Participants who were 18 years or older and experienced suicidal ideation were included. The intervention group (n=365) received access to the unguided web-based intervention, and the control group (n=359) was placed on a waitlist. Assessments were carried out at baseline and at 6 and 12 weeks. Participants reported high levels of suicidal ideation, depression, hopelessness, worrying, and anxiety at baseline. Compared to the control group, participants in the intervention group experienced a significant decline in suicidal ideation, depression, hopelessness, worrying, and anxiety both at post-test and at follow-up. An important limitation of the study was a high dropout rate, in particular in the intervention group. Our findings suggest that the online self-help intervention was more effective in reducing suicidal ideation and suicide-related symptoms than a waitlist control in a severely affected population. It can help in filling the gap between crisis help and face-to-face treatment.

1. Introduction

Every 40 seconds a person dies by suicide, which amounts to 800.000 individuals around the world each year. Many more people try to kill themselves (World Health Organization, 2017). Thoughts of suicide (or suicidal ideation) are a key element in the suicidal process. Such thoughts can start off as being vague and sporadic. As a consequence of an interaction between internal and external factors, they can gradually increase in frequency and intensity and can become more concrete. Eventually, they can evolve into a suicide attempt or suicide (Retterstol, 1993; van Heeringen, 2001). Interventions that focus on suicidal ideation, even before such thoughts evolve into suicidal behaviour are important in the prevention of suicide (O'Connor & Nock, 2014). Reducing suicidal ideation is therefore crucial for suicide prevention, and such a reduction can be achieved with cognitive

psychotherapy. For example, cognitive behavioural based psychotherapy (CBT; comprising cognitive behavioural and problem-solving therapy) aiming at the prevention of repeat suicide attempts shows a beneficial effect on suicidal ideation (Hawton et al., 2016). However, less than one-third of individuals experiencing suicidal ideation either seek help or make use of mental health services, indicating that many are missing out on effective treatment (Hom, Stanley, & Joiner, 2015). A number of barriers towards traditional forms of treatment have been identified, and include low perceived need, stigma and shame, a preference for self-management, availability, and high cost of care (Bruffaerts et al., 2011). Many of these barriers can be overcome through online interventions targeted at the general population since these are easily accessible anywhere at any time, affordable, and mostly anonymous or confidential (Hom et al., 2015; Kreuze et al., 2017). Indeed, there are some reports that suicidal individuals prefer online

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forms of treatment over face-to-face treatment, and that people with more severe ideation are more likely to choose online treatment than no treatment (Wilks, Coyle, Krek, Lungu, & Andriani, 2017).

Studies of online interventions have shown positive effects on suicidal ideation (Christensen et al., 2013; Mewton & Andrews, 2015; Saulsberry et al., 2013; Voorhees et al., 2009; Williams & Andrews, 2013). However, these interventions were developed to treat depression and do not target suicidal ideation and behaviour directly. Further research showed that interventions focusing specifically on suicidal ideation and behaviour were more effective in reducing suicide attempts and suicides than those that only address suicide-related psychiatric disorders such as depression and anxiety (Meerwijk et al., 2016). To the knowledge of the authors. only two online interventions (van Spijker et al., 2018; van Spijker, van Straten, & Kerkhof, 2014) have directly addressed the intensity and frequency of suicidal ideation in adults in the general population. Both interventions were mainly based on Cognitive Behavioural Therapy but they also included elements of Dialectical Behaviour Therapy, Problem Solving Therapy, and Mindfulness Based Cognitive Therapy. The first intervention, which was developed in the Netherlands, was studied in a randomised controlled trial (RCT). In the two-arm study, the intervention group received access to the intervention (which lasted six weeks) while the control group was directed to a website which gave information on suicidality, common treatment options, and mental health care institutions. The control group received access to the intervention after six weeks, which is the time it took to complete the self-help programme. The RCT showed a significant reduction in suicidal ideation in the Dutch general population (van Spijker et al., 2014), and good cost-effectiveness (van Spijker, Kerkhof, Lokkerbol, Engels, & Smit, 2016; van Spijker, Majo, Smit, van Straten, & Kerkhof, 2012). However, there were substantial limitations to this study, particularly due to the exclusion of individuals with severe suicidal ideation and/or severe depression and the lack of a controlled follow-up period. The second intervention was an adapted but closely aligned translation of the Dutch web-based self-help programme. It was studied in an RCT in Australia comparing the intervention group with a placebo control group who received access to a lifestyle programme. The self-help intervention showed significant reductions in the severity of suicidal thinking at post-intervention and at 6 months and 12 months follow-up, but the reductions were not significantly greater compared to those in the control condition (van Spijker et al., 2018).

The current study aimed at evaluating the effectiveness of a webbased self-help intervention in treating suicidal thoughts among people reporting suicidal thoughts, irrespective of the severity of these thoughts, using a waitlist control condition and a follow-up measurement three months after baseline for both the intervention and control groups. In contrast to the original Dutch study (van Spijker et al., 2014) but similarly to the Australian trial (van Spijker et al., 2018), individuals with severe suicidal ideation and/or severe depressive symptoms were recruited in the current RCT. Additionally, unlike in the Australian study (van Spijker et al., 2018), respondents who attempted suicide in the past month were included. The primary hypothesis was that the intervention would significantly reduce the severity of suicidal ideation. The secondary hypothesis was that the intervention would lead to significant improvements in key characteristics associated with suicidal behaviour, namely suicidal ideation attributes (van Spijker et al., 2014), depressive symptoms (Nock et al., 2008), hopelessness (O'Connor & Nock, 2014; Turecki & Brent, 2016), worry (Morrison & O'Connor, 2008; Surrence, Miranda, Marroquín, & Chan, 2009), and anxiety (Nock et al., 2008). Positive changes were expected after completing the intervention and at follow-up 12 weeks after baseline.

2. Methods

2.1. Study design

A two-arm RCT (one intervention group and one 12-week waitlist control group) was conducted to compare the effectiveness of Think Life with a waitlist information only control group. Participants were assessed at three time points: baseline, post-test (6 weeks after baseline) and follow-up (12 weeks after baseline).

All interested respondents were invited to register their email address, age, and gender on the login page of the Think Life-website. Subsequently, to screen for suicide risk, they were asked to fill in the first part of the baseline questionnaire, which included the Beck Scale for Suicide Ideation (BSS) (Beck, Steer, & Ranieri, 1988), the Suicidal Ideation Attributes Scale (SIDAS; van Spijker, Batterham, et al., 2014), and a question about the importance of being anonymous throughout the study. When eligible for participation and after giving informed consent, an online computer programme carried out a block randomisation (20 per block) stratified by gender, and participants were randomly assigned to the intervention group or waitlist control group. Before participants were informed about the randomisation outcome, they were asked to complete the second part of the baseline questionnaire which included additional items on sociodemographics and the remaining self-report measures on depression, hopelessness, worry, and anxiety. In order to be able to carry out the safety procedure (see below), participants were required to give their name and their general practitioner's or psychiatrist's name and telephone number. Immediately upon completing the questionnaire, the intervention group received a unique code that gave them access to Think Life. The waitlist control group was redirected to the digital portal site www. Zelfmoord1813.be, a website which is the main resource of suicide prevention in Flanders. After the follow-up period, the control group also received a unique code to gain access to Think Life.

Since the study group consisted of participants who potentially were at elevated risk of suicidal behaviour, a safety procedure was used. The safety procedure was carried out at two and four weeks after baseline, post-test and follow-up. At these time points, the participants were requested to fill in the Beck Scale for Suicide Ideation (BSS; Beck et al., 1988) and the Beck Depression Inventory - second edition (BDI-II; Beck, Steer, & Brown, 1996). Participants who scored higher than 26 on the BSS and/or higher than 39 on the BDI-II, were contacted by phone by a clinical psychologist. These cut-offs were also used in the study of van Spijker et al. (2014) and determined in consultation with clinical experts. During the telephone contact, a risk assessment was performed to determine participants' suicide risk. The risk assessment entailed asking about the frequency and intensity of suicidal thoughts and the presence of risk and protective factors for suicidal behaviour. If suicide risk was considered high, subjects were informed about this. Afterwards, participants' general practitioner or psychiatrist was contacted, informed about the high suicide risk and asked to contact the subject. If participants did not answer their phone, a voicemail was left asking for a callback. After three unsuccessful telephone calls, an e-mail was sent to the participants in which concern was expressed, and in which they were informed that their general practitioner or psychiatrist would have to be contacted if participants did not respond. If they did not respond to the calls or e-mail, their general practitioner or psychiatrist was contacted, informed about the urgency of the situation and asked to get into contact with the subject. Because of the safety procedure, the study could not be completely anonymous.

The study was approved by the Commission for Medical Ethics of the University Hospital Ghent (Belgian registration number: B670201422399). The trial protocol is available online.

2.2. Participants

The study was launched on April 22, 2015 and was covered considerably by the media in Flanders, Belgium. The high media coverage was used as a call to participate in the study. During the recruitment period between April 22 and December 7, 2015, all possible means were used to recruit participants from the general population. The web portal www.zelfmoord1813.be, which includes the Flemish suicide helpline, was the main source for recruiting participants. Other means

of recruitment were through, e.g., other healthcare websites, (mental) health care providers, social media, Google Ads, Facebook Ads, and newspaper ads. Inclusion criteria for the study were: age 18 years or older, mild to severe suicidal thoughts (defined as a score of ≥ 1 on the BSS), proficiency in Dutch, and having internet access and an e-mail account. Exclusion criteria were no current suicidal ideation and younger than 18 years old. Using mental health services or receiving other forms of help and support for psychological problems, was not an exclusion criterion.

2.3. Procedures

The unguided, online self-help intervention, originally developed by van Spijker, van Straten, and Kerkhof (2010), was adapted to the Flemish context. The intervention, called Think Life, encompasses six modules, which cover a variety of therapeutic content. Think Life is mainly based on Cognitive Behaviour Therapy (CBT). Additionally, it includes elements from Dialectical Behaviour Therapy (DBT), Problem Solving Therapy (PST), and Mindfulness Based Cognitive Therapy (MBCT). Compared to the original self-help intervention, Think Life constitutes of more CBT elements and less MBCT exercises. The six modules each focus on different aspects, including 1) the relationship between suicidal thinking and worrying/rumination, 2) dealing with suicidal crises, 3) detecting automatic thoughts, 4) recognizing common thinking patterns, 5) challenging negative thoughts, and 6) dealing with future setbacks. Every module begins with a psycho-educational section followed by a weekly assignment, core exercises, and optional exercises. Every module also contains a 'frequently asked questions'-section. During the study, the participant weekly receives access to a new module. A more detailed description of the intervention is available elsewhere (Kerkhof, van Spijker, & Mokkenstorm, 2013; van Spijker et al., 2010; van Spijker et al., 2014) and the original version is also published as part of a Dutch selfhelp book (Kerkhof & van Spijker, 2012).

2.4. Outcome measures

All outcome measures were self-report questionnaires and administered online.

2.4.1. Primary outcome measure

2.4.1.1. Suicidal ideation. The Beck Scale for Suicide Ideation (BSS; Beck et al., 1988) consists of 19 items that measure the severity of the actual suicidal ideation within the last week and 2 items that inquire about the participant's history of suicide attempts and the level of severity of the intention to die during the last attempt. All items receive a score from 0 to 2. The first five items are used to screen the presence of suicidal ideation. If a participant's scores 0 on item 4 and 5, the participant is directed to item 20. If not, all items need to be filled out. The total score is the sum of the first 19 items and ranges from 0 to 38. The higher the score is, the more severe the suicidal thoughts are. The BSS has been widely used and studies showed a high internal reliability and a moderate test-retest reliability (Beck et al., 1988; Beck & Steer, 1991; Brown, 2000).

2.4.2. Secondary outcome measures

2.4.2.1. Suicidal ideation attributes. The Suicidal Ideation Attributes Scale (SIDAS) (van Spijker et al., 2014) is specifically developed for online use. Its five items assess the severity of suicidal ideation via scores on a ten-point Likert scale. The sum of the five items is the overall score, ranging from 0 to 50. As with the BSS, a higher score indicates more severe suicidal ideation. A validation study by Van Spijker et al. (2014) demonstrated good convergent validity and high internal consistency.

2.4.2.2. Depression. The Beck Depression Inventory – second edition (BDI-II) (Beck et al., 1996; Van der Does, 2002) is widely used to assess

the symptoms and severity of depression. It consists of 21 self-report items on symptoms such as sadness, loss of pleasure, self-criticism, suicidal thoughts, and sleep. For every symptom, participants are asked to choose the statement that most accurately describes how they have been feeling the last two weeks. Each item receives a score from 0 to 3. The total score is the sum of the scores on the 21 items and can range from 0 to 63. Studies showed that the BDI-II is a valid and reliable instrument. This is also true for the Dutch translation (Van der Does, 2002).

2.4.2.3. Hopelessness. The Beck Hopelessness Scale (BHS) is used to measure attitudes towards the future (Beck & Steer, 1988). The BHS contains 20 true-false statements. The total score can range from 0 to 20. High scores on the BHS reflect severe feelings of hopelessness and predict suicidal behaviour. The BHS is widely used, and studies have shown good discriminant, concurrent, and predictive validity (Beck & Steer, 1988).

2.4.2.4. Worry. The Penn State Worry Questionnaire-Past Week (PSWQ-PW) is a 15-item self-report questionnaire that is designed to ascertain the degree of worrying (Meyer, Miller, Metzger, & Borkovec, 1990). Scores range from 0 to 90, a higher score indicating a higher tendency towards worrying in the past week. The PSWQ has a good convergent validity and high reliability (Stöber & Bittencourt, 1998).

2.4.2.5. Anxiety. The anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A; Bjelland, Dahl, Haug, & Neckelmann, 2002; Zigmond & Snaith, 1983) is a self-report questionnaire to assess anxiety. Its 7 items are scored on a 4-point Likert scale. A score from 0 to 3 is given to each item and therefore the total score ranges from 0 to 21. A score between 0 and 7 is an indication of no anxiety, between 8 and 10 possible anxiety and above 11 severe clinical anxiety. The validity and reliability of the HADS-A have been documented in several studies (Spinhoven et al., 1997).

2.5. Statistical analysis

Power and sample size calculations were based on the results of previous studies on online interventions (Andersson & Cuijpers, 2009; Richards & Richardson, 2012; van Spijker et al., 2010; van Spijker et al., 2014). An effect size of 0.35 was estimated. To detect such an effect size with $\alpha=0.05$ and $\beta=0.80$, a total sample of 200 subjects was calculated. However, since a possible dropout of 20–30% was expected, the total required sample size was estimated at 260 participants.

Differences between persons who declined participation or dropped out during the study and the participants of the study were examined with χ^2 tests (for categorical variables) and independent-sample t-tests (for continuous variables). The adequacy of the randomisation was assessed using χ^2 tests and independent-sample t-tests comparing the control and intervention group on socio-demographic and baseline clinical characteristics. Significant differences between study groups on those characteristics were controlled for in a multiple linear regression.

Analyses regarding the main hypotheses were performed on the intention-to-treat (ITT) sample and the per protocol sample. In the ITT sample, missing data were imputed using the multiple imputation procedure implemented in SPSS version 23 (IBM, USA). The participant's age, study group, and relevant available assessments of the outcomes were utilised for the imputation of each outcome measure. Fifty imputation sets were created for each imputation estimate, and pooled results from these were used. Mean changes between baseline and posttest and between baseline and follow-up measurement were examined using independent samples t-tests. The corresponding effect sizes were assessed using Cohen's d. To assess whether receiving treatment for psychological problems (i.e., usual care) at baseline had an effect on the primary outcome measure in both study groups a linear regression model was used with study group, receiving usual care and their

interaction as predictor variables. A significance level of 0.05 was used for all outcome analyses. All data were analysed using SPSS version 23 (IBM, USA).

The trial is registered at ClinicalTrials.gov, registration ID: NCT03209544.

3. Results

A total of 1688 potential participants signed up on the Think Lifewebsite. Among these, 964 were excluded because their registration was not complete, inclusion criteria were not met, or informed consent was not given. Participants who did not give their informed consent, only differed from the study group regarding age and importance of anonymity. They were significantly younger than the study group (M = 33.28 (SD = 13.02) vs. (M = 35.68 (SD = 13.55), t(1107) = -2.85, p = 0.005)) and anonymity was more important to them (79.9% vs. 69.5%; $\chi^2(1) = 11.84$, p = 0.001).

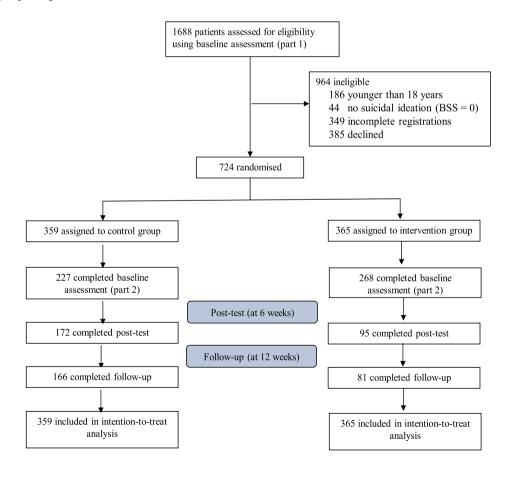
A total of 724 participants were randomly allocated to the control group (n=359), or to the intervention group (n=365). Fig. 1 shows the flow of participants in both conditions throughout the trial.

Between the first and second part of the baseline assessment, there was a dropout of 24.0% (n = 273) in the control group, and 18.9% (n = 296) in the intervention group. The attrition rate between baseline and post-test was 33.3% (n = 182) in the control group and 64.2% (n = 106) in the intervention group. Between post-test and follow-up, the attrition rate was 6.6% (n = 170) in the control group and 15.1% (n = 90) in the intervention group. A significant difference in attrition

rates between study groups was observed at baseline (part 2; $\chi^2(1) = 4.54$, p = .03), post-test ($\chi^2(1) = 37.23$, p < 0.001) and at follow-up ($\chi^2(1) = 46.57$, p < 0.001). The participants who did not complete the assessments, were younger (M = 35.0 years old vs. M = 37.4 years old; (t(372.51) = -2.18, p = .017), more often in treatment (71.6% vs. 57.3%; $\chi^2(1) = 11.23$, p = .001) but used less often medication (48.2% vs. 57.0%; ($\chi^2(1) = 4.22$, p = .04) compared to those who did not drop out. Furthermore, more males than females and other gender dropped out during the study (75.4% vs. 68.1% and 50.0%; $\chi^2(2) = 6.40$, p = .041). On all other baseline demographic and clinical characteristics there were no significant differences.

Overall, more than half of the participants (59.4%) were female and the mean age of the participants was 35.7 years. 52.2% were living together with someone, and two-thirds (66.1%) were single. The majority finished higher education (53.3%). Almost two-thirds of participants (62.2%) were in treatment for psychological problems, mostly seeing a psychologist (35.0%) or psychiatrist (28.1%). When asked if they were taking medication, more than half (51.8%) answered positively and mainly reported using psychotropics.

A history of suicide attempts was reported by approximately half of the participants (46.3%). The mean scores on the baseline clinical characteristics were considerably high, showing substantial scores for suicidal ideation (M=19.7, SD=7.0) and suicidal ideation attributes (M=27.5, SD=8.5). The participants also showed severe depressive symptoms (M=34.7, SD=11.2), moderate to almost severe signs of hopelessness (M=14.5, SD=3.4), high levels of worrying (M=65.0, SD=12.0), and severe anxiety symptoms (M=13.6, SD=4.0).



Note: BSS=Beck Scale for Suicide Ideation

Fig. 1. Participant flow-chart.

Table 1Demographic and baseline clinical characteristics.

Characteristics	Total	Control	Intervention	<i>p</i> -value	
Sex, n (%)				0.740	
Female	430 (59.4)	215 (59.9)	215 (58.9)		
Male	284 (39.2)	138 (38.4)	146 (40.0)		
Other	10 (1.4)	6 (1.7)	4 (1.1)		
Education level, n (%)	, ,		, ,	0.654	
No diploma	15 (2.6)	6 (2.2)	9 (1.6)		
Primary school	37 (6.5)	18 (6.6)	19 (6.4)		
Secondary education	214 (37.6)	109 (39.9)	105 (35.5)		
Higher education, non-	175 (30.8)	85 (31.1)	90 (30.4)		
university	, ,	, ,	, ,		
Higher education,	128 (22.5)	55 (20.1)	73 (24.7)		
university					
Living situation, n (%)				0.556	
Alone	272 (47.8)	127 (46.5)	145 (49.0)		
Together with someone	297 (52.2)	146 (53.5)	151 (51.0)		
Marital status, n (%)	, ,	, ,	, ,	0.613	
Single	376 (66.1)	184 (67.4)	192 (64.9)		
Married	111 (19.5)	55 (20.1)	56 (18.9)		
Divorced	71 (12.5)	31 (11.4)	40 (13.5)		
Widowed	11 (1.9)	3 (1.1)	8 (1.4)		
Treatment for psychological			, ,		
No	215 (37.8)	104 (38.1)	111 (37.5)	0.884	
Yes, general practitioner	119 (20.9)	55 (20.1)	64 (21.6)	0.666	
Yes, psychologist	199 (35.0)	92 (33.7)	107 (36.1)	0.541	
Yes, psychiatrist	160 (28.1)	75 (27.5)	85 (28.7)	0.742	
Yes, other	68 (12.0)	35 (12.8)	33 (11.1)	0.539	
Use of medication, n (%)				0.261	
No	274 (48.2)	125 (45.8)	149 (50.5)		
Yes	294 (51.8)	148 (54.2)	146 (49.5)		
Importance of anonymity, n	617 (100)	306 (100)	311 (100)		
(%)					
Important	429 (69.5)	222 (72.5)	207 (66.6)		
Not important	188 (30.5)	84 (27.5)	104 (33.4)		
History of suicide attempts,				0.320	
n (%)					
Never	389 (53.7)	189 (52.6)	200 (54.8)		
Once	182 (25.2)	86 (24.0)	96 (26.3)		
Twice of more	153 (21.1)	84 (23.4)	69 (18.9)		
Age, M (SD)	35.7 (13.6)	34.8 (12.7)	36.5 (14.3)	0.084	
Baseline outcome measures, M (SD)					
BSS	19.70	19.92	19.49 (7.08)	0.409	
	(7.01)	(6.94)			
SIDAS	27.45	28.07	26.84 (8.43)	0.054	
	(8.54)	(8.62)			
BDI	34.69	35.25	34.18 (11.19)	0.263	
	(11.25)	(11.30)			
BHS	14.49	14.46	14.53 (3.31)	0.804	
	(3.36)	(3.43)	, ,		
PSWQ-PW	65.02	65.44	64.63 (11.80)	0.431	
-	(11.97)	(12.18)			
HADS-A	13.55	13.66	13.45 (4.01)	0.551	
	(3.99)	(3.98)			

Note: Significance tests for categorial variables performed with χ^2 -test, for continuous variables with t-test. BSS=Beck Scale for Suicide Ideation. SIDAS=Suicidal Ideation Attributes Scale. BDI-II=Beck Depression Inventory-second edition. BHS=Beck Hopelessness Scale. PSWQ-PW=Penn State Worry Questionnaire-Past Week. HADS-A = Hospital Anxiety and Depression Scale-Anxiety.

Table 1 summarizes the demographic and baseline clinical characteristics of both study groups. There were no significant differences between study groups.

The amount of safety procedures per group is described in Table 2. Only at post-test the safety procedure was performed significantly more often in the control group (29.7%) than in the intervention group ((16.0%); $\chi^2(1) = 6.70$, p = .011). At post-test, 13 (7.6%) participants from the control group and 8 (8.4%) from the intervention group reported that they attempted suicide during the study ($\chi^2(1) = 0.06$, p = .80). No deaths due to suicide were reported during the study.

Table 3 shows mean changes between baseline and post-test, and between baseline and follow-up, and its effect sizes on the primary

Table 2 Performed safety procedures per group at different time points.

Time Tota	al Control	Intervention	ı <i>p</i> -value
4 weeks after baseline, n (%) 74 Post, n (%) 71	(29.3) 69 (32.4) (25.6) 50 (25.5) (24.7) 54 (29.7) (22.3) 43 (25.3)	24 (25.8) 17 (16.0)	0.10 0.96 0.01 0.11

Table 3Mean changes from baseline to post-test and to follow-up and effect sizes on suicidal ideation (BSS).

Time	Control (n = 359)	Intervention (n = 365)	d (95% CI)	p-value
	M(SD)	M (SD)	_	
Baseline - Post	3.99 (7.58)	6.67 (8.17)	0.34 (1.05; 4.32)	0.001
Baseline - FU	6.04 (7.28)	7.94 (7.89)	0.25 (0.17; 3.63)	0.032

Note: CI = Confidence interval; BSS = Beck Scale for Suicide Ideation; FU = Follow-up.

outcome measure i.e., suicidal ideation. The intention to treat analysis showed a significantly stronger decrease in suicidal ideation in the intervention group compared to the control group between baseline and post-test, and between baseline and follow-up (see Fig. 2). When controlled for baseline scores on the SIDAS measure, which approached a significant difference at baseline between study groups, the effect of the intervention remained significant regarding suicidal ideation at post-test ($\beta = 3.61$, p < 0.001) and at follow-up ($\beta = 4.54$, p < 0.001).

For all secondary outcome measures i.e., suicidal ideation attributes, depressive symptoms, hopelessness, worrying, and anxiety, a significantly greater reduction was found at post-test in the intervention group than in the control group. This effect persisted at follow-up (see Table 4). Additionally, per protocol analyses showed a significant larger decrease on the primary and secondary outcomes measures in the intervention group than in the control group, both at post-test and follow-up (see Supplementary Material Table S1).

There was no significant effect of receiving usual care at baseline on suicidal ideation in both study groups at post-test (p = 0.425) and at follow-up (p = 0.665; see Table 5).

4. Discussion

This trial aimed at assessing the efficacy and usability of an unguided web-based self-help intervention specifically targeting suicidal ideation in a community sample. The results support our hypotheses that the intervention was more effective in reducing suicidal ideation and suicide-related symptoms, such as suicidal ideation attributes, depressive symptoms, hopelessness, worrying, and anxiety than a waitlist control. Per protocol analyses showed similar results. Taken into account usual care at baseline, the effect of the intervention on suicidal ideation remained significant. Of note, these positive effects were found in a population of individuals who reported severe psychiatric problems. Therefore, the study sample probably represented more accurately a real-world population, which may have increased the external validity of this RCT (Kennedy-Martin, Curtis, Faries, Robinson, & Johnston, 2015). This may also explain the high proportion of people who received treatment for psychological problems. Furthermore, the positive results persisted during a three-month follow-up supporting valid conclusions on the long-term effects of the intervention.

Preceding a discussion of potential implications of the study findings for the prevention of suicide, a number of methodological issues need to be addressed. Some of them are inherent to research on online

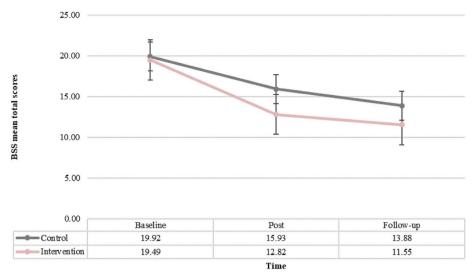


Fig. 2. Mean total scores on the Beck Scale for Suicide Ideation (BSS).

interventions. First, there was a high dropout rate during the course of the study, which was consistent with the Australian study (van Spijker et al., 2018) and other RCT's investigating unguided online intervention (Karyotaki et al., 2015; Melville, Casey, & Kavanagh, 2010; Richards & Richardson, 2012). Dropout rates also tend to be higher in intervention groups compared to control groups as was the case in our study (Christensen, Griffiths, & Farrer, 2009). Although high dropout rates are not uncommon in online interventions trials, they may generate an attrition bias. However, all participants were included in the intentionto-treat analyses and missing data was accounted for by using a multiple imputation procedure. Secondly, there was no difference in suicide attempts between both study groups. The data on suicide attempts was taken from the observed data at post-test. This data may have been biased because of the high dropout at post-test and the use of self-reports instead of patient records to assess suicide attempts. Furthermore, because the frequency of suicide attempts is lower than that of suicidal ideation, data on suicide attempts should be studied over a longer period of time and in a larger sample in order to increase power. Thirdly, although there was no effect of receiving usual care at baseline on suicidal ideation in both groups, we cannot rule out that receiving usual care during the study period may have contributed to the observed improvements in both groups. Furthermore, since the control group was not in a lifestyle placebo group, as in van Spijker et al. (2018), it is unclear whether Think Life has a more positive effect on suicidal ideation and suicide-related symptoms than a placebo control intervention. In future studies, usual care should be monitored throughout the study and an attention-control condition should be added. Fourth, because of the safety procedure, participants were required to give up their anonymity. A high number of potential participants may have declined participation because of this, which may have introduced a selection bias. Fifth, for technical reasons, the baseline questionnaire was split into two parts, and randomisation took place after completing the first part. As a consequence, all participants who completed part one but not part two had to be included in the study which caused a large dropout. In future research, the randomisation should take place after completing the baseline questionnaire to minimize missing data at baseline. Another limitation was that diagnostic information of the participants was lacking. Since there was no diagnostic interview at baseline, the results of this RCT could be interpreted while taking into account possible psychiatric disorders. However, this was consistent with the objective of Think Life, as it was developed for everyone who thinks about suicide, regardless of their

Table 4

Mean changes from baseline to post-test and to follow-up and effect sizes on the secondary outcome measures.

Measure	Time	Control $(n = 359)$	Intervention $(n = 365)$	d (95% CI)	<i>p</i> -value
		M (SD)	M (SD)		
SIDAS					
	Baseline - Post	2.96 (8.78)	6.03 (9.33)	0.34 (1.10; 5.04)	0.003
	Baseline - FU	5.15 (9.57)	9.10 (10.09)	0.40 (1.81; 6.10)	< 0.001
BDI-II					
	Baseline - Post	3.93 (9.84)	7.78 (10.66)	0.38 (1.20; 6.48)	0.005
	Baseline - FU	4.80 (10.79)	9.86 (12.05)	0.44 (2.48; 7.64)	< 0.001
BHS					
	Baseline - Post	0.46 (3.45)	2.11 (3.68)	0.46 (0.60; 2.69)	0.002
	Baseline - FU	0.76 (3.96)	2.99 (4.38)	0.53 (0.91; 3.54)	0.001
PSWQ-PW					
	Baseline - Post	2.57 (12.04)	7.36 (13.71)	0.37 (1.43; 8.16)	0.006
	Baseline - FU	3.40 (13.67)	12.27 (15.83)	0.60 (4.91; 12.83)	< 0.001
HADS-A					
	Baseline - Post	1.20 (3.63)	2.59 (3.89)	0.37 (0.61; 2.17)	0.001
	Baseline - FU	1.52 (4.28)	3.15 (4.40)	0.38 (0.66; 2.60)	0.001

Note: FU = Follow-up; CI=Confidence interval; SIDAS=Suicidal Ideation Attributes Scale; BDI-II=Beck Depression Inventory – second edition; BHS=Beck Hopelessness Scale; PSWQ-PW=Penn State Worry Questionnaire-Past Week; HADS-A = Hospital Anxiety and Depression Scale-Anxiety.

Table 5Effect of receiving usual care showing mean changes from baseline to post-test and to follow-up on suicidal ideation.

Time	Control (n = 359)		Intervention (n = 365)		p-value
	No usual care	Usual care	No usual care	Usual care	
	M (95% CI)	M (95% CI)	M (95% CI)	M (95% CI)	
Baseline - Post	4.05 (2.27; 5.82)	4.13 (2.80; 5.44)	6.20 (4.17; 8.24)	7.55 (6.06; 9.03)	0.425
Baseline - FU	5.67 (3.99; 7.35)	6.46 (5.18; 7.73)	7.35 (5.32; 9.39)	8.80 (7.28; 10.33)	0.665

Note: FU = Follow-up; CI = Confidence interval.

possible psychiatric diagnoses. A last concern regards the timing of the follow-up measurement. This was done twelve weeks after the baseline measurement. A longer follow-up period as was done in the Australian trial (van Spijker et al., 2018) is recommended to study the long-term effects of the intervention.

The results from the current study differ from those in the Australian study (van Spijker et al., 2018) but parallel results from previous studies of online interventions, as far as available (Christensen et al., 2013; Guille et al., 2015; Hetrick et al., 2017; van Spijker et al., 2014). The impact of the methodological limitations can therefore be considered as limited, and a number of implications for suicide prevention can be formulated. Given the beneficial effects of the intervention on suicidal ideation, hopelessness, worrying, depression and anxiety, which are strongly related to suicidal behaviour, the intervention under study can be expected to contribute to the prevention of suicide. Furthermore, studies have shown that the intervention is cost-effective with a favourable budget impact (van Spijker et al., 2012, 2016). Additional findings further supported implementation in the context of suicide prevention programmes. Although the recruitment period was merely 7 months, a substantial number of possible participants registered for the study. This demonstrates the considerable interest in a web-based intervention for coping with suicidal ideation. The substantial stigma in Flanders (Belgium) regarding psychological problems and traditional, face-to-face treatment may well explain this interest. Research has indeed shown that people in Flanders are less likely to seek help for mental problems and ask for treatment. They experience more shame and stigma (Reynders, Kerkhof, Molenberghs, & Van Audenhove, 2016). In the current study, more than one third was not in treatment for mental health problems. Making an anonymous, web-based intervention such as Think Life available to the general public, could contribute to breaking the stigma regarding suicidal ideation and psychological problems. Additionally, it may help in lowering the threshold to seek face-to-face help.

Men who feel suicidal constitute a risk group that is difficult to reach. They tend to use mental health services or seek help less often compared to women, possibly due to shame and stigma (Hom et al., 2015; Lai, Maniam, Chan, & Ravindran, 2014). Due to their perceived anonymity, online interventions such as Think life appear to appeal particularly to men who feel suicidal as almost half of the participants were male. Therefore, an anonymous intervention may contribute to increasing help-seeking behaviour in men who feel suicidal.

Given its beneficial effects in reducing suicidal ideation, Think Life was added to the Flemish online suicide prevention web portal www. zelfmoord1813.be. Future studies are required to examine long-term effects and investigate the temporal course of suicidal ideation in the people who use the online self-help intervention (Madsen, Spijker, Karstoft, Nordentoft, & Kerkhof, 2016).

In conclusion, Think Life can contribute to bridging the gap between crisis help via telephone or online chat, and face-to-face treatment. The present study provides evidence for beneficial effects of an online selfhelp intervention on suicidal ideation. It is important to note that the online provision of this intervention reaches a severely affected population. The results can add to the growing body of evidence on the effectiveness of internet-based treatments of mental health problems.

Contributors

EDJ, RvL, KvH, and GP designed the study and interpreted the data. GP was the main supervisor and obtained study funding. BAJvS and AJFMK conducted the original study in the Netherlands on which the current trial is based and provided all information on that study. JM provided information on the web-based intervention that is used in the Netherlands. EDJ, RvL, and GP adjusted the Dutch intervention. EDJ and RvL conducted a literature search, collected the data, and conducted statistical analyses. KvH and GP provided clinical support on the trial. EDJ and RvL wrote the manuscript. All authors critically reviewed the manuscript and provided revisions.

Declaration of interests

BAJvS and AJFMK are authors of the Dutch unguided, online self-help intervention (van Spijker et al., 2010) described in this manuscript. BAJvS and AJFMK are also authors of and receive royalties from an adapted paper version of the Dutch self-help programme published under the title 'Piekeren Over Zelfdoding' (Kerkhof & van Spijker, 2012).

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brat.2019.05.003.

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