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A randomized controlled trial of an internet-delivered treatment: Its potential as a low-intensity community intervention for adults with symptoms of depression

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ABSTRACT

Background: Internet-delivered treatments for depression have proved successful, with supported programs offering the potential for improved adherence and outcomes. Internet interventions are particularly interesting in the context of increasing access to interventions, and delivering interventions population-wide.

Methods: The study was a randomized controlled trial of an 7-module internet-delivered cognitive behavioral therapy (iCBT) program for adults with depressive symptoms ($n = 96$) compared to a waiting-list control group ($n = 92$). Participants received weekly support from a trained supporter. The primary outcome was depressive symptoms as measured by the Beck Depression Inventory (BDI-II). The program was made available nationwide from an established and recognized charity for depression.

Results: For the treatment group, post-treatment effect sizes reported were large for the primary outcome measure ($d = 0.91$). The between-group effects were moderate to large and statistically significant for the primary outcomes ($d = 0.50$) favoring the treatment group. Gains were maintained at 6-month follow-up.

Conclusion: The study has demonstrated the efficacy of the internet-delivered *Space from Depression* treatment. Participants demonstrated reliable and statistically significant changes in symptoms from pre- to post-intervention. The study supports a model for delivering online depression interventions population-wide using trained supporters.

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1. Introduction

Depression has been ranked among the leading causes of disease burden throughout the world (Mathers & Loncar, 2006), with high rates of lifetime incidence, early age onset, high chronicity, and role impairment (Richards, 2011). Twelve-month prevalence rates for depression have been estimated at 6.6% in the US (Kessler et al., 2003), 8.5% in Europe and 10.3% in Ireland (Ayuso-Mateos et al., 2001). Further, an overall 12-month prevalence rate of 12.3% for older adults (65+) in Europe has been reported and in Ireland the reported 12-month prevalence has been estimated at 11.9% (Copeland et al., 2004).

Epidemiological studies of the occurrence of depression have highlighted younger age groups, with 15–29 years identified as the peak age of onset (Craighead, Sheets, Brosse, & Ilardi, 2007), suggesting that lifetime prevalence will be higher among future cohorts (Craighead et al., 2007). Prevalence rates are higher for females than males (Ayuso-Mateos et al., 2001; Copeland et al., 2004; Ohayon, 2007) and depression exacts significant economic, personal, intra-personal and societal costs, and is associated with losses in quality of life and increased mortality rates (Cuijpers et al., 2007; Rapaport, Clary, Fayyad, & Endicott, 2005).

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1.1. Treating depression

Antidepressants are commonly used to treat depression, however relapse is high following cessation, and many patients prefer psychological therapies (Van Schaik, Klijn, & van Hout, 2004), which have proved equally effective as antidepressants (Cuijpers, van Straten, van Oppen, & Andersson, 2008). Cognitive Behavior Therapy (CBT) is the most extensively researched psychological therapy for depression (National Institute for Health and Clinical Excellence, 2006), and has been shown to maintain post-treatment gains and reduce the risk of future relapses and recurrences of depression (Hollon & DeRubeis, 2006).

Accessing evidence-based treatments such as cognitive behavior therapy can be problematic. The worldwide treatment gap in depression has been estimated at 56.3% (Kohn, Saxena, Levav, & Saraceno, 2004). Several barriers such as waiting lists, cost and/or physical difficulties in accessing services, and personal obstacles such as stigma, lack of motivation for change, negative perception of psychological and/or drug treatments play an important role in choosing to seek diagnosis and access treatment (Kohn et al., 2004; Mohr et al., 2010).

Difficulties in accessing evidence-based treatments are universal and in Ireland, for instance, people with depression encounter additional barriers due to a shortage of trained professionals alongside the relative underdevelopment of health services, which are cause for concern (Department of Health and Children, 2006). The fact that less than one third of GPs have training in psychological therapies is also of concern, especially considering that many people will initially bring their psychological difficulties to their primary care physician (Grandes, Montoya, Arietaleanizbeaskoa, Arce, & Sánchez, 2011). More recently, it has been reported that less than 20% of patients presenting to GPs with mental health difficulties are in receipt of specialist services (Hughes, Byrne, & Synnott, 2010; Tedstone-Doherty, Moran, & Kartalova-O'Doherty, 2008).

1.2. Stepped care models of treatment

Recent attempts to overcome barriers to accessing treatment involve the evolution of a new understanding in mental healthcare that recognizes both high-intensity (e.g. face-to-face therapy) and low-intensity (e.g. bibliotherapy) interventions to meet different levels of users' needs. Services deliver interventions in a stepped-care model, matching the level of intensity to a patient's presenting needs and to maximize the use of resources. Low-intensity interventions signify treatments that limit specialist therapist time, or use this time in a cost effective manner, for example, group treatments (Bennett-Levy, Richards, & Farrand, 2010). The Irish Health Service Executive (Health Service Executive, 2012) advocate for the implementation of a stepped-care model.

In the UK, The Improving Access to Psychological Therapies (IAPT) program has successfully implemented such a stepped-care model (Clark et al., 2009). However, in many countries access is severely constrained, and even where stepped care models are implemented, there is a need to expand the evidence base regarding different forms of scalable low-intensity intervention. Given the continued growth in high prevalence disorders (depression and anxiety disorders) there is a real need to increase access.

1.3. Delivering low-intensity interventions for depression

Clinician-guided and self-administered internet-delivered CBT for specific disorders, are one of a range of interventions that have proved a suitable evidence-based option for integration as a low-intensity intervention within a stepped care model (Bennett-Levy, Richards, Farrand, et al., 2010). Internet-delivered interventions have demonstrated their effectiveness in treating depression (Richards & Richardson, 2012). The provision of human support yields enhanced results compared to unsupported interventions (Andersson & Cuijpers, 2009; Richards & Richardson, 2012).

To date, a number of small-scale studies of internet-delivered treatments have been conducted in Ireland (Richards, Timulak, & Hevey, 2013; Sharry, Davidson, McLoughlin, & Doherty, 2013). However, larger community based projects are necessary to assess the effectiveness and scalability of such low-intensity interventions.

While other internet-delivered interventions exist and have shown promise the SilverCloud *Space from Depression* program has been developed specifically to address historical difficulties with engagement in internet-delivered interventions. The design of the platform was based using user-centered processes (Doherty, Coyle, & Matthews, 2010), and embeds a number of features designed to improve engagement, which have previously been categorized as Social, Interactive, Personal, and Supportive (Doherty et al., 2010).

The aim of this study was to demonstrate the effectiveness and potential of a novel, evidence-based internet-delivered intervention (*Space from Depression*) as a low-intensity community-based treatment for depression. The present paper reports on the main outcomes from the Irish national randomized control trial of the intervention (*Space from Depression*[1]).

1.4. Aware

Aware is a charity that aims to create a society where those with depression or related mood disorders, and their families, are understood and supported, are free from stigma and have access to a broad range of support options. Their objectives are 1) to provide information and educate people about depression and mood disorders, 2) provide emotional and practical support to individuals and their families and, 3) to support research into understanding and treating depression.

They achieve their objectives through the provision of face-to-face support groups, an online support group, and a low-cost telephone line, all of which are manned by trained volunteers. Aware is a well-recognized and respected brand name in Ireland, with a high number of users nationally. Therefore they are well placed to collaborate in providing a low-intensity depression treatment for the community that will include support for participants.

2. Method

2.1. Design

The study was a randomized controlled trial in which participants were randomized into two groups: 1) the internet-delivered *Space from Depression* intervention with support and 2) a waiting-list control group.

2.2. Research question and hypothesis

The research investigated if *Space from Depression*, a supported internet-delivered treatment is effective as a low-intensity community-based intervention for adults with depression. Based on previous successes with supported online treatments for depression (Richards & Richardson, 2012), and the specific *Space from*

[1] Previously named Mind Balance Depression (see Trial protocol).

Depression program (Sharry et al., 2013), it was hypothesized that participants in the trial would demonstrate significant decreases in depressive symptoms post-intervention, with corresponding improvements in comorbid anxiety and quality of life indicators.

2.3. Participants

Between January 2014 and March 2014 all users of the Aware charity who had expressed an interest to participate in an internet-delivered intervention were eligible to participate. The intervention and research study were advertised to users through the Aware website. Aware had been using the intervention for some time which allowed the supporters to gain experience in their role within the intervention.

In two recruitment phases, 641 users self-referred and read the information about the study and applied to participate in the research. In line with offering low-intensity interventions for people with mild to moderate distress (NICE, 2009), applicants with BDI-II scores <14 and >29 were excluded from the study. In addition, potential participants were excluded if they reported suicidal intent/ideation, psychosis, were currently receiving psychological treatment for depression, on medication for less than 1 month, alcohol or drug misuse, and/or reported depressive symptoms that preceded or coincided with a diagnosed medical condition.

Fig. 1 details the flow of participants through the trial.

2.4. Procedure

Potential participants were emailed about the intervention and study, they were directed to a website to access further information on the study and what would be involved in participating. Informed consent and baseline screening questionnaires were completed online. Thereafter, participants were randomly assigned to the immediate treatment group or a waiting list control group. Randomization was accomplished using a random assignment algorithm created by the IT team and independent of the researchers.

2.5. Measures

Participants were assessed at baseline and post-treatment. The intervention group was assessed at 3- and 6-month follow-up. The study variables assessed are summarized in Table 1.

As per protocol, at baseline, the Beck Depression Inventory-II (BDI-II), Sociodemographic & History Questionnaire, Generalized Anxiety Disorder-7 (GAD-7), and the Work and Social Adjustment Scale (WSAS), were completed for screening purposes. Thereafter the BDI-II, GAD-7, and WSAS were completed at the end of treatment, week 8, and at 3- and 6-month follow-up.

3. Measures

3.1. Screening measure

Sociodemographic Information & History Questionnaire was developed, based on a previous version (Richards et al., 2013) to collect demographic details on the participants. The items on the questionnaire collected data on the presence of a previous diagnosis of depressive disorders, duration of depression symptoms, experience of counseling/therapy and prescription of medication for depression. The presence of a previous diagnosis of an organic mental health disorder and comorbid psychosis, drug and alcohol misuse and/or any recent medical diagnosis were also recorded.

3.2. Primary outcome measure

The Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996) The 21-item Beck Depression Inventory – Second Edition (BDI-II) is a widely used questionnaire measuring symptoms and severity of depression based on the criteria for depressive disorder diagnosis as outlined in The American Psychiatric Associations Diagnostic and Statistical Manual of Mental Disorders–Fourth Edition (DSM-IV) (American Psychiatric Association [APA], 2000). The scale designates levels of severity, Minimal (0–13); Mild (14–19); Moderate (20–28); and Severe (29–63) (Beck et al., 1996).

The BDI-II has been found to have excellent internal consistency and test–retest reliability with a diverse range of samples (Arnau, Meagher, Norris, & Bramson, 2001; Beck et al., 1996; Steer, Rissmiller, & Beck, 2000), and has demonstrated good convergent validity with other measures of depression among clinical and non-clinical adult samples (Beck, Steer, & Garbin, 1988).

3.3. Secondary outcome measures

General Anxiety Disorder (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) comprises 7 items measuring symptoms and severity of anxiety based on the DSM-IV diagnostic criteria. The GAD-7 has good internal consistency (0.89) and good convergent validity with other anxiety scales (Kroenke, Spitzer, Williams, & Löwe, 2010). The GAD-7 is increasingly used in large-scale studies as a generic measure of changes in anxiety symptomatology, using a cut-off score of 8 (Clark et al., 2009; Richards & Suckling, 2009).

Work and Social Adjustment (WSAS; Mundt, Marks, Shear, & Greist, 2002) is a simple, reliable and valid measure of impaired daily functioning across five dimensions: work, social life, home life, private life and close relationships.

3.4. Interventions

3.4.1. Computerized cognitive-behavior therapy (iCBT) program

Space from Depression is an seven-module online CBT-based intervention for depression, delivered on a Web 2.0 platform using media-rich interactive content. The treatment comprises cognitive and behavioral components including self-monitoring and thought recording, behavioral activation, cognitive restructuring, and challenging core beliefs. Each module follows a structured format that incorporates introductory quizzes, videos, informational content, interactive activities, as well as homework suggestions and summaries. The content of each module is described briefly in Table 2 below. In addition, personal stories and accounts from other users are incorporated into the presentation of the material.

3.4.2. Waiting list control group

Participants in the waiting-list control group received no treatment for the duration of the first 8 weeks and completed the primary and secondary outcome measures (BDI-II, Sociodemographic & History, GAD-7, & WSAS) at week 8, before they were given access to the program with support from a trained volunteer.

3.4.3. Supporters

Participants were assigned a trained supporter who monitored their progress throughout the trial. A dashboard interface provided supporters with an overview of their participants' level of engagement with the program content. Each supporter was assigned 8 participants and provided asynchronous post-session feedback of between 10 and 15 min per participant per session.

The role of the supporter was mainly one of encouragement, support and feedback. They responded at a specific time once each

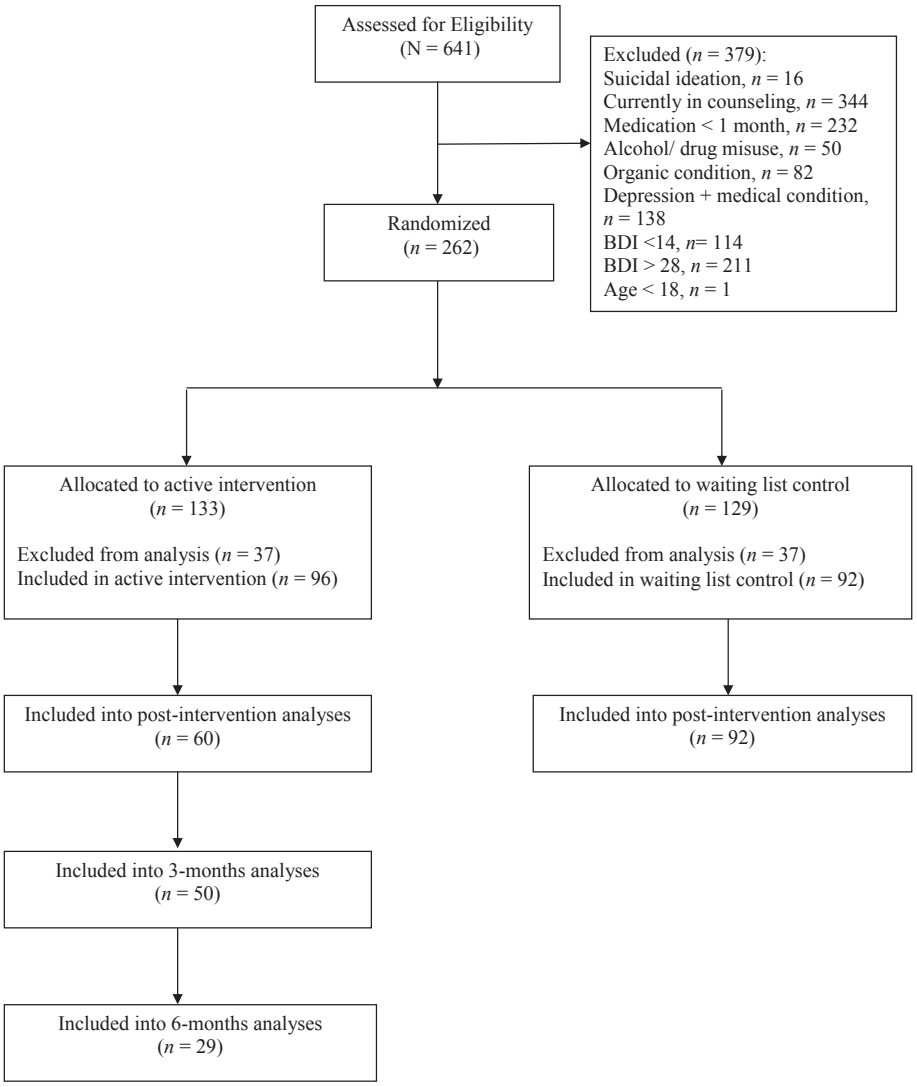


Fig. 1. Flowchart of the study CONSORT.

Table 1
Study measures.

Measure	Assessment	Time of assessment
Beck Depression Inventory-II (BDI-II)	Depression symptoms	Baseline, post-treatment and follow-up
Generalized Anxiety Disorder-7 (GAD-7)	Anxiety symptoms	Baseline, post-treatment and follow-up
Sociodemographic & History Questionnaire	Gender, age, marital status, education, occupation, socioeconomic status, and clinical history	Baseline
Work and Social Adjustment Scale (WSAS)	Work and Social Adjustment scale	Baseline, post-treatment and follow-up

week for a period of eight weeks and Aware's Education and On-Line Services coordinator in turn supported them. Supporters familiarized themselves with the program in advance of attending training, which consisted of fifteen hours face-to-face training over a period of two weeks. Training included information on CBT, detailed information on the program, the role of the supporter, how to respond to participants who were in distress and how to follow Aware's policy of confidentiality in terms of abuse and harm. To reduce risk to participants Aware employed the services of an assistant psychologist to review all of the communication between the supporters and the participants of the program. She reported directly to the Education and On-line Services coordinator, who regularly consulted with Aware's Clinical Director.

A '*Community of Practice*' was developed among the Aware supporters whom formed groups of five and had a senior supporter as a mentor for supervision. This provided a structure for guidance on how the support was delivered and to discuss any difficulties.

3.4.4. Data analysis

We employed an intention-to-treat (ITT) model for the analysis using maximum likelihood method to calculate missing data in the sample. Maximum likelihood does not assume that the first measurement remained stable, as in last observation carried forward, but estimates parameters for missing values (Gueorguieva &

Table 2
Space from depression[a]: description of module content.

Module name	Brief description
Getting started	Outlines the basic premise of CBT, provide information about depression, and introduce some of the key ideas of *Space from Depression*. Users are encouraged to begin to chart their own current difficulties with depression.
Tune In I: getting to grips with mood	The focus in this module is on mood monitoring and emotional literacy. Users can explore different aspects of emotions, physical reactions, action and inaction, and how they are related.
Tune in II: spotting thoughts	This module focuses on noting and tracking thoughts. Users can explore the connection between their cognitions and their mood, and record them graphically.
Change It I: boosting behavior	This module focuses on behavioral change as a way to improve mood. Ideas about behavioral activation are included, and users can plan and record activities, and chart their relationship with their mood.
Change It II: challenge your thoughts	This module supports users to challenge distorted or overly negative thinking patterns, with thought records, as well as helpful coping thoughts
Change It III: core beliefs	This module outlines the role that deeply held core beliefs could play in mood and depression. Users can use a range of interactive activities to identify, challenge and balance any unhelpful core beliefs.
Bringing It all together	In this final module, users are encouraged to bring together all the skills and ideas they have gathered so far, note their personal warning signs, and make a plan for staying well.

[a] Formerly named Mind Balance Depression.

Krystal, 2004). As this model takes into account all the available data from all participants who were randomized it can be considered a complete ITT analysis and suitable for RCT (Gueorguieva & Krystal, 2004). All effects were tested for significance at the 0.05 levels. Chi Square tests examined any differences in demographic and clinical characteristics between the two groups at baseline.

Full factorial repeated measures ANOVAs were employed to assess for significant changes over time in the primary outcome measure for depression (BDI-II) and in secondary outcomes (GAD-7 and WSAS). This was done for the ITT and the per protocol sample. The magnitude of the pre-to post-differences within-group effects for each of the groups (Cohen's *d*) was calculated using the pooled standard deviation. The magnitude of pre-to post-differences between-group effects was similarly calculated. Bonferroni corrected *p* values are reported for multiple comparisons (Table 4).

Further analysis was conducted to determine the proportion of participants who make clinically meaningful change at end of treatment and at follow-up. An assessment of reliable change was made using criteria of a change of 9 points or greater on pre to post treatment BDI-II scores. Similar criteria have been used in other studies of internet-delivered interventions for depression (de Gaff et al., 2009; Meyer et al., 2009; Titov et al., 2010). Similarly, the analysis of recovery has been used in other studies and was defined as a post-treatment BDI-II score of less than 10 (Beck et al., 1996) and a decrease of greater than 9 points on the BDI-II (Seggar, Lambert, & Hansen, 2002). Chi-square tests were used to examine whether the differences between the treatment group and waiting list was statistically significant for reliable change and recovery.

3.4.5. Ethics

Informed consent was obtained from each participant before randomization. Prior to consent, participants were provided with information on their role in the research, the aims and objectives of the study and were informed that they could withdraw from the study at any time, without prejudice. Participants meeting exclusion criteria were referred to other appropriate sources of support. The study protocol, information on the study, informed consent and related materials were submitted and approved by the ethics committee of the University (22/11/2013).

4. Results

4.1. Baseline characteristics

Chi Square tests revealed that at post-randomization (Table 1), there were no significant differences in the sample between the treatment group (TG) and waiting list control group (WL) on any variables. Further on baseline BDI-II scores there were no significant differences between those considered per protocol research completers ($M = 20.91$, $S.D. = 4.03$, $n = 139$) and those non-completers ($M = 20.73$, $S.D. = 3.87$, $n = 49$), $\chi 2(14) = 21.641$, $p = <0.05$.

Table 1 details the characteristics of the sample. The gender divide is normal of what is generally reported in studies of this kind and the mean age was 39.86 ($S.D. = 10.94$) (Hadjistavropoulos et al., 2014; Kenter et al., 2015; Meyer et al., 2014). The majority of the sample was university educated; this may reflect the relatively high education levels of the Irish population, and is similar across Europe (OECD, 2013). The majority was in fulltime (home-based or other) employment or fulltime students. Income levels compare well to those of the national population (OECD, 2013). The sample could be considered an upwardly mobile and functioning group that may have busy schedules and for whom accessing an intervention online would therefore be convenient. The characteristics of the sample suggest that the sample was representative of national demographics. The profile was composed of predominately middle-aged and educated females, which corresponds to figures for face-to-face services (Hunsley, Aubry, Verstervelt, & Vito, 1999).

Sixty percent reported their civil status as either in a relationship or married, while 30% reported their civil status as single. The majority did not report any dependents and this category included children or other adults being financially dependent on the participants (for example, a spouse, a parent, or other relative). There were no significant differences in the number of participants in the control group vs. treatment group who reported having a previous diagnosis of depression. Participants reported difficulties in various life areas and the greatest reported burdens were associated with work, family and financial difficulties.

The majority of participants reported symptom presence of between 1 and 5 years. Between 45 and 55% reported a previous diagnosis of depression and had received counseling/psychotherapy for depression in the past. A similar prevalence was true of past medication, but because of our eligibility criteria (on medication for 1 month or more), there where only a small number on medication and stabilized for more than one month.

Lastly, the entire sample reported confidence in their use of information technology (IT) with 85% of the participants reporting being confident or very confident in the use of IT (see Table 3).

4.2. Treatment response rate

As per protocol, participants were offered 8 modules of content to complete. While they were instructed to complete each of the eight modules, the choice, pace and control over the direction and

Table 3
Demographic and clinical variables.

Variable	Sub-variable	Treatment (n = 96)		Control group (n = 92)	*p*-value	Total (n = 188)	
		n	%	n	%	n	%
Gender	Male	25	26.0	26	28.3 0.86	51	27
	Female	71	74.0	66	71.7	137	73
Age	Mean age (SD)	40.63 (11.17)		39.05 (10.69)	0.49	39.86 (10.94)	
	Range	21–74		18–67		18–74	
Education level					0.10		
	High school	27	28.1	14	15.2	41	21.8
	Undergraduate	20	20.8	33	35.9	53	28.2
	Postgraduate	25	26.0	22	33.9	47	25.0
	Other certificate	23	24.0	21	22.8	44	23.4
	None	1	1.0	2	2.2	3	1.6
Employment status					0.13		
	Part-time or student	26	27.1	24	26.1	50	26.6
	Fulltime	39	40.6	51	55.4	90	47.9
	Unemployed	13	13.5	8	8.7	21	11.2
	Retired	4	4.2	4	4.3	8	4.3
	Disabled	0	0	0	0	0	0
	At home parent	14	14.6	5	5.4	19	10.1
Civil status					0.97		
	Have a partner	14	14.6	12	13.0	26	13.8
	Married	45	46.9	41	44.6	86	45.7
	Separated	3	3.1	3	3.3	6	3.2
	Divorced	2	2.1	2	2.2	4	2.1
	Single	28	29.2	29	31.5	57	30.3
	Other	4	4.2	5	5.4	9	4.8
Dependents					0.69		
	0	59	61.5	58	63.0	117	62.2
	1	9	9.4	6	6.5	15	8
	2	12	12.5	17	18.5	29	15.4
	3	9	9.4	7	7.6	16	8.5
	4	6	6.3	4	4.3	10	5.3
	5	1	1.0	0	0	1	0.5
Previous diagnosis of depression	Yes	47	49.0	54	58.7 0.23	101	53.7
	No	49	51.0	38	41.3	87	46.3
Difficulties in life areas	Work	23	24.0	18	19.6 0.78	41	21.8
	Financial	16	16.7	11	12.0	27	14.4
	Partner	3	3.1	3	3.3	6	3.2
	Family	16	16.7	14	15.2	30	16.0
	Other	16	16.7	21	22.8	37	19.7
	No	22	22.9	25	27.2	47	25.0
Income	<11,000	28	29.2	16	17.4 0.10	44	23.4
	11,000–22,000	20	20.8	11	12.0	31	16.5
	23,000–33,000	14	14.6	22	23.9	36	19.1
	34,000–44,000	18	18.8	19	20.7	37	19.7
	45,000–55,000	9	9.4	13	14.1	22	11.7
	>55,000	7	7.3	11	12.0	18	9.6
Time with symptoms	Less than 6 months	10	10.4	7	7.6 0.14	17	9.0
	1–2 years	28	29.2	15	16.3	43	22.9
	2–5 years	18	18.8	23	25.0	41	21.8
	5+ years	40	41.7	47	21.1	87	46.3
Previous therapy for depression	Yes	44	45.8	51	55.4 0.24	95	50.5
	No	52	54.2	41	44.6	93	49.5
Previous medication for depression	Yes	48	50.0	51	55.4 0.55	99	52.7
	No	48	50.0	41	44.6	89	47.3
Current medication for depression	Yes	19	19.8	20	21.7 0.88	39	20.7
	No	77	80.2	72	78.3	149	79.3
IT confidence	Very confident	44	45.8	47	51.1 0.60	91	48.4
	Confident	38	39.6	31	33.7	69	36.7
	Average	11	11.5	13	14.1	24	12.8
	Mildly confident	3	3.1	1	1.1	4	2.1
	Not confident	0	0	0	0	0	0

dose of their engagement was entirely up to them. Of the 96 randomized to the immediate treatment group, 88% ($n = 84$) began module 1 and 38% ($n = 36$) completed all modules. Graph 1 represents the treatment response rate over time.

It is important to remember that completing the 8 modules of the intervention is not necessarily meaningful given the modular and tailored nature of the content. We would not expect all users to progress through the intervention in a linear way in order to benefit from the intervention.

A session was defined as an instance when a client logged on to the system. Session time estimation will always be an imperfect calculation because users may be interrupted or take breaks within a session, and may not formally log out of the system. With regard to the treatment group, the total number of sessions completed was 1415, with an average of 14.7 sessions completed per user. The mean time spent on the program was 5 h and 22 min, while the

Table 4
Descriptive data (M, SD, ES and CI) for the BDI-II, GAD-7, and WASA by group over time (ITT & Per Protocol analysis).

Outcome measures	Pre-treatment score *M* (*SD*), *n*	Post-treatment score *M* (*SD*), *n*	Effect size (*d*) [95% CI]	Follow-up assessments			
				3 month Score *M* (*SD*), *n*	Effect size (*d*) [95% CI]	6 month Score *M* (*SD*), *n*	Effect size (*d*) [95% CI]
BDI-II							
ITT analysis							
Treatment group	20.90 (3.83), 96	15.67 (7.68), 96	0.91 [0.14, 2.45]	11.86 (6.90), 96	1.68 [0.92, 3.07]	14.91 (5.44), 96	1.29 [0.53, 2.38]
Waiting list	20.84 (4.17), 92	20.43 (6.97), 92	0.07 [−0.78, 1.50]				
Per Protocol analysis							
Treatment group	20.90 (3.83), 96	13.88 (9.27), 60	1.19 [−0.42, 3.53]	11.68 (10.26), 50	1.53 [0.77, 4.38]	13.17 (10.04), 29	1.52 [0.76, 5.46]
Waiting list	20.84 (4.17), 92	20.67 (7.50), 79	0.03 [−0.82, 1.68]				
GAD-7							
ITT analysis							
Treatment group	10.17 (4.71), 96	4.99 (2.58), 96	1.42 [0.48, 1.94]	5.17 (2.86), 96	1.32 [0.38, 1.89]	4.99 (1.83), 96	1.58 [0.64, 1.95]
Waiting list	9.50 (4.24), 92	7.66 (3.43), 92	0.48 [−0.39, 1.18]				
Per Protocol analysis							
Treatment group	10.17 (4.71), 96	5.50 (3.71), 62	1.08 [0.14, 2.00]	4.98 (4.34), 51	1.13 [0.19, 2.32]	5.69 (3.97), 29	0.98 [0.04, 2.54]
Waiting list	9.50 (4.24), 92	8.73 (4.29), 79	0.18 [−0.69, 1.13]				
WASA							
ITT analysis							
Treatment group	14.84 (5.85), 96	11.76 (4.56), 96	0.59 [−0.58, 1.50]	8.27 (4.52), 96	1.27 [0.10, 2.17]	9.10 (3.54), 96	1.22 [0.05, 1.93]
Waiting list	15.58 (5.16), 92	14.49 (5.62), 92	0.20 [−0.58, 1.35]				
Per Protocol analysis							
Treatment group	14.84 (5.85), 92	11.62 (6.11), 61	0.54 [−0.65, 2.07]	9.82 (7.53), 51	0.78 [−0.42, 2.85]	12.38 (8.10), 29	0.39 [−0.81, 3.56]
Waiting list	15.58 (5.16), 92	14.90 (5.98), 79	0.12 [−0.93, 1.44]				

Note. BDI-II, Beck Depression Inventory; GAD-7, Generalized Anxiety Disorder; WASA, Work and Social Adjustment Scale.

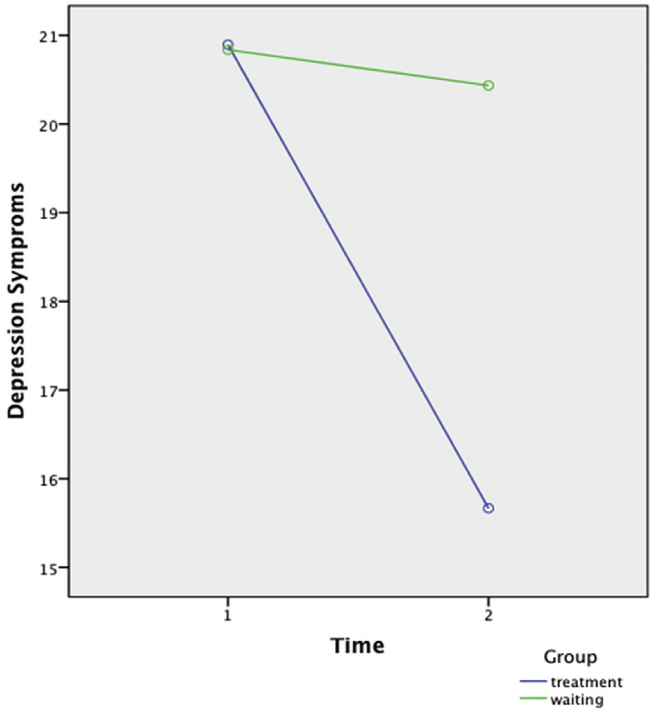


Fig. 2. Changes in depression symptoms pre-to post-intervention.

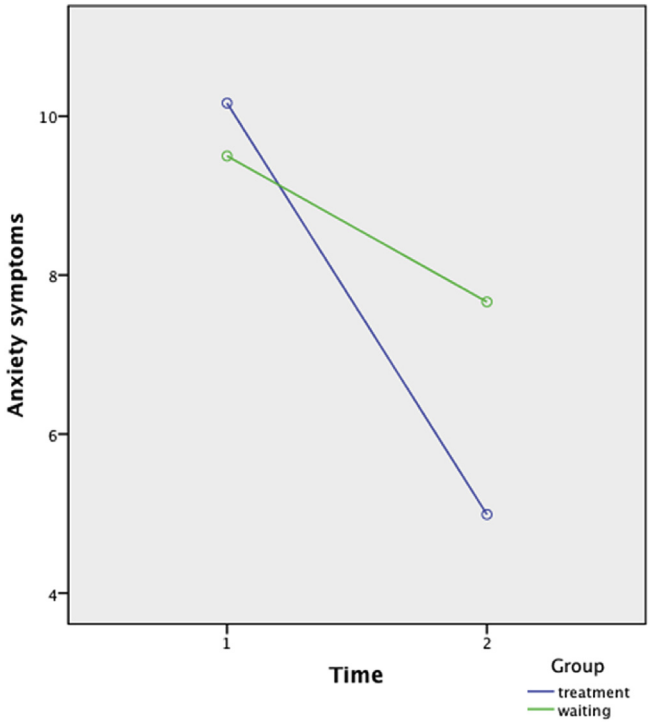


Fig. 3. Changes in anxiety symptoms pre-to post-intervention.

average length of session was 20.5 min.

4.3. Research data attrition

Fig. 1 captures the participant flow throughout the trial. Of the 641 individuals who were screened, 379 were excluded based on the established exclusion criteria (see Fig. 1). At sign-up, there were a total of 133 participants assigned to the treatment group and 129 assigned to the waiting list control group. Because of a technical error, where some participants scoring below 14 on the BDI-II were included, we had to exclude the data from 37 subjects from each group, leaving a final eligible sample of 96 participants in the treatment group and 92 in the waiting list control group pre-intervention.

In the treatment group, the research response at post-intervention was 60 (63%) participants, at 3-months follow-up 50 (52%) participants, and at 6-month follow-up 29 (30%) participants.

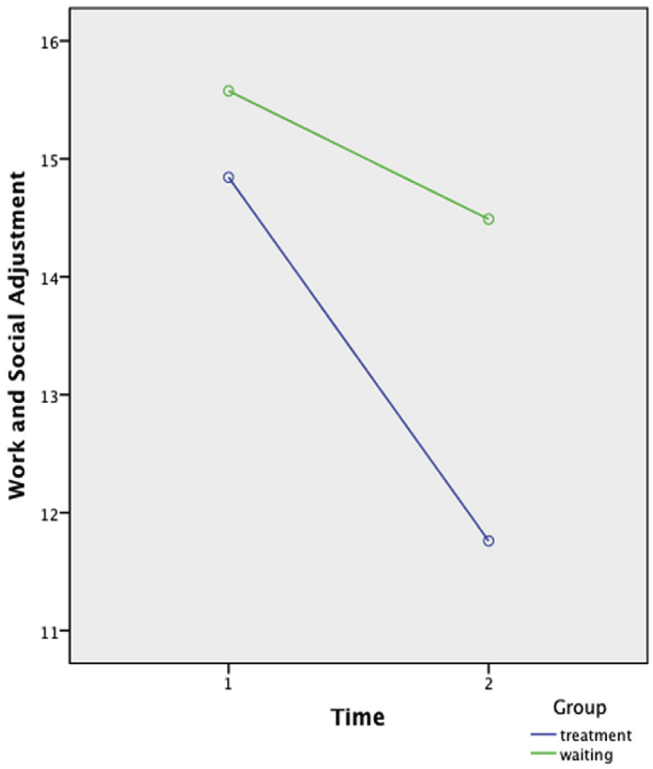


Fig. 4. Changes in work and social adjustment pre-to post-intervention.

In the waiting-list control group the response rate was high, with all 92 (100%) participants present at post-intervention assessment. The waiting list group was not followed up beyond this point as they entered treatment.

4.4. ITT analysis

The study sought to establish the effectiveness of a community based internet-delivered intervention for depression compared to a waiting list control group. Based on the generally reported success of online interventions for depression to date we hypothesized that positive changes in depressive and anxious symptoms could be achieved (Richards & Richardson, 2012). In addition, and specifically, we believed that using trained volunteers as supporters, that the *Space from Depression* intervention could achieve positive outcomes.

We employed an intention-to-treat (ITT) model for the analysis using maximum likelihood method to calculate missing data in the sample. For the purposes of comparison we also reported the outcomes from the per protocol analysis.

4.5. Beck Depression Inventory (BDI-II)

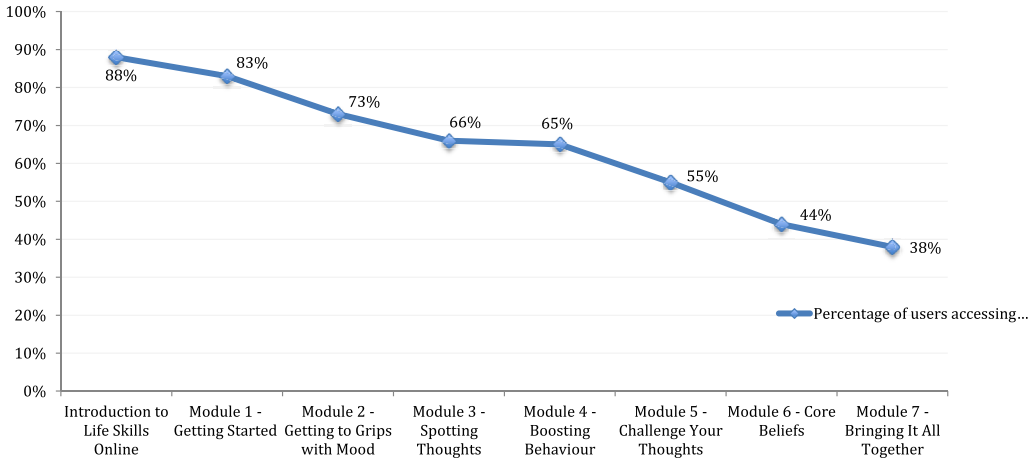
Repeated measures ANOVA determined a statistically significant difference between the treatment group and waiting list control group in mean depression symptoms post-treatment $F(1, 186) = 21.37$, $p = <0.001$. An inspection of the mean scores (Table 2) indicated that those in the treatment group reported much lower levels of depression symptoms post-treatment compared to their baseline scores, yielding a large post treatment effect for the intervention ($d = 0.91$). Fig. 2 gives a graphical representation of the changes in symptom severity. The between subjects effects were significant $F\ (1, 186) = 11.72$, $p = <0.01$, $d = 0.50$, favoring the treatment group at post-treatment. Post hoc tests (using the Bonferroni correction for multiple comparisons) revealed that the significant reduction in depressive symptoms for the treatment group was maintained and improved upon at 3-months ($d = 1.68$, $p = <0.001$) and 6-months ($d = 1.29$, $p = <0.001$) follow-up.

4.6. Generalized Anxiety Disorder (GAD-7)

Similarly, the repeated measures ANOVA model observed a statistically significant difference between the treatment group and waiting list control group in anxiety symptoms post-intervention $F(1, 186) = 25.84$, $p = <0.001$. An inspection of the mean scores (Table 2) indicated that those in the treatment group reported much lower levels of anxiety symptoms post-treatment than those in the waiting list control group, yielding a large post treatment effect for the intervention ($d = 1.42$), see Fig. 3. The between subjects effects were significant $F\ (1, 186) = 4.92$, $p = <0.01$, $d = 0.32$, favoring the treatment group at post-treatment. Post hoc tests show that the results achieved at post-treatment for participants in the treatment group were maintained at 3-months ($d = 1.32$, $p = <0.001$) and 6-months ($d = 1.58$, $p = <0.001$) follow-up.

4.7. Work and Social Adjustment (WASA)

Results (Table 2) from the ANOVA revealed a statistically



Graph 1. Percentage of users accessing modules over time.

significant difference between the treatment group and waiting list control group in work and social adjustment (WASA) post-intervention $F(1, 186) = 4.38$, $p = <0.01$. The treatment group demonstrated greater reduction in WASA scores compared to the waiting list scores pre-to post-treatment, yielding a moderate post treatment effect for the intervention ($d = 0.59$), see Fig. 4. The between subjects effects were significant $F(1, 186) = 7.67$, $p = <0.01$, $d = 0.40$, favoring the treatment group at post-treatment. Post hoc tests revealed that the significant reduction in symptoms for the treatment group was maintained and improved upon at 3-months ($d = 1.22$, $p = <0.001$) and 6-months ($d = 1.27$, $p = <0.001$) follow-up.

4.8. Per protocol analysis (research completers)

4.8.1. Beck Depression Inventory (BDI-II)

Results from the ANOVA determined a statistically significant difference between the treatment group and waiting list control group in mean depression symptoms post-treatment $F(1, 137) = 26.44$, $p = <0.001$, yielding a large post treatment effect for the intervention ($d = 1.19$), and these were maintained at 3-months ($d = 1.53$, $p = <0.001$) and 6-months ($d = 1.52$, $p = <0.001$) follow-up. The between subjects effects were significant $F(1, 137) = 14.03$, $p = <0.001$, $d = 0.64$, favoring the treatment group at post-treatment.

4.9. Generalized Anxiety Disorder (GAD-7)

ANOVA results observed a statistically significant difference between the treatment group and waiting list control group in anxiety symptoms post-intervention $F(1, 137) = 16.12$, $p = <0.001$, $d = 0.68$, yielding a large post treatment effect for the intervention ($d = 1.08$), which was maintained at 3-months ($d = 1.13$, $p = <0.001$) and 6-months ($d = 0.98$, $p = <0.001$) follow-up. The between subjects effects were significant $F(1, 137) = 6.49$, $p = <0.01$, $d = 0.43$, favoring the treatment group at post-treatment.

4.10. Work and Social Adjustment (WASA)

The results of the full factorial repeated measures ANOVA revealed a statistically significant difference between the treatment group and waiting list control group in work and social adjustment (WASA) post-intervention $F(1, 137) = 3.22$, $p = <0.01$, yielding a moderate post treatment effect for the intervention ($d = 0.54$) that was improved upon at 3-months ($d = 0.78$, $p = <0.001$), and maintained at the 6-months ($d = 0.39$, $p = <0.001$) follow-up. The between subjects effects were significant $F(1, 137) = 7.02$, $p = <0.01$, $d = 0.40$, favoring the treatment group at post-treatment.

4.11. Reliable and clinically significant change

We established clinically reliable change criteria of a movement of 9 points or greater on the BDI-II. We applied this to the ITT sample to determine the proportion of those who had reliably changed. In the treatment group 29.2% ($n = 28$) compared to 7.6% ($n = 7$) in the waiting list group achieved reliable change. The differences between the groups was statistically significant, $\chi 2(1) = 14.410$, $p = 0.000$. For the per protocol sample, in the treatment group 31% ($n = 30$) compared to 3.3% ($n = 3$) in the waiting list group achieved reliable change. The differences between the groups was statistically significant, $\chi 2(2) = 77.418$, $p = 0.000$.

An index of recovery from depression was established by identifying the percentage of participants whom achieved a post-treatment score of 10 or less on the BDI-II and a corresponding decrease of 9 points on the measure. Twenty-three percent ($n = 22$) of the 96 participants in the treatment group met this criteria compared to four percent ($n = 3$) of the 92 participants in the waiting list control. The differences between the groups was statistically significant, $\chi 2(1) = 15.742$, $p = 0.000$. For the per protocol sample, in the treatment group 22.9% ($n = 22$) compared to 3.3% ($n = 3$) in the waiting list group achieved recovery. The differences between the groups was statistically significant, $\chi 2(2) = 37.853$, $p = 0.000$.

5. Discussion

The aim of the paper was to evaluate the effectiveness of a newly developed internet-delivered treatment for depressive symptoms (*Space from Depression*) in a national community sample of adults. The primary outcome measure (BDI-II) assessed depressive symptoms. The results show that the active treatment caused statistically significant decreases in depressive symptoms post-intervention, and these were maintained at 3-month and at 6-month follow-up. The results from the present study show that the internet-delivered cognitive-behavior therapy (iCBT) program, *Space from Depression*, is effective in reducing depressive symptoms in comparison to a waiting list control group. These results support preliminary research findings on *Space from Depression* (Sharry et al., 2013).

The results also show that positive changes in depressive symptoms can be maintained by users 6-months post-treatment; a significant finding regarding maintenance of gains achieved from the use of the internet-delivered cognitive behavior therapy program. Previous research in this area has been consistent in demonstrating lasting effects of online interventions. Andrews, Cuijpers, Craske, McEvoy, and Titov (2010) have shown that symptom reductions are still maintained at a median follow-up of 26 weeks for online delivered treatments. It is possible that because iCBT provides motivated individuals with direct and convenient access to evidence-based therapeutic information and tools, this approach may encourage and enhance self-responsibility and thus contribute to stability of outcomes (Wagner, Horn, & Maercker, 2014).

Furthermore, this study highlights the effectiveness of the *Space from Depression* treatment in reducing comorbid symptoms of anxiety in comparison to a waiting list control group. Statistically significant reductions were observed in anxiety symptoms for the intervention group from pre-to post-treatment and these were maintained at 3- and 6-month follow-up. The results support the general efficacy of internet-delivered cognitive behavioral interventions for depression and anxiety. The study reports the first randomized controlled trial on delivery of treatment using the asynchronous online support model embodied by the SilverCloud platform and in addition contributes to the already established work in online treatments for depression and anxiety worldwide (Cuijpers et al., 2009; Richards & Richardson, 2012).

The study also investigated work and social adjustment in the sample. The results demonstrated that in this study sample there was a statistically significant change in functioning as measured by the Work and Social Adjustment measure (WASA) from pre-to post-treatment. Also similar to what was observed for depression and anxiety outcomes, it seems that individuals in the treatment group improved in their work and social functioning over time. This is a very encouraging sign for the *Space from Depression* intervention as achieving considerable improvement and maintenance of improvement in functioning in individuals who are depressed and anxious is highly significant. For instance, several studies have demonstrated the significant difference in depression between individuals who were not working compared to those who were

employed (Paul & Moser, 2009). Jahoda (1981) latent deprivation model supports the thesis that mental distress is a consequence of an individual not having the structure of time, social contact, a purpose that is shared, status and functioning all of which are associated with important psychological needs. Indeed in the current sample we found that those who were employed and without significant life stressors, in relationships and working were less at risk of depression severity (Richards et al., in review).

As expected, reliable change was achieved by a greater percentage of those in the treatment group compared to the waiting list control and the difference was statistically significant. The reported reliable change is similar to other studies in the literature. For instance, de Gaff et al. (2009) 37%; Meyer et al. (2009) 37%, and Titov et al. (2010) report a 59% reliable change in the treatment group, and each of these were based on ITT samples.

The criteria for *recovery* can be considered conservative and robust. The reported rates for recovery in the intervention group for the primary outcome measure (BDI-II) were 23%. In other studies recovery has been defined differently and accounts for fluctuations in reported results across studies. However studies of internet-delivered interventions that have used similar criteria report similar recovery rates, for instance, de Gaff et al. (2009) report a recovery rate of 23%, and Meyer et al. (2009) report a recovery rate of 25% and each of these were for the CCBT interventions used in the studies and based on a ITT protocol. Ruwaard et al. (2009) report a 44% recovery rate based on completers in the study.

The participants in the treatment group spent an average of 5 h and 22 min in treatment and an average time of 20.5 min per session. Importantly it was the participants who determined their required dose; and although only speculatively, this may be regarded as a significant feature of internet-delivered treatments – patients being in control of the pace and amount of treatment required? The results lend support to the strategies used by the *Space from Depression* program to keep participants engaged in treatment. The design of the platform was based using a user-centered processes (Doherty et al., 2010), and embeds a number of features designed to improve engagement, which have previously been categorized as Social, Interactive, Personal, and Supportive (Doherty et al., 2010). It is positive to see that 38% of participants completed all eight modules of treatment; it is encouraging to see that at session 4, 65% of participants continued to be engaged in their treatment.

We had a positive research response rate from the waiting list participants post-intervention and we would speculate this is related to the demand for access to evidence-based interventions and in particular the convenience of the internet-delivery to fit with peoples schedules. The research attrition rate was low for post-treatment follow up data from the intervention group, but somewhat higher as time passed for data collections at 3-month (52%) and 6-months (30%) follow up. This trajectory is not unusual even with a robust protocol for follow up in place that included an initial automatic email reminder, followed by a personal email reminder, followed by phone call reminders.

The research attrition in other similar studies was somewhat smaller, for instance, Proudfoot et al. (2004) had 69% of participants filling the forms at post-treatment and 67% at follow up. Titov et al. (2010) reported 90% of participants filling the forms at post intervention and 73% at follow up, Warmerdam, Van Straten, Jongsma, Twisk, and Cuijpers (2010) reported 83% providing data at the end of treatment and 75% at follow up, as with Ruwaard et al. (2009) 88% provided data post intervention and 77% at follow up. Only Meyer et al. (2009) reported 49% of participants providing data at post-treatment and 35% follow up.

5.1. Strengths of the study

Together with the positive outcomes reported for depression, this study also highlights some key successes: first, while Ireland is a small country, it was a first national study of an internet-delivered intervention for depression. The study alludes to the potential of an internet-delivered cognitive behavior intervention, with support from trained volunteers, to accomplish significant outcomes at a population level. In locations where behavioral and mental health services are underdeveloped, or where structures simply do not exist, or where there is a potential to offset risk and escalation of difficulties and benefit from early intervention, such a model of service provision could be feasible (cf. Cuijpers & Riper, 2015).

Second, the fact that participants were all self-referred possibly tells us something about the levels of digital literacy and of the need for access to evidence-based interventions nationally. Digital interventions may be a preference for some groups and certainly the current group reported high levels of confidence with IT. The demand to participate in the study exceeded our recruitment capacity due to a limited availability of supporters, which resulted in our having to exclude people from participating. It is a known fact that in many countries not everyone who needs or seeks help for a mental health difficulty can in fact receive help. However, based on the significant benefits to enhance healthcare, innovation that uses internet-delivered evidence-based interventions can be a welcome support towards a solution (Bennett-Levy, Richards, Farrand, et al., 2010). One could speculate that in the information age in which we live such digital interventions may increasingly become commonplace and even sought after and demanded as a preferred mode of access.

Thirdly, an exciting and interesting finding concerned the use of trained volunteer supporters for this study. It has already been reported that varying levels and types of supporters can achieve positive outcomes in internet-delivered interventions (Baumeister, Reichler, Munzinger, & Lin, 2014; Richards & Richardson, 2012), and this study adds supporting evidence for using trained para-professional supporters in guided internet-delivered interventions for mild to moderate symptoms. Additionally, as described earlier, the benefits of developing a '*community of practice*' among trained supporters may be a significant component to the success of the internet-delivered intervention; this is an area of study worth further examination.

Fourth, potentially the experiment has unfolded a model for the delivery of a population wide intervention for depression and anxiety. This type of intervention could easily be delivered through a charity network or as a primary care initiative (Andrews & Williams, 2014). It has the potential to reduce barriers to treatment access and to deliver effective evidence-based treatment interventions. Such a model of delivery could ameliorate against the costs, personal stigma and other barriers that prevent people from accessing treatments (Kohn et al., 2004; Mohr et al., 2010). As a primary care intervention it could contribute to realizing the significant benefits of early intervention and consequently offset the development of a chronic course in disease management. This of course has enormous consequence on healthcare providers and the costs of delivering care.

Finally, the construct of treatment response in internet-interventions is not so easily determined and therefore poses important question to researchers and clinicians regarding dose and response in internet-delivered treatment. It is important to remember that dose and treatment completers do not align so neatly with completing the 8 modules of the program. The idea of 8 sessions is not necessarily meaningful given the modular and tailored nature of the content. We would not expect all users to progress through the intervention modules in a linear way so as to

benefit from the intervention. Dose and response in internet-delivered interventions is an area that requires further research.

5.2. Limitations

The study did not include an official diagnosis of participants; rather levels of depression, anxiety, and social functioning were self-reported. However, these self-report measures (BDI-II, GAD-7, and WASA) are well-established measures that have provided information regarding the relevance of internet-delivered treatments for depression in multiple international studies. Our eligibility criteria included those with mild to moderate symptoms and this may have caused a constriction of the sample and a consequent possibility of either inflated or deflated effect sizes. Also, because of attrition at the follow up the results need to be considered with care at this time point.

6. Conclusion

The current study showed that the internet-delivered cognitive-behavior therapy program – *Space from Depression* – could be employed as a population level intervention for mild to moderate symptoms of depression and was effective in improving symptoms of depression and anxiety among many of its users. Importantly, outcomes from the treatment group were maintained into follow up. The figures for reliable change are positive and can be considered appropriate for community-based interventions. The supporters were trained volunteers who have developed a community of practice between them. This model would require further examination to explore what aspects of it contribute to a community of practice and its relevance to delivering internet interventions. Another point that needs careful consideration is the dose of treatment. It is the case that treatment duration is difficult to quantify and qualify and perhaps aspects of what have been traditionally considered advantages of internet-delivered interventions such as being self-paced, user-centered, expanding patient choice, and the user being in control of their treatment may be salient aspects to be further explored.

Other features relate to engagement, and while the supporter function is intended to enhance engagement and adherence to treatment and consequently positive outcomes, other aspects such as interactivity, social features and personalization of content seem also to contribute. The study has shown the potential for internet-delivered delivered interventions for population and community health and they may have a considerable influence especially in areas where services are underdeveloped and where access is limited. The study highlights the possibilities for innovation in health service delivery.

Conflict of interest

The authors declare no conflict of interest. Derek Richards is Director of Clinical Research and Innovation at SilverCloud Health. Derek Richards is also Research Fellow, School of Psychology, Trinity College Dublin (TCD) and adheres to both research ethics and TCD policy on good research practice.

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