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BRIEF CLINICAL REPORT

Internet-delivered cognitive behaviour therapy for post-traumatic stress disorder: a randomised controlled trial and outcomes in routine care

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Abstract

Background: Despite its potential scalability, little is known about the outcomes of internet-based cognitive behaviour therapy (iCBT) for post-traumatic stress disorder (PTSD) when it is provided with minimal guidance from a clinician.

Aim: To evaluate the outcomes of minimally guided iCBT for PTSD in a randomised control trial (RCT, Study 1) and in an open trial in routine community care (Study 2).

Method: A RCT compared the iCBT course (n=21) to a waitlist control (WLC, n=19) among participants diagnosed with PTSD. The iCBT group was followed up 3 months post-treatment. In Study 2, treatment outcomes were evaluated among 117 adults in routine community care. PTSD symptom severity was the primary outcome in both studies, with psychological distress and co-morbid anxiety and depressive symptoms providing secondary outcomes.

Results: iCBT participants in both studies experienced significant reductions in PTSD symptom severity from pre- to post-treatment treatment (within-group Hedges' g=.72–1.02), with RCT findings showing maintenance of gains at 3-month follow-up. The WLC group in the RCT also significantly improved, but Study 1 was under-powered and the medium between-group effect favouring iCBT did not reach significance (g=0.64; 95% CI, −0.10–1.38).

Conclusions: This research provides preliminary support for the utility of iCBT for PTSD when provided with minimal clinician guidance. Future studies are needed to clarify the effect of differing levels of clinician support on PTSD iCBT outcomes, as well as exploring how best to integrate iCBT into large-scale, routine clinical care of PTSD.

Keywords: anxiety; cognitive behaviour therapy; effectiveness; e-health; online; post-traumatic stress disorder

Introduction

Internet-delivered cognitive behaviour therapy (iCBT) seeks to enhance the accessibility of effective psychological treatments. The efficacy of iCBT for post-traumatic stress disorder (PTSD) compared with control conditions has meta-analytic support (d=0.60; 95% CI, 0.24–0.97; Lewis *et al.*, 2019). These treatments are being increasingly integrated into routine care with studies showing medium to large pre- to post-treatment effect size reductions in PTSD symptom severity (d=0.72–1.6) (e.g. Ruwaard *et al.*, 2012).

Most evaluations of PTSD iCBT have examined therapist-assisted programs involving considerable clinical support (e.g. average therapist time per participant was 570 minutes in Ruwaard *et al.*, 2012). The effectiveness of minimally guided programs has not been well studied, yet such programs are highly scalable and may improve the coverage of evidence-based care. In the only study of minimally guided iCBT for PTSD, Hirai and Clum (2005) evaluated the effects of an 8-week program in 27 adults experiencing subclinical PTSD symptom severity. Compared with a waitlist control (WLC), this program was more efficacious in reducing PTSD-related avoidance symptoms and the frequency of intrusive trauma-related thoughts. However, significant between-group differences were not observed for other PTSD symptoms including hyper-arousal and the intensity of participants' intrusive thoughts about their index trauma. These findings require replication, especially among individuals diagnosed with PTSD. Furthermore, the therapist contact in Hirai and Clum (2005) did not involve clinical guidance and only sought to prompt course completion. The effects of providing minimal therapeutic support require examination as this contact may enhance risk management and better reflect the level of support recommended for implementing iCBT in community care (e.g. Newby *et al.*, 2021).

This investigation examined the outcomes of PTSD iCBT with minimal therapeutic guidance. Consistent with prior evaluations, minimal therapeutic input was operationalised as therapist contact in response to participant request or symptom deterioration on standardised assessment measures, in addition to automated system emails to encourage program engagement. Study 1 was an RCT comparing iCBT with WLC among adults with PTSD. Study 2 evaluated the program's outcomes when delivered in routine care by community-based clinicians. We predicted that iCBT would produce medium to large effect size reductions in PTSD symptom severity at post-treatment compared with WLC and that these improvements would be maintained for 3 months. We expected the effectiveness of the course in routine care would be comparable to that of the RCT, but that adherence would be lower.

Study 1: Method

A CONSORT-revised 2010-compliant parallel RCT compared PTSD iCBT with WLC [trial registration: ACTRN12614001213639, ethical approval: St Vincent's Hospital Human Research Ethics Committee (SVH HREC) 2014/SVH/28, research conformed to the Declaration of Helsinki with participants providing informed consent, trial protocol: extended report].

Participants

Participants were self-referred and recruited via advertisements across Australia from September 2014 to April 2016. Individuals applied via the Virtual Clinic (www.virtualclinic.org.au). Participants were Australian adults [$n = 40$, mean age = 41.60 years (*SD* 13.81), 90% female] with PTSD (diagnosis via Mini International Neuropsychiatric Interview version 5) who reported they were not experiencing a psychotic disorder, substance use disorder, or severe depression, suicidal ideation, or dissociation (see extended report in Supplementary material for full participant demography and inclusion/exclusion criteria). The most common type of trauma reported was sexual trauma or assault (~75% of participants) and the unexpected loss of others (~50%).

Participants were randomly allocated to groups by an independent person using a 1:1 ratio and random number generator (www.random.org). In total, 21 participants in the iCBT group and 19 in WLC were eligible for analysis (participant flow in extended report in Supplementary material). Statistically significant group differences in baseline clinical variables were not found, and inspection of the distributions of demographic variables suggested the groups had comparable demographic characteristics (see extended report in Supplementary material).

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Intervention

The PTSD iCBT course involved six lessons delivered over 10 weeks. Lessons included an illustrated story, homework summary, and supplementary resources teaching fundamental CBT skills (e.g. psychoeducation, de-arousal skills, cognitive restructuring, written exposure to the trauma memory, *in vivo* exposure and relapse prevention) based on the theoretical models and treatment protocols of cognitive processing therapy and prolonged exposure (e.g. Resick *et al.*, 2008; see also extended report in Supplementary material). iCBT participants received automated email reminders and study personnel spent an average of 38.00 minutes ($SD = 67.29$) per participant on personalised email and telephone contact. There was an average of 9.76 ($SD = 6.72$) email exchanges (i.e. emails sent/received) and 4.05 ($SD = 4.88$) telephone calls per participant. Three participants required a higher level of support (>30 min) for management of self-harm/suicidality (two participants) and guidance on implementing written exposure whilst limiting avoidance/dissociation (one participant) (see extended report in Supplementary material for further details).

Assessments

The primary outcome was the PTSD Checklist-Civilian version (PCL-C), a psychometrically sound, self-report questionnaire of PTSD symptom severity. Secondary outcomes included the Kessler Psychological Distress Scale (K10), Patient Health Questionnaire-9 (PHQ-9, indexing depression) and Generalised Anxiety Disorder-7 (GAD-7, indexing generalised anxiety). Outcome measures were administered at pre-treatment, mid-treatment (week 5 of the waiting period for WLC), post-treatment (week 11 for WLC), and 3-month follow-up (iCBT only). The PCL-C and K10 were also completed before each iCBT lesson.

Study 1: Results

Of those who started iCBT, 66.7% (n=14/21) completed all six lessons [56% ($n = 14/25$) of those randomized]. Intention-to-treat linear mixed models (ITT LMM) with random intercepts for subjects examined the effect of treatment on outcome measures (pre-, mid-, and post-treatment time points) with Hedges' g estimating effect sizes. As seen in Table 1, there was no significant group by time interactions for any outcome measure (PTSD $F(2, 89.16) = 1.17$, $p = 0.32$; K-10 $F(2, 92.19) = 3.63$, $p = 0.30$; PHQ-9 $F(2, 72.25) = 1.06$, $p = 0.35$, GAD-7 $F(2, 73.49) = 0.47$, $p = 0.63$). In comparison to the WLC group, iCBT participants experienced moderate effect size reductions in PTSD symptom severity (between-groups $g = 0.64$), however, this did not reach statistical significance. There was no significant change in any outcomes between post-treatment and follow-up for the iCBT group.

In those completing post-treatment assessments, 61.5% of the iCBT ($n = 8/13$) and 17.7% of the WLC group ($n = 3/17$) no longer reported PCL-C scores indicative of probable PTSD at post-treatment (PCL-C total ≥ 44). Using a reliable change index (RCI) of 13.20 points on PCL-C scores (computed with $SD = 13.75$ and $r = 0.88$), 38% ($n = 5/13$) of iCBT and 29% ($n = 5/17$) of WLC participants reliably improved across the treatment period with no participant reliably deteriorating.

Study 2: Method

An open pre- to post-treatment trial of the PTSD iCBT course was conducted from 27 July 2016 to 29 June 2019 via the THIS WAY UP digital mental health service (SVH HREC 2020/ETH03027). Community clinicians working in routine care settings prescribed the iCBT course to their patients and supported program engagement. Clinicians were encouraged to contact their

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Table 1. Changes in outcome measures for the PTSD iCBT and WLC groups

	Pre-treatment		Mid-treatment		Post-treatment		3-month follow-up		Pre–post within-group differences			Post-follow-up within-group differences			Post-treatment between group differences
	EMM	*SD*	EMM	*SD*	EMM	*SD*	EMM	*SD*	*t*	*r*	*g* (95% CI)	*t*	*r*	*g* (95% CI)	*g* (95% CI)
Study 1															
PCL-C															
iCBT	59.29	13.75	47.84	12.76	43.12	12.31	45.29	11.51	4.86***	.71	1.02 (.29–1.75)	−.90	.92	−.11 (−.94–.71)	.64 (−.10–1.38)
WLC	61.05	13.76	53.84	13.76	51.68	13.42			2.97**	.57	.67 (−.01–1.34)				
K10															
iCBT	32.71	7.65	25.19	7.11	26.28	6.83	25.96	6.40	3.68***	.62	.89 (.17–1.61)	.21	.92	.03 (−.80–.85)	−.03 (−.75–.69)
WLC	31.68	7.65	29.47	7.65	26.06	7.45			3.43**	.60	.75 (.07–1.43)				
PHQ-9															
iCBT	15.91	6.24	11.64	5.79	11.96	5.45	11.70	5.08	3.40**	.78	.63 (−.08–1.34)	.19	.90	.03 (−.80–.85)	.26 (−.47–.98)
WLC	15.47	6.24	13.21	6.24	13.22	6.02			2.15*	.67	.43 (−.23–1.09)				
GAD-7															
iCBT	11.95	5.56	8.68	5.28	8.49	5.05	8.78	4.80	2.75**	.58	.70 (−.01–1.41)	−.20	.92	−.02 (−.85–.80)	.29 (−.43–1.02)
WLC	12.26	5.56	10.42	5.56	10.06	5.41			1.92	.73	.34 (−.32–1.00)				
Study 2															
PCL-5	42.99	18.59	36.30	17.08	29.92	16.48			7.16***	.66	.72 (.41–1.03)				
K10	29.84	8.88	26.29	8.06	23.69	7.44			8.86***	.64	.93 (.61–1.24)				
PHQ-9	13.97	7.07	11.41	6.71	9.41	6.41			6.26***	.57	.71 (.40–1.02)				

iCBT, internet-based cognitive behaviour therapy treatment group; WLC, waitlist control group; PCL-C, PTSD Checklist-Civilian version; PCL-5, PTSD Checklist for *DSM-5*; K10, Kessler Psychological Distress Scale; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalised Anxiety Disorder-7; EMM, estimated marginal mean; *r*, Pearson correlation between measurement occasion for calculation of within-group effect sizes. *$p<.05$, **$p<.01$, ***$p<.001$.

patients after the first two iCBT lessons and as needed throughout the course (e.g. in response to patient distress, see extended report in Supplementary material). However, clinicians could contact their patients and provide concurrent treatment(s) at their discretion without reporting this to THIS WAY UP. Clinicians included psychologists (37.6%), medical specialists (32.5%), general practitioners (26.5%), and social workers/other allied health (3.4%). The iCBT program was the same as Study 1 except participants were given 90 days to complete their course. Participants [$n = 117$, mean age = 44.89 years (*SD* 13.78), 61.5% male] completed the K10 prior to each lesson, and the PTSD Checklist for *DSM-5* (PCL-5) and PHQ-9 before lessons 1, 4 and 6.

Study 2: Results

Overall, 56.4% ($n = 66/117$) of participants completed all six lessons, with 72.7% ($n = 85/117$) completing ≥4 lessons. As in Study 1, ITT LMM estimated changes from pre- to mid- to post-iCBT and demonstrated that participants experienced significant ($p < .001$), medium to large effect size reductions on outcome measures (Table 1). Among those completing post-treatment assessments, 45.8% ($n = 22/48$) no longer reported a PCL-5 score indicative of probable PTSD at post-treatment (PCL-5 total ≥ 31), with 39.6% ($n = 19/48$) experiencing reliable improvement in PTSD symptom severity (RCI = 10.52 reduction in PCL-5 scores computed with $SD = 18.59$ and $r = 0.84$).

Discussion

In research and routine community care settings, iCBT delivered with minimal therapeutic guidance was associated with medium to large effect size reductions in PTSD symptom severity across treatment (within-group g=.72–1.02), with a third to half of those who completed treatment achieving symptom remission and/or reliable improvement. Evidence of maintenance of treatment gains was found, and most iCBT participants completed the majority of treatment components indicating reasonable program acceptability.

In the RCT, iCBT produced moderate effect size reductions in PTSD severity compared with WLC (between-group g=.64); however, differences did not reach statistical significance. A recent meta-analysis of iCBT for PTSD found that treatment produced medium effect size reductions in PTSD symptoms compared with control conditions [$d = 0.60$; 95% CI, 0.24–0.97; Lewis *et al.*, 2019]. The magnitude of our between-group difference is consistent with this, but our restricted sample size resulted in only 66% power to detect a statistically significant result. Our findings may also indicate the limited impact of the current program among those experiencing severe symptoms or that minimal therapeutic contact may be insufficient to enable robust symptom improvement.

However, the current study has limitations. Definitive conclusions regarding program effectiveness should be avoided as our sample size was small and it is unclear if results would persist over the longer term or generalise to samples with more diverse characteristics (e.g. gender, ethnicity, co-morbid conditions). Current treatment attrition rates were suboptimal (RCT iCBT attrition = 33.3% *vs* WLC = 10.5%). Although current adherence is broadly consistent with other PTSD iCBT programs, adherence remains a serious concern for online therapies in general and ongoing research needs to identify methods of minimising drop-out (see Newby *et al.*, 2021 and extended report in Supplementary material). Additionally, it is unknown how reliably and extensively participants engaged with therapeutic activities (e.g. writing trauma narratives). This was not systematically evaluated and probably differed across participants. Furthermore, the nature of the WLC condition was unclear because data as to whether WLC participants accessed PTSD treatment while waiting were

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unavailable. Consistent with the 'real-world' nature of Study 2, therapist contact during iCBT was not assessed or controlled, and probably varied across participants as clinicians employed their own professional judgement for managing their patients. Rather than the iCBT, symptom improvements may have resulted from possible concurrent treatment(s), clinician-contact factors, other unmeasured variables (e.g. changes in participants' biopsychosocial context), or a combination of factors. Future research should examine what levels of therapeutic guidance during iCBT are feasible and achievable in community settings.

Current PTSD iCBT outcomes and adherence appear weaker than those of 'gold-standard' in-person cognitive and behavioural therapies for PTSD, which are considerably longer and involve extensive therapist guidance (e.g. see McLean *et al.*, 2022). Future studies need to quantify and explain these differences, but it is conceivable that these longer, intensive therapies are more effective at providing a larger 'dose' of tailored treatment than brief iCBT programs. Future study should inform how best to integrate iCBT into large-scale, routine clinical care. Rather than replacing in-person evidence-based treatment, PTSD iCBT may be useful within stepped-care approaches to service provision given its accessibility and scalability.

Conclusions

When delivered with minimal therapeutic support, iCBT for PTSD was associated with reductions in symptom severity and may have utility when embedded within established healthcare systems.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/S1352465822000285

Data availability statement. The data that support the findings of this study are available on request from the corresponding author, A.M. The data are not publicly available due to ethical and privacy restrictions.

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Conflict of interest. The authors declare none.

Ethical standards. These studies were conducted with the approval of the St Vincent's Hospital Human Research Ethics Committee (RCT: HREC/14/SVH/28, THIS WAY UP evaluation: HREC 2020/ETH03027). These research studies conformed to the Declaration of Helsinki with all participants providing informed consent.

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