



A randomized controlled trial of self-compassion versus cognitive therapy for complex psychopathologies

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Abstract

Third wave cognitive behavioural therapy has drawn attention to the value of interventions focusing on improved psychological functioning and wellbeing, rather than recovery or absence of disorder alone. The current study compared behavioural therapy combined with either self-compassion training or cognitive therapy (experimental treatment with standard treatment) in a randomized controlled trial for an initial presentation of a depressive disorder or post-traumatic stress disorder at a publicly funded outpatient unit. A battery of reliable and valid scales to assess the severity of the presenting problem and level of self-compassion were administered at both commencement and end of a 12-week treatment intervention. Basic sociodemographic variables were also recorded. Effective randomization was achieved for all variables except self-compassion, for which the standard treatment group reported higher levels than the experimental group. The greater efficacy of the experimental protocol was indicated by significant time by group interactions in severity measures over time in the experimental group relative to the standard group. This study contributes to a relatively fledgling literature on the therapeutic efficacy of self-compassion, providing both researchers and clinicians with valuable insight into the circumstances in which training in self-compassion may be of potential benefit when incorporated into standard practice. The trial was registered with the Australian New Zealand Clinical Trials Registry (TRN 12617000885392, June 16, 2017).

Keywords Self-compassion · Depressive disorder · Post-traumatic stress disorder · Randomized controlled trial · Cognitive therapy · Behaviour therapy

Introduction

Depressive disorders and Post-Traumatic Stress Disorder (PTSD) are persistent and disabling mental health conditions, with negative impacts on individuals, families and communities (Ramnero, Folke, & Kanter, 2016). Cognitive Behavioural Therapy (CBT) is the leading evidence-based and cost-effective treatment for a broad range of conditions

such as depressive disorders and PTSD (Feliu-Soler et al., 2018; Mayo-Wilson et al., 2014). Cognitive Therapy (CT) is acknowledged as a main therapeutic method within ‘second wave CBT’. CT strategies include psychoeducation about the impact of thinking on feeling and behaviour, identifying, and challenging negatively biased thinking, substituting logical evidence that corrects unhelpful assumptions, thereby reducing overall psychological symptoms (Cristea et al., 2015; Feliu-Soler et al., 2018).

However, using CT to challenge negative thinking can be of limited benefit for severe anxiety, depressive disorders, or trauma symptoms, due to self-criticism and/or strong negative emotions such as shame and guilt (Gilbert, 2009, 2010; Valdez & Lilly, 2016). Clients who understand the logic of healthier thinking can still struggle emotionally to ‘feel’ any better and experience symptom relief (Gilbert, 2010). Recent compassion-based interventions that are increasingly incorporated within ‘third wave CBT’ indicate that in such circumstances it may be beneficial to first build clients’ capacity for compassion to facilitate their better integration of cognitive and emotional processing (Gilbert, 2009, 2010).

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This research focuses on increasing interest in self-compassion (SC) in particular as an effective treatment target for a range of psychological disorders. However there is as yet no consensus method adopted among experts to operationally define SC. In Neff's (2003b, 2012) influential model SC is proposed as an adaptive form of self-relation, particularly during times of difficulty and general suffering. This model proposes SC as comprising three components, each with positive and negative counterparts: (1) self-kindness versus self-judgement, (2) common humanity versus isolation, and (3) mindfulness versus over-identification. These components are importantly interconnected and synergistic, working at an individual's system level to produce a more (or less) compassionate way of responding to the self, which can be measured using the Self-Compassion Scale (SCS; Neff, 2003a). Further, Neff and Germer (2013) developed mindful self-compassion (MSC) as a structured eight week or five-day intensive group-based program to specifically cultivate SC. It includes psychoeducation on SC and related topics, core and optional meditations, informal self-compassion practices, plus a four-hour silent retreat. Though developed for non-clinical populations, the program is considered to have the potential to be applied to some clinical populations and is increasingly being adapted to be suitable and safe for use in the presence of psychological conditions (Diedrich, Hofmann, Cuijpers, & Berking, 2016; Krieger, Berger, & Grosse, 2016).

Of particular interest within CBT is Gilbert's (2009, 2010, 2014) Compassion Focused Therapy (CFT), developed and tailored specifically for use with clinical populations. In this model compassion is conceptualised as motivation and is defined as sensitivity to suffering in the self and others, along with a commitment to try and prevent or alleviate this suffering, with SC being the flow of compassion from self-to-self. CFT is further operationalised in terms of particular attributes (i.e., care for wellbeing, sensitivity, sympathy, distress-tolerance, empathy, and non-judgment) and skills (i.e., compassionate attention, reasoning, behaviour, sensation, feeling, and imagery). An increased capacity for compassion effects a strengthening of the contentment/soothing motivational system in humans, thought to play an important role in the regulation of threat and drive systems, which are implicated in the development and maintenance of psychopathology, particularly in anxiety, depressive disorders and trauma-based conditions (Gilbert, 2009, 2010, 2014; Kirby, Tellegen, & Steindl, 2017).

Both Neff and Gilbert's models are secular, while drawing theoretically on Tibetan Buddhist perspectives of human suffering (Kirby et al., 2017). However, Gilbert's model is of particular interest due to its clearly developed evolutionary psychology, attachment theory, neurophysiology and physiology theoretical underpinnings that have been drawn together within a typical psychotherapy process. Many familiar CBT interventions are deployed for the purpose of the cultivation of

a compassionate mind, to help with the regulation and management of psychopathology (Gilbert, 2010; Gilbert & Choden, 2013; Kirby et al., 2017).

A recent meta-analysis of compassion-based research more broadly (Kirby et al., 2017) found such interventions resulted in significant moderate increases in compassion, SC and mindfulness, reductions in depressive disorders, anxiety and psychological distress, and increases in wellbeing. A subsequent meta-analysis of self-compassion-based interventions (Ferrari et al., 2019) similarly found increases in SC and mindfulness, significant large effects on eating behaviour and rumination, moderate reductions in stress, anxiety, depressive disorders, self-criticism, and small significant increases in positive affect and life satisfaction. Additionally, at follow-up improvements in depressive disorders continued, while gains in SC were maintained for self-compassion-based intervention groups. Despite these initial promising results, both reviews noted a very limited number of intervention studies with clinical populations, resulting in obvious limitations for the conclusions that could be drawn about the relationship between SC and psychopathology, particularly pertaining to treatment, recovery and maintenance (Ferrari et al., 2019; Kirby et al., 2017; MacBeth & Gumley, 2012).

Clearly people vary in their base level of SC. However, research indicates that SC can be taught, learned, and/or strengthened and that this is related to improved mental health (Diedrich, Grant, Hofmann, Hiller, & Berking, 2014; Germer & Neff, 2013; Krieger et al., 2016). Yet it is also recognised that for many people SC does not come easily. For example, backdraft (Germer & Neff, 2013), blocks and fear of (self) compassion (Gilbert, 2010) are identified as potential barriers that may need to be addressed in treatment, particularly for complex presentations that are nevertheless most likely to benefit from self-compassion training.

Study Aims

The current study used a Randomized Controlled Trial (RCT) to evaluate the effectiveness of an experimental treatment of augmented SC training, using key activities and techniques drawn from MSC and CFT, coupled with Behavioural Therapy (BT). That is, SC and BT. The intervention was tailored to fit within a local standard 12 session program of individualised CBT-based treatment for depressive disorders and PTSD. The study sought to compare the experimental group (SC with BT) with a control group receiving CT and BT. Novel features of the study included a clinically derived cohort, individual (versus group based) self-compassion training as part of the experimental treatment, and the inclusion of PTSD as a diagnosis for the novel treatment condition.

Method

Design, Analysis, and Approvals

A single-blind 2 (treatment) $\times$ 2 (time) repeated measures RCT was conducted. That is, clients were naïve as to which treatment arm they had been assigned. Standard treatment was compared with an experimental treatment protocol across a 12-session program. Key analyses comprised 2 $\times$ 2 repeated measures ANOVA. The required sample size was determined for the interaction between treatment and time (the effect of most interest) using G*Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007). For $\alpha = .05$ and power = 80% it was determined that a ‘small effect size’ of Partial Eta Squared = .02 (equivalent to Cohen’s $f = .14$) would require 29 participants per group. The study was approved by the authors’ institutional research ethics committee.

Setting

The Centre for Anxiety and Related Disorders (CARD) is a publicly funded, multi-disciplinary, tertiary treatment service for adults with anxiety and/or depressive disorders. It is staffed by therapists with backgrounds of nursing, social work, psychiatry, or psychology, all of whom have completed, or are undertaking, postgraduate qualifications in CBT. Clients are referred by General Practitioners (GPs) and other health and welfare professionals. Standard treatment comprises 12 sessions of CBT (CT with BT) in accord with the National Institute for Health and Clinical Excellence (NICE) Guidelines (Clark, 2011).

Therapeutic Protocols

As applied in this study, the standard CARD protocol comprised CT with BT. CT consisted of psychoeducation, cognitive restructuring (techniques that create awareness of distorted thoughts and how to modify these) and behavioural experiments (derived directly from a cognitive problem formulation that generates information and/or tests core beliefs) (Cristea et al., 2015; Greenberg & Pascual-Leone, 2006). BT comprised psychoeducation and either graded exposure (imagined or in vivo) for PTSD or behavioural activation (the encouragement to engage in routine, pleasurable and important/necessary activities) for depressive disorders (Mazzucchelli, Kanter, & Martell, 2016).

The experimental intervention combined self-compassion training with BT (as described for standard treatment). Key activities and techniques for facilitating the development of SC were drawn from the MSC program by Neff and Germer (2013) and CFT by Gilbert (2010). These included psychoeducation on 1) Neff’s three elements of SC; 2) Gilbert’s three emotion regulation systems; 3) common blocks

or barriers to SC and tools for addressing these; 4) skills training in mindful breathing and/or soothing breathing rhythm; 5) SC inducing practices of taking a SC break; 6) how would you treat a friend; 7) compassionate letter writing to self; and 8) building a (self) compassionate image.

Participants and Procedure

Participants comprised clients who met the inclusion criteria of being aged between 18 and 65 years, with a primary diagnosis of either a depressive disorder or PTSD and referred by their GP or other health care professional to this service for the first time. Both diagnoses were included due to their prevalence of presentation at CARD and their shared phenomenology. Informed written consent was obtained prior to enrolment in the study. An administrative staff member of CARD who was not involved in the study allocated participants to one of the two treatment arms using a computer-generated block randomization schedule. Within this, participants were also allocated randomly by diagnosis, to one of two senior CARD therapists.

A semi-structured interview conducted during the first session allowed a final determination of primary diagnosis based on International Statistical Classification of Diseases and Related Health Problems 10th Revision (World Health Organization, 1996) and management plan. Some potential participants were excluded at this point due to a diagnosis that was incompatible with the study treatment options. Table 1 summarizes the 62 participants who completed all requirements for inclusion in the analyses by treatment protocol, diagnosis, and therapist, and Fig. 1 presents a CONSORT statement fully detailing participants’ recruitment and retention.

Measures

The scales described below were administered at both pre- and post-treatment. Pre-treatment data, which were collected prior to group allocation, also included standard sociodemographic details (age, gender, marital status, education, and employment).

Self-Compassion Scale (SCS; Neff, 2003a, 2016) This 26-item self-report instrument assesses the degree to which an individual’s thoughts are self-compassionate. A 5-point scale (‘almost never’ to ‘almost always’) allows participants to indicate how often they act in the manner described. Six groups of items (self-kindness, self-judgement, common humanity, isolation, mindfulness, and over-identified) reflect the conceptualization of SC. Recent evidence suggests the preferred scoring options to be this 6-factor correlated model or a single bifactor model. The latter is reported in the current study, which comprises a total score ranging from 26 to 130 with

Table 1 Summary of study participants by treatment, diagnosis, and therapist

	Standard treatment (<i>n</i> =31)		Experimental treatment (<i>n</i> =31)		Full trial (<i>n</i> =62)	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
Diagnosis						
PTSD	15	(48.4)	15	(48.4)	30	(48.4)
Depressive disorder	16	(51.6)	16	(51.6)	32	(51.6)
Therapist						
A	15	(48.4)	16	(51.6)	31	(50.0)
B	16	(51.6)	15	(48.4)	31	(50.0)

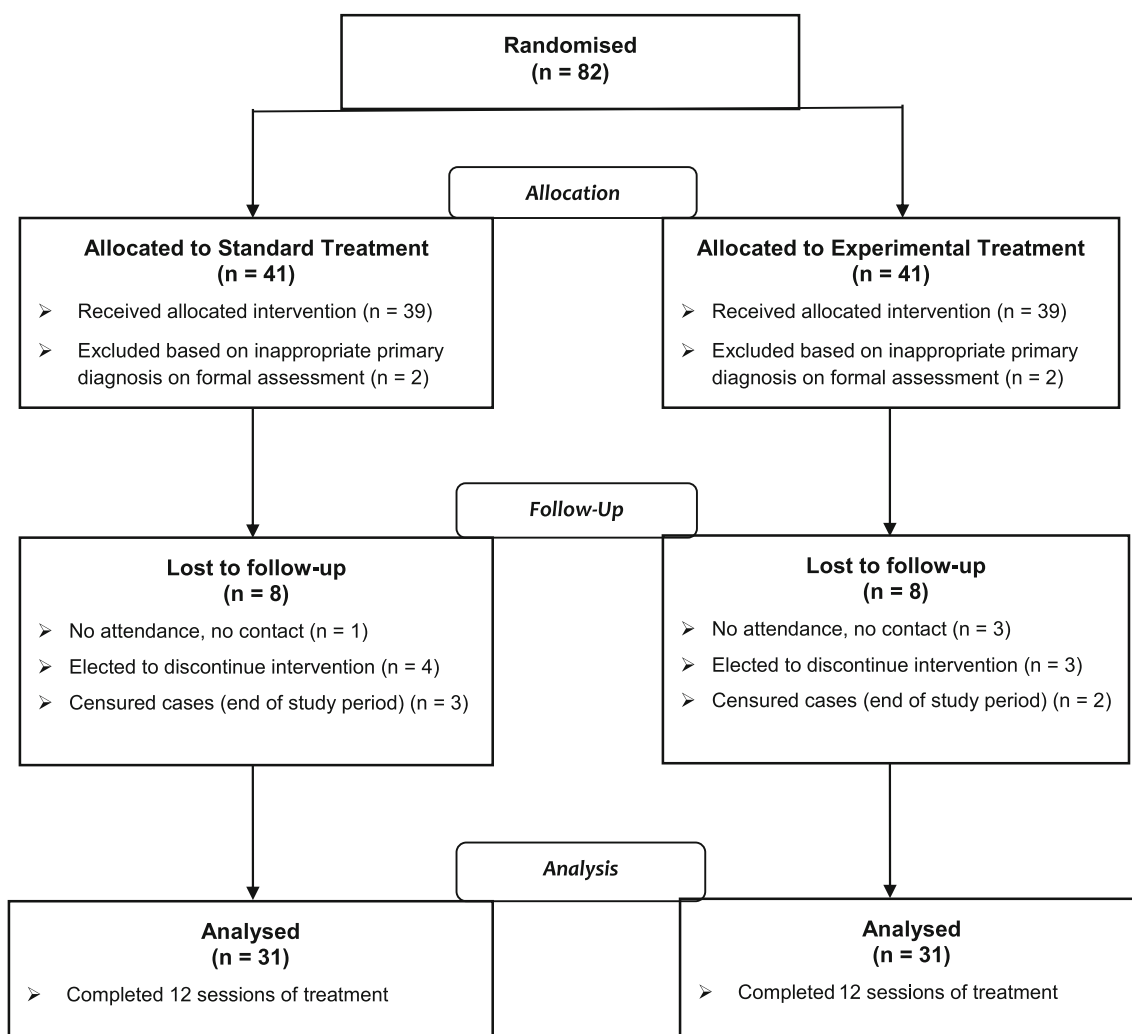
the three negatively worded subscales reverse coded (Neff, 2019; Neff et al., 2019). The full-sample internal reliabilities were 0.89 (pre-treatment) and 0.95 (post-treatment).

Kessler Psychological Distress Scale (K10; Kessler et al., 2003)

This 10-item screening instrument is capable of recognizing non-specific psychological distress (e.g., PTSD, anxiety, and

depressive disorders). Responses, scored 1 to 5, are summed to yield a total score ranging from 10 to 50, with higher scores reflecting greater psychological distress. Internal reliabilities were 0.88 (pre-treatment) and 0.89 (post-treatment).

Patient Health Questionnaire (PHQ9; Kroenke, Spitzer, & Williams, 2001) The 9-item major depression module, based

**Fig. 1** CONSORT Statement Describing Participant Selection and Retention

on DSM-IV diagnostic criteria, quantifies how often problems (e.g., ‘feeling down, depressed or hopeless’) may have bothered participants during the past two weeks (‘not at all’, ‘several days’, ‘more than half the days’, ‘nearly every day’). Scores of 0 to 3 are summed to yield a total ranging from 0 to 27. Higher scores reflect more severe depression. Internal reliabilities were 0.83 (pre-treatment) and 0.86 (post-treatment).

PTSD Checklist - Civilian (PCL-C; Weathers, Huska, & Keane, 1991) This frequently used instrument evaluates traumatic experiences and PTSD symptoms in non-combat, civilian populations (Wilkins, Lang, & Norman, 2011). It contains 17 items that are based on DSM-IV criteria for PTSD. Each item quantifies whether traumatic distress has been experienced over the previous two months using a 5-point scale (‘not at all’ to ‘very much’). In the current study the total score (range 17–85) was used to quantify symptoms. Internal reliabilities were 0.91 (pre-treatment) and 0.90 (post-treatment).

Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002) This instrument surveys five domains of functional impairment (work, home management, social leisure activities, private leisure activities, and family and relationships). A 9-point response scale for each of the five items (0 = ‘not at all’ to 8 = ‘very severely’) provides an overall score ranging from 0 to 40, with higher scores reflecting greater impairment. Internal reliabilities were 0.80 (pre-treatment) and 0.85 (post-treatment).

Results

Sample Description and Pre-Treatment Randomization Check

Mean age at referral was 37.2 years ($SD = 13.5$) for the standard treatment group and 40.3 years ($SD = 12.0$) for the experimental group. These means did not differ significantly ($t_{(60)} = 0.97$, ns). While the study comprised predominantly women ($n = 46$, 74.2%), the proportions did not differ between treatment groups ($\chi^2_{(1)} = 0.08$, ns). This was also true for marital status ($\chi^2_{(1)} = 1.49$, ns), for which only 17 participants (27.4%) reported having a partner. The dominant level of educational attainment was secondary school ($n = 28$, 45.2%), while 22 participants were students (35.5%) and 19 participants were employed on a part-time basis (30.6%). Neither education level ($\chi^2_{(2)} = 1.63$, ns) nor employment status ($\chi^2_{(4)} = 3.68$, ns) differed between treatment groups.

A series of *t* tests (Table 2) indicated that other study variables also largely demonstrated pre-treatment equivalence, although there was a significant group difference for SC such that, at the commencement of the study, those to receive

standard treatment reported higher SC than those to receive the experimental treatment.

Intervention Effectiveness

SC was assessed for differential change that may be attributable to the intervention. While there was an overall significant effect for time (but not treatment), of more importance was the significant interaction demonstrating a greater increase in SC over time among the experimental group, relative to the standard group, suggesting that the introduction of SC training to the intervention group was effective (Table 2 and Fig. 2).

Trial Results

Post-treatment data are also shown in Table 2 along with evaluations of change (ANOVAs) for the K10, PHQ9, PLC-C, and WSAS. A significant group by time interaction was noted for each measure; suggesting greater improvement in general psychological wellbeing, depression, PTSD symptoms, and functional impairment in the experimental group relative to standard treatment (see also Fig. 3). Note that these effects were independent of diagnosis.

Potential Effects of Diagnosis and Therapist

The above analyses were repeated by first including diagnostic group (depressive disorder, PTSD) and then therapist (A, B) to determine if any effects might be attributable to these variables. Note, however, that neither diagnosis nor therapist was appropriately powered to provide significant effects. Indeed, only a single significant interaction between time and diagnosis was noted ($F_{(1,58)} = 5.15$, $p = .027$). For PLC-C, participants with PTSD reduced their symptoms more (Mean = 58.8, $SD = 13.7$ to Mean = 41.6, $SD = 10.2$), relative to those with a depressive disorder (Mean = 52.8, $SD = 13.9$ to Mean = 35.9, $SD = 9.8$). Clearly the PLC-C is a measure more relevant to those with a specific PTSD diagnosis. There were no significant effects involving therapist.

Discussion

The reported RCT compared a local standard treatment protocol (CT with BT) and a new, third wave approach to CBT comprising self-compassion training with BT (the experimental treatment). This comparison was prompted by a body of literature suggesting that some individuals, such as those who engage in greater self-criticism and experience complex psychopathology, respond better when interventions are included that deliberately target activation of the (self) compassion system(s), thought to play a role in the healthy regulation of threat and drive systems implicated in many psychopathologies

Table 2 Pre-treatment group comparisons

	Standard pre-treatment (n=30)		Experimental pre-treatment (n=31)		t	Standard post-treatment (n=30)		Experimental post-treatment (n=31)		F _{treatment}	F _{time}	F _{interaction}
	Mean	(SD)	Mean	(SD)		Mean	(SD)	Mean	(SD)			
SC	63.4	(11.5)	53.4	(11.0)	3.45**	72.5	(15.4)	86.9	(14.2)	0.61	146.31***	47.82***
K10	32.7	(7.7)	35.2	(7.1)	1.28	26.0	(6.8)	20.7	(5.2)	0.99	126.20***	16.80***
PHQ9	17.0	(6.1)	17.8	(4.7)	0.56	10.1	(5.1)	7.5	(4.0)	0.67	203.69***	7.79**
PCL-C	56.7	(15.3)	61.0	(11.8)	1.25	42.0	(9.9)	35.4	(9.8)	0.18	172.49***	12.60***
WSAS	21.5	(9.2)	24.5	(8.2)	1.37	15.1	(8.8)	10.8	(6.5)	0.13	96.78***	13.08***

Note. ** $p < .01$, *** $p < .001$

(Ferrari et al., 2019; Gilbert, 2009, 2010; Kirby et al., 2017). Key features included the use of a relatively homogenous, clinically derived cohort to examine the extent to which clients with a complex psychopathology experienced greater improvement after experimental treatment as opposed to those who had received standard treatment (Diedrich et al., 2016; Ferrari et al., 2019; Krieger et al., 2016; MacBeth & Gumley, 2012; Valdez & Lilly, 2016).

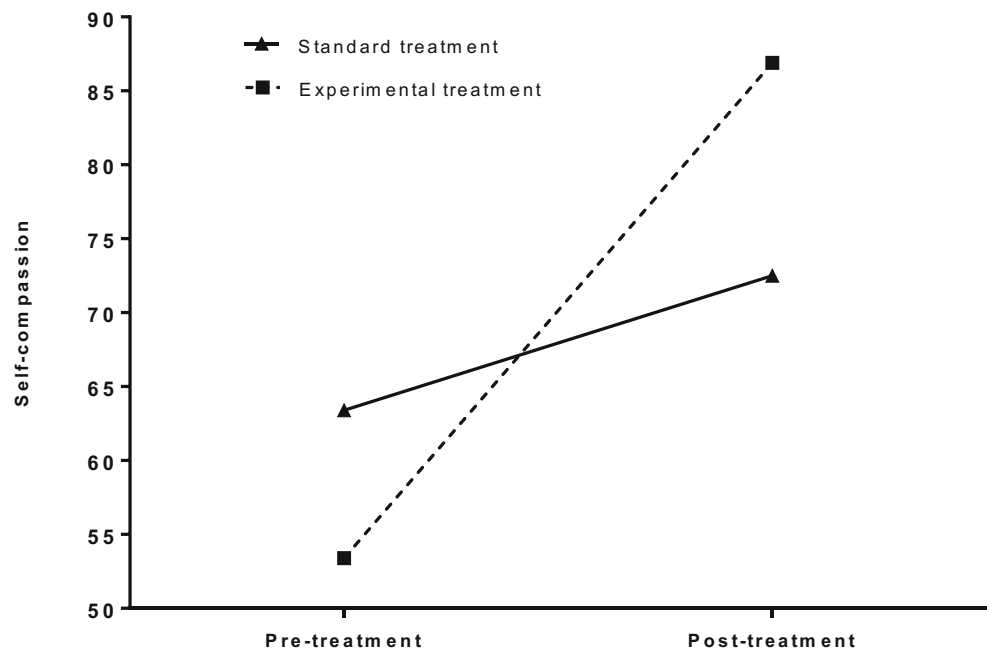
The obtained results demonstrated self-reported improvements in both study groups across all of general psychological distress (K10), depression (PHQ9), symptoms of PTSD (PCL-C), and functional impairment (WSAS), regardless of initial diagnosis (depressive disorder or PTSD). However, this improvement was significantly better among those whose treatment included training in SC. The observation that both groups improved their level of SC is perhaps suggestive that SC may be a general characteristic that has the potential for enhancement even when not taught directly (Finlay-Jones,

2017; Marsh, Chan, & MacBeth, 2018). Nevertheless, the greater improvement among those receiving the experimental treatment allows the conclusion that the change was due to the intervention.

Overall, the reported findings help to support the potential value of self-compassion training, in this circumstance when combined with BT, to the treatment of complex psychopathology. That is, the evidence supported the uptake of SC with BT, with a clinically greater increase in SC for individuals from pre- to post-treatment in the experimental group (Ferrari et al., 2019; Gilbert and Choden, 2013; Kirby et al., 2017; Marsh et al., 2018).

Such findings are important as they serve to augment the growing body of evidence for novel treatment modalities such as the combination of self-compassion training with other evidence-based therapies (Ferrari et al., 2019; Kirby et al., 2017). The results are of additional importance due to the need to apply techniques that are cost effective as well as

Fig. 2 Demonstration of Greater Improvement in SC for the Experimental Group Relative to the Standard Group



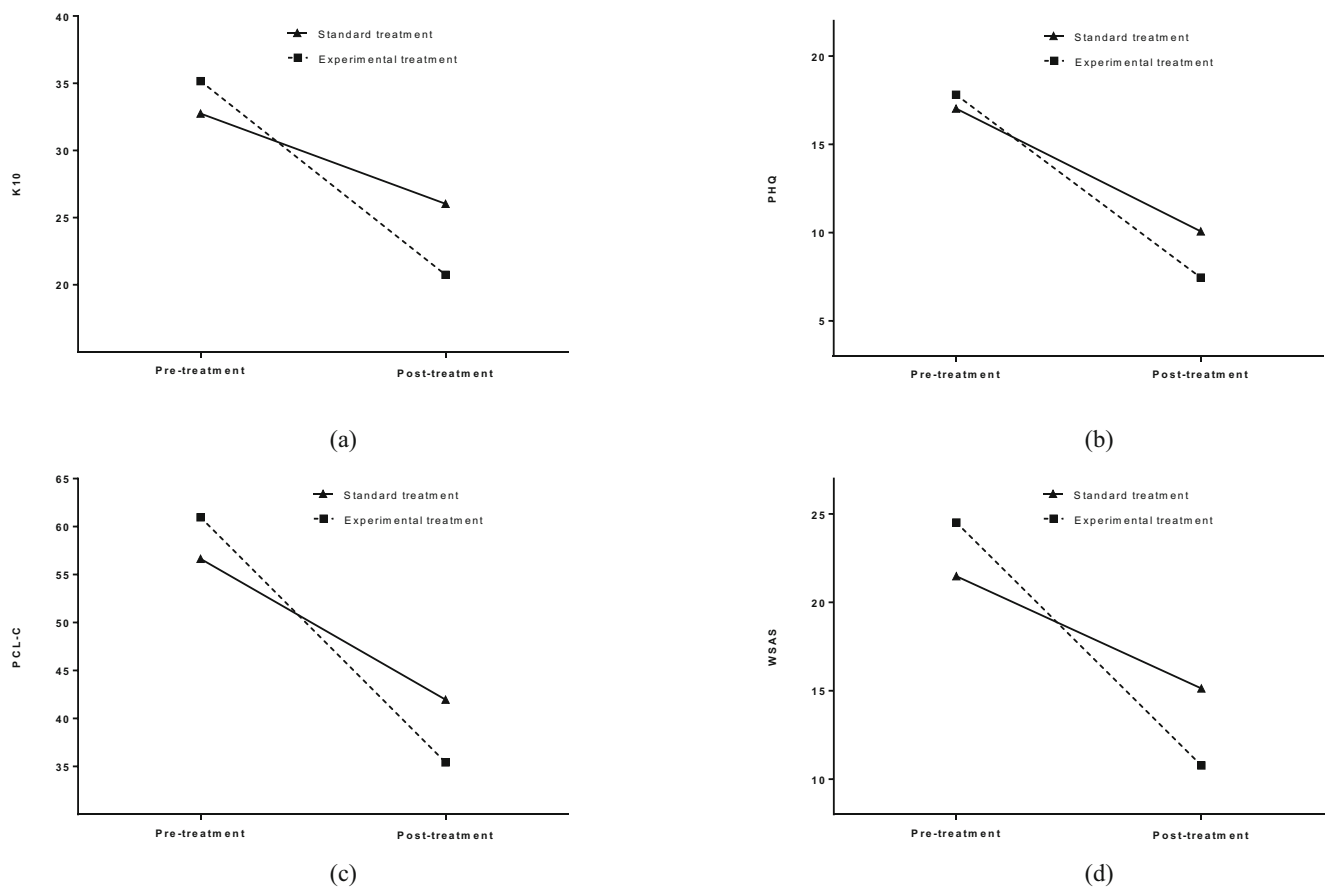


Fig. 3 Demonstration of Greater Improvement in Clinical Severity Measures for the Experimental Group Relative to the Standard Group for **a** K10; **b** PHQ9; **c** PCL-C; **d** WSAS

therapeutically effective, particularly for publicly funded clinics such as the context of the current study. Given the high demand for services, there is a need to minimise attrition and recurrence in such public clinics. Treatment options that promote psychological functioning and wellbeing, rather than focusing on recovery from the disorder alone, and that can be delivered within the allowable 12 session treatment program are therefore very attractive (Bluth & Neff, 2018; Koszycki et al., 2016; Marsh et al., 2018). Therapeutic programs must also engender a willingness and enthusiasm to participate on the part of clients, thus resulting in the best use of public funds.

Limitations

A key shortcoming was the significant difference in pre-treatment SC reported by the standard and experimental groups, with SC higher for the standard treatment group prior to participation in the trial. Such an effect compromises the interpretation of results and is difficult to account for. Although the most plausible source of this difference is random error, it may nevertheless have offered some clinical advantage and contributed to smaller overall differences

between the two groups across time, thus acting against hypothesis. A further potential limitation was the use of the same therapists to deliver both treatments. While this strategy offers the benefit of comparability, two points are noted. First, the onus was on the individual therapists to quarantine strategies relevant for use with each intervention protocol. There was therefore a noted challenge to the therapists to present appropriate material to each client depending on the randomisation outcome. Second, while having received formal training in compassion and self-compassion-based intervention (MBCT, CFT, and MSC), both therapists were far more experienced in the CBT techniques relevant to the standard intervention which may have created a source of bias.

Third, the study compared SC with only one of many cognitive-based interventions. For example, while cognitive processing therapy (CPT) was not considered, it represents a well-established CT-based intervention for PTSD. CPT addresses strong emotional loads that are the result of exposure to trauma and/or act as barriers to recovery-related beliefs (Monson et al., 2006; Resick et al., 2015; Resick & Schnicke, 1992). Researchers are encouraged to compare SC with CPT in future studies, particularly when the primary focus is PTSD.

A final limitation concerns the presentation of both interventions as standard 12-session CARD programs. This was largely a pragmatic decision although it again offered comparability across the two arms of the study. However, there is no theoretical reason why two quite different interventions should, per se, require the same number of sessions. The implementation of all relevant components of MSC and/or CFT may in fact require an increase in the number of allowable sessions.

Future Research

For the current research, complex cases (depressive disorders and PTSD) were chosen for inclusion. This may have impacted on the level of improvement achieved, but also does not represent the range of clients who may potentially benefit from the experimental treatment, or indeed variants of it. Future studies could therefore usefully examine other clinical cohorts to better establish the characteristics of clients for whom such interventions are best suited. This information may allow a more informed choice about the types of intervention appropriate to specific client groups. For example, research could be conducted using clients who have already displayed treatment resistance to standard CBT interventions to determine whether they benefit from a more self-compassion-based intervention. Additionally, the inclusion of follow-up assessments would allow a determination of whether the addition of self-compassion training to treatment protocols contributes to the maintenance of improvements or recovery from psychopathology beyond the treatment endpoint, or indeed to an ongoing strengthening of treatment gains with clients being able to apply their SC-derived skills in later contexts.

Finally, as supported by Gilbert (2010) and Neff (2003b), the key mechanism of change in SC interventions is the development of an attuned and compassionate relationship to self and the experiences associated with psychological distress (e.g., depression, PTSD). To this end, multifaceted lower-order mechanisms of change are sought, some of which are primarily cognitive in their target (e.g., asking clients to consider how they would treat a friend, compassionate letter writing). However, such approaches are likely to differ from traditional CT in their effectiveness, in terms of striving to cultivate a congruent inner emotional tone and felt experience; and hence a more thorough integration of cognitive and emotional processing (McLean, Steindl, & Bambling, 2018). These potential mechanisms of action would be a worthy focus of future research.

Summary

An RCT designed to compare treatment outcomes for experimental (SC with BT) and standard (CT with BT)

interventions for individuals with PTSD and/or a depressive disorder demonstrated greater improvement in SC and severity for the experimental group compared with those who received standard CBT, highlighting the potential role of CFT in the management of complex psychopathologies.

Data Availability The data reported in this study are available from the author upon reasonable request.

Declarations

Ethical Approval All procedures described were in accordance with the ethical standards of the institutional research committees of the authors and the 1964 Helsinki declaration and its later amendments, or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors report no conflicts of interest.

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