Digital-Based Interventions for Complex Post-Traumatic Stress Disorder: Protocol for a
Systematic Literature Review

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Abstract

The 11th edition of the International Classification of Disease has included Complex Post-Traumatic Stress Disorder (cPTSD) as a clinical diagnosis separate to Post-Traumatic Stress Disorder (PTSD). Research has shown that cPTSD differs significantly from PTSD on core symptoms relating to the individual's sense of self; which has driven research investigating treatment approaches to address these specific features of cPTSD. Evidence for effective treatments for cPTSD delivered within in-person settings has been synthesised, however, authors have noted significant access barriers to such specialised treatments. Digital-based intervention (DBI) approaches may overcome such access barriers and have shown effectiveness in treating non-complex PTSD across several systematic reviews and meta-analyses. The current protocol however, proposes a methodology for conducting the first systematic review of research investigating the use of DBIs for treating cPTSD, as there has not yet been a comprehensive synthesis of this research. The review seeks to understand (1) the treatment approaches employed in DBIs for addressing symptoms of cPTSD, (2) the symptoms of cPTSD that are targeted by DBIs, (3) the evidence for the acceptability and effectiveness of DBIs in treating symptoms of cPTSD, and (4) measures taken to ensure the safe and confidential delivery of DBIs for cPTSD. A systematic search of Scopus, PsychINFO, and EBSCOhost is proposed, using search terms targeting 'cPTSD' and 'DBIs'. Literature will be screened against eligibility criteria by two independent reviewers and included studies will be assessed for quality using the Quality Assessment Tool for Quantitative Studies. Data will be extracted by the same two reviewers, then analysed and synthesised in narrative form by a single reviewer. The findings from the systematic review will provide an understanding of the state of current evidence and inform directions for direct future research aiming to develop effective DBIs for cPTSD.

Complex Post-Traumatic Stress Disorder (cPTSD) refers to a cluster of symptoms associated with traumatic experiences which are chronic/prolonged and interpersonal in nature (Ford, 2017). These experiences are difficult, or impossible to escape from, due to physical, psychological, financial, or societal restraints (e.g., childhood abuse, intimate partner violence, war imprisonment) (Herman, 1992). In contrast, Post-Traumatic Stress Disorder (PTSD) ordinarily results from single incident traumas which are either impersonal or interpersonal (e.g., motor vehicle accidents, natural disasters, robbery) (Ford, 2017). Due to the chronic and interpersonal nature of their trauma, compared to individuals experiencing PTSD, those experiencing cPTSD show a disorganisation of their sense of self and how they relate to the world (Ford, 2017). This necessitates tailored treatment options to adequately address the symptoms unique to cPTSD. Delivering such treatments through digital-based interventions (DBIs) would help overcome some of the barriers to in-person treatments which this population currently face (e.g., financial limitations, stigma, and fear). However, while we have considerable evidence for the use of DBIs for the treatment of PTSD (e.g. Kuester et al. (2016), research investigating the efficacy of these approaches for cPTSD has not yet been synthesised. Therefore, this protocol outlines a methodology for conducting the first systematic review of literature investigating DBIs for cPTSD.

The Nature of Complex Post-Traumatic Stress Disorder

Although first suggested by Herman in 1992, cPTSD has only recently been included as a clinical diagnosis separate to PTSD, within the latest edition of the International Classification of Disease (ICD-11); released in 2018 and scheduled for use in January 2022 (World Health Organization, 2018). The ICD-11 characterises cPTSD as comprised of six core symptoms, inclusive of the three core symptoms of PTSD; (1) re-experiencing of the trauma – through flashbacks or nightmares; (2) avoidance – of any reminder of the trauma, either external places/people or internal thoughts; and (3) a continuous sense of threat –

displayed as hyperarousal or being easily startled (Maercker et al., 2013). Differentiating cPTSD from PTSD however, are three additional core symptoms, which reflect a disturbance in self-organization (DSO): (1) affect dysregulation – exaggerated or diminished emotional responses; (2) negative self-concept – feelings of failure, worthlessness, guilt or shame; and (3) interpersonal disturbances – difficulty establishing or maintaining relationships (Maercker et al., 2013). A diagnosis of cPTSD requires the individual to experience at least two of the core PTSD symptoms, and all three of the DSO symptoms (Ford, 2017). The ICD-11's differentiation between cPTSD and PTSD has been demonstrated across a large body of work; see Brewin et al. (2017) for a review.

In terms of clinical characteristics, prevalence rates of cPTSD have been found to range from 0.5% to 1% within community-based samples (Hyland, Murphy, et al., 2017; Maercker et al., 2018; Wolf et al., 2015) and between 2.6% to 42.8% within clinical samples (Ben-Ezra et al., 2018; Hyland et al., 2018; Hyland, Shevlin, et al., 2017; Karatzias et al., 2016; Nickerson et al., 2016). Further, current evidence indicates that functional impairment resulting from cPTSD tends to be greater than that of PTSD (Cloitre et al., 2013; Cloitre et al., 2014; Perkonig et al., 2016). Compared to individuals diagnosed with PTSD for example, those with cPTSD have been found to have lower levels of education and self-reported socioeconomic status (SES), higher rates of unemployment, and are more likely to be unmarried and live alone (Karatzias et al., 2016; Perkonig et al., 2016).

Following release of the ICD-11's classification of cPTSD and emerging literature highlighting the functional impact of this disorder beyond that of non-complex PTSD, questions of effective treatment approaches for cPTSD have begun to attract both clinical and research attention. Summarising this literature, Karatzias et al. (2019) systematically reviewed and meta-analysed 51 randomised control trials investigating the effectiveness of in-person psychological interventions for individuals diagnosed with PTSD, who were also

assessed as experiencing clinically significant disturbances in one or more of the DSO symptoms indicative of cPTSD. Whilst not specific to a cPTSD diagnosis, the authors found that trauma-focused therapies such as Cognitive Behavioural Therapy (CBT), Exposure Therapy, and Eye Movement Desensitisation and Reprocessing therapy (EMDR) were all superior to treatment as usual (TAU) for reducing both PTSD symptoms and two of the DSO symptoms specific to cPTSD; negative self-concept and interpersonal disturbances. However, insufficient data were available to review the effectiveness of these therapies for improving the third DSO symptom, affect regulation. Others have also highlighted that in addition to considering the effectiveness of trauma-focused approaches for cPTSD, phase-based approaches may need to be considered (see De Jongh et al. (2016) for a critical review).

Digital-Based Interventions for Trauma

The use of DBIs for treating different mental health disorders is a growing field of interest (Ebert et al., 2018). These approaches are delivered by a variety of technologies and provide consumers with choice in accessing self-help and human-supported mental health support. As such, the descriptors for DBIs are diverse and interchangeably use umbrella terms such as e-Health, e-Mental Health, e-Therapy; with technology centric terminology, e.g., internet/online/tele/computer/cyber/electronic/mobile/web -based interventions. For the purpose of this review, DBIs refer to the use of digital technologies such as computers, smart phones and tablets to remotely deliver interventions based on psychological frameworks. We have adopted ‘digital-based interventions’ in order to encompass both interventions that require a connection to the internet and those which do not. DBIs also vary in terms of their level of human support, from completely self-guided, including the support of automated systems (e.g., notifications and prompts), to including the support of a human (e.g., peers, coach, trained clinicians). Further, how the human support is delivered may vary, both in

terms of scope (e.g., supportive check-ins, therapeutic contact) and communication modality (e.g., video-conferencing, text-chat functions, email) (Andersson, 2016).

Whilst trauma-focused psychotherapies show promise for treating cPTSD, current reviews have focused on studies investigating these approaches delivered within in-person settings, with a synthesis of research on DBI approaches for this population currently lacking. In contrast, eight systematic reviews and meta-analyses investigating DBIs for non-complex PTSD have been published since 2016 (Kuester et al., 2016; Lewis et al., 2019; Sijbrandij et al., 2016; Simblett et al., 2017; Simon et al., 2019; Turgoose et al., 2018; Wickersham et al., 2019; Young & Campbell, 2018), with a ninth currently under development (Steubl et al., 2019). Across these reviews, the literature supports the effectiveness of internet-based CBT (i-CBT) for reducing symptoms of PTSD, showing superiority to TAU/waitlist conditions, and equal effectiveness to in-person CBT (Knaevelsrud & Maercker, 2007; Kuester et al., 2016; Lewis et al., 2018; Lewis et al., 2019; Sijbrandij et al., 2016; Simblett et al., 2017; Young & Campbell, 2018). As a result, i-CBT has recently been added to the treatment guidelines for PTSD, published by the International Society for Traumatic Stress (ISTSS, 2018). Furthermore, DBIs such as teletherapy (counselling via videoconferencing or the telephone) and mobile apps have also shown efficacy in treating symptoms of PTSD (Kuhn et al., 2018; Simblett et al., 2017; Turgoose et al., 2018). However, one review found the efficacy of mobile apps for the treatment of PTSD to be weak (Wickersham et al., 2019); though, notably, this review included only five studies, two of which were pilot studies limited by small sample sizes.

On the whole, DBIs for PTSD have been shown to be effective and indicate that DBIs may also be effective for the treatment of cPTSD. As discussed by others, DBIs for cPTSD provide an opportunity to overcome barriers to traditional in-person treatments, such as financial limitations, stigma, fear, and limited availability of qualified therapists (either due to

long treatment waitlists or remote location) (Lewis et al., 2019; Simon et al., 2019; Steubl et al., 2019). However, the lack of synthesis of research in this area to date, leaves it unclear what types of DBIs have been used for the cPTSD population thus far, what psychological frameworks they have followed, and whether they have shown effectiveness in reducing cPTSD symptoms overall. Conducting a review of such research is challenged by the lack of homogeneity in terminology used across the literature prior to the introduction of the ICD-11's cPTSD label. That is, the characteristic presentation of cPTSD has been labelled in the past by terms such as: Herman's (1992) 'complex trauma'; the ICD-10's 'Enduring Personality Change after Catastrophic Experience' (EPCACE) (World Health Organization, 1992); the Diagnostic and Statistical Manual of Mental Disorders' (4th ed.) 'Disorders of Extreme Stress Not Otherwise Specified' (DESNOS) (American Psychiatric Association, 2000) and; Van Der Kolk's (2005) 'developmental trauma disorder'.

The current review aims to address this gap in understanding through conducting the first systematic search of the literature, aiming to identify and synthesise research which has investigated DBI approaches for the treatment of symptoms which reflect those outlined within the ICD-11's cPTSD diagnosis (regardless of whether samples were labelled with cPTSD specifically). Findings from the review will improve the understanding of the maturity of DBI approaches for addressing cPTSD and provide guidance for future research aiming to investigate the efficacy of current DBIs, as well as those aiming to develop new DBIs for this population. The specific research questions addressed will include: (1) What treatment approaches do DBIs for cPTSD symptoms follow; (2) What symptoms of cPTSD do DBIs target; (3) What is the efficacy and acceptability of DBIs for cPTSD symptoms; and (4) What processes are employed to ensure the safe and confidential delivery of DBIs for those experiencing symptoms of cPTSD?

Method

This systematic review has been registered with PROSPERO, the International Prospective Register of Systematic Reviews (Prospero, 2016) (registration number: CRD42020172921). Further, the present protocol follows the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P); a checklist for which can be found on page 24 of Shamseer et al.'s (2015) guidelines.

Information Sources and Search Strategy

The literature for the systematic review will be compiled through a systematic search of the following databases: Scopus, EBSCOhost and PsychINFO. Across all searches, results will be limited to those published from 2005 to 2020. The cluster of search terms used across the databases are outlined in Table 1 and reflect potential synonyms for cPTSD and DBIs. The DBI terms are split into 'digital' and 'intervention' clusters to account for the extensive variability in how these interventions are referred to across the literature (e.g. 'internet-based...' vs. 'internet delivered...' vs. '...delivered via the internet').

Two independent reviewers (MB and KDB) will use Rayyan (Ouzzani et al., 2016) to screen the compiled literature against the eligibility criteria. Rayyan is an online tool which allows independent reviewers to blindly sort literature into include, exclude and maybe folders, and to label each excluded article with a reason for exclusion. Rayyan also allows for the identification and removal of duplicates. First, the reviewers will begin by screening the title and abstract of each study, then review the full text of all articles placed in the include and maybe folders. Any discrepancies between reviewers will be discussed and resolved, with the input of a supervising author (MN) where required.

Following screening, a search for potentially relevant but uncaptured studies will be conducted through a backward search of the reference lists of included studies, as well as a forward search of articles which have cited the retained studies. The reference lists of

relevant systematic reviews and meta-analyses will also be searched. Finally, the database searches will be saved, and the alert function will be used so the authors are notified whenever a new article is added to the database that matches the search. A flow chart outlining the selection process will be presented within the final review.

Table 1.

Search Terms Entered into the Databases for the Systematic Literature Search

Line 1	“complex post-traumatic stress disorder” OR “complex posttraumatic stress disorder” OR CPTSD OR “C-PTSD” OR “complex ptsd” OR “complex trauma” OR DESNOS OR “disorders of extreme stress not otherwise specified” OR “enduring personality change after catastrophic experience” OR EPCACE OR “developmental trauma disorder” AND
Line 2	online OR internet OR web OR digital OR virtual OR computer* OR email OR tele* OR cyber OR electronic OR mobile OR eTherapy OR “e-Therapy” OR eHealth OR “e- Health” OR “e-Mental” OR eMental OR “self-help” AND
Line 3	therap* OR intervention OR treatment

Eligibility Criteria

Participants. Studies eligible for inclusion are required to have recruited participants with a primary diagnosis of cPTSD, with or without other comorbidities. Studies which assessed participants for cPTSD using a measure which reflects the ICD-11 diagnostic criteria are preferable; e.g. The International Trauma Questionnaire (Cloitre et al., in press). However, as the ICD-11’s diagnosis was only released in 2018, to capture relevant studies published before this, eligibility also includes studies which assessed participants for cPTSD based on them having a history of exposure to complex trauma (i.e. prolonged and

interpersonal). Such studies must however, have provided outcome measures for at least one of the symptoms of cPTSD which differentiate it from PTSD (i.e. the DSO symptoms). This approach is similar to that employed by Karatzias et al. (2019) in their systematic review and meta-analysis of in-person psychological interventions for cPTSD. Studies whose participants were assessed as having subthreshold cPTSD are also eligible, provided the outcomes of interest were reported (see below).

Interventions. Eligibility for inclusion in this review requires studies to have investigated remotely delivered DBIs for cPTSD. Such interventions may include those that were completely self-guided (i.e. no support or guidance from a therapist), as well as interventions with either synchronous or asynchronous human guidance/support (e.g. psychotherapy delivered via videoconference or feedback provided via email). Studies which investigated DBIs that address one or more of the core symptom of cPTSD are eligible for inclusion. Studies are not eligible for inclusion if they investigated the use of digital media as an organically occurring mental health support (e.g. online support groups, social media communities), or that are not based on a psychological framework (e.g., supportive counselling via videoconference).

Outcomes. Studies are eligible for inclusion provided they reported the outcome of the DBI on at least one of the three core DSO symptoms of cPTSD; provided participant eligibility criteria have also been met. Outcomes may be measured either by self-report or clinician-ratings. In addition to the efficacy of DBIs, the current review is also interested in the acceptability of these interventions for individuals experiencing cPTSD. Therefore, studies are also eligible if they reported acceptability outcomes only, such as dropout rates, client satisfaction scales, or adverse event reporting.

Comparators. Studies eligible for inclusion may analyse outcomes against any of three types of comparators: (1) waitlist conditions or treatment as usual (TAU), (2) active

treatment groups, such as in-person interventions or digital interventions not based on a psychological framework (e.g., supportive counselling via videoconference, relaxation techniques, online support groups), or (3) comparison across pre- and post-intervention measures within the same group.

Research Design. Eligibility for inclusion in the review requires studies to have employed either a randomised control trial, a controlled trial, or a repeated measures research design. Case studies and qualitative research designs are also eligible for inclusion in the review, as such studies are likely to include data relevant to the third and fourth hypotheses; e.g., comments on risk management strategies, client satisfaction ratings, and adverse event reporting. Meta-analyses and literature reviews will be excluded from the review; however, they will be screened for inclusion of relevant studies not captured within the initial searches. Finally, studies must be published in English, in a peer-reviewed journal.

Data Extraction

Data will be extracted by two independent reviewers (MB and KDB) and will fall under three main categories: participant data, intervention related data, and outcome data. Participant data will include: sample sizes, age, gender, ethnicity, recruitment strategy, trauma experienced, and technique for assessing cPTSD. Intervention related data will include: therapeutic approach taken (e.g. CBT, ACT, EMDR, etc.), duration of treatment, number of sessions, duration of sessions, details of any human support, whether there were any in-person components, technologies used (e.g. email correspondence, videoconferencing, website login, mobile application etc), clinical variation from in-person protocols described, and any risk management and mitigation strategies taken. Should an included paper not report the measures taken to ensure safe delivery of the DBI, the authors of the paper will be contacted for additional information. Finally, outcome data will include: identification of the symptoms included in the analyses, pre- and post- intervention measures of symptom severity

for both the target intervention and comparators, dropout rates, client satisfaction and rating scales, and adverse event reporting. All data will be recorded and matched across reviewers, with any discrepancies resolved and overseen by a third reviewer (MN) where necessary.

Data Synthesis

An initial scan of the literature suggested to the authors that, across papers, the heterogeneity in intervention types investigated, as well as the techniques used to measure outcomes, will be too great to allow for the statistical comparisons in a meta-analysis. Therefore, data will be synthesised qualitatively in narrative form. Specific narrative techniques to be used will be decided following extraction of the data (Popay et al., 2006).

Risk of Bias Assessment

Risk of bias will be assessed by two independent reviewers (MB and KDB) using the Quality Assessment Tool for Quantitative Studies (QATQS), developed by the Effective Public Health Practice Project (1998). The QATQS requires two reviewers to independently rate each included study as being 'strong', 'moderate', or 'weak' on six components: (A) selection bias, (B) study design, (C) confounders, (D) blinding, (E) data collection method, and (F) withdrawals and dropouts. Each paper is then given a global rating based on the number of 'weak' ratings recorded; i.e. the paper will be rated as 'strong' overall if it receives no 'weak' ratings across the six components, 'moderate' (one 'weak' rating), or 'weak' (two or more 'weak' ratings). The two reviewers are then required to compare their component ratings for each paper, discuss/settle any discrepancies, then agree on a global rating. Within the final review, papers with a 'weak' overall rating will be excluded, unless doing so would result in less than five papers being included. In this case, such papers will be included, however, their limitations will be highlighted. Risk of bias ratings for all included studies will be displayed within the results section of the final review.

Dissemination and Amendments

The findings of this systematic literature review will be submitted to a peer-reviewed journal for publication, which will be made available electronically and in-print. The review will also be included as part of the first author's thesis, to meet the requirements of their Doctor of Philosophy; thesis by publication. Finally, any amendments which occur to this protocol will have the date, description, and rationale for change recorded and discussed in the methods section of the systematic review.

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