Short-term Psychodynamic Psychotherapy for Functional Somatic Disorders: A Meta-analysis of Randomized Controlled Trials

Running Head: STPP for Functional Somatic Disorders

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Word Count: 3549

Key words: short-term psychodynamic psychotherapy, somatoform disorders, somatization, somatic symptom disorders, medically unexplained symptoms, functional somatic disorders, emotion, alexithymia

Acknowledgements: This research was supported by the Dalhousie University Department of Psychiatry and the Nova Scotia Department of Health and Wellness.

Conflicts of Interest: Some of the authors (AA, JT, AC, ML, HS) provide training in short-term psychodynamic therapy methods

Abstract

Introduction: Functional somatic disorders (FSD) are common and costly, thereby driving the need for the development of effective brief treatment options. Short-term Psychodynamic Psychotherapy (STPP) is one candidate treatment method. ***Objective:*** To review and meta-analyse, where possible, randomized controlled trials (RCTs) of STPP for FSD. ***Methods***: Following a systematic search of the literature, we performed a meta-analysis of available groups of RCTs of the effects of STPP on a range of outcomes at post-treatment, medium- and long-term follow-up. ***Results:*** In meta-analyses of 17 RCTs, STPP significantly outperformed minimal treatment, treatment-as-usual or waitlist controls on somatic symptom measures at all time frames, with small to large magnitude effect sizes. Descriptive reviews of five RCTs suggest that STPP performed at least as well as other bona fide psychological therapies. Limitations of this meta-analysis include small samples of studies and possible publication bias. ***Conclusions:*** STPP is a valid treatment option for diverse FSD conditions resulting in somatic symptom reductions that persist over time. STPP should be included in FSD treatment guidelines.

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Introduction

Functional somatic disorders (FSD) are a collection of conditions with distressing symptoms related to functional impairments in neurobiological systems implicated in pain and emotion regulation. FSD is an umbrella term that includes somatoform disorders, psychophysiological disorders, so-called medically unexplained symptoms, and most conditions under the rubric of DSM-5 somatic symptom and related disorders [1]. These conditions account for up to one-half of primary care visits and medical consultations as well as an excess of hospital days, medications, investigations, and disability costs [2-4]. Given the major health system and patient burden of these disorders coupled with access limitations to public mental health services, the establishment of efficacious short-term therapies is of prime importance [5].

Short-term psychodynamic psychotherapies (STPP) are treatments of 40 or fewer sessions that emphasize psychodynamic concepts and techniques. These interventions share a focus on emotional and relational processes that are linked to developmental deficits, unresolved conflicts, and past adverse experiences. These methods commonly use the triangle of conflict linking feelings, anxiety and defenses, and the triangle of person linking past, current and therapeutic relationship experiences [6]. The methods also emphasize unconscious content in terms of thoughts, fantasies and feelings tied to adverse life events. The range of techniques used in STPP include supportive techniques, interpretation, challenge to defenses, efforts to develop insight, and efforts to experience and express unprocessed feelings related to adverse events and psychological conflicts (See Figure 1). These treatment elements are distinguishable from cognitive behavioral therapy techniques [7]. For these reasons, STPP is considered a type of therapy that is distinct and can be studied as a collection even while technical treatment details vary among STPP subtypes [8]. Some forms of STPP, such as Intensive Short-term Dynamic Psychotherapy (ISTDP) [9, 10] and Emotional Awareness and Expression Therapy (EAET) [11] emphasize helping the patient to somatically experience and process unconscious feelings to correct emotion dysregulation underlying somatic symptoms in FSD [12] while other methods such as Time Limited Dynamic Psychotherapy [13], Luborsky's Supportive Expressive Therapy

[14] and Malan's Short-term Dynamic Psychotherapy [6] emphasize building insight into unconscious processes more so than emotional experiencing.

STPP methods have been studied in over 250 randomized controlled trials for a wide range of conditions [15]. STPP has been found efficacious for depression [16], anxiety [17], personality disorders [18] and common mental disorders in general [8]. In 2009, we reported on 23 trials of STPP for mixed somatic conditions and found it to be effective and superior to controls, with moderate to large treatment effects that tended to be sustained or increase at follow-up [19]. That meta-analysis, however, included only 7 RCTs of FSD, whereas the others were uncontrolled or non-randomized studies, and some examined clear somatic diseases such as Crohn's disease [20] and rheumatoid arthritis [21] rather than FSD.

Alongside RCTs, meta-analyses are currently placed at a high level of evidence and are commonly used to inform treatment guidelines, despite the fact that meta-analysis is controversial because of limitations in this research method [22]. Where possible, clinical expertise integrated with a review of the literature may be more clinically useful. Along this line, Henningsen and colleagues recently reviewed the literature on FSD and concluded that emotional factors including adverse childhood experiences, attachment disorders, personality disorders and problems identifying emotions are risk factors for FSD [23]. They also concluded that treatments such as STPP, which focus on the emotional impacts of childhood adversity and personality dysfunction, may be clinically useful [23]. Given these recommendations and the need for a current estimate of the impact of STPP on FSD, here we provide an updated review and meta-analysis.

In this review, we included only RCTs and excluded studies of somatic conditions or diseases with known structural pathology. We meta-analyzed RCTs that compared STPP to treatment-as-usual/waiting list/minimal treatment and targeted somatic symptoms as the primary outcome at three separate follow-up time-points used in previous STPP meta-analyses [8]: short-term (<3 months), medium-term (3-9 months) and long-term (>9 months). We also conducted meta-analyses of subgroups of RCTs based on certain methodological features, treatment characteristics, or disorder types to determine the effects of STPP in more homogeneous samples. Finally, we provide a brief descriptive review of RCTs that compared STPP to bona fide comparator psychological interventions.

Methods

Study registration

We registered our research plan with PROSPERO, a prospective registry of systematic review protocols, prior to commencing this study (PROSPERO 2017 CRD42017083235). We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations for the background, search strategy, methods, results, discussion and conclusions [24].

Selection Criteria

We included all RCTs of adult patient populations treated with STPP. The following criteria were used: verbal face-to-face treatments informed by known STPP theorists; treatments that were 40 or fewer standard-length sessions; provided in either group or individual formats; and provided in any clinical setting. Studies had to provide outcome data. We included studies of STPP for any FSD and excluded studies of somatic conditions with known structural pathology or disease.

Search Strategy

Our prior meta-analysis covered studies published prior to 2008; for this updated review, we searched for all studies published from January 2006 through November 2019 and combined these with the search results from the 2009 meta-analysis. Such an interval allowed detection of studies published from 2006-2008 that might have been missed in the prior search window and went up to current time. All studies included in the previous review were evaluated for inclusion in this review. A broad search was conducted, and this is described in the PROSPERO registration (See Online Supplement).

Selection process

Two reviewers (PL, CD) screened titles and abstracts to confirm eligibility. Full-text versions of studies were then examined for inclusion/exclusion by pairs of reviewers (PL, AA and JT, LR). Disagreement between authors over inclusion or exclusion was discussed toward reaching consensus and when consensus could not be reached, a third author (SK) was consulted.

Data extraction

Descriptive data were extracted and tabulated by pairs of reviewers (AC, HS, ML, HH, JA, AA). The features extracted included the number and gender of patients, type of STPP, treatment duration, and follow-up intervals. Reviewers also recorded, where possible, whether or not outcome ratings were blinded, therapy was manualized, adherence ratings were performed, and the treatment placed a primary emphasis on emotion experiencing (versus the development of insight).

Raw data for effect sizes for the various outcome measures were extracted separately by a reviewer (HH) who has no affiliation with STPP. Data entry was spot checked by 2 others (AA, SK).

Outcomes

The primary outcome category was somatic symptoms. Secondary outcomes included anxiety, depression, general symptoms, interpersonal problems, physical function, quality of life and health care use and cost. Study designs were classified into the following two categories based on the control or comparison conditions used: a) treatment-as-usual/minimal treatment/wait-list, or b) bona fide active comparison psychological treatments.

Quality ratings

The quality of the included RCTs was assessed independently by 2 reviewers (AA, DB) using the Cochrane Collaboration's Assessment of Bias tool in terms of allocation concealment, blinding and the handling of withdrawals and drop outs [25]. Differences in findings were discussed to reach consensus. Further, qualitative features of RCTs were evaluated by blinded, pairs of reviewers (AA, DB, KK) based on parameters described previously in this journal [26].

Data analysis

Where data were available for 3 or more RCT studies, they were combined in a meta-analysis comparing STPP to controls/comparisons using the software program RevMan. Where STPP was compared with two different control/comparison conditions and both controls were included in an overall meta-analysis, the number of patients in the STPP condition was halved to avoid inflating numbers by double-counting patients. We classified outcomes into short-term (up

to 3 months), medium term (3-9 months) and long-term (over 9 months) [8], and measured effect size (ES) using standardized mean differences. The random effects model was used for all the analyses because we could not definitively exclude between-study variation even in the absence of statistical heterogeneity. Consistent with convention, we defined effect sizes as small (ES or *d* of 0.20-0.49), medium (ES or *d* of 0.5-0.79) and large (ES or *d* of ≥ 0.8) [27]. Significance was assessed using 95% confidence intervals, and heterogeneity by using I^2 statistic. A value of 50-70% for the I^2 statistic indicates moderate heterogeneity. We explored any heterogeneity further through sensitivity analyses of the effect of omitting each study in turn. When multiple measures were used for the same outcome, we also undertook sensitivity analyses of the effect of substituting one for the other. We tested for publication bias for our primary outcome using funnel plot asymmetry, where low *p* values suggest publication bias.

To examine more homogeneous samples, when there was a sufficient number of studies, we undertook subgroup analyses of those studies that had adherence ratings, had video or audio review, had fewer than 12 sessions, were of higher quality, used STPP that was primarily focused on emotion experiencing, or were conducted on a sample with chronic pain. These analyses were done only on the primary outcome of somatic symptoms.

Where there were not sufficient studies to combine in a meta-analysis for our primary outcome, results were summarized in a descriptive form.

Results

Characteristics of Included Studies

Our search identified 491 titles through bibliographic databases and 253 studies through other sources such as the ISRCTN trial registry (Online Supplement Figure 1). After removing duplicates, 438 records were screened, and 45 full texts were read for eligibility. Following exclusions, 17 RCTs were included for meta-analysis. These 17 studies included 2004 patients with a mean age of 42.9 years (SD 10.9), 67.5% of whom were female. These studies were generally of chronic somatic conditions present for many months to years. Six studies were of functional gastrointestinal disorders, 5 were of mixed chronic pain conditions, 2 were of fibromyalgia, 2 were of mixed somatic symptom conditions, 1 was of bruxism and 1 was of urethral syndrome with pelvic pain. Eleven RCTs had treatment-as-usual or minimal treatment conditions, and 2 had wait-list controls. Six had bona fide comparison psychological treatments:

2 compared STPP with group cognitive behavioral therapy (CBT) and one compared it to individual CBT all for chronic pain; 1 compared it to Structured Relaxation Training for IBS, 1 to Mindfulness-based Stress Reduction (MBSR) for chronic pain and one to paroxetine for irritable bowel syndrome. Treatments averaged 13.5 (SD 7.6, range 3-33) sessions. All studies had follow-up evaluations beyond post treatment; the longest follow-up assessments averaged 10.4 (SD 10.5, range 2.5-48) months (Online Supplement Table 1).

All but 2 of the RCTs delivered treatment following a specific STPP model, and all but one had a manual or guide for treatment delivery. Four RCTs (23.5%) used Psychodynamic-Interpersonal Therapy (PIT) [28], 3 (17.6%) used Intensive Short-term Dynamic Psychotherapy (ISTDP)[9, 29] , 2 used Emotional Awareness and Expression Therapy (EAET), [11], and 1 each used Short-Term Dynamic Psychotherapy (STDP) [6], Supportive Expressive Therapy [14], Time-limited Dynamic Psychotherapy [13], the Affect Consciousness Model [30], a combination of Malan's STDP plus ISTDP, and a combination of EAET plus ISTDP. Two studies had general short-term psychodynamic approaches without a specific, cited model (Online Supplement Table 1).

Study Quality

The overall quality of the RCT studies was moderate using the Cochrane Risk of Bias Tool [25]. Ten of the 17 (58.8%) studies had blinded measurement of some outcomes (6 did not, 1 unclear), 9 (52.9%) had adequate allocation concealment (7 unclear, 1 did not), 11 (64.7%) had random sequence generation such as by a computer program (3 were unclear, 3 did not), and 13 (76.4%) had complete outcome data or adjustments to correct for missing data such as intention to treat methods (3 did not, 1 unclear). It was not possible to determine if outcome reporting was complete due to lack of published protocols, except for 3 studies that did appear complete. Blinding of either therapists or patients is not possible in psychotherapy research so this was rated as absent in each case (Online Supplement Table 2).

Other measures revealed variability of study rigour. All but 1 study (94.1%) used treatment manuals or manual-like guides, 9 studies (52.9%) had adherence ratings and 9 studies (52.9%) used video or audio recording for case review and/or supervision. Sixteen of the studies (94.1%) described the longitudinal development of the somatic condition, 13 (76,4%) described past/current medication use, 11 (64.7%) described weakness of controls (4 were not applicable, 2

did not), 7 (41.1%) had objective measures, only 3 (17.6%) described adverse effects beyond drop-out rates, and only 4 (23.5%) reported rates of deterioration after treatment beyond drop-out rates. All of the studies (100%) described treatment components (Online Supplement Table 3).

Outcomes

Primary outcome: Somatic Symptoms

It was only possible to undertake meta-analyses of studies comparing STPP to minimal treatment, treatment as usual or wait-list controls. STPP outperformed minimal treatment/TAU/waitlist controls on somatic symptoms, with significant effects at all three time points. There were large effects at short-term and long-term, but small effects in the medium-term, based on a smaller sample of 4 studies. (Table 1, Online Supplement Figure 2).

RCTs of STPP versus bona fide psychological treatments were too varied to meta-analyze so we describe them herein. One well-powered RCT in fibromyalgia found that group EAET was equivalent to group CBT on the primary measure (pain severity) but had greater effects than CBT on a specific measure of fibromyalgia in follow-up [31]. In an RCT for older veterans with chronic pain, group EAET combined with ISTDP led to greater pain reduction than group CBT in short and medium-term follow-ups [32]. A well-powered study of ISTDP found it to be equivalent to individual CBT in reduction of chronic pain [33], and another, found ISTDP was superior to MBSR in reducing chronic pain in both short-term and medium-term follow-ups [34]. Finally, a study of IBS found that EAET was equal to structured relaxation training in reducing IBS symptoms [35].

Secondary Outcomes

Meta-analysis showed that on measures of anxiety and depression, STPP led to greater effects than minimal treatment/TAU/ wait list controls with significant medium to large effects at short-and long-term follow-up; effect were modest and not significant at medium term follow-up. The effects on general symptoms were large but non-significant in the short-term but large and significant in long-term follow-up. STPP also outperformed controls on measures of physical function at short-term follow-up, although this large effect was non-significant and STPP had a small, non-significant effect on physical function at long-term follow-up. As with

somatic symptoms, heterogeneity was high for the majority of these analyses. (Table 1, Online Supplement Figure 2).

Subgroup and sensitivity analyses

Subgroup analyses showed STPP was significantly superior to minimal treatment/TAU/wait list controls in studies that had adherence ratings, video or audio review, were shorter (</= 12 sessions), of higher quality, focused primarily on emotion experiencing, and conducted on pain populations. Heterogeneity was lower in these subgroup analyses, likely reflecting more uniformity of the clinical samples (Table 2).

Sensitivity analyses of somatic outcome measures examined the effect of substituting one measure for another when multiple instruments were used for the same outcome. These analyses made little difference to the findings. Similarly, our overall and subgroup results were largely unaltered on sensitivity analyses of the effect of omitting each study in turn, including the one outlier study [44]. However, heterogeneity was greatly reduced when this single outlier study was excluded. For instance, the result for overall somatic symptoms in the short term was -0.47 [-0.70, -0.23], $p<0.0001$, I^2 =55% and that for the long-term was -0.17 [-0.32, -0.02], $p<0.03$, I^2 = 9%

Publication Bias

We used funnel plots to assess possible effects of publication bias on our primary outcome. Egger's regression asymmetry test on somatic symptom measures was positive (-3.49 (90% C.I., -5.65 to -1.33, $p= 0.047$) indicating possible publication bias. We did not use trim and fill given this method performs poorly in the setting of heterogeneity [24]. We found similar results for Egger's regression asymmetry test in the case of depression (-4.04 (90% C.I., -6.39 to -1.69, $p = 0.038$) and anxiety (-4.87, 90% C.I., -7.53 to 2.2, $p = 0.029$). There was inadequate data to evaluate the case of general symptoms.

Discussion

Since the last review and meta-analysis over a decade ago [19], many new RCTs of STPP for people with FSDs have been published, reflecting increased interest in both this treatment and clinical population. We updated the original meta-analysis by adding 10 new RCTs and by

focusing only on functional somatic disorders, excluding somatic conditions with clear disease or tissue pathology. Our meta-analyses suggest that the use of STPP facilitates sustained benefits for patients with a spectrum of functional somatic disorders.

In the current meta-analyses, STPP outperformed minimal treatment/TAU/waitlist controls on reducing somatic symptoms at all follow-up time frames, including long-term follow-up (> 9 months). The positive effects of STPP were large in magnitude at both short- and long-term follow-ups, although small at medium-term. Benefits of STPP on secondary measures of anxiety, depression, general symptoms, and physical function were more variable, but often large in magnitude, and all favoured STPP. Statistically significant benefits of STPP were observed when meta-analyses examined subgroups of studies that were much more homogeneous, including studies that were of higher quality, used audio or video review, rated adherence, and had STPP that was of shorter duration or focused on emotion experiencing. In 5 head-to-head RCTs, STPP appeared to be at least as effective as bona fide psychological treatments in reducing somatic symptoms such as pain. Overall, the current analyses make a good case that the use of STPP has a substantial treatment effect for FSDs.

It is difficult to compare the findings of the current meta-analysis to those of the previous one [19]. That earlier meta-analysis included numerous non-randomized and uncontrolled trials as well as several studies of somatic conditions with disease or structural pathology. The current analyses included only RCTs—17 in total—and limited inclusion to studies of patients with FSD. Given the larger sample size, inclusion of only RCTs, and more homogeneous patient samples, we believe that the current meta-analyses provide more reliable indices of the effectiveness of STPP for FSD.

These analyses indicate that improvements in somatic symptoms were maintained over time. This finding of sustained or increasing gains over follow-up has been noted in meta-analyses of STPP for mixed psychiatric disorders [36-38] and depression [16]. It has been postulated that psychodynamic therapies may create adaptive changes in relational and personality functioning that enable growth to continue after treatment [39], although there is evidence that this observation may not be unique to psychodynamic therapies [40, 41].

STPP models focus on the awareness and processing of unconscious, emotion-laden material often related to childhood adversity and later trauma. Such difficulty accessing such emotions is common in FSD patients [12, 23]. Beyond emotion activation and processing, STPP

also assists patients to regulate anxiety and thereby settle the autonomic nervous system (ANS) much as some CBT methods do. Thus, it is logical that STPP should be beneficial in patients with functional somatic disorders who have such histories and unprocessed emotions and conflict leading to a dysregulated ANS. There is some evidence from related research that emotional processing predicts treatment outcomes in psychotherapy overall [42] and STPP in specific [43-45]. Patients with FSD, in particular, report that emotion processing in STPP is very important [46].

Nonetheless, we cannot draw a conclusion that STPP's specific treatment ingredients are responsible for the observed benefits in these studies. To answer such a research question requires different methods [22] including dismantling procedures or detailed study of case series such as those that informed the development of many STPP models [6, 47]. This is but one limit of the value of traditional meta-analyses pointing to the need for consideration of diverse research inputs to inform treatment guidelines [22].

Beyond this factor, this study has other limitations. First, the quality of studies was variable and moderate overall. Second, despite the finding of large benefits with STPP on the primary outcome of somatic symptoms in short and long-term, treatment effects on some of the secondary outcomes were not always statistically significant, raising questions about how generalized the benefits of STPP are. Finally, there were relatively few studies in some of the analyses, especially at medium-term (3 to 9 months post-treatment) suggesting the need for additional research. Although STPP appeared to perform at least as well as bona fide controls, there were inadequate numbers of similar comparators to meta-analyze, leaving in question how STPP compares to treatments such as CBT.

Conclusions

This review and meta-analysis provide evidence that the use of STPP leads to treatment benefits for those with diverse somatic symptom conditions, yielding sizeable and sustained benefits relative to treatment-as-usual/waitlist/minimal treatment controls. Five further individual studies suggest STPP effects are at least comparable to a range of other bona fide psychotherapies. Hence, STPP should be included in treatment guidelines for these common clinical presentations.

Future research into possible therapeutic mechanisms when treating somatic symptom disorders should emphasize both between- and within-model key therapeutic processes, such as emotion processing; such studies may then be meta-analyzable to make more specific recommendations about effective processes [48]. Future studies should also consider current study quality recommendations [26] and should include the broader range of outcomes that are targeted specifically by psychodynamic therapy, such as improved relationship function, as well as determine potential healthcare cost savings of these often high-service-using clinical populations [49]. Finally, more studies are needed that compare STPP against other manualised psychotherapies such as CBT.

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