**Introduction**

Cognitive behavioural therapy (CBT) originated in the ground-breaking work of Aaron Beck in the 1960s, as an experimental psychological treatment for depression (Beck, 1976). Since the late 1970s, the application of CBT has widened to the treatment of anxiety, phobias, obsessive compulsive disorders, and more recently, chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME). In CBT’s areas of traditional usage (depression and anxiety), meta-analytic studies report that around 80% of patients who undergo psychotherapy are better off than those who receive no treatment (Smith and Glass, 1977) and that CBT brings about more enduring improvements than any other form of psychotherapy (Hollon et al., 2006). The measures of effectiveness used are often quality of life scales (e.g. the SF-36) or mood scales (e.g. the Beck Depression Inventory), to demonstrate CBT’s usefulness for improving quality of life (Beck, 2011). There is some evidence that CBT is a more enduring treatment than antidepressant medications, although the exact mechanisms that bring about benefits remain unclear (Hollon et al., 2006). Moreover, patients with psychiatric conditions express a threefold preference for talking cures over medications (McHugh et al., 2013). Given such apparent success and patient enthusiasm, health bodies have turned to CBT as a treatment approach in other health conditions, including CFS. In 2007, the UK Government invested £300 million in the launch of its ‘Improved Access to Psychological Treatments’ (IAPT) initiative, with a stated goal of training 6,000 CBT therapists across the NHS in England (Clark, 2011; IAPT, 2015). The IAPT recommends that CFS patients be referred for psychological assessment and treatment at specialist CBT centres (IAPT, 2014).

The National Institute for Health and Care Excellence (NICE) recommends CBT as an evidence-based treatment for CFS/ME and the National Health Service promotes CBT on its patient web resources (NICE, 2007, 2014; NHS Choices, 2015a). However, while there is considerable evidence demonstrating the effectiveness of CBT in the treatment of depression or anxiety, the evidence for the efficacy of CBT in the treatment of CFS/ME is inconsistent and highly contested (e.g. Fink, 2016; Twisk and Maes, 2009). In addition, many CFS patients are sceptical about the rationale for psychotherapy and reject the notion that their illness is psychogenic. One survey finds that 43% of CFS patients referred to CBT clinics are dissatisfied with a psychiatric diagnosis (Deale and Wessely, 2001). As such, CFS may be a very different illness domain in which to apply CBT in clinical practice, both in terms of applicability and patient response. These issues raise important questions about how patients with CFS might be prescribed CBT and whether or not patients might be appropriately informed, with full disclosure of pertinent information relating to CBT. Trachsel et al. (2015) noted that psychotherapy often begins and proceeds without the formal informed consent of the patient. We searched commonly used literature databases (e.g. PubMed, PsychINFO) and could not find any empirical evidence on informed consent in CFS treatment. In response, we conducted a scoping narrative review to explore the rationale for CBT treatment in CFS, with an objective to identify the salient facts that might need to be conveyed to a patient with CFS in order to gain their consent, including disclosure of potential efficacy and adverse outcomes associated with CBT. Informed consent is an important aspect of practice for doctors prescribing CBT and for CBT therapists treating CFS patients.

**The rationale for CBT treatment for CFS**

Chronic fatigue syndrome is an illness of prolonged unexplained fatigue, lasting six months or longer, together with other defining symptoms, such as post-exertional malaise, unrefreshing sleep, cognitive problems and pain; it is identified via diagnostic criteria as an illness of exclusion (e.g. Carruthers et al., 2011). The underlying mechanisms of CFS remain unclear (DoH, 2002). The website *NHS Choices* states that, “CBT is a type of therapy that can help you manage CFS by changing the way you think and behave…CBT works by breaking the negative cycle of interconnected thoughts, feelings, physical sensations and actions” (NHS Choices, 2015b). Patients with CFS are prescribed CBT to challenge their illness beliefs (cognitions) and graded exercise therapy (GET) to increase their activity levels and diminish their fear avoidance behaviour (Sharpe et al., 1991; White, 2005). The symptoms that many CFS patients present with, such as fatigue or pain, are posited to be ‘maintained’ by ‘dysfunctional illness beliefs’, embedded within a social and health system that rewards illness behaviours (Halligan and Aylward, 2006; Wessely, 1997). Patients are encouraged to view their illness symptoms as unhelpful thought processes, through CBT (White, 2005). Knoop et al. (2010: 489) state that:

“Three different cognitive processes may play a role in the perpetuation of CFS symptoms. The first is a general cognitive representation in which fatigue is perceived as something negative and aversive and CFS is seen as an illness that is difficult to influence. The second process involved is the focusing on fatigue. The third element is formed by specific dysfunctional beliefs about activity and fatigue”.

The role of psychotherapy is to challenge the patients’ illness beliefs and to offer a ‘cognitive-behavioural model’ that addresses unwanted cognitions and behaviours (Sharpe et al., 1991; Wessely et al., 1989). This CBT model of CFS is framed around three interconnecting factors (‘precipitating’, ‘predisposing’, and ‘perpetuating’) – the 3Ps. This framework is similar to Lang, Melamed, and Hart's (1970) three systems model of fear maintenance and desensitisation. Deary et al. (2007: 782) state, “The sine qua non of any CBT model is a vicious circle, the hypothesis that a self perpetuating interaction between different domains maintains symptoms, distress and disability”. The ‘CBT model of CFS’ is discussed conceptually in Wessely et al. (1989) and is formulated as a theoretical model by Surawy et al. (1995), who noted benefits using CBT in treating 100 CFS patients in clinical practice. Others have sought to validate CBT as an intervention in CFS (e.g. Moss-Morris et al., 2013; Wiborg et al., 2010). The 3-Ps/CBT model is also embedded within a wider biopsychosocial model (Engel, 1977), in which biological, social and psychological factors are regarded as important in understanding CFS. Moss-Morris et al. state that: “It is unlikely that CFS can be understood through one aetiological [mechanism]. Rather it is a complex illness which is best explained in terms of a multi-factorial cognitive behavioural model”. (2013: 303).

The cognitive behavioural model of CFS (3Ps-BPS) noted above is largely conceptual, with the aetiology and pathogenesis of CFS left open to debate. Vercoulen et al. (1998) used structural equation modelling to generate a cognitive-behavioural model of CFS in which factors such as beliefs about the disease being somatic were linked with fatigue outcomes. Song and Jason (2005) tested the Vercoulen et al. model and found that the model fit well for individuals with fatigue from psychiatric disorders, but not for patients with clear CFS. Such results indicate that CBT may be more appropriate for treating psychiatric morbidity or comorbidity, than CFS in the absence of psychological conditions. Researchers have also sought to validate the CBT model for CFS using mediation analysis, a statistical method to test how a mediating variable transmits the effect of an independent variable onto a dependent variable. Stahl et al. (2014) sought to validate CBT’s efficacy in CFS by testing the role of “fearful cognitions” as a mediator between avoidance behaviour and illness outcomes (e.g. fatigue). While such studies appear to support the hypothesis that ‘illness beliefs’ mediate fatigue in CFS, it is important to remember that mediation analysis is a correlation test, which does not prove causality (MacKinnon et al., 2007) and Stahl et al. concede that the positive effects that they observed using CBT could have been brought about by other factors and other possible treatments.

The CBT model of CFS is contested. There is considerable evidence emerging from biomedical studies that offers an alternative rationale for many of the symptoms experienced by patients with CFS. Maes and Twisk (2010) compared Wessely’s biopsychosocial (BPS) model of CFS (essentially an illness belief model) with the biomedical model (evidence of biological abnormalities) and concluded that the psychogenic model is weak as an explanatory model of CFS aetiology or symptomology. The US Institute of Medicine (IOM, 2015) conducted an extensive review of the literature on CFS and concluded that CFS is a “serious physical illness”. Similarly, the US National Institutes of Health (NIH) concluded that CFS is “not a primary psychological disease” (Green et al., 2015). Both the IOM and NIH point to a range of biological/physiological abnormalities observed in CFS patients, including immune dysfunction, cardiac dysfunction and neuro-cognitive deficits. The ‘neuro-immune model’ of CFS conflicts with the cognitive behavioural model. For instance, while the CBT model of CFS suggests symptoms such as pain or fatigue are the result of aberrant thoughts and somatisation, the neuro-immune model suggests cellular stress, increased cytokines, and central system hypersensitivity, may help explain the pain and fatigue patients report. While the CBT-BPS model of CFS includes a biological element, this is usually minimised within a narrative that CFS may start with a viral illness that triggers the condition. There appears to be no impetus to isolate the virus or explore pathogenesis, as maladaptive beliefs and illness seeking behaviours are considered to maintain the condition (Moss-Morris et al, 2013). In contrast, biological research suggests neuro-immune and cellular abnormalities result in illness continuance (see Edwards et al., 2016).

**The efficacy of CBT for CFS**

While groups like the US Association for Behavioral and Cognitive Therapies recommend CBT as an evidenced-based treatment for CFS (ABCT, 2016), the strength of the efficacy evidence is highly contested. Moss-Morris et al. (2005) observed a decrease in self-rated fatigue in CFS using CBT, but Wiborg et al. (2010) observed that reduced fatigue in three randomised trials of CBT was not mirrored by an increase in physical activity as measured objectively with actometers. Jason et al. (2007) observed improvements in quality of life scores following CBT in CFS, but noted in a later study (Jason et al., 2008) that “improvers” may be quite different in profile from “non-improvers”; suggesting that those who respond less well are a discrete cohort with differing immune profiles. CFS is difficult to diagnose and it is speculated that clinical trials of CBT for CFS often include patients with psychiatric conditions in treatment groups. A Cochrane review of psychotherapies for functional syndromes, which included CFS, noted multiple methodological concerns in psychotherapy trials, including high drop-out rates and selective biases in sampling (Van Dessel et al., 2014). CFS patients with psychiatric comorbidity (e.g., having depression in addition to CFS) may respond better to psychotherapy than CFS patients without psychiatric comorbidities. CBT may also treat the depression or anxiety an individual might experience while grappling with a chronic illness like CFS (Egede, 2007), without necessarily treating the underlying causes of CFS.

The largest clinical trial of CBT in CFS treatment (the PACE trial) reported that 22% of CFS patients “recovered” after CBT plus standard medical care, compared with 7% who received standard medical care only (White et al., 2013). The trial has attracted much criticism (e.g. Goldin, 2016; Kindlon, 2011a). Detractors point to the way in which recovery was operationally defined, such that participants could be classed as “recovered” even if they reported symptom deterioration between trial entry and follow-up. A Cochrane review found that 40% of CFS patients reported a reduction in self-rated fatigue following CBT at trial end, compared with 26% in usual care (Price et al., 2008). Only 16% more patients reported benefit from CBT following intensive one-to-one therapy compared with no-care, given usual care is not a comparable control. Price et al. also reported that the benefits of CBT are not sustained over the long term and that there is little evidence of improvements in physical function. The PACE trial demonstrated similar results, with little improvement in objective tests of physical function and between-group differences not sustained at two-year follow-up (Chalder et al., 2015; Sharpe et al., 2015). Price et al. (2008) concluded that, “The benefits of CBT in sustaining clinical response and reduction of fatigue symptoms at short and medium term follow-up are inconclusive”.

Despite the inconsistent evidence for long-term benefit, UK health authorities recommend CBT, along with graded exercise therapy, as treatments for CFS (NICE, 2007). The NICE guidelines are derived from a mixture of reviews of “best available evidence”, including a commissioned systematic review by Chambers et al. (2006) of all treatments, and what NICE call “consensus techniques”, gauging a range of medical and stakeholder opinions (Baker and Shaw, 2007). Some ME/CFS groups have raised concerns over the NICE guidelines. The 25% ME Group (a charity supporting members with severe ME/CFS) stated that the recommendations were “unfit for purpose” (25% ME Group, 2010). Similar sentiments were expressed by other patient organisations and while these groups do not represent all patients with CFS, it is important to consider why patient groups are dissatisfied with CBT and GET.

**Potential adverse outcomes in CFS**

Some estimates of adverse outcomes in psychotherapy suggest a rate of 5% (Boisvert and Faust, 2003). This figure is consistent with results from a survey of psychological therapy service-users in England, where 1 in 20 reported that they had experienced lasting bad effects from therapy (Crawford et al., 2016). “Non-serious” negative outcomes may be even more frequent. The PACE trial found no significant evidence of serious adverse effects using CBT to treat CFS (Dougall et al., 2014). Serious adverse events included death, hospitalisations, or significant deterioration; non-serious adverse events constituted new symptoms (White et al., 2007). In contrast, a detailed review of harms by Kindlon (2011b) suggests that 20% of patients with CFS report adverse reactions to CBT. Kindlon highlights how CBT trials explore adverse events in terms of stark hospitalisations or illness events, rather than more nuanced or psychological outcomes. For example, if a CFS patient fails to improve following CBT, they may erroneously blame themselves for this failure, particularly if the CBT therapist postulates that success is dependent on commitment to therapy. This is an iatrogenic outcome not often covered by assessments of adverse outcomes in trials of CBT.

We might also assert that prescribing psychotherapy may influence patients to believe they are suffering from a psychological illness, yet there is no evidence that CFS is a mental health condition; the World Health Organisation (WHO) classifies ME/CFS as a neurological condition (WHO G93.3; 2007). This raises questions about the consequences of giving psychotherapy to patients with no primary psychopathology. In addition, patients with CFS may be reluctant to report all harms to therapists, given the biases of the therapeutic relationship, even if harms occur (Kindlon, 2011b). Patients may simply drop out of therapy. Price et al. (2008) suggest a 16–20% drop-out rate in RCTS of CBT, we might expect higher in clinical practice. This may negatively affect patients’ future trust in therapy, therapists and doctors: another adverse outcome not often considered in harms audits.

Duggan et al. (2014), Vaughan et al. (2014), and Jonsson et al. (2014) found that clinical trials of psychotherapies often fail to properly investigate or report adverse outcomes. This might help explain why clinical trials of CBT find little evidence of harms, yet multiple CFS patient surveys report sizeable negative responses to CBT and associated therapies. In a 2015 ME Association survey (*n*=1428), of those patients who had CBT alone, only 8% reported CBT improving symptoms, while 73% reported no improvement, and 18% reported symptom deterioration. While unsolicited patient group surveys may be unrepresentative, it is important researchers consider the reasons behind these results.

It is also important to highlight that negative therapeutic outcomes may be higher for children and young people undergoing psychotherapy, than for adults (Rhule, 2005). This may well be because children are less able to articulate their choice not to engage in therapy. Over the last decade, children with CFS have been recruited into clinical trials of CBT (Stulemeijer et al., 2005), exercise trials, and non-scientific approaches, such as the Lightning Process, a therapy derived from life-coaching and neuro-linguistic programming (e.g. the SMILE trial by Crawley et al., 2013). Children are vulnerable and may experience unique psychological pressures (i.e. from parents and medical professionals advising that CBT is the best treatment); yet children may be less equipped to express choice or report harms, given these pressures. In this regard, informed consent in the treatment of children with CFS is even more complex than in adults, and children require more stringent safeguards.

**Additional considerations: exogenous factors**

An estimated 40% of improvement in psychotherapy may result from external or extra-therapeutic events (Asay et al., 1999). In addition, there is consistent evidence relating to the power of the therapeutic alliance, between therapist and patient, in influencing outcomes (Blatt et al., 1996; Krupnick et al., 1996; Lubrosky et al., 1997). The essence of therapy “is embodied in the therapist” (Wampold and Imel, 2015). Comparative studies of therapists who use the same treatment show 30% variability in outcomes being attributable to the therapist (Lambert, 1992). In other words, it may not be the CBT that is bringing about positive outcomes (e.g. improving mood), but the therapist. The ‘therapist effect’ undermines the received view of CBT in which cognitive restructuring is believed to be the active element (Wampold, 2007). A recent study on the provision of CBT via the internet for depression, failed to find any improvement using such technology (Gilbody et al., 2015), demonstrating the importance of the interpersonal nature of CBT.

Advocates of CBT for CFS (White et al., 2013) argue that carefully constructed RCTs of CBT demonstrate its overall positive effect at reducing fatigue in CFS. However, it is important to note that the treatments often used to compare CBT against may be inadequate as controls. For example, CBT is often compared against ‘usual medical care’ (care from a physician in community practice); but GPs often only offer 10–15 minute slots for patients to express a problem; in contrast, CBT therapists (in trials and practice) offer patients multiple one-hour sessions that might span a year. In addition, a patient with CFS referred for CBT by their physician may well expect some benefit, being socialised to trust in medical expertise. CBT therapists might also promote the virtues of CBT to the patient. We might conceive of this as a placebo effect, defined as “an expectancy response whereby the expectation that a treatment will be effective, elicits a self-fulfilling therapeutic benefit in the patient” (Kirsch, 1985). The placebo effect has been found to be particularly powerful in a range of therapeutic interventions for conditions such as depression, anxiety and chronic pain (Benedetti, 2014). A qualitative study of therapists’ perceptions of consent found that therapists view psychotherapy as partly experimental with unforeseen consequences that are not easily disclosed (Goddard et al., 2008). This gives credence to the argument that placebo/expectancy and therapist effects may make up a major part of the benefits observed in CBT trials in CFS. Ascertaining the size of the placebo effect is notoriously problematic; there are no placebo psychotherapy trials in which the CBT is blinded - patients know they are receiving psychotherapy.

**The application of informed consent in CFS**

Informed consent guidelines for professional psychotherapists, such as the British Association for Counselling and Psychotherapy (BACP, 2013), are commensurate with those for medical professionals, such as the guidelines of the UK General Medical Council (2010) or the American Medical Association (2014). Doctors and psychotherapists are duty bound to respect patient autonomy and to provide adequate informed consent to patients. Consent goes beyond simply asking the patient if they agree to treatment: it involves providing detailed information about the treatment, efficacy, adverse effects, and alternative options (Beahrs and Gutheil, 2001). However, it is uncertain how medical professionals apply regulations or negotiate consent in practice. Beauchamp and Childress (2009) divide informed consent into three possible phases: (1) preconditions for informed consent (the competence and voluntariness of the patient); (2) information (the disclosure material, recommendations, and the patient's understanding of the material and recommendations); and (3) consent elements (the patient's decision and its authorisation). However, the decision about what information to disclose is left to the discretion of the practitioner. Practitioners will call upon training and experience to decide what facts are “relevant in disclosure” (Goddard et al., 2008).

Relevant disclosure need not provide an in-depth account of every material fact about CBT, but the information the patient needs (Fisher and Oransky, 2008). Practitioners must provide germane information according to what Beauchamp and Childress (2009) refer to as a “reasonable person standard” — the facts relevant for a reasonable person to consent to a treatment and to make well-informed choices about that treatment. Failure to provide representative information through omission, or ignoring patients’ concerns about treatment, would undermine disclosure and consent. In Table 1, we offer health professionals a summary guide about how to address informed consent with CBT patients, including how to accept a patient’s decision to reject treatment or withdraw from treatment, given CBT may not be useful for many patients.

INSERT TABLE 1 HERE

**Discussion**

The recent upsurge in CBT’s popularity has pushed CBT beyond its traditional use in the treatment of depression or anxiety, to be applied in other health conditions, such as chronic fatigue syndrome. CFS is a complex illness with a contested aetiology. There are conflicting models of CFS; a biomedical model and biopsychosocial model. Each offer different perspectives on the illness and potential treatment approaches, with CBT emerging within a 3Ps-BPS model that focuses on altering ‘perpetuating’ factors. Health authorities in the UK recommend CBT for CFS, in combination with graded exercise therapy. It is important that physicians gain informed consent prior to entering patients into psychotherapy, with the CBT therapist acting as a second line of responsibility to assess the soundness of consent. Consent is important given patients may acquiesce to the expert authority of health professionals. Our review identifies some of the salient information that might need to be disclosed to a patient with CFS. (1) While there is some evidence that roughly 20-30% of patients who undergo CBT report some benefit, particularly in self-reported fatigue and mood scores, there is inconsistent evidence for the effectiveness of CBT to improve physical function, particularly over the long-term; (2) the rationale for CBT in CFS is complex and based on a theoretical/conceptual model; (3) the CBT model of CFS asserts that the illness is ‘perpetuated’ by patients’ illness beliefs, yet this view is highly contested by many CFS patients and patient groups; (4) there is a growing body of biomedical research that offers an alternative rationale for many of the symptoms found in the disorder; (5) there is some evidence that benefits from CBT may result from factors such as therapist effects or placebo, rather than ‘belief modification’; (6) CBT may help CFS patients if they have psychiatric comorbid depression or anxiety, that commonly emerge in chronic illness states – this would make CBT an adjunct support therapy, rather than a primary treatment for CFS.

It might be argued that health practitioners should not be expected to grasp the science behind psychotherapies and that it may be difficult or even counterproductive to offer full and frank disclosure to CFS patients. However, hospital doctors often convey complex information about medical procedures in time-pressured situations. In contrast, GPs and CBT therapists have the time to offer more detailed explanations and to engage with patients. Relevant information about the nature of CBT should be conveyed to potential patients in such a way as to make current scientific knowledge easily understandable, without being exhaustive (Table 1). Doctors and therapists should be able to communicate the potential benefits of CBT, but also the potential iatrogenic risks. While there is little evidence of serious harms associated with CBT, CFS patients entered into CBT may wrongly perceive they are suffering from a psychological disorder and patients may lose faith in physicians if CBT fails to help them – both RCTs and patient surveys reveal that CBT fails to help the vast majority of patients (70-80%). We must be cautious about asserting that the proposed ‘active ingredient’ of CBT in CFS is belief modification, given there are no fully blinded trials of CBT. More research is needed to compare CBT with other relevant treatment approaches.

There is some suggestion that patients are often entered into psychotherapy by unethical means, such as non-disclosure of key facts (Blease, 2011; Trachsel et al., 2015). Doctors and therapists may breech ethical guidelines if they coerce CFS patients into CBT without first offering full disclosure and gaining consent. Practitioners should not alter language to present CBT as something different from what it is, or inform patients there are no other treatment options available, or use threats of withdrawal of medical support as a punitive action if the patient does not accept CBT. Many CFS patients may not be receiving adequate disclosure prior to accepting CBT. Given the demands on GPs’ time, it is likely that GPs may simply follow guidelines (e.g. NICE, 2007 or IAPT, 2014) and refer CFS patients to psychotherapy on an implicit assumption that CBT is beneficial. Our review does not find benevolence for all CFS patients; in fact, evidence suggests CBT is a non-curative supportive therapy, that carries some risks of iatrogenesis, that need to be carefully disclosed to patients being offered CBT.

**Conclusion**

Cognitive behavioural therapy is increasingly promoted as a treatment for chronic fatigue syndrome. However, the evidence for the success of CBT in CFS remains inconsistent to weak. In CFS, CBT is a psychotherapy treatment offered in the absence of clear disease aetiology. While clinical trials and systematic reviews show that CBT brings about short-lived benefits for some patients, there is little evidence that CBT is a cure for CFS, or restores full functional ability over the long term. Patients should be informed of the rationale behind CBT, potential benefits, and possible adverse reactions, prior to entering treatment. CBT may generate negative outcomes for some CFS patients if they blame themselves for lack of improvement, or if they wrongly perceive that they are suffering from psychological illness. Factors such as therapist effects and placebo may contribute to treatment outcomes. Informed consent may only be achieved via full and open disclosure of these facts. Doctors and therapists should respect the autonomy of patients and offer patients choice, whether or not to participate in psychotherapy, armed with salient information.

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