



RESEARCH IN HEALTH PSYCHOLOGY

RESEARCH THESIS:

Investigating the impact of providing a cognitive behavioural therapy intervention for frequent attenders at the Emergency Department with medically unexplained symptoms: A mixed method study

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A portfolio of evidence submitted in partial fulfilment of the requirements of the University of the West of England, Bristol for the degree of Professional Doctorate in Health Psychology

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Declaration of contributions

All aspects of this research thesis were Samantha Gibson's own work. Samantha Gibson provided the initial idea for this investigation and conducted the research study design, participant recruitment, data analysis and write up of results.

Samantha Gibson received appropriate supervision from Dr Julian Bath and Dr James Byron-Daniel throughout the investigation and statistical advice from Dr Deirdre Toher.

Foreword

I have been studying for the Professional Doctorate in Health Psychology since January 2012 and I have passed all taught components of the course. All work has been submitted, passed and marks have been verified by the University of the West of England's examination board.

The Professional Doctorate in Health Psychology is awarded by completing five areas of competency outlined by the British Psychological Society's Board of Examiners in Health Psychology. These are:

1. Professional Skills in Health Psychology
2. Health Behaviour Change Interventions
3. Consultancy Skills in Health Psychology
4. Teaching and Training in Health Psychology
5. Research

The Research competency was assessed in two parts: Part I included completing a Systematic Review. This Systematic Review been assessed and passed by the University of the West of England and BPS examination board (please see Appendix 12 for systematic review). Part II of the Research Competency involved conducting an empirical research study in a topic relevant to Health Psychology. This doctoral thesis demonstrates the research study undertaken to fulfil the requirements of Part II of the Research competency.

Abstract

Background

There are a cohort of people who attend the Emergency Department (ED) extremely frequently. In many cases the symptoms driving their presentations are medically unexplained (MUS).

Objectives

The primary aim of the research was to identify if providing a CBT intervention to frequently attending (high risk) patients with MUS in the healthcare setting they are comfortable with (ED) had impacted their attendance patterns to the ED in the following 12-months.

Design

A feasibility study using a non-randomised historical control mixed method design was conducted to investigate the impact of providing CBT to 'high risk' group of frequent attenders with Medically Unexplained Symptoms at the Emergency Department. Quantitative participants were an opportunistic sample consisting of 50 of the most frequently attending (high risk) patients at two Emergency Departments allocated to either control or intervention group. The qualitative research design employed semi-structured interviews. Ten participants were recruited from patients who had attended the CBT intervention. Interviews were transcribed verbatim and analysed using Thematic Analysis.

Results

The primary outcome measure for the study identified that patients who received the CBT intervention had significantly ($p=0.001$) reduced their ED attendances. The study also identified that inpatient bed days were reduced ($p=0.001$) following the intervention. In addition, the qualitative approach identified four meaningful themes through thematic analysis: The ED and Me; Psychological Impact; My Treatment and The Long-term Impact: What's Changed?

Conclusion

This small feasibility study has provided insight into the patients' perspectives that supports the statistical data of their behaviour pre and post intervention. This study supported the declaration that providing a CBT intervention to high risk frequent attenders with MUS in the ED has a measurable impact on their health care utilisation, not only in the ED, but across the hospital.

*‘The ED has become the bottom of the societal birdcage.... All societal problems have become diseases. If your mother no longer loves you and the police don’t want you, you can come and see us’,
(Henry, cited in Mason 2015: 524).*

Background

Frequent attenders (FA’s) at the Emergency Department (ED) have become a major news topic given the increasing pressure on the National Health Service (NHS) to improve efficiency and reduce waiting times. News stories about ED’s (also known as an Accident & Emergency – A & E) have been published with headlines such as ‘A & E swamped with repeat visitors, with some patients attending up to 70 times a year’ (Rutherford, 2015); Revealed: ‘Repeat offender’ patients visit London A & E departments 200 times a year’ (Bentham, 2015) and a BBC News investigation reporting, ‘A & E: some patients visit 50 times a year’ (Tiggle, 2014). It is claimed that these FA’s are a significant contributor to queues and the increased waiting times witnessed today at ED’s with attendances that are deemed ‘inappropriate’ (Bodenmann *et al.*, 2014).

Certainly, there is a cohort of people that attend the ED too frequently and/or have frequent admissions. In many cases, it has been noted that the symptoms driving their frequent presentations are medically unexplained (MUS) (Kolk, Schagen and Hanewald, 2004; Rief and Broadbent, 2007; Brown, 2006 among others). It would seem that the needs of these patients are not being met by a traditional medical approach. In one respect, it could be argued that their own psychopathology and the nature of health

service combine to make their experience of the hospital unsatisfactory (Salmon, 2007). Furthermore, even with numerous investigations and treatments they continue to come back time and time again. This is problematic because ED's are not designed or tailored to provide continuous care for non-emergency conditions even when they are of a chronic nature (Fuda & Immekus, 2006). Better treatment can be provided by primary care and alternative patient settings with General Practitioners and specialists. However, at the turn of this century it was noted that currently, there is an absence of treatment for this patient group with most patients receiving little or none (Sharpe, 2000) and it would seem this remains the case today. Moreover, with repetition of testing and investigations being the current norm; it has been concluded that when this happens the *'...only certainty is that investigation, referral and labels make frequent attenders worse not better'* Spence (2014: 208). Indeed, it is contested that we need to understand what is driving their behaviour to treat them but there remains a scarcity of valid evidence on how to treat this group (Spence, 2014).

What are Medically Unexplained Symptoms (MUS)?

MUS are a term used to incorporate a group of conditions that includes: Functional Syndromes; Somatised Mental Disorders; Hypochondriasis; Somatoform Disorder; Dissociative Conversion Disorders or indeed any organic illness where disability is greater than expected (Brown, 2006).

Nonetheless, MUS as a diagnostic term has not been without criticism (Henningsen, 2007). Furthermore, even the 'term' MUS remains contentious. Its critics have contested that it fails to recognise non - medical explanations or even account for symptom severity (Henningsen, 2007; Henningsen *et al.*, 2011).

Additionally, Henningsen *et al.* (2011) highlight those alternatives such as somatoform has proven to be objectionable to patients who fear it implies symptoms originate from a purely psychogenic cause.

Further problems are reported because each department in a general hospital has its own label/terminology for MUS (see Table 1) which complicates definition and identification.

Table 1. Functional somatic syndromes by specialty (jcpmh, 2017).

SYMPTOMS	SYNDROME	SPECIALITY
Bloating, constipation, loose stools, abdominal pain	Irritable Bowel Syndrome	Gastroenterology
Fatigue (particularly post-exertional and long recovery) pain, sensitivity to smell	Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis	Infectious Diseases, Endocrinology, Rheumatology, Pain Clinics
Headache, vomiting, dizziness	Post-Concussion Syndrome	Neurology
Pelvic pain, painful sex, painful periods	Chronic Pelvic Pain	Gynaecology
Pain and tender points, fatigue	Fibromyalgia/Chronic Widespread Pain	Rheumatology
Chest pain, palpitations, shortness of breath	Non-cardiac chest pain	Cardiology
Shortness of breath	Hyperventilation	Respiratory Medicine
Jaw pain, teeth grinding	Temporo-mandibular Joint Dysfunction	Dentist, Oral Medicine
Reaction to smells, light	Multiple Chemical Sensitivity	Allergy clinic

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Worryingly, it has been estimated that between 20% (Reid *et al.* 2002) and 52% (Nimnuan *et al.*, 2001 cited in IAPT, 2014) of people frequently attending secondary care settings in the UK have MUS. At the time of writing no further numbers could be identified probably because of the difficulty with identification.

Further criticism has come from Edwards *et al.* (2010). They argue that most physicians and patients are unhappy with the MUS label when it is termed as a 'specific disorder'. Instead, they proposed that 'clinical and social predicament' be used given it includes such a broad spectrum of presentations. They argued that physicians struggle with MUS as symptoms differ to known pathologies and the change would allow them to focus on holistic treatments.

Creed *et al.* (2011) argue MUS remains an unsatisfactory term because it invalidates patient's symptom experience and reinforces dualism. They conclude that the term translates as dismissive and this is missing the fact that evidence based treatment approaches exist. Additionally, the Improving Access to Psychological Therapy (IAPT) MUS Task and Finish group (IAPT, 2014) advised that the term was not utilised for patient treatments and specific diagnostic terminology should replace it (see table 1).

In short, a clear definition has previously remained elusive and led to a lack of consensus. However, the DSM-5 (2013) has now been published with Somatic Symptom Disorder (SSD) which is characterised by bodily symptoms that are distressing and/or cause significant disruption of functioning. SSD intends to provide a holistic i.e. biopsychosocial diagnostic tool that unlike the DSM-IV allows for co-morbid medical condition/s. This is in line with Browns inclusion criteria (2006). The key component for SSD is that bodily symptoms must cause significant distress and disruption to daily life and be associated with excessive behaviours, thoughts and feelings.

Nonetheless, whilst recognising that the phrase ‘medically unexplained symptoms’ or MUS can be problematic and contentious, it remains widely used across medical sites and disciplines and thus seems the appropriate term to use in this instance.

Healthcare Utilisation and Costs

Reviewing the available research has identified MUS as a major problem in healthcare over utilisation (Kolk, Schagen and Hanewald, 2004; Rief and Broadbent, 2007; Brown, 2006 among others). Whilst exact costings are not known varying estimates have been attempted. For example, the estimated cost in the USA is thought to be more than \$100 billion per year (Kroenke, 2007). Whilst in the UK, it has been quoted that at least 20% of attendees at ED are MUS patients (Rief & Broadbent, 2007). Furthermore, a cohort study conducted retrospectively of costs in an NHS region, uncovered that investigations for patients with MUS utilised double the financial cost in comparison to other service users (Reid *et al.*, 2002). Whilst there has not been a later financial review Konnopka *et al.* (2012) estimated that the cost burden of each patient in 2006 was between 432 and 5,353 USD. In the UK, the Centre for Mental Health (2016) reported that MUS cost the NHS in England an estimated £3.25 billion a year which equals £700 per patient identified with MUS for lower users rising to £3,500 a year for the costliest 5% (based on data provided by Bermingham *et al.*, 2010).

Indeed, it has been claimed that 16 percent of budgets in western industrialised societies are spent on patients with MUS (Barsky, Orav, & Bates, 2005). This figure would equal approximately £8.5 billion per

annum in the United Kingdom. However, as this fails to include benefits or social care, one could contest that this estimate is very conservative indeed. Consequently, Spence (2014) estimated that each year frequent attenders use enough NHS resources to fund NHS London and if addressed it would fill the funding deficit currently experienced.

There has not been a cost analysis conducted for non-western countries, therefore, it has been difficult to define if costs are problematic in the rest of the world. However, the prevalence of MUS has been reported and compared in a systematic review looking at a diversity of cultural settings. The review also highlighted similar symptoms and disability as seen in industrialised nations (Sumathipala *et al.*, 2008).

In 2007, Salmon proposed the main reason for over utilisation of healthcare recourses was with clinician's failure to acknowledge the influence of psychosocial factors on physical symptoms. The paper defined that the need to 'rule out' organic causes with extensive investigations not only cements the patient's belief that they have an 'undiagnosed' physical illness but escalates the cost to the health service (Salmon, 2007: 246). Skinner *et al.* (2009) proposed that junior doctors were at fault due to their lack of experience with this patient group that was leading to repeated clinical investigations and reinforcing illness belief. Moreover, these clinical investigations not only cost the health service vast sums of money but also leaves patients dissatisfied and maintains their belief that their needs have not been met (Hahn *et al.*, 1994). Later qualitative research by Kornelsen *et al.* (2015) supported this stance stating that testing and retesting takes time and the lack of results often leads to frustrated patients and doctors. However, crucially, Hatcher *et al.* (2011) stated that mortality rates were lower for the MUS group when

compared to the rest of the patient population. This is critical as it is claimed that one of the reasons for this patient groups high cost is the doctors defensive practice of over prescribing/requesting investigations for fear of missing a pathology. However, this has been contended by IAPT (2014) who claimed that MUS patients have double the mortality rate than cancer, accidents and suicide. They propose that its comorbidity with severe depression (with high suicide risk) leads to patients with MUS needing careful assessment and diagnosis.

Patient Dissatisfaction

MUS patients continually report lower levels of satisfaction than other patient cohorts with their clinicians (Jackson *et al.*, 2004). In addition, clinicians report higher levels of stress and anxiety with this patient cohort and are more likely to label them as 'frustrating'. Therefore, not only are the patients costing more and utilising more services than other attendees but all stakeholders in the interaction remain dissatisfied (Hahn *et al.*, 1994: 647). Chew-Graham *et al.* (2017) noted that the personal cost to patients can be substantial. This has especially been the case when they feel they are not listened to and their symptoms are rejected by health professionals. They have noted that when this happens it leads them feeling dismissed and encouraged repeated presentations at the ED (Chew-Graham *et al.*, 2017).

Mental Health Diagnosis

Worryingly, those who receive a diagnosis of MUS report poorer quality of life than individuals whose symptoms are explained with a medical diagnosis (Nimnuan Hotopt & Wessely, 2001). This research also

highlighted that up to 70% of people with MUS have comorbid depression and/or anxiety disorders. Moreover, a study by the European Consultation Liaison Psychiatry Workgroup (ECLW) studied data on 34500 inpatients. They identified that approximately 14% (N=4830) of the cohort had somatoform disorders but only 61 were referred to the liaison psychiatry service (cited in Fink *et al.*, 2011). However, any link between MUS and psychiatric diagnosis has previously been disputed in a literature review conducted by Burton (2003). The outcome of the review declared that psychological assessment did not identify any comorbid mental health diagnosis in the vast majority of patients with MUS. But a recent study conducted by Rohricht and Elanjithara (2014) concluded that in the participant group the highest predictor of patient functioning was their depression score and this correlation needed further research.

Nevertheless, a diagnosis may be irrelevant given the problem of patient engagement in referrals for psychological interventions. It appears that the vast majority view body symptoms need body treatments and thus deem any referral to psychology as inappropriate and rejection by their treating practitioner (Fink *et al.*, 2011). In addition, it could be contended that it is not only the patients who feel a mental health referral is inappropriate or unacceptable, but practitioners do as well. This is highlighted by Fink *et al.* (2011) who found that very low patient numbers are referred on from medical specialities for a psychotherapeutic intervention. In addition, Brownell *et al.*'s qualitative study (2016) reported that physicians avoided mental health referrals for fear of offending even when they thought patients would benefit.

Importantly, Barsky and Ahern (2004) reported that even if a referral has been made the refusal and drop out and non-attendance numbers are large. This may be particularly problematic when developing interventions for differing demographics. Rohricht & Elanjthora (2014) claimed that talking therapies are less acceptable to Black and Minority Ethnic (BME) populations who request body based solutions when reviewing a MUS clinic in a community setting. They proposed that the attendance rate for the clinic was low because BME communities perceived there was a mismatch between physical symptoms and the psychological interventions provided and this restricted uptake. However, an approach to tackle this has been proposed by Speckens *et al.* (1995). They noted that the engagement process is improved when interventions are conducted in the medical setting known to patients, such as GP surgeries or ED's. This point was re-stated in the IAPT positive practice guide for MUS confirming that services 'embedded in a physical health framework may encourage engagement (IAPT, 2014, p14).

Spectrum of Medically Unexplained Symptoms (MUS)

Research has identified that different levels of MUS can be distinguished (Creed *et al.*, 2011 olde Hartman *et al.*, 2009 among others) and the onset of symptoms has been a crucial component for treatment success (olde Hartman *et al.*, 2009). In support, Creed *et al.* (2011) claimed three distinct groups of MUS patients exist; low, intermediate and high risk that are defined by chronicity of symptoms:

- 'Low risk' short term mild symptoms experienced – will consider that psychosocial factors may be contributing and prognosis is very good.

- 'Intermediate risk' patients presented at health providers with comorbidity of other symptoms or psychiatric diagnosis. Problems may occur if they are treated in isolation e.g. only physical symptoms receive medical treatment. Thus, if patients are provided with a treatment that looks at the presentation holistically the prognosis is deemed good for the future.
- 'High risk' group are those with persistent symptoms that they view as disabling. They are more likely to have numerous admissions for diagnostic testing or surgical procedures and have poor relationships with clinicians that lead to seeking second opinions. They may be in the midst of legal claims or in receipt of disability pensions.

This correlates with a qualitative study by Dwamena *et al.* (2009) looking at the attitudes of 19 high-utilising MUS patients in primary care. They also noted that the patients could be allocated to three groups:

- 1) Successful in life with psychological insight seeking symptoms explanations.
- 2) Disabled by physical symptoms and subsequently excused from social obligations and showing limited psychological insight. Wanting their symptoms recognised and care providers to facilitate relief from symptoms and provide support.
- 3) Excessive worry regarding undiagnosed illness, excessive care demands and unhappy when demands are not facilitated.

These levels were first identified by Barsky (1996) who had previously noted that the earlier MUS is identified the better the outcome. He suggested that patients became harder to treat after numerous investigations and referrals. Later, Olde Hartman *et al.* (2009) stated that a more severe condition (high risk) led to a worse clinical outcome. However, a review by Guthrie's (1996) noted that studies had failed to target this group and to date this remains the case. Nonetheless, Raven (2011) has argued that there is a necessity in targeting the high cost and high use end of spectrum patients as interventions can be costly and it is difficult to justify any intervention not targeting them. In reality, there is no extra money for these interventions so the value in addressing attends alone may not benefit the hospitals. But attends get expensive quickly when tests are run (in some cases repeatedly) and inpatient stays magnify costs greatly.

Identifying Medically Unexplained Symptoms (MUS)

Symptom severity has been identified with a screening tool called the Patient Health Questionnaire – 15 (PHQ-15) developed by Kroenke, Spitzer and Williams (2002). Kroenke *et al.* (2002) acknowledged that the PHQ-15 is simplistic in nature, but confirmed their research identified is a correlation with the top 10-20% of scorers and the severe end of the MUS spectrum. Nevertheless, utilising the PHQ-15 as a screening tool has been criticised by Den Boeft *et al.* (2014), who argued that it lacks sensitivity to identify MUS when subjected to a validation study. Concluding that using the cut offs proposed by the PHQ-15 led to it missing 80% of MUS patients.

An alternative to screening tools is utilising physician's judgement (PJ) as a diagnostic criterion for case selection. Olde Hartman *et al.* (2009) argued that this enables patients to be distinguished for example, when they repeatedly attend for acute injury that remains problematic compared with individuals consistently attending with varying complaints without a medical diagnosis. This was confirmed Rasmussen *et al.* (2008) study that recognised high levels of accuracy in physicians subjectively identifying MUS and supported previous research conducted by Reid *et al.* (1999) and Abdulwahid, Booth, Kuczawski and Mason, (2015). Both studies reviewed the case notes of frequent attenders to secondary care and noted that physicians could reliably agree on a MUS diagnosis.

Research into Treatment Options

Certainly, sourcing research addressing severe/high risk MUS has proved difficult. Van Dessel *et al.* (2014) conducted a systematic review looking at 21 studies of which 18 were from primary care and 3 recruited from secondary care outpatient departments. The studies utilised psychological treatments for somatisation and MUS. They concluded that CBT interventions produced effective symptom reduction and recorded lower levels of psychological distress in the treatment groups which was maintained at 12 months follow up. However, the effect sizes, whilst significant were small. In addition, reviews of primary care studies have highlighted that Cognitive Behavioural Therapy (CBT) was the most successful intervention when compared to other psychological therapies and pharmacology (Burton, 2003) for mild/moderate groups. Reattribution Therapy is another treatment in primary care that has previously been widely used with MUS patients but recent reviews have argued this approach has been proven ineffective over the longer term (Deary, Chalder & Sharpe, 2007; Gask, Dowrick, Salmon, Peters, &

Morris, 2011). Recently, transdiagnostic approaches for MUS have been published (Salkovskis, Gregory, Sedgwick-Taylor, et al. 2016; Chalder & Willis, 2017). Both have identified common cognitive and behavioural responses to symptoms across MUS conditions. These included, avoidance of activity, negative cognitive distortions, symptoms focus that led to detrimental behavioural responses and shared fixed beliefs about the unacceptability of emotions. The transdiagnostic approach suggested that all could be addressed by utilising the necessary treatment components multiple models.

In addition, Sumathipala (2007) published a systematic review that included both primary care and secondary care outpatient settings of MUS interventions. It compared psychological interventions, case management and pharmacological treatments and concluded that CBT was the most efficacious in reducing reported disability and physical symptoms experienced. However, it also reported highly selective inclusion criteria and highlighted that only short-term outcomes were recorded. This supported a review by Kroenke (2007) comparing randomised controlled trials into current treatments of MUS that again concluded that of 34 clinical trials investigated, CBT was the most effective treatment intervention. Impressively, Tyrer *et al.* (2014) identified a dramatic reduction in hospital bed days and Emergency Department visits which reduced further over the second year of the study when a CBT intervention was introduced for health anxious cardiac patients. Whilst, Blichard (2004), CBT study measured GP visits and a reduction of 39% was seen in the treatment group over the following year. Martin et al (2007) saw the biggest reduction for GP visits with their CBT intervention. However, this was not the same for visits to specialists which remained static.

A randomised trial conducted in a secondary care setting that provided Group CBT to individuals identified as high utilisers of primary care and secondary care outpatient services (Shroder *et al.*, 2012). This Danish study reported significant results ($p < 0.002$) when compared to TaU (provided by general physician). However, they excluded any individual over the age of 45 as they stated, 'we regard the possibility of improvement to be lower in older people' (Schroder *et al.*, 2012: 444) with no explanation of why they felt this was the case. This is problematic given that a systematic review conducted by Lacalle and Rabin (2010) identified that there were peaks in ages for frequent attenders of ED's and these were between 25-44 and in the age group 65+.

Demographics

As previously mentioned Lacalle and Rabin have stated that analysis of frequent ED attenders had uncovered peak ages for attending of between 25-44 and in the age group 65+. Furthermore, Van Dessel *et al* (2014) also stated in their review that younger and older age groups were underrepresented noting the mean age for participants was 43 (range 35-49 years). This matches the unpublished systematic review presented in appendices (see appendix 11) of this thesis (for identification from this point will be referred to as Gibson, 2013) which identified that 11 of 12 studies provided demographic data that calculated to a mean age for the treatment groups of 37.23 years and a mean of 39.12 years in controls. This further supports an earlier meta-analysis by Kleinstauber, Witthoft and Hiller (2011) of 27 studies into MUS and short-term psychotherapy where the mean age in the treatment groups was 44.4 years.

Additionally, the lack of reporting on race and ethnicity has been noted. This demographic was only reported on in 1 study out of 12 when reviewed (Gibson, 2013) which may mean another underrepresented cohort and again could be problematic for the generalisability of studies.

In addition, the opposite was true for females. Kleinstauber *et al.* (2011) calculated the gender of participants and reported that the percentage of females was 72%. This was based on a selected sample of patients willing to receive psychotherapy. This supports the Gibson (2013) review that stated 79% of participants were female in the treatment conditions with an 81% in control groups. Finally, the latest systematic review by Van Dessel *et al* (2014) identified that the number of female participants in treatment groups ranged from 66% to 89%. However, it is unknown whether was a true reflection of all suffers of MUS because the studies reviewed failed to document the genders, ethnicities and ages of those who declined the short-term psychotherapy interventions.

Thus, it must be noted that we cannot be sure that the studies reflect the true demographics of MUS patients or if they simply highlight the ones who opted in. Certainly, failures in reporting participant demographics appear to be problematic. Obviously, it is not always possible to reduce selection bias in a self-selecting participant pool (Heckman, 1990), however, the research reviewed failed to define ethnicity in all but one case. Therefore, the generalisability of the interventions cannot be made across different races and ethnic groups. Furthermore, it would be beneficial if the demographics of those refusing to

participate were included so that interventions could be designed with them in mind or could simply acknowledge that the intervention remained untested in this area.

CBT & Improving Access to Psychological Therapy Services (IAPT)

Nonetheless, one possible explanation for the success of CBT may be that it proposes that an interaction of biological, behavioural, social and psychological factors maintains illness and therefore it is in a prime position to treat MUS as it does not threaten an individual's illness belief (Malins *et al*, 2016, Speckens, 1996). However, to date the health care services do not incorporate this (JCMPh, 2016). Indeed, this represents a challenge to most healthcare setups built on dualism where symptoms are perceived and treated as either mental OR physical (IAPT, 2014). Without developing holistic understanding or creating a willingness to adapt to the construct that all presentations have components of both, it is no surprise that success has thus far been limited.

'No health without mental health' published by The Department of Health in 2011 recommended transitioning this patient cohort to psychological therapy services. Improving Access to Psychological Therapies (IAPT) was charged with providing MUS services throughout the UK. Pilot sites have developed pathways and created therapeutic interventions for this patient group (IAPT, 2012). Indeed, an interim report was published reviewing the MUS services provided by these pilot sites for primary and secondary care services in the United Kingdom (de Lusigna *et al.*, 2013). It concluded that there are very good results being achieved at low intensity level (e.g. with mild symptomology). However, a comprehensive stepped-care model is still needed 'as many patients have highly complex needs requiring high-intensity, individual

input' (de Lusignan *et al.*, 2013: 7). In addition, Kellett, Webb, Wilkinson, Bliss, Ayers and Hardy (2016) produced a retrospective analysis of a 6-month cohort of GP referred patients with MUS to IAPT. The success of the service in meeting the needs of this patient cohort was difficult to define as they had not evaluated or measured physical symptoms outcomes. Certainly, reading the paper uncovered problems with the research, in particular the choice of the 'third wave' intervention i.e. Acceptance and Commitment Therapy (ACT) over standard CBT. No clear rationale for the use of ACT was provided and the paper went on to quote a meta-analysis by Ost (2008) that stated there was an inadequate number of controlled clinical trials for ACT interventions for it to be considered an empirically validated treatment.

CBT Interventions

As previously mentioned CBT research has proven to be successful in helping individuals with MUS. Olde Hartman *et al.* (2017), have stressed that CBT delivered by specialists has shown to be more effective than when delivered by primary care professionals. However, it would seem that the term CBT encompasses a diversity and variety of treatments which makes comparisons difficult. Whilst many studies utilise manuals or protocols (see Gibson, 2013 for review) it has been difficult compare these manuals as in some cases the same manual has been applied for anything from 1 session to 20 (Speckens *et al.*, 1995 & 1996). Therefore, how much of the manual was used must be questioned. Nonetheless, it was noted that studies not using a manual failed to achieve the same results in patient outcome measures (Gibson, 2013). Four studies (Martin *et al.*, 2007; Speckens *et al.*, 1995 & 1996; Sharpe, 1992) have used Sharpe's guided self-help protocol (1992). However, Speckens *et al.*, 1995 used it in conjunction

with Salkovskis (1989). A further two studies have described utilising a 'treating somatisation' protocol (Allen *et al*, 2006; Escobar *et al*, 2007) since published by Woolfolk & Allen (2007).

Frequent Attenders in the Emergency Department

Additionally, research specifically targeting frequent attenders at ED's has begun to emerge and the following papers were identified. Skinner *et al.* (2009) highlighted that developing care plans for any patients attending more than ten times at the ED reduced attendance by 31% in a 6-month period. However, the study reported that individuals who were not case managed also reduced attendance without explanation. Furthermore, Newton *et al.* (2010) researched the care plan approach and reduced attendance at ED in central London for the top 32 frequent attenders over a 12-month period. The study included a high number of homeless patients who did not have access to GP services. However, the study failed to verify if the attenders had reduced their healthcare usage or had started frequenting other ED's in close proximity. Following on from this, Althaus *et al.* (2011) conducted a systematic review of research reporting on frequent attenders in the ED and concluded that case management was the most effective intervention for this group. However, the review concentrated on alcohol/drug misuse and the homeless and omitted any research regarding somatisation or MUS. Moreover, Mason (2015) contended that there were underwhelming results for case studies when subjected to a systematic review. This conclusion was supported by Soril, Leggett, Lorenzetti, Noseworthy, and Clement's systematic review (2015). They analysed three types of interventions: case management, individualized care plans and information sharing and concluded that none of the interventions were likely to yield cost savings for the

healthcare system. They proposed that 'personalizing and tailoring' interventions may prove to be most effective at reducing high users.

Natural Attrition in Frequent Attenders

Peddle *et al.* (2011) argue that ED's see a static number of FA's over time but the population is dynamic and as fast as one FA stops someone else will step in to take their place. Additionally, Raven (2011) stated that this is a heterogeneous population and most will not remain FA's by the following year. This supported a previous economic study in the United States of America by Fuda and Immekus in 2006, who noted this attrition was similar for insured and uninsured individuals. Though, Lacalle & Rabin (2010) reported that from their research that 28-38% of FA's will not attend the following year, however, 56% will still be frequently attending. Kennedy *et al.* (2004) claimed a natural attrition could be seen when reviewing data of a retrospective study in both the intervention and the control group. They determined that attendance patterns reduced on their own over time. Nonetheless, the Kennedy study has been critiqued for its methodological flaws by Peddle *et al.* (2011) who argued that the control group had received 'informal management' and therefore, the impact of this cannot be ruled out. The assertion of a natural attrition was previously suggested by Kne (1997 cited in Peddle *et al.*, 2011) who argued that FA's are not a 'constant' problem. Crucially, when discussing FA's these studies do not differentiate between Psychiatric, Drug/Alcohol misuse and include under 18's so it is difficult to make comparisons across the board. In Gibson (2013) twelve studies were reviewed and reported drop-out rates of approximately 15% of original participants (309 from 1823). Importantly, refusal rates were tallied and 46.96% did not opt in for the interventions. This is twice the figure for a later study where 25% did not attend an MUS clinic

offered in primary care by Liaison Psychiatrists (Rohricht & Elanjithara, 2014). It was concluded that this was a result of the clinic being based within a mental health setting.

What Constitutes a Frequent Attender?

Indeed, as well as problems with defining MUS presentations, it has also been noted that there is no uniform definition of what constitutes frequent when talking about FA's (Pines *et al.*, 2011). Of course, not having consensus on what constitutes a FA is problematic in published studies. Mason (2015) reported when reviewing research that they ranged from 3 to 12 in a 12-month period. Some studies have included +1 as a qualification (Raven, 2011). Locker, Baston, Mason and Nicholl (2007) supported using a minimum of 5 as the optimum number claiming it corresponds with non-random events and if used universally it would enable better comparisons across studies. This is supported by research conducted by Martin *et al.* (2012) who looked at attends at an urban ED over a 10-year period. They concluded that on the 5th visit a correlation could be seen with an increase in resources. Furthermore, some studies investigate frequent users as a group whilst others separate out specific populations. It could be contended that grouping together all FA's may not spotlight differences in their reasons for attending (Gibson, 2014).

Who Should Be Targeted?

Raven (2011) argues that it is financially difficult to justify not targeting the high cost and high-end users. Given that money is in short supply across the NHS, attends alone may not justify the need for an intervention. However, medical testing and inpatients stays can greatly increase the cost. Indeed, the NHS

are facing 'unprecedented financial and operational pressures', with spending cuts needed to alleviate this (The Kings Fund, 2017). It could be argued, that there are few ethically viable ways to achieve these cuts. But, one way would be by introducing 'effective' ways to get patients better and reducing 'unnecessary' testing and investigations is another (Webb, 2010). It is contended that both could be achieved by providing evidence based psychosomatic interventions at the point of contact.

Nevertheless, it must be recognised that the hospitals are not the only stakeholders in improving the treatment MUS patient receive in the ED. As previously mentioned, research has identified that the patients are unhappy about it also (Lefvert, 2009; Sandoval *et al.*, 2010 & Persson, 2014). However, of the CBT interventions previously identified as successful, their best results were in reducing psychological distress and symptom reduction which would obviously be very important to the patient group.

Why the Current Study is Needed?

In 2016, the Centre for Mental Health urged Clinical Commissioning Groups to fund specialist MUS services that can be employed across traditional boundaries of physical and mental health. In particular, the group identified that there was little evidence for the cost-effectiveness and success of services delivering support for people with MUS. They also noted that around 5% of all those with MUS 'problems are particularly severe, persistent and complex' and need dedicated clinical services. They have recognised that the costs to the NHS are monumental and this gap needed to be filled.

Certainly, as has been spotlighted, there is an ongoing problem with unnecessary over utilisation of ED's and one group highlighted are FA's with MUS. It has also been identified that this group have never been targeted previously and there is a need for the development for an evidenced based intervention. Whilst IAPT are tasked with treating low risk MUS, there is no national or local provision for high risk groups thus the status quo prevails with unhappy patients and frustrated staff. This is where Health Psychology is in the perfect place to step in and end the dualistic service that is currently provided. Speckens *et al* (1995) highlighted that providing the intervention in the area the patient is comfortable with may improve the uptake. IAPT (2014) highlighted that appropriate placement of services within secondary care may prove crucial when setting up MUS clinics. Proposing that psychological treatment should be embedded in standard care packages thus it is accessible for all patients presenting to secondary care. The Joint Commissioning Panel for Mental Health (JCMPh, 2016) recommended that one area MUS services should be commissioned was ED's. Explaining that this would enable patients to access services that are appropriate for the severity and complexity of their problems. This would not only provide cost-savings for the healthcare but would improve outcomes for MUS patients. Moreover, they recommended the following outcome measures for MUS services. These included process measures (calculating bed days, service uptake and usage), patient satisfaction measures, patient outcome measures (physical, social and mental health symptoms).

Research has also informed that CBT is effective as it addresses individual's behaviour and cognitive distortions (Malins *et al*, 2016, Speckens *et al*, 1996). This is the first study to offer an ongoing

psychological intervention in the ED to all patients who are flagged as currently attending on a frequent basis. Any patient who has attended 5 or more times in the previous year will be offered the intervention as this is the number that has been recognised as problematic for unnecessary investigations. It is hoped that the intervention will not only reduce their current attends, testing and admissions but will also identify what drives their attendances by employing a mixed method approach. Given that it has been reported that there is a natural attrition for this patient group the treatment group will be compared over a 2-year period with a control group frequently attending another ED in the local area with similar demographic population to the ED where the intervention is being provided. This will identify if the intervention has made an impact on the long-term attendance patterns and account for natural attrition.

The beneficiaries of the study will be policymakers who will be able to see if providing psychological interventions to FA's in the ED reduces hospital expenditure and ED attendance numbers, practitioners who are 'frustrated' by providing ineffective treatments as they will have an alternative treatment pathway and to the patients who currently are repeating treatment patterns that are ineffective by providing an intervention that reduces their negative symptom experience.

The feasibility of the study relies on there being significant reductions in secondary care activity and cost. As has been highlighted, over utilisation by this patient cohort is a worldwide issue. Previous treatment recommendation from IAPT (2014) has highlighted that to achieve the best cost and health benefits, evidence based treatments need to be commissioned. This study could identify that including Health Psychologists as a part of the treatment pathway could provide economic, time and over capacity savings.

Furthermore, with the inclusion could be easily sustainable as economic, time and over capacity savings are easily measured and can be replicated and scaled up as necessary.

The Proposed Research Aims / Objectives

The aim of the research was to identify whether a CBT intervention to frequently attending (high risk) patients with MUS in the healthcare setting they are comfortable with (ED) had impacted attendance patterns and if so how?

Objectives

1. Identify if the CBT intervention impacted on future attendance patterns for the patients who have received it when compared to a control group receiving treatment as usual (TaU).
2. Identify if providing the intervention in the ED encouraged attendance.
3. Define what (if anything) was most useful about the CBT intervention in helping clinic attendees reduce/manage their symptoms.
4. Identify why they no longer attended the ED e.g. have their needs been met? or if still attending, what is driving their attendance?

Hypotheses

H₁: Patients who have received the CBT intervention in ED, compared to a control group, will have lower attendances at the study site.

H₂: Patients who have received the CBT intervention in ED compared to a control group will have lower inpatient bed days at the study site.

METHODOLOGY

Introduction

To answer research questions, it needs to be acknowledged that philosophical assumptions are made that subsequently influence the research design. These assumptions result from researcher's ontological (nature of one's reality) and epistemological (nature of knowledge) stances (Dures, Rumsey, Morris & Gleeson, 2010). The two historical approaches that have dominated the debate for decades are quantitative and qualitative (Murray & Chamberlain, 1999). These have emerged from two very separate paradigms being underpinned by differing ontological and epistemological assumptions (Dures *et al.*, 2010). But perhaps worryingly, it has also been noted that psychological methodological debate has always been a 'battleground for prejudices' Michell (2003b).

Quantitative approach

Traditionally, the quantitative paradigm has adopted a 'positivist' epistemological position (Shadish, Cook & Campbell, 2002). This emerged from the Pythagorean doctrine that proclaimed that the structure of the 'natural world' was 'fundamentally quantitative' (Michell, 2003a). This approach has sought to promote the assertion that an objective, quantifiable and deductive stance must be held (Marks & Yardley, 2004). It is often based on experimental methods or closed ended questionnaires/surveys to measure relationships between variables and test hypotheses (Maxwell & Delaney, 2004). In addition, it utilises statistical analyses on large samples sizes to enable generalisations (Sale, Lohfeld & Brazil, 2002). However, the stance has not been without criticism for the assertion that reality is a 'fixed entity' and verified experimental hypotheses produce facts/laws (O'Byrne, 2007). Another criticism from Michell

(2003a) included its failure to recognise the non-fixed entities such as human imagination. Post Positivism has in some way addressed this with a critical realist ontological approach. Whilst remaining true to positivist paradigm it acknowledges scientific hypotheses testing can only define 'probable facts' (O'Byrne, 2007). However, criticism continues exemplifying that no psychological attributes have been measured as quantitative thus far (Michell,2003b). Nonetheless, enhancing this argument is beyond the scope of this study except to ensure these stances are considered and reflected upon.

Qualitative approach

In rejection of the positivist/post positivist stance; it has been contested that the qualitative approach was being used by the founding fathers of Psychology, Wundt, James and Freud (1874; 1878; 1886 cited in Baker, 2011). Michell, (2003a) added that these pre-dates, the emergence of quantitative experimental design adopted by psychologists at the end of the 19th Century (Michell, 2003a).

Qualitative researchers have adopted a constructivist/interpretivist epistemological position (Marks & Yardley, 2004). This proposes that we all experience a socially constructed reality developed and influenced by lived experiences which are dynamic and therefore subject to change (Dures *et al.*, 2010). In addition, Braun and Clarke (2013) have suggested that there are two main categories of qualitative research; experiential and critical. The first focuses on participant's interpretations and meaning whilst attempting to uncover views, behaviours and practices. In comparison, they highlight that critical research does not take the data at face value but focuses on the researcher's interpretation of what the responses represent (Braun & Clarke, 2013). Research methods adopted by qualitative researchers

include observations, focus groups, individual/group interviews and action research. Whilst sample sizes tend to be smaller when compared to quantitative methods; they are claimed to be able to generate detailed and descriptive data for interpretation to enable understanding rather than generalising (Sale *et al.*, 2002).

Mixed Methods in Research

Mixed methods research has arisen in an effort to bridge the divide between the qualitative and quantitative fields (Johnson & Onwuegbuzie, 2004). Yancher (2006) has reported the 'growing recognition' that methods utilised should match the research question and not be limited by traditional perspectives of either/or in the 'qualitative-quantitative debate'. It has been argued that for a complete and balanced overview; utilising mixed methods (i.e. both qualitative and quantitative approaches) provides what has been termed as the 'third paradigm' to best understand the research problem (Dures *et al.*, 2010; 333).

Emerging in the 1950's, researchers began to mix approaches and techniques by integrating qualitative and quantitative methodologies (Creswell, 2003). Studies often researching phenomenon utilising multiple paradigms began addressing complex and under-researched topics (Creswell & Plano Clark, 2007; Giddings, 2006). Increasingly since the Millennium, the interest these mixed methods have generated, has led to support for and advocating of, a paradigm (Johnson, Onwuegbuzie & Turner, 2007; Gilbert, 2006; Haverkamp, Morrow & Ponterotto, 2005; Johnson & Onwuegbuzie, 2004; Creswell, 2003

among others). This interest has led to mixed methods researchers identifying themselves not as positivist or interpretivist but as 'pragmatist' (Creswell, 2003).

By adopting a pragmatist epistemological position, mixed methods researchers do not ascribe to one philosophy or approach but utilise multiple inductive, deductive and abductive perspectives to understand research questions (Johnson & Onwuegbuzie, 2004).

The strength of mixed methods has been in its potential to provide the flexibility of the qualitative enquiry with theoretically grounded hypothesis testing delivered by the quantitative component (Andrew & Halcombe, 2009). Moreover, they suggest that when quantitative highlights 'how often' and 'how strongly'; qualitative provides the 'why that happened' insight (Dures *et al.*, 2010). Additionally, Dures *et al.*, (2010) proposed that it can also address the bias any approach to social phenomena is partial to. But, Yardley and Bishop (2015) argued that this may have been relevant historically but today few psychologists retain such fixed beliefs. They highlight that 'postmodern society' recognised that knowledge is not value free or accepted without context.

However, mixed methods itself has not been without criticism. For example, Yancher (2006, p280) highlighted that there is a concern that mixed method approaches may fail to 'do justice to all perspectives at once'. Whilst this concern may be understandable, Michell (2003b) argues that 'mainstream psychology' would be mistaken to engage in any 'pre-emptive' exclusion of any methodology.

Approach Taken

After reviewing the literature and reflecting on the best fit to achieve the aims of this study it was decided that this research would be best approached from a pragmatist epistemological position. It was felt that a quantitative approach would provide a measurement approach to place numbers to observations and a qualitative approach would be able to highlight why this may have happened. However, neither alone would be able to address the research aims.

As discussed there have been qualitative studies (Kornelsen *et al.*, 2015; Brownell *et al.*, 2016; Dwamena *et al.*, 2009) in this area but whilst these have provided valuable insights into individual perspectives, policy makers and steering committees are unlikely to fund a service on this evidence alone in the NHS (MRC, 2006). When this research was proposed, it was highlighted by the hospital steering committee that any service delivered would need to demonstrate a benefit to the hospital by a quantified reduction in attendances (which would help in achieving 4-hour ED wait target) and unplanned occupied bed days (which have a domino effect on elective treatments throughout the hospital). Additionally, there was concern that it has been suggested by the Clinical Commissioning Group (CCG) that future hospital funding may be restricted to one ED visit per month for each patient as it has been proposed that any further visits represented a 'failed admission'. Therefore, within the hospital there was a fear that they may end up providing treatment that they are unable to claim back the costs on. So, any intervention that targeted this problem would be viewed favourably when services were commissioned. Thus, a quantitative study was deemed to be of necessity. Nevertheless, it was recognised that the approach

alone would not enable us to understand questions such as why patients might have attended less since intervention. Or indeed why did it have little or no impact? In addition, it was also acknowledged that the impact of placement of services, patient experience etc. would benefit from qualitative approach.

The decision was prompted when presenting the research proposal to my peers, supervisor and course directors, it became apparent that the quantitative approach would only identify what had happened but would fail to identify why this was the case. I was asked if I had considered a mixed methods approach by an expert in the field who was present at the time. In all honesty, I was not that familiar with the approach at that time but it gave me food for thought and encouraged me to reflect on my choice of methodology for the study and prompted me to research in the area. The literature review I conducted reassured and encouraged me to reconsider my approach. In particular, Creswell and Clarke's (2011) assertion that novice researchers could learn and conduct mixed methods. Yancher (2006, p275) argues that the most crucial component for deciding methodological approaches remains 'critical reflection and sound rationale'. So, I embarked on further reading (Dures *et al.*, 2010; Andrew & Halcombe, 2009; Creswell & Plano Clark, 2007; Johnson & Onwuegbuzie, 2004; Creswell, 2003 among others) and it became obvious that by adding in the qualitative component to the study, this could provide insight into the patient's experience of the intervention and its subsequent success or failure. Explained more succinctly by Dures *et al.* (2010) the quantitative would highlight applicability to a wider group whilst the qualitative could provide insight into the psychosocial impact of the intervention.

Also, the decision to adopt a mixed methods approach was supported by its successful application in previous health research studies. For example, Cramer *et al.* (2011) used a mixed method approach when

conducting a feasibility study utilising CBT intervention with women diagnosed with depression. It was also utilised for enhancing the population impact of CBT intervention for PTSD (Zatzick *et al.*, 2011). Plus, it was successfully used in an Emergency Department study providing a brief intervention to reduce hazardous and harmful drinking in attending patients (D'onofrio *et al.*, 2012).

To sum up, the use of the qualitative strand is being utilised to explain the quantitative results as it is felt that alone they cannot fully explain the outcome of the intervention or provide insight into the patient experience of attending.

The Quantitative Component

Trial Design

A feasibility study using a non-randomised historical control design was conducted to investigate the impact of providing CBT to 'high risk' group of frequent attenders with MUS at the ED. The research investigated the impact of providing CBT (delivered by a BABCP accredited CBT practitioner) plus treatment as usual (TaU as required) to 'high risk' group of frequent attenders with MUS at the ED i.e. within the healthcare setting they were familiar with.

Participants

Participants were an opportunistic sample consisting of 50 of the most frequently attending (high risk) patients at two Emergency Departments in the South of England who were allocated to either control or intervention group.

Sample Size and Selection

Qualifying experimental participants were identified from reports generated by the hospital Information Technology (IT) departments. Every three months the top 10 frequent attenders at ED are identified by reports produced. Thus, over three-year period a potential 120 frequent attenders can be identified. Following inclusion in the report, a patient's hospital records were then reviewed by the Emergency Medical Consultant who defined if they met the criteria for MUS before inclusion. Only on the Emergency Medical Consultant's agreement (and treating Medical Consultant if appropriate) were individuals

considered for the intervention arm of the study. The control group were identified by the Emergency Medical Consultant (at Control Group Hospital) retrospectively reviewing hospital records following identification by reports of frequent ED attenders generated by the Control Group hospital IT department. The Consultant defined if they met the criteria for MUS before inclusion.

Study Exclusions

- Patients who were under 18 years of age
- Patients under the care of a community mental health team.
- Patients with a current drug or alcohol misuse diagnosis.

(These exclusions were defined as the current Trust Policy mandated that referral pathways to specialist services were followed for these groups).

Effect Size

Estimation of the sample size needed was based on having at least 80% power ($\beta = 0.20$) to detect a reduction in health care utilisation based on a previous study by Sumathipala *et al* (2000). Participant numbers for the study were therefore, defined using $\alpha=0.05$, power=0.8 and an equal allocation ratio. It was calculated using G*Power version 3.1.9.2 (Cunningham, 2007) that an independent samples t-test with N=25 in each group would have a minimum detectable effect Cohen's d (Cohen, 1988) size of 0.808708, which under Cohen's effect size rating (Cohen, 1969) is a large effect size (see figure 1).

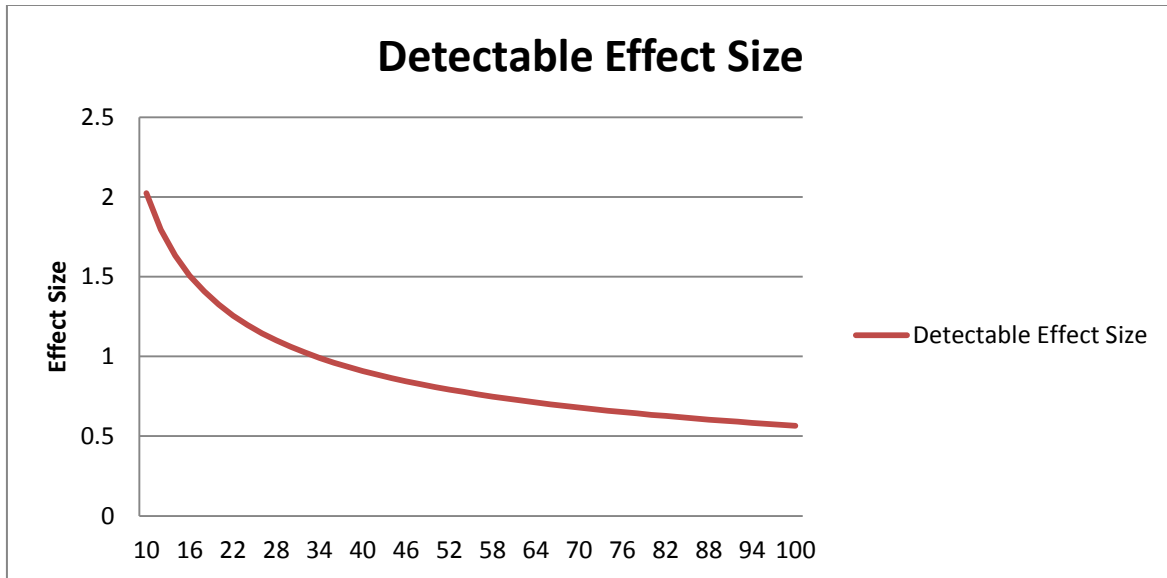


Figure 1. Effect Size by participant numbers.

Demographics of Groups

There were 50 participants in total in the quantitative study 25 in each group. Mean age of 46.40 in control with a range = 67 (20 – 87) and a standard deviation of 21.89. The mean age in experimental group was 43.56, range = 58 (20 – 78) and a standard deviation of 18.13. In total, there was 20 Males and 30 female participants. The gender split in the control group was 11 males and 14 females and 9 males and 16 females in the experimental group. Ethnicity was documented as White British for all but 3 participants who identified as White Other (2 in control group, 1 in experimental group). The Demographic make-up of each area groups were recruited from was reported in 2011 census as 91.9% White British in control area and 83.8% in experimental (Dorset Statistics, 2017). No participants were excluded on ethnicity, gender or age if over 18 years old.

Attrition/Refusals

In the experimental group, there was 4 patients who were excluded. Two patients refused the intervention and did not start (1 male and 1 female and both White British). 27 participants originally started the intervention sessions. However, 2 participants died during the study and their data was withdrawn (both Males of White British origin).

Randomisation and Blinding

Randomisation was not possible as the major stakeholder had predefined that 'all appropriate frequent attenders should be offered the intervention'. Additionally, the impossibility of double-blinding psychological treatments has been reported by Kleinstauber *et al.* (2011). They noted that it was not possible to carry out a double-blind study as psychology patients can easily know/or find out what treatment they are receiving. Therefore, a non-randomised controlled trial was conducted.

The Intervention

The intervention group participants comprised of clinic patients who have attended a CBT intervention held one day per week in the ED over the previous 3-year period. In the first instance, contact was made with the participants by the Psychologist (BABCP accredited CBT practitioner) inviting them to attend the ED for an assessment to begin a psychological intervention to help them better manage their symptoms. The Consultant Liaison Psychiatrist conducted the initial patient assessments with the Psychologist to verify risk status (that they did not have an enduring/severe mental health diagnosis, were a risk to themselves/others or were at risk from others) and to determine if they were suitable to be offered CBT. All attending patients (who did not meet exclusion criteria – see page 42) were offered 10-16 sessions of CBT (with a mean attendance rate of 12 sessions).

The CBT provided utilised an adaptation of CBT for somatisation protocol (Woolfolk and Allen, 2007) and Salkovskis *et al.* (2003) protocol (see Tables 2 and 3). This allowed for inclusion for work with health anxious behaviours where appropriate.

Table 2: Summary of the treatment session aims of Cognitive-Behavioural Treatment for Severe and Persistent Health Anxiety (Hypochondriasis) – Salkovskis *et al.* (2003)

Assessment and engagement – identifying symptoms, beliefs, behaviours and consequences.
Create a shared CBT formulation – including triggers, meaning and maintenance factors.
Introduce self-monitoring for information gathering using thought diaries.
Questioning beliefs – challenging interpretation of bodily sensations with re-attribution.
Conducting behavioural experiments – to challenge catastrophic thinking, role of maintenance factors and generate evidence against illness beliefs.
Dealing with rumination and worry – looking at advantages and disadvantages of behaviours.
Reduce reassurance seeking – inviting spouse/significant others to session if appropriate.
Contacting treating health professionals advising of negative role of reassurance – limiting frequency of consultations.
Identification and reattribution of assumptions and meaning of physical symptoms.
Identify triggers and warning signs – relapse prevention blueprint.
Preparation for discharge with offer of top up sessions if required.

Both Woolfolk and Allen (2007) and Salkovskis *et al.* (2003) interventions included components to challenge cognitive distortions with restructuring, introduced behavioural experiments and activation and strategies to manage negative emotions.

Table 3: Summary of the treatment sessions aims of Treating Somatization: A Cognitive-Behavioural Approach – Woolfolk and Allen (2007)

Assessment and engagement – eliciting symptoms, beliefs, behaviours and consequences.
Provide treatment rationale – impact of stress on physical symptoms.
Create CBT formulation - identify treatment target symptoms.
Introduce relaxation techniques – to be practiced twice daily.
Complete symptom monitoring and activity logs.
Develop long-term/short-term behavioural goals to increase activity and pleasurable activities.
Include spouse/significant others (if relevant) to understand support/barriers to recovery.
Introduce distraction techniques.
Discuss rationale for cognitive restructuring – practice examining and challenging thoughts.
Conduct sleep hygiene assessment - provide education and stimulus control techniques (if appropriate).
Discussing the sick-role – consider impact of illness (advantages and disadvantages).
Teach assertiveness skills providing rationale for use – plan assertive behavioural experiment.
Identify triggers and warning signs – relapse prevention blueprint.
Preparation for discharge with offer of top up sessions if required.

These treatment components have been documented as treatment necessities by Salkovskis *et al.* (2016). Previous studies have utilised more than one protocol (Speckens et al, 1995; 1996) with good outcomes.

Additionally, Chalder (2014) had previously recognised that treatment protocols can easily be adapted to ensure that they include physiological as well as cognitive, behavioural and affective mechanisms in information for patients (Chalder, 2014). Furthermore, transdiagnostic approaches for MUS have suggested that all could be addressed by utilising the necessary treatment components multiple models. (Salkovskis, *et al.* 2016; Chalder & Willis, 2017). Historical notes were reviewed by the psychologist and it was identified that the patient cohort's previous attendances had been either majorly symptom driven or anxiety led. Thus, the inclusion of both was felt necessary. This assumption was also supported by Soril, *et al's* (2015) who proposed that 'personalizing and tailoring' interventions may prove to be most effective at reducing high users.

All suitable patients were offered between 10 – 16 sessions of CBT (1 hour per week) held at the ED (interview room). All patients continued TaU at ED if presenting with physical symptoms. Patients were required to sign a treatment agreement (see appendix 2) advising that all therapy sessions would be confidential unless 'safeguarding' concerns for themselves or others were evident. General Practitioner's (GP's) as care managers were copied on patient appointment letters to advise that the patient was attending ED (see appendix 1) for the CBT clinic (as per NHS guidelines). No patient identifying data was held by the practitioner at any time outside of the hospital environment.

Quantitative Measurement

Outcomes

For the primary outcome, quantitative measurements were used to calculate any change in ED attendances by the target group pre and post intervention (12 months pre and 12 months post intervention). Raw data of ED attendances was provided by the hospital IT departments. The target group was then compared with the control group receiving TaU at a local hospital in the region.

In addition, a secondary outcome was measured quantitatively calculating any change in bed days utilised by the target group pre and post intervention (12 months pre and 12 months' post intervention). This group was then compared with the control groups' data 12 months pre and 12 months post intervention. The raw data (bed reports) were provided by each of the hospital's IT departments for comparison.

The statistical test utilised to look at the changes in each group was a gain score analysis using Independent samples *t*-test to compare the two groups. The independent samples *t*-test and MANOVA are statistics designed to detect differences between or among groups (Wilson, Voorhis & Morgan, 2007). Originally, a two-way MANOVA was considered but given the sizes of the experimental and control group, it was defined inappropriate due to lack of power (Wilson et al., 2007).

Additionally, an ANCOVA taking gender, age, pre-intervention behaviour and whether they were in the treatment or control group as explanatory variables with post-intervention behaviour [either number of

admissions or bed days as appropriate] was considered. However, again as the study was an initial trial and therefore it was not powered to do this but was powered to see whether there is a main effect of intervention group. Smolkowski (2013) highlighted there has been an ongoing debate between the use of gain scores and ANCOVA. Declaring that ANCOVA should only be used for randomised trials and when groups are equivalent at baseline. If this is not the case then analysis of gain scores should be utilised. This supports Oakes and Feldman (2001) who insist the use of ANCOVA is only appropriate in the analysis of randomized controlled trials. Fitzmaurice, Laird, and Ware (2004) who demonstrate that the choice between analysis of gain scores and ANCOVA was dependent on the research question. They defined that for ANCOVA tests the question would read akin to 'given that participants start with the same score, how do they differ at post-test?' However, noting that gain scores answer different question i.e. how do groups, on average, differ in gains? It was therefore decided that analysis of gain scores was the best fit for this study.

Previous research has highlighted that uptake and adherence to psychological interventions in physical health domains have been low (see Barsky and Ahern, 2004). Therefore, it was proposed that an outcome measure would be included to measure uptake levels and attrition rates for the intervention ensuring the generalisability of the results of the study.

Also, self-measurement questionnaires were completed at assessment and on discharge for the experimental group. These included Patient Health Questionnaire – 15 (PHQ-15) developed by Kroenke, Spitzer and Williams (2002). This tool has been validated as identifying the top 10-20% of scorers which is

the severe end of the MUS spectrum. Secondly, the Patient Health Questionnaire (PHQ-9) for depression; Generalised Anxiety Disorder questionnaire (GAD-7); Work and Social Adjustment Scale (WSAS) were completed. These measurement tools are widely used throughout the NHS and in IAPT. As the psychologist's time was provided by the local IAPT service for this pilot it was a pre-requisite that these measures were used in line with the national strategy (IAPT, 2011). No measurements were completed by the control group who were a retrospective cohort and remained anonymous to the researchers therefore it was not possible to collect data for comparison.

Intention to Treat (ITT)

An Intention to Treat (ITT) analysis was not conducted for the 2 participants who died before completing the intervention as inclusion would not have been appropriate for the experimental group in isolation. Ethical constraints had meant that the control arm had provided data for 25 patients only. There was no way of knowing if there were other patients who originally met the inclusion criteria but their data had been excluded. Therefore, it was advised in personal communication (Toher¹, 2018) that inclusion would have presented an overly optimistic picture on the primary outcome measures (reduction in attendances).

¹ Programme Leader: Mathematics and Statistics Degree Course

The Qualitative Component

This research proposed to explore the experimental group's experience of the intervention provided and understand their perspective. Therefore, because the study aims were exploratory, it was decided that descriptive analysis would be most appropriate. Both Interpretative Phenomenological Analysis (IPA) and Thematic Analysis (TA) were considered before deciding which would be best fit for the study.

Thematic Analysis (TA)

TA is a form of qualitative analysis that was developed by Holton in the 1970's (Merton, 1975 cited in Braun & Clarke, 2013) but only became a 'distinctive method' when defined in detail by Braun and Clarke (2006). Since this time, it has grown in popularity across the field of psychology and the social sciences (Brown *et al.*, 2007, Tippens *et al.*, 2013; Braun & Clarke, 2004 among others). It is claimed that TA is flexible descriptive method that is independent of theory and epistemology which can therefore be applied across a range of approaches (Braun & Clarke, 2004). Its aim is to uncover detailed accounts of the dataset by identifying, analysing and reporting patterns within. TA provides a method to organise and describe data in rich detail by looking for commonly recurring themes (Braun & Clarke, 2013).

Additionally, it has been noted that TA allows for unanticipated insights enabling researchers to not only spotlight similarities within datasets but also emerging differences (Braun & Clarke, 2006). TA has previously been used to explore patient's perspectives and experience within healthcare research (Tippens *et al.*, 2013); explore experiences and perspectives of intervention delivery (Brown *et al.*, 2007)

Nevertheless, it has not been without criticism. For example, TA has been criticised for failing to relay individual nuances on the participant story and for its lack of interpretive power (Wilkinson, Joffe & Yardley, 2004).

Interpretative Phenomenological Analysis (IPA)

IPA is a form of qualitative analysis which, as the name suggests, comes from the theoretical perspective of Phenomenology. It has an ideographic focus to examine an insider's perspective (Smith, Jarmen and Osborn, 1999, cited in Murray & Chamberlain, 1999). Whilst it can also identify patterns across data; it does not attempt to provide a causal explanation of a phenomenon but to understand what the experience meant to the individual. The focus of IPA lays in how individuals make sense of their lived experience. It pays minimal attention to the broader social context but emphasises understanding how individuals construct their reality (Braun & Clarke, 2013). However, it has been contended that IPA fails to uncover how experiences are seated within the wider sociocultural context plus it can lack the overall descriptive narrative of TA (Braun & Clarke, 2013).

Whilst both TA and IPA would have the potential to provide valuable insights to individual's experience of the treatment intervention, the aim of the project was to explore and describe the intervention groups experience rather than their individual perceptions and nuances. In addition, it was felt that TA was best suited for a mixed method approach because of its 'flexibility' highlighted by Braun & Clarke (2006). It was decided that this would be the best fit of methodology for this study.

In addition, historical experience of the cohort had ruled out questionnaires as a source of data because all intervention participants had previously had them posted before appointments and all but one failed to complete them. It was decided that as the study wanted to understand the participants experience and ‘interviews are ideally suited to experience-type research questions (Braun & Clarke, 2015 p81) interviews were deemed to be the most suitable means of data. Nonetheless, there are disadvantages of interviews which should be noted. These include that they can be time consuming which restricts the numbers unlike questionnaires for example (Murray & Chamberlain, 1999).

Interview Design

It was felt that a semi-structured telephone interview would be more time efficient, accessible and inclusive plus it would not rely on sourcing accommodation in the hospital or community hubs that was historically difficult. In addition, Shuy (2002) noted that telephone interviews also offered flexibility to the participants regarding timing, mobility problems and transport. Moreover, Trier- Bierniek (2012) argued that telephone interviews can result in rich data even where issues are sensitive or traumatic in nature. Highlighting those interviews conducted over the telephone can yield a more honest conversation because participants are not only being interviewed in familiar, comfortable surroundings but they also feel more anonymous (Trier-Bieniek, 2012). This view supports a systematic review conducted by Novick in 2008. The review reported that there was no difference between the quality of findings and data interpretation with telephone interviews and those conducted face to face. Furthermore, it concluded that telephone interviews provided other benefits including decreased travel costs and accessibility to geographically dispersed respondents.

Semi-structured interviews have been described as the most widely used data collection tool in qualitative research (Willig, 2008). When designing the interview questions care was taken to ensure the use of medical jargon was minimised. However, the abbreviation CBT was included as it was felt that as all participants had attended the intervention clinic this would be a term they understood.

In total the interview schedule contained five sections (see appendix 3). It started with an opening question that allowed participants to get used to answering questions and expressing their views. This was particularly important for anxious or nervous participants as it helped to put them at ease and build rapport (Kvale & Brinkman, 2009). The interview started with them being asked to introduce them and then talk about their experience of ED before attending the intervention, 'Think back to before you attended the CBT clinic, what was your experience of the emergency department at this time?' It was hoped this provided a straightforward introduction to the interview, and gave them a chance to provide their journey from the beginning.

The question was introduced following piloting of the interview with a patient who had attended the intervention and agreed to provide feedback to help in the development of the questions. She reported that she felt 'thrown in at the deep end' so the format and order of questions was amended. Charmaz (2002) suggested that it was good practice to review the interview guide after the first interviews to ensure that the data you are getting will be able to answer your research question. Charmaz, (2002) proposed that the schedule should not be fixed and questions should be changed, added or removed if

necessary as issues are uncovered. In this case, the pre-testing of the interview questions and format was conducted to ensure that they were relevant and appropriate for participants and were producing data that informed the research question. The pilot participant suggested the opening question could be more generic about the experience and the above question was agreed by the researcher as suitable. The Department of Health has highlighted the importance of service user involvement in health research (Department of Health, 1999).

Additionally, patient involvement was felt necessary to ensure that the phrasing of the questions was clear, precise and without ambiguity and elicited answers with depth that produced data. Taking care in phrasing and ordering of questions has been shown to be important because this was what elicits the 'story' and what one hoped would produce answers needed for the research question (Smith, 1995). Therefore, the phrasing in some way defines if it has been meaningful to participants.

Following the piloting feedback, it was felt that the interview questions should be ordered to take the participants through the timeline of their experience to elicit 'reliving'. Mathieson (1999 in Murray and Chamberlain, 1999) talks about seeing the process of the interview like building a story with a start, middle and end.

Throughout the interview process, Fielding and Thomas (2008) advocate the use of prompts and probes to encourage participants to open up. Therefore, some questions were phrased in two parts with probes

and prompts added e.g. 'in what way?' And 'can you give me an example?' Plus, the interviewer was encouraged to use prompts and probes as they felt necessary.

Furthermore, all responses were repeated back by the interviewer to not only ensure they were correct but also to help build rapport. Anderson and Jack (1991) contended that repeating for clarification shows active listening and expresses interest and participation in the process and aids the rapport process as interviewees feel a partnership is taking place.

The interview schedule consisted of five sections (see appendix 3). The first consisted of questions regarding their historical ED relationship. As research suggested that clinical investigations not only cost the health service vast sums of money but also leaves patients dissatisfied and maintains their belief that their needs have not been met (Hahn *et al.*, 1994). In addition, a later qualitative research by Kornelsen *et al.* (2015) supported this stance stating that testing and retesting takes time and the lack of results often leads to frustrated patients and doctors. The second section of the interview related to attending intervention to verify if the placement within the medical setting known to patients, ED's encouraged attending. The point was re-stated in the IAPT positive practice guide for MUS confirming that services 'embedded in a physical health framework may encourage engagement (IAPT, 2014, p14) however, it is yet untested within an ED environment. Section three focused on their experience of the intervention with hope to gaining new insight into which elements were deemed most useful to the participants. Section four asked about their current experience e.g. their symptoms and ED attends. Again, research (Van Dessel *et al.*, 2014) has highlighted that successful interventions have produced a remission in

psychological distress and symptom reduction and section five focussed on what they thought of the overall experience. This was developed as Kvale and Brinkmann (2009) suggest a clean-up question as a final note. They stated that this should be included in the hope that it triggers useful and often unanticipated data. Therefore, the interviewer concluded with 'is there anything else you would like to add about your experience?'

Ensuring Quality in Qualitative Research

It has been acknowledged that the researcher is an active agent within the qualitative research process and with this they bring their own assumptions, experiences and beliefs (Braun & Clarke, 2006). Thus, quantitative standards such as lack of bias, validity, reliability and generalisability may not prove appropriate. Without question developing universal quality criteria has proved a significant challenge in the qualitative domain (Tracey, 2010). Particularly as some would argue that a quality standard must be underwritten by specific theories or standpoints (Cunliffe, 2011; Ellingson, 2008; Denzin, 2008; Guba & Lincoln, 2005). But it could be argued that utilising a universal model would deny subjectivity and multiplicity of qualitative studies.

This topic has been particularly problematic in applied health research where researchers attempt to influence practice. Health policy makers and clinicians subscribe to evidence-based practice (Dept. of Health, 2006). Therefore, there is a necessity to display quality and rigour in qualitative work particularly for those unfamiliar with qualitative language and advancements made in its theoretical underpinnings. Positively, the Department of Health (2004) has encouraged the inclusion criteria to be broadened

acknowledging that 'lay' perspectives and multidisciplinary models of health are important in planning service provision.

In response to this (Tracey, 2010) has provided a model for qualitative best practice standards. The 'eight big tent' criteria published by Tracey (2010) offers a universal model for quality in qualitative research. Its criteria deliver a structure for examining the quality and presentation of the end results, whilst accepting the sometimes-complex differences in how researchers arrive at them (Tracey, 2010).

This study followed the 'eight big tent' criteria (Tracey, 2010) in an attempt to ensure quality has been achieved. Tracey defines eight key markers for quality in qualitative work (see appendix 4 for full table):

1. Worthy topic
2. Rich rigour
3. Sincerity
4. Credibility
5. Resonance
6. Significant contribution
7. Ethics
8. Meaningful coherence

The primary focus of the criteria is placed on researchers displaying a clear step by step account of their method and analysis. In addition, providing honest self-reflection with the acknowledgement of strengths and weaknesses is encouraged to ensure researchers have recognised their role in the process of

collection and analysis (Tracey 2010; Richardson, 2000). A reflective chapter has been included in this study to meet these criteria.

The plausibility and trustworthiness of study findings are important components for the research 'credibility' (Tracey, 2010). To this end, the results should display detailed and full descriptions of the dataset. Crucially, any contradictory participant accounts should be included.

Furthermore, research credibility can be improved by incorporating the practices of crystallisation and triangulation. This approach benefits from applying multiple data sources thus allowing differing aspects of participant experience to be explored. This project utilised both the quantitative and qualitative arms for crystallisation and triangulation.

Additionally, TA subthemes and themes were discussed with another qualitative researcher. This was done to encourage insight and understanding and allowed the consideration of different organisations of themes (Tracey, 2010).

Recruitment & Consent

Qualitative semi structured interviews were conducted by an independent NHS practitioner. Interview participants were an opportunistic sample of individuals who had attended the frequent attenders' clinic (the intervention arm) at the ED. The aim was to recruit a minimum of 6 participants. Braun & Clarke have in their extensive guide to qualitative research defined that sufficient data from a small project can be

obtained from between 6-10 interviews for TA (2013 p50). However, it was decided that all patients who had completed the intervention would be invited to participate (see Figure 2).

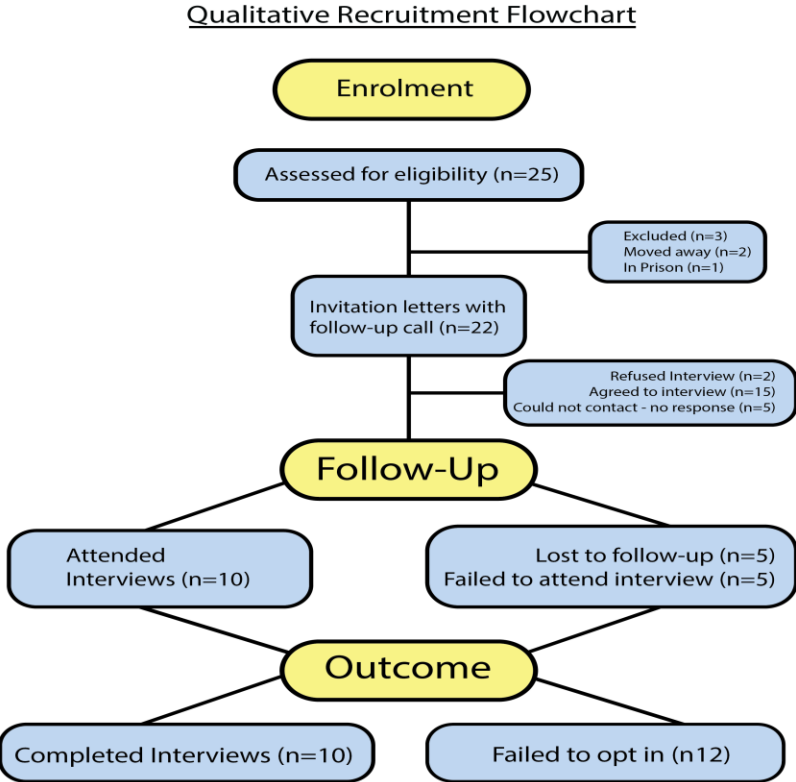


Figure 2: Qualitative Recruitment Flowchart [adapted from Chan *et al.*, (2016) CONSORT 2010 statement]

Whilst no patients were intentionally excluded; it was known to the experimenter that 1 previous intervention attendee was on remand in prison and 2 had left the area without forwarding details. The remaining 22 participants were contacted by letter and then followed up with a telephone call one week later to ask if they had received the letters and discuss if they would be willing to participate. From the 22

potential participants, 17 were spoken to directly and 5 potential participants were left voicemail messages to contact the experimenter. The voicemails were followed up 1 week later and again 1 month later all with the same message for contact. From the 17 potential participants spoken to, 15 agreed to attend the telephone interviews (letters were sent confirming interview appointments) and 2 refused (claiming lack of time on both occasions). However, 7 failed to answer the call at their appointment times (Did Not Attend – DNA's). All failed appointments were subsequently rebooked by telephone with 2 further participants attending successfully and 5 failing to answer the phone at the agreed time. One further attempt was made to rebook these appointments by the experimenter over the following months without success. In total 10 participants participated in the interviews over a six-month period from date of first letter of invite.

Data saturation

When considering data saturation for this study, it became apparent that saturation had a variety of meanings and variable transparency within the qualitative research field (O'Reilly and Parker, 2012). Indeed, it would appear from a literature search that there is no definitive agreed number or formula for achieving data saturation. With some arguing that data can never be completely saturated as new data can always be discovered (Wray, Markovic and Manderson, 2007). Thus, it has been contended that the imposition of data saturation as an indicator of 'quality' is inappropriate outside of the confines of grounded theory where there is an established framework for its use (O'Reilly and Parker, 2012). Moreover, O'Reilly and Parker (2012) argue that findings are not invalidated if there has been an adequate explanation why collection was ended. Additionally, they propose that when this is reported it

is suggesting that a full exploration of the phenomenon remains necessary and will be discussed in the study limitations. This study was conducted for a Professional Doctoral thesis and from the beginning was a small-scale study rather than large. Additionally, as part of a thesis there were time constraints imposed on the study and data collection to accommodate the need to write up and submit the doctoral dissertation. The current study had been delayed by ethical approval and with hospital IT departments providing data. Therefore, it was decided that a limit on collection time needed to be imposed. Every effort was made before this date to try and complete as many interviews as was possible. Given that Braun & Clarke (2013, p50) had defined that it was adequate for small projects to obtain 6-10 interviews for TA and that many participants had given up their time and shared their experiences for their stories to be heard; it was felt that the analysis of the interviews should be included in the final dissertation even if saturation could be questioned. Nonetheless, this will be acknowledged in the studies limitations. This stance has been supported by Bryman (2001) who proclaimed that evaluators should encourage researchers to be transparent about why data collection was stopped instead of making highly challengeable claims about data saturation being achieved.

Benefits of the Study to Interviewees

There may be no benefit to participants. However, it was hoped that by sharing their opinions and experience of past services, the participants have helped to define how Psychological services in the hospital setting could be provided in future.

Materials

The attendees were sent a letter of invitation (see appendix 5) containing an overview of the research and participant information sheet (see appendix 6) outlining the research. In addition, two copies of the informed consent form (see appendix 7) and a prepaid return envelope were enclosed. After 7 days, they were contacted by the chief researcher by telephone to verify they had received the letter and if they had any questions. Contact details for the chief researcher and PALS were provided in the letter (as per NHS protocol) so that any questions they may have had could be answered before the potential participant made their final decision on whether to provide consent.

The information sheet and consent form was designed in line with NHS guidelines, and were approved by the Health Research Authority and University ethics (see appendix 9). The information sheet outlined the purpose of the research and why participants had been invited to take part. It assured them that all data obtained in the interview would remain anonymous, and that in the event of publication the participants would not be identifiable. It also stated that during the interview they did not have to answer any questions that made them feel uncomfortable and that the interview could be terminated at any point if they did not wish to continue. Participants were informed that their participation in the study was completely voluntary and that they could withdraw from the study at any time and for any reason. If they agreed to participate they returned the consent form in the prepaid envelope addressed to chief researcher provided with the letter. A further copy was provided for the participants records.

Once consent had been received they were contacted by telephone by the chief researcher to arrange a suitable interview time. Interview times were arranged at the participant's convenience with day and evening appointment slots available. They were also given a contact number in the letter that was manned during office hours and had facilities to leave a message outside these times should they have wanted to cancel or amend their interview appointment. This number could also be used if they have any queries after the interviews. They were given a second opportunity to read the information sheet and ask any questions before the start of each interview.

The skill of an interviewer has been identified as a crucial component to successful enquiry by Braun & Clarke (2013). They state that an individual who is conducting the interviews needs to be practiced in building quick rapport with participants. Additionally, the ability to handle silences as a means of extracting more information and the flexibility in adapting the interview to follow the route taken by Participants is valuable

Psychological Well-being Practitioners (PWP) are highly skilled in conducting interviews and mental health assessments via telephone. A PWP conducted the interviews using a hands-free headset at the allotted times (see appendix 3 for schedule). All interviews undertaken with participants were conducted via telephone and transcribed in real time (and no recordings were made at any time).

The interviewer was a highly experienced PWP who is skilled at documenting telephone assessments via telephone. The interviewer verified before beginning interviews that the participants still wished to

continue in the study before starting. At the end of the interview the participants were advised that they could receive a copy of the final report and an overview of what the research had highlighted and what this means in lay terms (any reports sent to participants will be forwarded to the Health Research Authority for review and approval prior to dissemination).

Once all interviews were transcribed they were sent by the interviewer to the Principal Investigator via NHS N3 secure network and deleted from the interviewers' computer. On receipt, names were amended to pseudonyms and participant number allocated to ensure anonymity.

Qualitative Data Analysis

The qualitative research study used TA to code the interviews. As discussed, TA is a systematic approach that enables the creation of themes that appear across a dataset. It was first introduced by Holton (1970's cited in Braun & Clarke, 2013) and has been called the 'definitive code based approach' Fereday and Muir-Cochrane, 2006). But the process used in this research was from procedures developed by Braun & Clarke (2006). They developed a 6-phase guide that was clear and allowed ease of replication (see table 4).

	Phases	Description of Analysis
1	Familiarisation with the data	This phase involves reading and re-reading the data, to become immersed and intimately familiar with its content
2	Coding	This phase involves generating succinct labels (codes!) that identify important features of the data that might be relevant to answering the research question. It involves coding the entire dataset, and after that, collating all the codes and all relevant data extracts, together for later stages of analysis.
3	Searching for themes	This phase involves examining the codes and collated data to identify significant broader patterns of meaning (potential themes). It then involves collating data relevant to each candidate theme, so that you can work with the data and review the viability of each candidate theme.
4	Reviewing themes:	This phase involves checking the candidate themes against the dataset, to determine that they tell a convincing story of the data, and one that answers the research question. In this phase, themes are typically refined, which sometimes involves them being split, combined, or discarded.
5	Defining and naming themes:	This phase involves developing a detailed analysis of each theme, working out the scope and focus of each theme, determining the 'story' of each. It also involves deciding on an informative name for each theme.
6	Writing up:	This final phase involves weaving together the analytic narrative and data extracts, and contextualising the analysis in relation to existing literature.

Table 4. 6 Stages of Thematic Analysis (Braun & Clarke, 2006)

N.B. Reprinted from Qualitative Research in Psychology, [online], 3, (2) Braun, V. and Clarke, V. Using thematic analysis in psychology. p77-101, (2006), with permission from Taylor Francis.

The first stage of the analysis was for the researcher to familiarise herself with the data. This was started by reading and rereading the transcriptions and noting initial observations. This process of note taking provided familiarity with the data and helped generate keywords and phrases that culminated into initial codes (see appendix 11) whilst simultaneously asking the question, is there enough meaningful data?

In the next step, different colours were used to highlight quotes that were similar. For example, statements that described 'familiarity' were highlighted in green. Each colour denoted a code and in some cases the same data fit more than one code and additional colours were applied. On completion, the next stage was developing themes. These initial codes were then grouped together to permit detailed analysis and to afford more meaningful themes. Miscellaneous data or data that was deemed insufficient to create a meaningful theme were grouped together. Codes which appeared to provide richness in detail and those that were similar were and developed into more encompassing codes and became sub themes. This is when a narrative started to be seen in the data and a story was starting to be seen. Any themes that appeared unsuited or weak were discarded following further analysis. At this stage, all data that had provided the text for the themes was reread to ensure it was representative of theme and not taken out of context. Any data that was not relevant was then removed. This was my no means a linear process and there was much back and forth re-reading to see 'what was going on in the data'. from stages to ensure that themes worked independently. Again, data extracts were re-examined for accuracy and to ensure that those included were the most descriptive and importantly most pertinent to the chosen theme. Finally, TA subthemes and themes were discussed at length with a colleague who had previously

conducted qualitative research. This practice provided greater insight and understanding and encouraged the consideration of different organisations of themes. Following this stage, the themes were ready to be included in the results section.

Data Management Plan

The data generated by this study was anonymised and stored on password protected NHS computers. This database was then stored on an archival CD, which was password protected (access remains restricted to authorised members of the research team and sponsor organisation) and archived with the study site file in accordance with Good Clinical Practice guidelines, the Data Protection Act 1998, and Sponsor's standard operating procedures.

Costs for postage, telephone calls, use of computers and stationary were provided by the trust as a proviso for patient confidentiality and with the understanding that the information would also be utilised for clinical audit purposes. IT reports were already created monthly for both ED's so no extra charge was incurred. The Interviewer and Chief researcher volunteered their time free of charge.

Ethical Considerations

Full ethical approval and permission for this research has been provided by the Health Research Authority (project number: 144246 – see appendix 9 for approval letter) and with University of the West of England (application number: HAS/15/07/193 – see appendix 8 for approval letter) and in collaboration with Dorset Research as per local NHS trust guidelines (see www.dorsetresearch.org). Furthermore, all work

was carried out in line with BPS and BABCP codes of ethics. Patient's data has been anonymised and all patients were given the right to refuse participation. Those who agreed to participate were notified of their right to withdraw themselves and/or their data from the study at any time up to 4 weeks following interview completion (see appendix 6). Additionally, participants were offered the opportunity to ask questions regarding the interview process, withdrawal from the study, how their identity would be protected (i.e. anonymity) or any other information of the study. All participants were provided with an ethics approved information sheet on recruitment. All participants who agreed to proceed with the interview were requested to sign consent forms in duplicate, one copy for the researcher's records and the other retained by the participant.

There were no foreseeable ethical issues. However, it was noted in the participant information leaflet (see appendix 6) that 'any participation in research can raise sensitive issues or painful emotions'. It also reassured that this was not the expected outcome of the interviews but 'should the interviewer be concerned for your personal welfare whilst conducting the interview, the interview will be stopped and confidentiality would be broken to enable a referral to be made to an appropriate healthcare professional'. An agreement was made with the primary care mental health team that in the unlikely event of participants become highly distressed they would triage the participants to an immediate assessment as necessary. Additionally, should the interviewer require supervision following the interviews this was also arranged pre-agreed with the primary care mental health team.

Limitations of the Study Methodology

All studies contain limitations and in this study the data was coded and themes identified by one person and this analysis was then discussed with an experienced TA researcher. Whilst this process provided consistency in the method; it could be argued that it failed to include multiple perspectives. Future studies could include the coding of data by two or more individuals with themes being developed using discussions with other researchers, and/or the participants themselves. Certainly, another coder may have been beneficial to address potential bias. Whilst I acknowledge that some bias is unavoidable it was hoped that this would be minimised by utilising TA and another researcher to confirm themes. Indeed, there has been criticism of having two coders, stating this process can reduce flexibility in coding analysis (Berends & Johnson, 2005).

Silver & Lewins (2014) claimed that utilising software in research is unnecessary for robust studies. However, it can provide a transparency in illustrating analytical decisions, tasks and sequence processes that are undertaken. Furthermore, it provided a visual reminder of content and frequencies and offers a system that can link quantitative and qualitative data (Silver & Lewins, 2014). Indeed, this study began by using NVivo software but it was changed when discussion about feeling remote from the data was supported in the Professional Doctorate Progression Viva with a very experienced expert researcher. It was suggested that TA would work better manually particularly given the inexperience of the researcher and this proved to be the case in this instance.

Additionally, future research should include randomisation and conducting measurements and interviews of the control group to aid comparison. This was not possible in this study due to ethical controls that insisted the control data remained anonymous to the researcher. Furthermore, because of the anonymity of the control group it must be acknowledged that given the proximity of each site that there may have been duplicate participants in each.

As previously highlighted, this study was conducted for a Professional Doctoral thesis and from the beginning was a small-scale study rather than large. With this, there were time constraints imposed on the study and data collection to accommodate the need to write up and submit the doctoral dissertation. However, every effort was made before this date to try and complete as many interviews as was possible. But, this process may have been stopped before data saturation was completed. Therefore, this would suggest that a full exploration of the phenomenon could remain necessary.

The Researcher's Perspective

There are many factors that can influence a researchers' findings including their own experience, beliefs and bias (Berger, 2015). As a counterbalance; reflective practice should be incorporated in to the research process (Tracey, 2010). This qualitative project was supported by a critical realist ontology and contextualism epistemological perspective. The realist position was rejected by the researcher who disagreed with the proposition that there is one truth to be discovered. Suggesting instead that the human experience emerged from both subjectivity and contextual factors (Madill, Jordan and Shirley,

2000). Moreover, the use of reflexivity within contextualism complimented the researchers understanding and professional practice.

Firstly, the current study was conducted with individuals who were distressed by their ongoing physical symptoms, sometimes fearing for their own mortality and often deeply upset by their interactions with the health service. A lot of the fear, frustration and dissatisfaction was directed at the researcher (in the role of psychologist) particularly in the early sessions which made them often very challenging.

Nevertheless, on reflection it could be argued that the emotional impact of working with this patient population could have influenced the interpretation and analysis of the data. To address this, clinical supervision was utilised and the researcher's own frustrations were discussed. Supervision provided clarity on the importance of developing working alliances which would become crucial in managing these difficulties. With work, successful therapeutic alliances were developed and subsequently created an environment that was empathetic, attentive and compassionate. This elicited mutual respect and limited where possible, any power imbalances within settings. Thus, it is hoped that my personal biases have helped in the provision of a platform that could illuminate the difficulties confronting frequently attending MUS patients in the ED.

Secondly, the researcher had a powerful sense of being overwhelmed and confused by the data when first attempting to analyse it. Initially, a software package (NVivo) was being used to conduct the TA. However, during the refinement of the themes, there was a real struggle to see the meaning and purpose of the data. An assumption was that the researcher was confused by the clinical experiences and

identifying what codes were related and/or distinct from each other proved challenging. This was originally attributed to having specific research expectations that proved to be abstract and thus was creating a barrier in achieving such undefined outcomes. This was remedied in the Doctorate Progression Viva when the researcher expressed this frustration to the reviewers. Their experience and questioning provided insight that using the software was not helpful in a first TA research project. So, all quotes were put onto post it notes and this process enabled quotes to be moved around with ease and thankfully themes began to emerge.

Finally, NHS ethical approval proved problematic and time consuming as the panel were reticent about providing approval for this study to be given the hospital numbers of the control group. This was a problem because it meant that this study cannot be sure if any of the intervention patients were frequently attending the neighbouring hospital and thus in the control group. This was very upsetting at the time but with supervision and reflection, it can now be seen that it their job to protect patient confidentiality. Therefore, today their judgement is respected and this potential flaw is acknowledged.

RESULTS

This chapter details the results of the feasibility study using a non-randomised historical control mixed method design examining if delivering a CBT intervention to frequent attenders at Emergency Departments with MUS impacted their subsequent attendances and bed days utilised. The results chapter of this study are analysed and presented in two sections.

The first presents the quantitative results which displays the outcome data from the study. The pre and post intervention measurement score utilised descriptive statistics to provide indicative analysis into the clinical effectiveness of providing the interventions in the ED.

The second section of this chapter presents the analysis of the interview data from the qualitative arm of this research.

Demographics of Groups

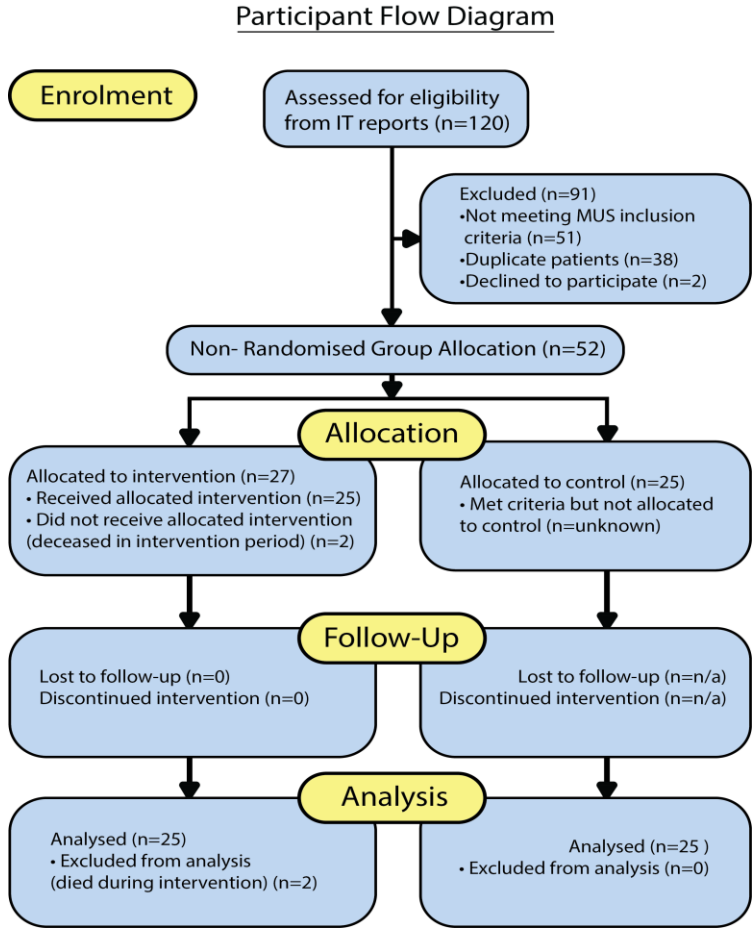


Figure 3: Participant Flow Diagram [adapted from Chan *et al.*, (2016) CONSORT 2010 statement]

There were 50 participants in total in the quantitative study, 25 in each group. Mean age of 46.40 in control with a range = 67 (20 – 87) and a standard deviation of 21.89. The mean age in experimental group was 43.56, range = 58 (20 – 78) and a standard deviation of 18.13 (see table 5).

Table 5: Baseline Characteristics of Study Participants		
Characteristic	Experimental Group (n=25)	Control Group (n=25)
Gender (female/male)	16/9	14/11
Age (mean/SD)	43.56 (18.13)	46.40 (21.89)
Ethnicity (White/British)	96%	92%

In total, there was 20 Males and 30 female participants. The gender split in the control group was 11 males and 14 females and in the experimental group 9 males and 16 females (see figure 4).

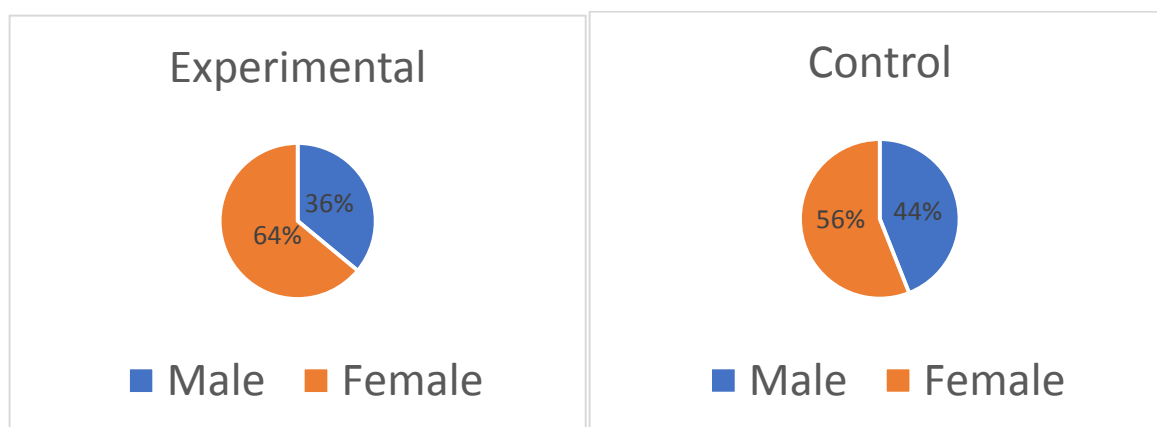


Figure 4. Gender split across conditions.

Ethnicity was documented as White British for 47 participants and 3 participants identified as White Other (2 in control group, 1 in experimental group). The Demographic make-up of each area groups were recruited from was reported in 2011 census as 91.9% White British in control area and 83.8% in experimental (Dorset Statistics, 2017).

Quantitative Analysis

The original data identified that the two groups were not equivalent at baseline (see table 6). Therefore, gain scores analysis (also termed change scores) was conducted (for rationale see p47).

Table 6: Baseline Data for the Experimental and Control Samples		
	Experimental Group Total (n=25)	Control Group Total (n=25)
Pre- Intervention ED attends	450	193
Post Intervention ED attends	220	150
Pre- Intervention Bed Days	554	249
Post Intervention Bed Days	253	349

The two groups were analysed on their differences between post-test and pre-test scores. This analysis of gain scores then utilised Two-Sample T-Tests as reported below.

An independent-samples t-test was conducted to compare attendances at the ED in the CBT Intervention condition and the non-intervention condition. There was a significant difference in the gain scores for the intervention group (M = 9.20, SD = 7.69) and the non-intervention group (M = 1.72, SD = 4.04) conditions; $t(36.30) = 4.31, p = 0.001$.

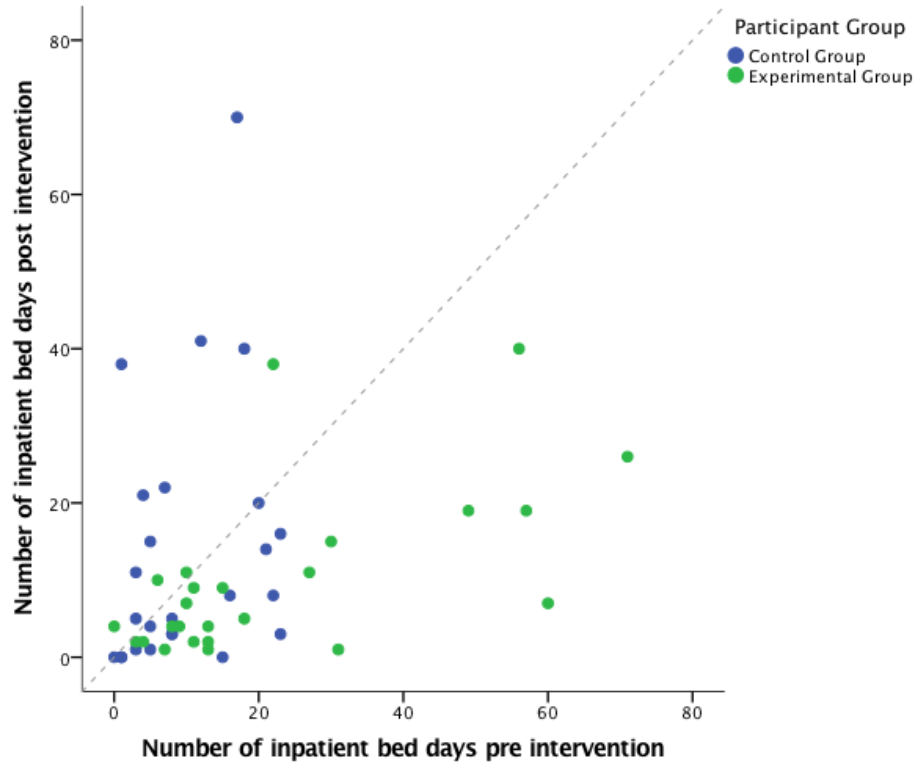


Figure 6. inpatient bed days pre and post intervention by group

The graph (figure 6) displays the line of change for inpatient bed days pre and post the intervention. Again, this spotlights that the experimental groups bed days have reduced for 21 of the participants. However, 9 of the control group have increased their inpatient bed days in the same period.

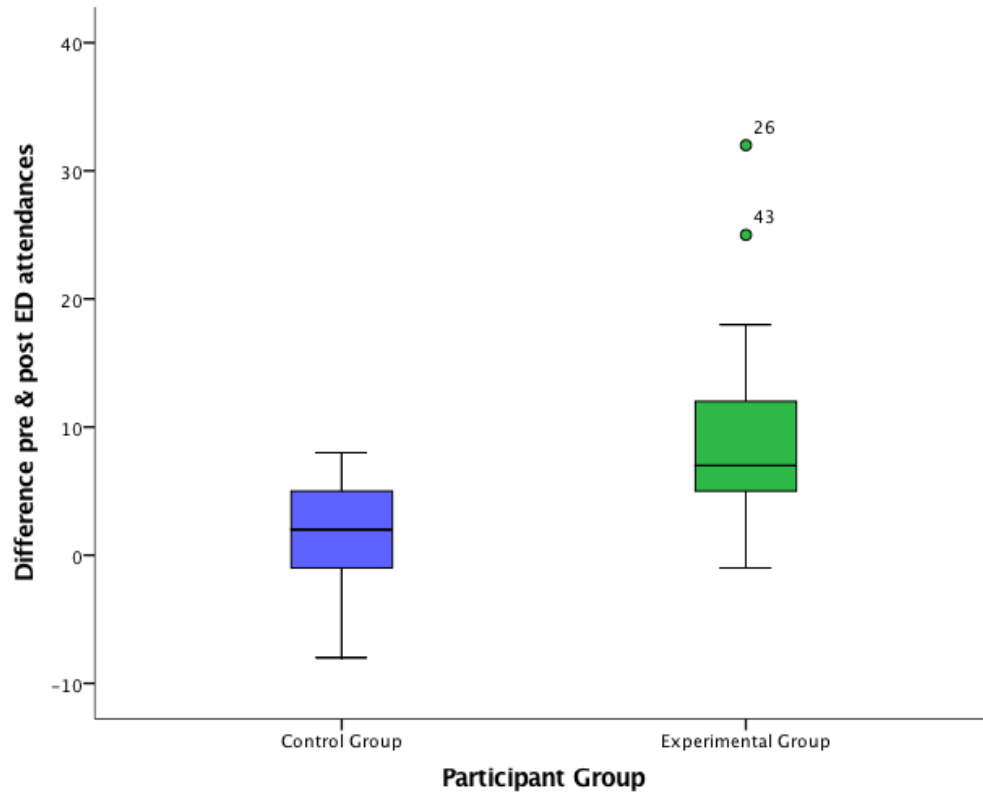


Figure 7. Difference in Differences (DiD) 12 months pre- intervention – post intervention ED attendances

Looking at Difference in Differences (DiD) identified that the experimental group produced a greater DiD score than the control group. This implies that there was a greater reduction in attendances for the experimental group than the control groups. The scores were calculated by subtracting the post intervention scores from the pre- intervention scores, thus, a larger number identifies a reduction in attendances on average.

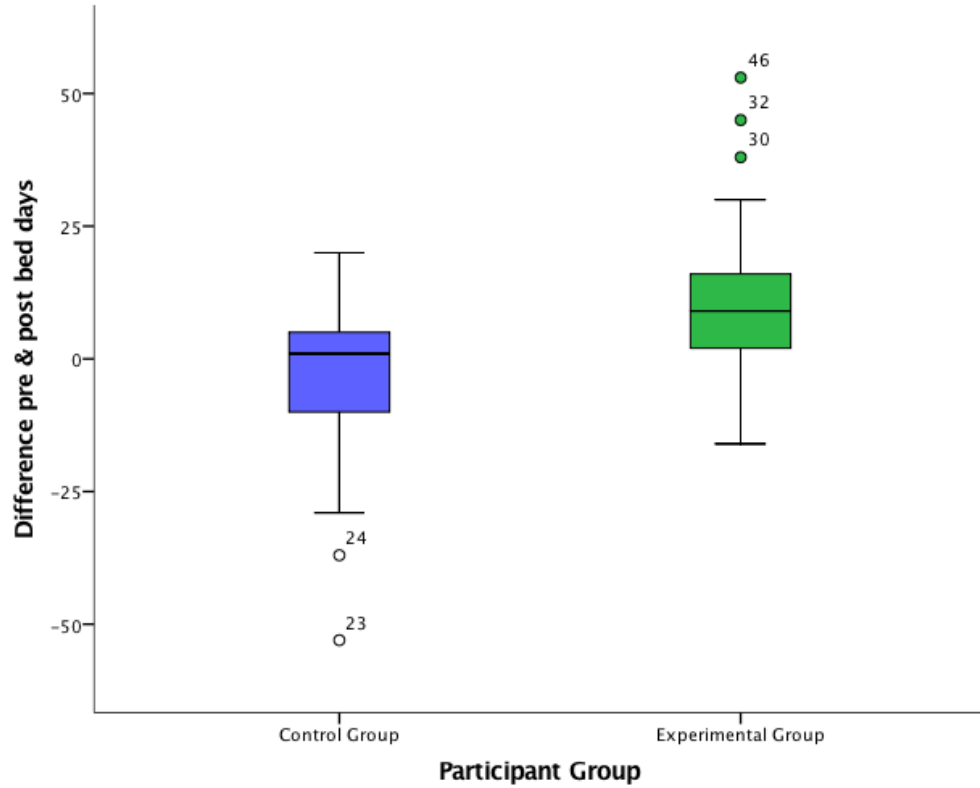


Figure 8. Difference in Differences (DiD) 12 months pre- intervention – post intervention inpatient bed days

Looking at Difference in Differences (DiD) identified that the experimental group produced a greater DiD score than the control group. This implies that there was a greater reduction in inpatient bed days for the experimental group than the control groups. The scores were calculated by subtracting the post intervention scores from the pre- intervention scores, thus, a larger number identifies a reduction in inpatient beds days on average.

Because the DiD data identified extreme outliers in both conditions that may have skewed the results. A Mann Whitney U test was completed. The test indicated that the inpatient bed day reduction was significantly greater for the experimental group (Mdn = 31.64) than for the control group (Mdn = 19.36), $U = 159.00$, $p = 0.003$.

The results reported above have highlighted that providing a CBT intervention does influence ED attendances and Bed Days utilised by frequently attending MUS patients. Specifically, the results indicated that when an intervention is provided, the ED attendances and Bed Days utilised decreased.

Psychometrics Analysis

The following tables show the descriptive statistics for psychometric evaluations. These self-measurement questionnaires were completed at session 1 and at discharge (session 12) for the experimental group. They included Patient Health Questionnaire – 15 (PHQ-15), The Patient Health Questionnaire (PHQ-9) for depression; Generalised Anxiety Disorder questionnaire (GAD-7); Work and Social Adjustment Scale (WSAS). Table 7 highlights the probable clinical effectiveness of the psychological intervention when comparing the pre and post intervention measurements by the reduction in scores. No psychometric outcomes were obtained for the control group.

Psychometric	Pre-intervention Mean	Standard Deviation	Range
PHQ-15	15.68	5.65	6-25
PHQ-9	16.08	5.11	8-27
GAD-7	15.92	3.83	7-21
WSAS	25.52	7.30	12-38

Table 7. Psychometric Questionnaire Pre- Intervention Outcomes

The pre-intervention outcomes of PHQ-15 (M=15.68, SD=5.65, Range 6-25) denotes a mean group score that is classified as severe for somatic symptoms. The PHQ-9 outcomes (M=16.08, SD=5.11, Range 8-27) identify a mean score classifiable for moderate/severe depression. The GAD-7 group mean score (M=15.92, SD=3.83, Range 7-21) denotes severe anxiety. Finally, the WSAS outcomes pre-intervention (M=25.52, SD=7.30, Range 12-38) denotes a mean group score that is classified as moderate functional impairment.

Psychometric	Post intervention Mean	Standard Deviation	Range
PHQ-15	9.68	4.70	2-21
PHQ-9	8.12	3.84	0-18
GAD-7	5.88	3.50	0-14
WSAS	17.84	6.30	10-34

Table 8. Psychometric Questionnaire Post Intervention Outcomes

The post intervention outcomes of PHQ-15 (M=9.68, SD=.70, Range 2-21) denotes a mean group score that is classified as medium levels of somatic symptoms. The PHQ-9 outcomes (M=16.08, SD=3.84, Range 0-18) identify a mean score classifiable for mild depression. The GAD-7 group mean score (M=5.88,

SD=3.50, Range 0-14) denotes mild anxiety. Finally, the WSAS outcomes pre-intervention (M=17.84, SD=6.30, Range 10-34) denotes a mean group score that is classified as significant functional impairment.

Psychometric	Pre-intervention Mean	Post-intervention Mean	Outcome %
PHQ-15	15.68	9.68	-38.3%
PHQ-9	16.08	8.12	-49.5%
GAD-7	15.92	5.88	-63.1%
WSAS	25.52	17.84	-30.1%

Table 9. Psychometric Questionnaire Outcomes Pre & Post Intervention

All mean scores reduced from pre- intervention to post intervention. The PHQ-15 scores were 38.3% lower post intervention with the mean reducing from 15.68 to 9.68. Additionally, the PHQ-9 mean reduced by 49.5% from 16.08 to 8.12. The largest reduction was seen in the mean anxiety measurement where a 63.1% reduction was recorded with means reducing from 15.92 to 5.88. The WSAS mean reduction was 30.1% with means pre- intervention recorded as 25.52 and post intervention of 17.84.

Qualitative Analysis

Overall 10 participants were recruited, 4 males and 6 females. Participants were aged between 22 and 74 years old. All had completed the intervention at least 12 months prior. In the group, 9 patients identified as White British, and 1 identified as White - Other. It was made clear to individuals that the focus of the interview was on the participants experience of ED and the intervention. Full participant demographics can be seen in table 10.

Participant	Gender	Age	Ethnicity
Patient 1	Male	47	White - British
Patient 2	Female	44	White - British
Patient 3	Male	22	White - British
Patient 4	Female	45	White - Other
Patient 5	Female	27	White - British
Patient 6	Female	31	White - British
Patient 7	Female	74	White - British
Patient 8	Male	53	White - British
Patient 9	Female	31	White - British
Patient 10	Male	63	White - British

Table 10. Participant demographics and interview details

Themes

Overall, 4 main themes with subthemes were identified. These themes are presented in a temporal order.

Theme	Subtheme	Code
1. ED and Me	Lack of control	Deferring to others
		The hospital wanted to help me
		Never any discussion
		Powerless – their hands were tied
	Trust/Mistrust	Need to be believed/ I was being judged
	Hospital systems	They kept discharging me
		Staff- they didn't know what to do with me
Appointments - I was at the hospital a lot		
2. Psychological Impact	Emotional toll	Relief to have an appointment
		But I'd get so angry
		I was really scared
3. My Treatment	Help Seeking	Proximity to hospital
		Mismatch of Psychiatric treatment and physical symptoms
	Communication	I couldn't get them to listen
4. The Long-term Impact: what's changed?	Changes in thinking	Really, I know it was my worry
		knowing about thinking and rumination
	Changes in behaviour	I try to do something before it gets really bad
		Learnt not to ignore it and make it all worse
	Understanding & acceptance	Just time you know
		Accepting - live with it

Table 11. Summary of main themes and subthemes

The first theme explores the initial impact of dealing with the ED and hospital systems before the intervention. The second called focused on the psychological impact of living with MUS and the

negative emotional experience of this. The third theme, My Treatment identified why and who was seeking help for their symptoms. The final theme discusses the long-term changes that have been established following the intervention and the impact of this. A full summary is provided in table 11.

The ED and Me

The theme encompasses the relationship, good and bad, that the participants had with the ED before the intervention. It describes how participants viewed their interactions with the department and the disparity sometimes felt between what they had experienced when compared to their hopes and expectations. It not only highlighted the supportive relationships with staff but also, how in some cases, the patients perceived a negative judgement from staff in their ED interactions and a frustration in hospital practices. This is illustrated by Patient 4 when expressing frustration at the hospital systems and protocols. Patient 4 describing the lack of investigative treatment, they had received in ED and how unhappy they were with treatment and practice being restricted to pain relief only. This was the case even when the procedures had previously been conducted and failed to identify anything untoward as highlighted below:

Well they didn't know what to do with me did they. So, it was just morphine and home.

They tried you know but (Gastro Consultant Name given) wouldn't do another scan and the endoscope didn't find anything so, so their hands were tied. I think they were as fed up with it all as I was (Patient 4)

This frustration was echoed by Patient 8 who was dissatisfied with the repetition of pharmacological therapy on each attendance and being discharged without further investigation, '...I was asking them over and over again for help but they kept discharging me, giving me drugs and discharge every time' (Patient 8). The pattern of attending and no further investigation was also highlighted by Patient 1. However, despite this they continued attending even though they did not feel their needs were being met saying, '*It was a waste of time going there and nothing changing, some staff are great they really are, but some look at you like 'oh he's here again' like I had a choice' (Patient 1)*. Others expressed this lack of investigation in the ED led to them feeling dismissed or that it was lacking care. This was highlighted by Patient 10 who stated:

I know they do their best but I'd get so angry. There was never any discussion, no-one tried to get to the bottom of it. I mean, at the time I was really scared and they just fobbed me off (Patient 10).

This perceived dismissal also led Patient 1 to escalate their complaint but shared they were not satisfied with the hospital's response reporting that, '*...I even complained to (Chief Executive name given) and PALS were useless, just didn't give a shit' (Patient 1)*. Whilst two patients talked about the negative judgement of ED staff and their perception that their reason for attending the ED was not believed. Patient 5 and Patient 2 both felt that this view was linked to drug procurement:

...I always felt like I shouldn't be there, that some of the nurses thought I was putting it on for drugs or whatever (Patient 5).

...I wasn't sure if I was being judged or treated like a drug addict (Patient 2).

Reasons for attending the ED were also deferred to others. Such as in the case of Patient 1 who claimed, '*...I didn't want to go there but Debbie (fiancé) couldn't stand to see me in pain and would call the ambulance*' (Patient 1). Patients expressed what appeared to be a lack of control claiming others (family members) were responsible for their attending the ED as exemplified again by Patient 2, '*...I hated going, they are all great but I hated going there. My husband would make me when the sickness was so bad. He was so worried*' (Patient 2). This deferring responsibility for repeat attending to others inferred a lack of accountability for his/her action or inaction. However, in another example, Patient 7 talked about their trust and faith in the opinion of the ED health professionals had led to their repetition in attending the ED.

I think the hospital staff are wonderful and trust they know what's best (Patient 7).

Furthermore, the interviewees talked of their wanting help and their 'relief' and 'gratitude' at being given an appointment with the psychologist (Patient 3, Patient 8); whilst others failed to see any difference between the appointment with the psychologist and other medical appointments (Patient 5, Patient 1). When invited to the intervention at the ED, patients spoke of relief at the offer of help stating their desperation to be listened to and for help with their ongoing symptoms. This was illustrated by patient 3 quoted below.

My first thought was relief, relief to have an appointment, I was desperate for someone to sort it out. No-one was listening to me (Patient 3).

Whilst another (Patient 8) talked of gratitude at receiving the appointment for the CBT intervention.

Thank goodness, I think. I was asking them over and over again for help but they kept discharging me, giving me drugs and discharge every time (Patient 8).

Indeed, it would appear that being referred to a psychologist in the ED was far from a negative experience for some. For example, Patient 6 reported happiness at being offered an intervention to provide coping skills to manage their symptoms and Patient 5 viewed the referral as positive that the 'hospital' wanted to help her 'get better'.

She was nice I saw her in majors (ED ward) and she said she could help me, you know cope better with it all, so I was happy (Patient 6).

...it was good that the hospital wanted to help me get better (Patient 5).

The patients also emphasised the importance of being listened to regarding their symptom experience. This was evident, not only from their previous ED interactions, but when they commenced the CBT intervention. For example, patient 7 complained that ED staff 'never listened to me' in the quote below.

Sometimes I felt that before, that they never listened to me and every time it's someone new so you've got to go through the whole thing again... (Patient 7).

Whilst another patient (patient 4) highlighted the importance to them of feeling that someone ‘believed’ their symptom experience saying, ‘(Psychologist named) explains things really well and always believed me’ (Patient 4). But to Patient 5, having ‘someone to talk to’ about their MUS changed their attendance experience to a positive one, not only of the intervention but also of the hospital as a whole.

(psychologist named) is nice to talk to and it was good that the hospital wanted to help me get better. I always felt like I shouldn't be there, that some of the nurses thought I was putting it on for drugs or whatever but I wasn't and I would be crying and stuff it was so bad. It was just good to talk about this stuff with someone (Patient 5).

However, not all patients found being invited to attend the intervention a positive experience, unfortunately Patient 2 reported being worried that the invitation to the CBT intervention meant that they were being judged negatively by ED staff because of their frequent attendances.

I found the term frequent flyers confusing and wasn't sure what to expect. I wasn't sure if I was being judged or treated like a drug addict, but (Psychologist named) was easy to talk to (Patient 2).

However, two other patients (Patient 1 and 5) described viewing the invite to the CBT intervention as a routine ‘appointment’ rather than something out of the ordinary. For these patients it perhaps signified that spending time at the hospital had become routine and normal.

Just thought it was another appointment. I was always there for something so didn't really think anything about it (Patient 5).

No particular thoughts specifically – just another medical appointment (Patient 1).

Nonetheless, not all the patients were happy with the invite to attend the psychological CBT intervention at the ED. However, it was stated by Patient 4 that the unhappiness resulted from not understanding the purpose of the intervention stating, ‘if I’m honest, I wasn’t happy about it. But then I didn’t really know what it was about’ (Patient 4).

Psychological Impact

The theme psychological impact looked at living with MUS and the subsequent emotional toll of the patients’ interactions with the ED and the CBT intervention. The negative emotions emphasised by the patients included anger and fear. Patients reported being ‘scared’ and ‘terrified’ that the symptoms were an indicator of something seriously wrong with their health but expressed frustration at not having a voice in their interactions. This was exemplified by Patient 10 and Patient 7 who illustrated the emotional impact they felt regarding their experience of ED at this time:

I know they do their best but I’d get so angry. There was never any discussion, no-one tried to get to the bottom of it. I mean, at the time I was really scared and they just fobbed me off (Patient 10).

... they never listened to me and every time its someone new so you’ve got to go through the whole thing again. I was terrified that something terrible was wrong with me and I couldn’t get them to listen (Patient 7).

However, in opposition, positive emotions were expressed around being invited to the CBT intervention in the ED. For example, Patient 3 recalled their feelings being relief stating, *'My first thought was relief, relief to have an appointment....'* (Patient 3) at what they viewed as help being offered. Plus, Patient 6 who proclaimed happiness at the offer of help with coping strategies to better manage the ongoing negative symptoms asserting, *'I was happy'* (Patient 6).

My Treatment

The third theme looked at how the patients viewed their treatment and how proximity and convenience had a role in their choices. For example, Patient 8 proclaimed that *'...it was easy for me to get there as I live close by'* and Patient 10 reported that the proximity of their home to the hospital made attendance easier. Alternatively, the distance of mental health services was spotlighted as a potential barrier for patients' attendance had the intervention been provided there e.g. at the primary care mental health facility. So, it would appear for some that location was an important factor. Illustrations of this were given by Patient 8 and Patient 9 who stated that:

I have been there before but it's so far from me. They discharged me coz I kept cancelling I didn't have the bus money so the hospital was better as I could walk if I was broke (Patient 8).

Is it in the hospital? (info on Department of Psychological Therapies (DoPT) given by interviewer) No I don't go to Bxxxxxxx (area of DoPT) (Patient 9).

The interviewee Patient 7 also highlighted when asked about the location of the intervention that when their home was not in the proximity of the hospital, transport to the hospital could be provided if necessary. 'It would have been better closer to home but (community Matron) arranged transport as he said it was important' (Patient 7) but this is not a facility available from or offered by mental health providers.

In addition, the interviewees also reported that going to a single provider for their care (i.e. the hospital ED department) was appropriate in their opinion, 'Yes, it made sense as they were helping me' (Patient 4) and 'Yes, I was there all the time anyway coz it was just getting worse' (Patient 6). This view has been supported in the positive practice guide for MUS suggesting that embedding services in a physical health framework may encourage engagement (IAPT, 2014). It was also noted by Patient 5 that their current treatment and hospital attendances would have hindered their ability to attend alternative venues for treatment, so again supported having the intervention delivered in the ED at the hospital. When asked about going to the primary care mental health facility they responded,

I don't know. Hard to say now but probably not cause then I was in pain so much that I was at the hospital a lot (Patient 5).

But the mismatch of physical symptoms and a psychological intervention was also noted by Patient 7 who still reported confusion of being offered one to help with the other, it should be noted that this was even after attending the CBT intervention at the ED.

No what is that? (interviewer explained Department of Psychological Therapies - DoPT)

No why would I have gone there? (Patient 7)

Patients also spotlighted that having someone to ‘talk’ to was an important component of the intervention. Patient 5 discussed how they had found it beneficial to have the facility ‘to talk’ about their ongoing symptoms. Whilst Patient 1 felt it was beneficial to ‘talk’ generally about ‘what was going on in their life’. Additionally, Patient 10 agreed that having the space to discuss what they wanted and ‘someone to talk things over with’ was helpful. Twenty years ago, the correlation between social isolation and increased use of ED services independent of chronic illness was documented by Geller, Janson, McGovern and Valdini (1999) but with a growing population of single dwelling households, this may need to be investigated again.

[The Long-term Impact: what’s changed?](#)

The final theme demonstrated there had been a change in how the patients viewed their situation following the intervention. This identified that the intervention had elicited, changes in how they viewed their symptoms. Additionally, it uncovered how they had changed their behaviours following the intervention and how it had provoked a different reaction to their negative thoughts over the longer term. The Interviewees highlighted how they were no-longer passive towards their health and described how they now felt empowered to be proactive with their behaviour and symptoms. For example, Patient 8 talked about a new behaviour of addressing symptoms as they arose, *‘Me, I’ve learnt not to ignore it*

and make it all worse' (Patient 8). Previously the behaviour had been to wait for the symptoms to worsen and then present at the ED for treatment.

Recognising and acknowledging the impact anxiety and worry had on their symptoms had led to a new insight for another participant. Patient 4 highlighted they now recognised that worry was driving their attendances at the ED, '*...I know it was my worry not my health that was making things bad now'* (Patient 4). Additionally, this change in attitude and acceptance was echoed by Patient 3 who defined that their '*anxiety is there'* but they had learnt to deal with it in a different way.

Indeed, two patients who attended the intervention commented on how since this time their life circumstances have changed and this had provided positive benefits for their anxiety symptoms. The first (Patient 5) reported that she was expecting her second child and despite encountering health problems she no longer believed she had health anxiety. The second (Patient 4) was now in employment and reported positively that working had now replaced worry in their day.

Well I'm pregnant with my second child so things have changed as I have problems with my blood pressure and stuff – weirdly that's not worrying me though (laughs) (Patient 5).

Yes, I'm happy (laughs) it was a bad time then but I'm working now and haven't got time to worry now (Patient 4).

The participants also talked about the educational aspect of the intervention and how they had learnt about cognitive distortions and cognitive strategies to help manage these to aid their symptoms. The educational aspect of the intervention was identified by Patient 5 as the most useful part.

Yes, we did a lot of things but learning about how brains get pain wrong helped most I reckon (Patient 5).

The theme noted that patients found understanding cognitive distortions and cognitive strategies beneficial and had utilised these techniques. Challenging negative interpretations of thoughts has been identified as an important component of CBT (Woolfolk & Allen, 2007). This CBT strategy was highlighted as most useful by Patient 3 and Patient 4 regarding what had changed for them since the intervention,

(Psychologist named)'s methods to cope and strategies –one was rationalising more – you know arguing with myself (Patient 3).

Yes, that I catastrophise. She made me keep a diary and that got me to see how my symptoms were always worse when I was alone and obviously that they hadn't killed me like I thought they would (laughs) (Patient 4).

Another participant (Patient 6) also talked about learning about rumination in the intervention and reported that since the intervention they were using CBT tools such as problem-solving forms to address their negative thought processes.

The problem-solving forms – knowing about thinking and rumination. I did that a lot and get now that it made it worse (Patient 6).

Another CBT tool that had proved beneficial was used being used by Patient 3 to address ongoing worry. The worry tree (Butler & Hope, 2001) which they proclaimed had provided a method to problem solve troublesome anxious thoughts when asked what had been most useful for them.

Breaking down a situation I was worrying about, worry tree, thinking about all the things I was doing for my family, reframing thoughts (Patient 3).

But probably one of the simplest changes was exemplified by Patient 2, who highlighted the most helpful change experienced had come from having a health professional normalising their anxious emotion.

Learning it's normal – anxiety - but you have to let it happen and then it goes. It helped her saying everyone has anxiety – I really thought it was just me (Patient 2).

As well as changing their cognitions, the participants also talked about how they had changed their behaviour following the intervention. This was exemplified by Patient 4 who had continued to time anxiety symptoms since the intervention and this has reassured that the symptoms are time limited, stating, *'timing my anxiety and seeing that it has to go away – I still do this now and its gone pretty quick'* (Patient 4). Whilst Patient 6 identified that being proactive rather than passive was a new behaviour since the intervention that had improved their symptom experience and subsequently reduced their hospital attendance. They stated that, *'... I try to do something before it gets really bad'* (Patient 6). This proactive stance was shared by others as exemplified by Patient 8 below:

Me, I've learnt not to ignore it and make it all worse...like I said, I take my meds on time and deal with my stress (Patient 8)

There was also evidence of a change in the participants understanding and an acceptance of their MUS. The interviewees talked about recognising that it was 'not being so bad' when using CBT tools:

The thought things, where I wrote out what I thought was wrong, and then compared what happened. I got an app for my phone and that made me see it wasn't so bad (Patient 5).

Following the intervention, it would appear that for some, the MUS and anxiety symptoms remain. However, attending the intervention has given the participants insight and coping skills to self-manage demonstrating that they no longer rely on the ED to provide treatment/reassurance. Also, the interviews spotlighted that there was now an understanding around the limitation of what the hospital can provide to manage symptoms. This was specified by one of the interviewees when talking about being unwell, *'I've had shingles and it's been awful but there is nothing they can do – just time you know'* (Patient 9). Finally, for other interviewees there was acceptance displayed that anxiety, not illness, was driving their attendances at the ED. Like Patient 4 who proclaimed that, *'...I know it was my worry not my health that was making things bad now'* (Patient 4). Importantly, the theme highlighted that whilst the anxiety remains, their behaviour has adapted since the intervention.

The results of this study and the themes that have been identified have highlighted that the outlook of the interviewees has moved from an unhappy passive one (feeling dismissed and not believed) to

empowered and insightful (I deal with it differently). Overall the themes of this study have offered an insight into the long-term behavioural and cognitive changes made by those attending the intervention. These results will now be discussed in relation to the study aims, the implications for clinical practice, and future research

Discussion

Introduction

There has been call for the development of treatment interventions to target high risk frequent attenders with MUS at ED's (Spence, 2014; Raven, 2011). The aim of the research was to identify if providing a CBT intervention to frequently attending (high risk) patients with MUS in the ED setting they are familiar with had impacted attendance patterns and if so how? As hypothesised the patients who received the CBT intervention had significantly ($p=0.001$) reduced their ED attendances and inpatient bed days ($p=0.001$) following the intervention. These results go against the assertion by Barsky (1996) who claimed that patients became harder to treat after numerous investigations and referrals. These results are also in opposition of Old Hartman *et al.* (2009) argument that a more severe condition (high risk) led to a worse clinical outcome. However, the results could be seen to support Guthrie's (1996) contention that studies had previously failed to target this group and thus can be offered forward to provide new knowledge in this under researched domain.

It was not the aim of the current study to synthesise its qualitative and quantitative data. Primarily, the objective of the quantitative approach was to identify if the CBT intervention impacted on future attendance patterns for the patients who have received it when compared to a control group receiving TaU ([objective 1](#)). Thus, examining the clinical effectiveness of the intervention in reducing attendances/inpatient bed days for those who attended. Overall, the current study provides support for the inclusion of CBT psychological interventions delivered in ED's for frequent attenders with MUS. The

results support the hypotheses H_1 and H_2 that delivering interventions reduced attendances and inpatient bed days at the study sites.

The qualitative approach from conducting thematic analysis from interviews produced four meaningful themes: The ED and Me; Psychological Impact; My Treatment and The Long-term Impact: What's Changed. The first theme explored the initial impact of dealing with the ED and hospital systems before the intervention. This highlighted that the interviewees felt powerless in their interactions and felt dismissed and judged negatively for attending. The next focused on the psychological impact of living with MUS and the negative emotional experience of this. The third theme highlighted why and who was seeking help for their symptoms and demonstrated that it was not always the patient's choice to go to the ED. Finally, theme four discussed the long-term changes that have been established following the intervention and the impact of this on their health and presentations at hospital. In consideration of the research findings, the current study supports the placement of a CBT Psychology clinic in the ED to help these patient's better management their ongoing negative symptoms.

Quantitative Findings

The results reported above have highlighted that providing a CBT intervention does have an effect on ED attendances and Bed Days utilised by frequently attending MUS patients. Specifically, the results

indicated that when an intervention is provided, the ED attendances and Bed Days utilised decreased. However, this current study did not measure the same outcomes as old Hartman *et al's* (2009) and Barsky's (1996) therefore, cannot refute their previous claims that the earlier MUS is identified the better the outcome. As proclaimed by Guthrie (1996), it would appear from the research that studies had failed to target this group and this study has highlighted that when interventions are delivered they can improve clinical outcomes.

Indeed, as noted by Raven (2011), there remains a necessity in targeting the high cost and high use MUS patients as attends get expensive quickly when tests are run (in some cases repeatedly) and inpatient stays magnify costs greatly. This intervention reduced ED attendances (measured in the previous year) by 250 and inpatient bed days by 301 for the 25 patients in the experimental group. Therefore, it can be seen that the intervention easily pays for itself in hospital cost savings and reducing the knock-on effect across the hospital of non-elective admissions.

Psychometrics Analysis

The use of psychometric questionnaires for the experimental group identified a mean group score that is classified as severe for somatic symptoms. The PHQ-9 outcomes reported a mean score classifiable for moderate/severe depression. The GAD-7 group mean score denoted severe anxiety. Finally, the WSAS outcomes pre-intervention highlighted a mean group score that is classified as moderately severe psychopathology. These results supported Nimnuan Hotopt & Wessely (2001) who have previously

highlighted the prevalence of depression and/or anxiety disorders comorbid with MUS diagnosis. In addition, these results support Rohricht and Elanjithara (2014) statement that the highest predictor of MUS patients functioning was their depression score. Following the intervention, all mean scores reduced from pre- intervention to post intervention for example, the PHQ-15 scores were 38.3% lower post intervention with the mean reducing from 15.68 to 9.68. Additionally, the PHQ-9 mean reduced by 49.5% from 16.08 to 8.12. The largest reduction was seen in the mean anxiety measurement where a 63.1% reduction was recorded with means reducing from 15.92 to 5.88. This supports the primary care review finding reported by Van Dessel *et al.* (2014). That review identified that CBT reduced symptoms and lowered levels of psychological distress in the treatment groups which were maintained at 12 months follow up. However, it should be acknowledged that whilst the WSAS mean scores reduced by 30.1% with means pre- intervention recorded as 25.52 and post intervention of 17.84, these were still classifiable as 'significant' for functional impairment. Furthermore, whilst these scores suggested that the intervention had appeared to be psychologically beneficial for the experimental group; no generalisation can be made as psychometric scores for the controls were not recorded.

Natural attrition

The findings also highlight that over a two-year period, without providing a treatment intervention that statistically significant numbers of patients have continued to attend the ED. This does not support previous findings highlighted by Kennedy *et al.* (2004) and Peddle *et al.* (2011). However, as previously noted the FA's studies reporting 'natural attrition' did not differentiate between Psychiatric, Drug/Alcohol

misuse plus included under 18's so it may be that 'natural attrition' remains a factor within these groups for frequently attending.

Demographics

The mean ages of participants in this study were comparable to that of previous reviews reported (Van Dessel et al, 2014; Lacalle and Rabin, 2013; Gibson, 2013 and Kleinstauber, Witthoft and Hiller, 2011). This supported Lacalle and Rabin's identification that there are peak ages for attending of between 25-44 and in the age group 65+. Nonetheless, the current study did include a greater range than those reported above i.e. 20-87 in the control and 20-78 in the experimental. Moreover, it should be noted that the positive results of the current study challenge the assertion by Schroder *et al.* (2012) that individuals over the age of 45 should be excluded as the possibility of improvement would be lower in older generations.

Gender split was improved in this study 40% male and 60% female across the 2 groups which would have changed to 43% male and 57% female if refusals/attrition were included. This differs from previous studies (Kleinstauber *et al.*, 2011; Gibson, 2013; Van Dessel *et al.*, 2014) where the number of female participants in treatment groups ranged from 66% to 89%. Obviously, it is not always possible to reduce selection bias in a self-selecting participant pool (Heckman, 1990), however, the larger proportion of male participants could mean the intervention could be more generalizable to that gender than previous research.

Again, as noted, the lack of reporting on race and ethnicity has been problematic (Gibson, 2013). In the current study ethnicity was documented as White British for all (including 4 attrition participants) but 3 participants who identified as White Other (2 in control group, 1 in experimental group). However, no participants were excluded on ethnicity, gender or age (if over 18 years old). Nonetheless, this may prove to be an issue for the generalisability of the study.

Research Attrition

Barsky and Ahern (2004) reported that refusal, drop out and non-attendance numbers are large in this patient group when referred to mental health services. Of the original 29 participants invited to attend the intervention 2 patients refused to attend after initial assessment (6.9%) and 2 patients died during the study (6.9%) so their data was excluded. This was lower than previous attrition numbers of approximately 15% and refusal rates of 46.96% identified by Gibson (2013). Furthermore, 25% was recorded by Rohricht & Elanjithara, (2014) in a Liaison Psychiatry clinic offered in primary care. It could therefore be argued that placing the clinic in the ED (the area patients are comfortable with) may improve uptake as predicted by Speckens *et al* (1995) and recommended by JCMPPH, (2016).

CBT Intervention

The study utilised CBT protocols (Woolfolk and Allen, 2007; Salkovskis, 1989) because it was noted that studies that did not use a manual failed to achieve the same results in patient outcome measures (Gibson, 2013). Additionally, Chalder (2014) argued that treatment protocols can easily be adapted to ensure that they include physiological as well as cognitive, behavioural and affective mechanisms. The

use of two protocols also enabled the suitable treatments for both somatising and health anxious patients. The need for this flexibility was supported by Soril, *et al's* (2015) who proposed that 'personalizing and tailoring' interventions may prove to be most effective at reducing high users. However, most importantly, it has enabled the study to be replicated by others in the future.

Qualitative findings

Four meaningful themes were identified when analysing the qualitative data: The ED and Me; Psychological Impact; My Treatment and The Long-term Impact: What's Changed. The findings of these will be discussed along with the remaining objectives of the current research study. The first theme explored the initial impact of dealing with the ED and hospital systems before the intervention.

The emergence of the theme ED and Me provided a narrative for the patient experience good and bad, of their relationship with the ED. It showed the repetitive cycles of attending the ED and the limitations of the treatments provided to this patient cohort and their distress at a lack of investigative procedures. This was the case even when the procedures had been conducted and failed to identify anything untoward (Patient 4-p75, Patient 8-p76) previously. This highlighted the misunderstanding by the patient group of what ED's are designed to provide and the lack of understanding of how ED's are ill equipped in the provision of continuous care for non-emergency conditions, even when they are of a chronic nature (Fuda & Immekus, 2006). Additionally, this supported previous research (Creed, 2011; Dwamena *et al.*, 2009; Lefvert, 2009; Sandoval *et al.*, 2010 & Persson, 2014) that identified that MUS patients are unhappy with

their treatment from health providers. Indeed, this can also be linked to why patients had a belief that the staff judged that they were attending to procure drugs (Patient 2, Patient 5-p84). Given that repeat attenders are given drug therapy to help reduce their symptoms and whilst they are stating that they are dissatisfied with this outcome, they keep persisting in returning to the department.

Certainly, it could be argued that on some level the patients are aware that this behaviour is inappropriate and this may be why they blamed others for their attendance (Patient 1- p84, Patient 2--p85). Interviewees deferred responsibility of their attendance at the ED to partners perhaps displaying a lack of accountability for their personal health. This dichotomy should be investigated further in future research.

Additionally, the interviewees talked of their wanting help and their relief at being given an appointment with the psychologist (p85); whilst others failed to see any difference between the appointment with the psychologist and other medical appointments (Patient 5-p87, Patient 1-p88). This acceptance of psychology appointments should encourage health professionals to consider referrals which are currently avoided for fear of offending (Fink *et al*, 2011; Brownell *et al*, 2016). However, given the demographics of this study; this outcome may not be transferable to all populations. Indeed, it is accepted that this study has not addressed Rohricht & Elanjthora (2014) claim that talking therapies are less acceptable to BME populations.

Placement of Psychological Intervention

Speckens *et al.* (1995) proposed that the engagement process would be improved when interventions were conducted in the medical setting known to patients, such as ED's. This was supported in the positive practice guide for MUS confirming that embedding services in a physical health framework may encourage engagement (IAPT, 2014). This was discussed in the third theme 'my treatment' where interviewees reported that location had impacted their decision to attend (p89). They talked about it 'making sense' (Patient 4-p91) attending at the hospital and also noted it was difficult to go elsewhere for appointments because 'I was at the hospital a lot' (Patient 5-p91). Nonetheless, one patient even after the psychological intervention still felt there was a mis-match between their physical symptoms and treatment at a psychological therapy centre (Patient 7-p91). However, an unexpected revelation regarding the placement of the clinic and their choice to attend was identified. It would appear that the proximity of their homes to the hospital impacted their decision to attend and the availability of hospital transport. Thus far, no geographical study has been conducted to see if proximity to hospitals leads to increased attends but it would be interesting to see if this factor plays a role.

The theme Psychological Impact focused on living with MUS and the negative emotional experience of this. It should not be surprising that experiencing negative physical symptoms would produce negative emotions such as frustration, anger (Patient 10-p88) and fear (Patient 7-p89) all of which produce their own negative physical symptoms (Jackson *et al.* 2004). However, in opposition to this,

just being offered the intervention produced the positive emotions of happiness (Patient 6-p89) and relief (Patient 3-p89). Additionally, the interviewees spotlighted that feeling listened to was an important component of the intervention for some of them (Patient 1-p92, Patient 5-p91). They discussed how they had found it beneficial to have the space and facility to talk about their ongoing situation/symptoms. This is perhaps in direct opposition of their previous experience of ED where they felt there was no discussion and supports Chew-Graham *et al* (2017) who noted that when patients feel they are not listened to, they repeatedly present looking for validation and satisfaction. Therefore, it would appear that providing the intervention has addressed this need and subsequently broken this negative cycle.

Cognitive Changes

In addition, they were able to identify that the intervention had elicited changes in how they viewed their symptoms at different times. For example, they noted that symptoms were worse when alone (Patient 4-p95), when they fight against it (Patient 2-p95), when they are unable to be rational (Patient 3-p94) or when they are ruminating (Patient 6-p94). The participants were also able to define cognitive behavioural skills they were using to help address their negative symptoms such as problem solving (Patient 6-p94), de-catastrophising (Patient 4-p95), understanding how pain pathways (Patient 5-p95) and using worry trees (Patient 3-p95). These outcomes highlight the success of the treatment intervention and particularly Salkovskis *et al.* (2016) and Chalder and Willis (2017) who proposed that interventions including components that challenge cognitive distortions with restructuring and provide strategies to manage negative emotions can reduce distress caused by MUS. In

addition, it provided support for previous studies that have also utilised more than one protocol (Speckens et al, 1995; 1996) with good outcomes.

Behavioural Changes

Finally, theme four discussed the long-term changes that have been established following the intervention and the impact of this on their health and presentations at hospital today. All the interviewees were no longer frequently attending the ED. Positively, they discussed how they were no longer passive towards their health and how they now feel empowered to be proactive with their behaviour and symptoms. For example, Patient 8 (p88) highlighted taking medication in a timely fashion and dealing with stress before it becomes disabling. This was echoed by Patient 6 (p88) who reported no longer ignoring stuff and 'getting it sorted early'. In addition, there appeared to be a change in their understanding and acceptance of their MUS. P9 for example, stated (p97) that 'there is nothing they can do – just time' when talking about a current illness. Whilst, Patient 4 could define 'it was my worry not my health' (p97). This change in attitude and acceptance was echoed by Patient 3 (p97) who defined that their anxiety was still present, but they had learnt to deal with it differently. Additionally, Patient 8 exemplified not only a change in how they felt about their symptoms but also in their long-term behaviour. They stated that they were more organised now around their medication and appointments understanding their diagnosis was 'a lifelong thing'. Finally, Patient 5 (p97) discussed getting a CBT iPhone App that enabled them to log their health worries and then compare outcomes to manage their health anxiety which allowed them to see that 'it wasn't so bad'. So, it would appear that some of the symptoms and anxieties remain, however, attending the intervention has given the participants insight

and coping skills to self-manage and no longer rely on the ED to provide treatment/reassurance. These behavioural changes again support Salkovskis *et al.* (2016) and Chalder and Willis (2017) who proposed that introducing behavioural experiments and behavioural activation and encouraging exposure to feared situations would increase the success of interventions with MUS populations. Furthermore, it has contributed to the evidence for Chalder (2014) who noted that treatment protocols can easily be adapted to ensure that they included behavioural and affective mechanisms for patients (Chalder, 2014). Finally, it supported the assumption by Soril, *et al's* (2015) who proposed that 'personalizing and tailoring' interventions may prove to be most effective at reducing high users.

What are the implications for clinical/research practice from this study?

Previous interventions with patients with MUS have primarily focussed on primary care services (Burton, 2003; Sumathipala, 2007; Dwamena *et al.*, 2009; Schroder *et al.*, 2012; Van Dessel *et al.*, 2014) and the limited numbers that were placed in ED's have grouped all frequent attenders as one cohort (drug and alcohol, self-harm etc) despite the reasons driving their attendance differing greatly. This study has provided evidence that providing a CBT intervention to high risk frequent attenders with MUS in the ED has a measurable impact on their health care utilisation, not only in the ED, but across the hospital. Importantly, utilising protocols has enabled the replication of the intervention across ED domains where frequent attenders with MUS are problematic.

Furthermore, it has demonstrated that high risk patients can benefit from interventions that they have previously been excluded from (Guthrie, 1996) as was suggested by Raven (2011) and JCMPPH (2016).

Positively, the study also provided the measurable outcomes requested by JCMPH (2016) and demonstrated symptoms and process reductions in all axis.

Additionally, it has shown that interventions need not be limited to younger age groups as has previously been reported by Van Dessel et al (2014) and was the case with research conducted by Schroder *et al.* (2012). This is significant given that it has been noted that ages 65+ were a peak demographic group for FA's (Lacalle and Rabin, 2010). Furthermore, uptake of the intervention was improved by placement of the service in the ED with much lower attrition rates and anecdotal evidence reported. This supports the predictions by Speckens *et al* (1995) who proclaimed that providing the intervention in the area the patient is comfortable would improve the uptake. Plus, IAPT (2014) highlighted appropriate placement of services within secondary care may prove crucial when setting up MUS clinics. Likewise, it fulfils the request made by The Joint Commissioning Panel for Mental Health (JCMPH, 2016) who recommended that one area MUS services should be commissioned was ED's.

The current study identified that the patient group accepted the referral to psychology because it was placed within the hospital. This should encourage health professionals to consider such referrals where services are available. Moreover, there were positive cognitive and behavioural changes from attending the intervention documented by the study that were still evident 12 month later. This enabled the patients to feel empowered and proactive towards their health and healthcare and less reliant on ED services.

This evidence has also provided support for the use of a mixed methods approach as these results would not be achieved by either quantitative or qualitative alone. The current study and its approach taken has given a detailed insight into the patients' perspectives that can be seen to match with the statistical data of their behaviour pre and post intervention.

Key implications for health Psychology

This study has contributed to the evidence based research that Health Psychology Practice can develop and implement treatments to transcend traditional boundaries across physical and mental health. This study demonstrated that applied health psychology could provide a valuable and cost-effective service to deliver interventions to this patient cohort. In the process saving hospitals money, reducing ED attendances and non-elective hospital bed days utilised. Plus, most importantly providing unhappy patients with coping skills and strategies to manage their negative symptoms and emotions.

Limitations and future directions

This was a small feasibility non-randomised trial and in such failed to randomise participants or blind them to the intervention and a larger study could address this in the future. It is accepted that all studies contain limitations and one of the current study was the lack of diversity of the sample population. Additionally, it should be acknowledged that this study was only conducted in one metropolitan district in England. Population demographics, health service configurations and commissioning arrangements vary across the UK, and because of this, the findings and experience may not be generalisable. Evidence of improvement over time in FA's without the provision of an intervention has been highlighted in literature

(regression to mean effect) from cohort studies. It must be acknowledged that this natural attrition could be what has been witnessed. However, as previously noted the natural attrition in FA's included all and not just MUS patients i.e. Psychiatric, Drug/Alcohol misuse plus under 18's. Therefore, it may be that 'natural attrition' remains a factor within these groups for frequently attending. Again, this was a small feasibility study and further research is needed to clarify it is also a factor influencing the MUS FA's.

Furthermore, it should be acknowledged that the researcher was also the therapist and this may have implications for the findings of this study. Efforts were made to minimise any confirmation bias on the researcher's part through reflection and supervision as it was accepted that it is our natural tendency to interpret data in a way that is consistent with what we believe. However, future research could minimise potential bias by employing independent researchers and therapists. Another implication of that dual role may have been that the subjects were not blinded to the purpose of the study. They had established a therapeutic relationship with the researcher and thus, may have been answering in a way that they thought she wanted them to act. Additionally, they may have felt duty-bound to take part, despite steps taken to reassure potential participants that this was not the case. Nonetheless, one could assume a higher recruitment rate than was achieved if that had been the case.

There may also be Implications of the researcher not collecting directly collecting the qualitative data herself. This was intended to provide freedom for critique to the participants. However, a potential benefit of the dual role of the interviewer could be that they already felt comfortable talking to her because of their time working together and therefore, it may have engendered a more open and honest

exchange. Furthermore, this separation of roles may have inadvertently led to missing nuances of what individuals were conveying or an understanding about the general tempo and atmosphere during the interview. For example, had the researcher conducted the interviews comments in the transcript may have triggered a multi-faceted recollection of the interview situation, e.g. if they were enthusiastic when talking about a specific subject. Alternatively, it could be argued that if the interviewer was also the main clinician working with interviewees, they may have tried to present an overly negative picture in order to elicit more support or may have wanted to present an overly positive picture to avoid potential criticism. Again, this can be addressed in future research design and implementation.

Also, in this study the data was coded and themes identified by one person and this analysis was then discussed with a supervisor. Whilst this process provided consistency in the method; it could be argued that it failed to include multiple perspectives by including others expertise. Future studies could include the coding of data by several individuals with themes' being developed using discussions with other researchers, and/or the participants themselves.

Additionally, the control group consisted of retrospective data provided by a different organisation rather than consenting patients which also limited the study's findings. For example, ethical approval was denied for patient identifiers for the control group as they were not patients under treatment from the researcher. Therefore, she was unable to include them in interviews, or request psychometric scores from them. Moreover, it should be accepted that there may have been some of the same patients from the

experimental group who had started attending at the control groups ED. This again could be addressed by utilising a waitlist control group in future research and gaining full consent.

In addition, it could be argued that TaU provided by the ED to all patients who attended during the intervention may have had an impact on the final results. Denying treatment would not be ethical or acceptable and therefore this cannot be rectified but has been acknowledged. Also, a question regarding the patients' attribution of symptoms should be included in any future research, it would be useful information to define what the interviewees felt was the cause of their symptoms to tailor future interventions to address this.

Nonetheless, the current study has highlighted that interviewees deferred responsibility of their attendance at the ED to partners. This may be because of a lack of accountability for their personal health. This dichotomy should be investigated further in future research to ensure that this is incorporated in future interventions. Finally, it would be beneficial if those refusing to participate were included in interviews so that interventions could be designed with them in mind but at present it need to be acknowledged that the intervention remained untested in this area.

What happens next - service improvement/dissemination

The service has been funded directly by the hospital and will be expanding in April 2018. An additional practitioner will be provided by the local IAPT (LTHC) Service who will treat mild to moderate presentations which will enable a stepped care pathway. In addition, the findings of the current study are

to be condensed for submission to publications over the coming months. Furthermore, the author has also been approached to present an update at the European Emergency Medicine conference in 2018.

Conclusion

In conclusion, this study has given a detailed insight into the patients' perspectives that supports the statistical data of their behaviour pre and post intervention. This study supported the declaration that providing a CBT intervention to high risk frequent attenders with MUS in the ED has a measurable impact on their health care utilisation, not only in the ED, but across the hospital. It has highlighted that high risk patients can benefit from interventions that they have previously been excluded from (Guthrie, 1996). Furthermore, it has shown that interventions need not be limited to younger age groups as has previously been the case. It has shown that the uptake of psychological interventions was improved by placement of the service in the ED. Finally, the study has added to the evidence that Health Psychology Practice can develop and implement treatments to transcend traditional boundaries across physical and mental health by providing valuable and cost-effective services to deliver interventions to frequent attenders with MUS.

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Appendices

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The Royal Bournemouth and 
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Private & confidential

8th September 2015

Dear

Royal Bournemouth Hospital (RBH) is currently running a clinic to help patients who frequently attend the Emergency Department to manage their ongoing symptoms. Given your increase in attendance at RBH we feel that the clinic may be of benefit to you. I would therefore like to offer you an appointment for assessment with myself and my colleague Dr xxxxxx.

Tuesday 16th September @ 1530 in the Emergency Department

Please report to the reception on arrival. If you are unable to attend please telephone the number below and we will contact you to rearrange a suitable alternative.

Yours truly,

Samantha Gibson
Specialist Psychologist
(01202) 704379

Copies to: Dr
RIO

Frequent Attenders Clinic Service Treatment and Confidentiality Agreement

We understand that accessing services can make people feel quite anxious, particularly around confidentiality, how information they share with their therapist is stored, and who it might be shared with. Therefore, we have written this information sheet to explain our rules around treatment and confidentiality. If you have any questions or comments once you have read through this please ask your therapist.

Treatment

1. The people who benefit most from therapy attend all their sessions.
2. We understand that in exceptional circumstances you may need to cancel your appointment. If so please contact the Admin Team as soon as possible on 01202 704379 so that your appointment can be offered to another client.
3. Cancelling or not attending an excessive number of appointments may result in you being discharged from the service, and any missed sessions cannot be replaced.
4. Therapy requires a working partnership. You and your therapist may jointly agree on tasks and assignments for you to do at home in between your sessions. It is important that you make time to complete these tasks as this will increase the benefits of therapy. If you have any difficulty completing the tasks, please discuss them with your therapist.
5. You will be asked to complete a short questionnaire at the beginning of each session to monitor your progress; therefore, please arrive ten minutes before your appointment time with the therapist.

Confidentiality

Confidentiality is very important. All the information that you provide is kept securely by Dorset HealthCare and handled in accordance with the Data Protection Act. We will, as far as possible, keep whatever you tell your therapist confidential between you and the service. Your therapist is bound by professional codes of ethics around confidentiality.

Your therapist will make notes about each of your sessions and will keep them in a confidential electronic file, together with reports and letters. Apart from the exceptions listed below, the content of this file will remain confidential, and all members of staff who come into contact with your file will also be bound by these same rules.

Regular exceptions to confidentiality:

- Your therapist is obliged to write to whoever referred you to the service to keep them informed of the therapy you are receiving and your progress. If you were not referred by your GP (for example you self-referred) a letter will be sent to your GP informing them of your referral to our service. Your GP will also be notified of your completion of treatment and when you are discharged from the service.
- It may be the case that you are being seen by other health professionals whilst accessing our service. With your consent, we may share relevant information with these people. This is often useful to ensure people receive well-coordinated care. The same levels of confidentiality apply to all health professionals involved.
- All therapists receive regular clinical supervision to ensure their work is of the highest standard. This means that from time to time your therapist may discuss the work they are doing with you with their supervisor. Their supervisor is bound by the same rules of confidentiality.

If you wish to discuss specific information with your therapist and do not wish it to be disclosed to anyone outside of the service, please discuss this with your therapist.

Other important exceptions to confidentiality:

There are a small number of other situations under which a therapist might have to break confidentiality:

1. When it would be in the wider public interest to share the information. For example, when a service user discloses the intent to commit a serious crime or gives any information about a serious crime that has been committed.
2. If a therapist believes that a child or other vulnerable person might be at risk of neglect or abuse by someone. Under these conditions, therapists are legally bound to seek professional advice and possibly to pass this information on to appropriate agencies.
3. If you are at risk of harming yourself or another person. For example, if you were feeling actively suicidal or actively planning to harm another person.
4. In certain rare circumstances, a court may order the release of either information or notes about your care. Where possible, we will seek to obtain your consent prior to any such disclosure.

Information Sharing

Each Talking Therapies service is required to provide information to a central national system that helps the Department of Health monitor standards of care, ensure equal access for everyone and decide how talking therapies services, should be funded in the future. All the information you give is kept securely and handled in accordance with the Data Protection Act. Your name is automatically removed when data is reported and the content of the discussions you have with your therapist is not shared.

Please tick the box if you do not give permission for your data to be centrally reported (leave the box blank if you are happy for us to share this information)

Record of Dependents
Trust

policy asks that where service users have dependents under the age of 18 that certain information is collected about those dependents. Therefore, could you please complete the following section where relevant?

FULL NAME	DOB	RESIDENCE ADDRESS

This information will be kept confidential. However, if you have any queries about disclosing this information please speak with your therapist or contact the service on 01202 704379.

Please tick box if you would like copies of any correspondence concerning your care and treatment

I have read and understood

the above treatment agreement

Name:Signed:

Date:.....



Before starting the interview

Introduce yourself to the patient and confirm that it is convenient for them to talk at that time. Y/N

Confirm the patients name and date of birth. Y/N

Ensure that they have signed the consent form and do they have any questions/concerns regarding it. Y/N

Confirm that they still wish to proceed with the interview now. Y/N

Re-emphasise that the interview is about the Royal Bournemouth Hospital clinic at the Emergency Department delivering Cognitive Behavioural Therapy (CBT) to help patients who frequently attended to manage their ongoing physical problems.
Y/N

Interview Questions

Think back to before you attended the CBT clinic, what was your experience of the emergency department at this time?’

Do you remember your first thoughts when you were first invited to the hospital to attend the clinic to see Sam Gibson Specialist Psychologist?

Had you previously had any experience of CBT/psychology services?

If yes, did the previous experience influence you to attend? In what way?

Do you think that the holding the clinic in the Emergency Department had an impact on your decision to agree to attend?

Would you have attended if, for example, the clinic was run at the Department of Psychological Therapies instead of the Emergency Department?

Can you tell me what (if anything) was most useful about the CBT intervention in helping you to manage your symptoms?

Do you remember any skills or strategies that you were taught? Can you give me an example?

What did you find most useful about the sessions?

Was there any aspect of the sessions that you found unhelpful?

Did you complete all the sessions offered by the hospital? If not why not?

Do you feel you received enough sessions with the CBT clinic or would you have preferred more or less?

Do you still have concerns about your health condition or have new concerns emerged?

If yes, what concerns do you have? What would help them?

What has happened since your discharge from the clinic run by Sam Gibson? Have there been any changes in the condition you were attending for?

Do you have any new problems with your health?

Have you had further contact with the hospital?

Have you been to an A & E department? Readmitted? Re-referred? Recalled?

If yes to any, what happened? Who decided you should go?

Has GP referred you back to hospital for any reason?

Overall did you find it a positive, neutral or negative experience attending the CBT clinic at RBH?

Is there anything else you would like to add about your experience?

Conclude the interview with the following statements:

This is the end of the interview but before we finish I need to let you know the following:

You can withdraw your interview data from this study for up to 4 weeks from today by telephoning or emailing Sam Gibson on the contact information on the participant information sheet and the letter sent to you.

When the research has been completed we will you send a copy of the final report and an overview of the results.

Do you have any questions or concerns regarding the research? Y/N

Thank you very much for participating today and for all your time and contribution to our study.

Script for Telephone Interview Date of issue 01/07/15 Version number (2)

Eight Big-Tent Criteria (Tracy, 2010)

Criteria for quality (end goal)	Various means, practices, and methods through which to achieve
Worthy topic	The topic of the research is <ul style="list-style-type: none"> • Relevant • Timely • Significant • Interesting
Rich rigor	The study uses sufficient, abundant, appropriate, and complex <ul style="list-style-type: none"> • Theoretical constructs • Data and time in the field • Sample(s) • Context(s) • Data collection and analysis processes
Sincerity	The study is characterized by <ul style="list-style-type: none"> • Self-reflexivity about subjective values, biases, and inclinations of the researcher(s) • Transparency about the methods and challenges
Credibility	The research is marked by <ul style="list-style-type: none"> • Thick description, concrete detail, explication of tacit (nontextual) knowledge, and showing rather than telling • Triangulation or crystallization • Multivocality • Member reflections
Resonance	The research influences, affects, or moves particular readers or a variety of audiences through <ul style="list-style-type: none"> • Aesthetic, evocative representation • Naturalistic generalizations • Transferable findings
Significant contribution	The research provides a significant contribution <ul style="list-style-type: none"> • Conceptually/theoretically • Practically • Morally • Methodologically • Heuristically
Ethical	The research considers <ul style="list-style-type: none"> • Procedural ethics (such as human subjects) • Situational and culturally specific ethics • Relational ethics • Exiting ethics (leaving the scene and sharing the research)
Meaningful coherence	The study <ul style="list-style-type: none"> • Achieves what it purports to be about • Uses methods and procedures that fit its stated goals • Meaningfully interconnects literature, research questions/foci, findings, and interpretations with each other

N.B. Reprinted from *Qualitative Inquiry* [online] 16, 10, Tracy, S. J. Qualitative Quality: Eight “Big-Tent” Criteria for Excellent Qualitative Research, pp. 837 – 851, (2010), with permission from Sage Publications

The Royal Bournemouth and 
Christchurch Hospitals
NHS Foundation Trust



The Royal Bournemouth Hospital

Castle Lane East
Bournemouth
Dorset
United Kingdom
BH7 7DW

Tel: 01202 704379
www.rbch.nhs.uk

Name & address

1st February 2015

Dear

CBT in the Emergency Department

Royal Bournemouth Hospital has been running a clinic at the Emergency Department delivering Cognitive Behavioural Therapy (CBT) to help patients who are frequently attending to manage their ongoing physical problems.

I am conducting a research project looking at what impact attending the clinic has had on the patients both positive and negative. As a clinic attendee I would like to invite you to participate in my research. Please take your time to read the enclosed information sheet and feel free to discuss it with others if you wish.

I will contact you again in a week to see if you are interested in taking part. I have enclosed two consent forms for you to read and complete if you decide to participate. Please retain one copy for your records and return a copy in the prepaid envelope provided.

Thank you very much for your time and consideration. If you have any queries, or wish to know more, you can contact me as follows:

Tel: 01202 704379
Email: samanthagibson@nhs.net
Liaison Psychiatry Department
Post Point 49
Royal Bournemouth Hospital
BH7 7DW

I look forward to hearing from you

Yours sincerely

Samantha Gibson
Specialist Psychologist
Royal Bournemouth Hospital

Participant Information Sheet

You are being invited to take part in this study. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it will involve.

Please take your time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to take part. You can telephone me on 01202704379 or email me (samanthagibson@nhs.net), if there is anything that is not clear or if you would like more information. In addition, if you have any concerns please call Patient Advice and Liaison Service (PALS) at Royal Bournemouth Hospital on 01202704886 or email pals@rbch.nhs.uk.

What is the purpose of the study?

Royal Bournemouth Hospital has been running a clinic at the Emergency Department (ED) delivering Cognitive Behavioural Therapy (CBT) to help patients who are frequently attending to manage their ongoing physical problems. This study would like to identify if attending the clinic changed the attendance patterns of the clinic patients. It also aims to identify why they no longer attend the ED and what (if anything) was most useful about the CBT in managing their symptoms.

Who is being invited to participate in the study?

All the patients who have attended the ED for CBT sessions with Samantha Gibson are invited to participate.

What does it involve?

Participation would involve a single confidential interview, conducted by a trained practitioner on the telephone. The interview will take up to 1 hour and take place at a time that suits you. Interviews can be conducted daytime or evenings up to 8:30pm.

Do I have to complete the interview?

No, your participation in this research is entirely voluntary. You have the right to answer as many or as few questions asked as you wish. You also have the right to withdraw from the study up to four weeks after you have completed the interview.

What are the potential disadvantages and risks of taking part?

There is a slight chance you might find it upsetting in some way, although I hope you will find it enjoyable and interesting. Any participation in research can raise sensitive issues or painful emotions but also positive insights. We do not expect that participating in this study will have any detrimental effects on you. It is entirely your choice as to what you want to share with the researchers. We would also like to reassure you that there are no right or wrong answers and no judgements will be made on the basis of your answers. However, should the interviewer be concerned for your personal welfare

whilst conducting the interview, the interview will be stopped and confidentiality would be broken to enable a referral to be made to an appropriate healthcare professional.

What are the potential benefits of taking part?

There may be no benefit to participants. However, it is hoped that by sharing your opinions and experience of past services, you may be helping to define how Psychological services in the hospital setting could be provided in future.

Will it be recorded?

No, the interview answers would, with your consent, be documented (typed into a secure database) word for word by the interviewer as the interview is being held. The interviewer will be required to retain strict confidentiality regarding the information given.

What if I change my mind about participating?

Participation in this research is entirely voluntary, and you would be able to withdraw from the research, without giving reasons, prior to, and during, the interview. You would also have the opportunity to withdraw all or part of your interview material from the study for up to one month after the interview has taken place.

Will my name be included/published?

No, all information you provide in the interview is confidential. Identifying information (your name) will be changed and a pseudonym given to any of your data used in publications arising from this research. However, the telephone interviewer will verify your name and date of birth for security clearance before starting the interview but this will not be included in any documentation regarding this research.

Will I know what the findings of the study are?

On completion of the research, a copy of the final report and an overview of the results will be sent to you.

Thank you for reading this information, again if you require further information please contact Samantha Gibson as follows:

Tel: 01202 704379
Email: samanthagibson@nhs.net
Liaison Psychiatry Department
Post Point 49
Royal Bournemouth Hospital
BH7 7DW

Or to contact Patient Advice and Liaison Service (PALS) at Royal Bournemouth Hospital:

Tel: 01202704886
Email: pals@rbch.nhs.uk
PALS Co-coordinator
Royal Bournemouth Hospital
Bournemouth, BH7 7DW



University of the
West of England

Patient Identification Number:

CONSENT FORM

Title of Project: Investigating the impact of providing a Cognitive Behavioural Therapy intervention for frequent attenders at the Emergency Department with Medically Unexplained Symptoms.

Name of Researcher: Samantha Gibson

Please initial all boxes

- 1. I confirm that I have read and understand the information sheet dated 01/02/15 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

- 3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

- 4. I agree to take part in the above study.

Consent form Date of issue 01/07/15 version number (2)



Applied Sciences
Glenside Campus
Blackberry Hill
Stapleton
Bristol BS16 1DD

Faculty of Health &

Tel: 0117 328 1170

Our ref: JW/lt

19 July 2018

Miss Samantha L Gibson
Specialist Psychologist
Dorset Healthcare University Foundation Trust
Royal Bournemouth Hospital
Dept. of Liaison Psychiatry
Education Centre Post Point F49
Castle Lane East
Royal Bournemouth Hospital,
Bournemouth
BH7 7DW

Dear Samantha

[Application number: HAS/15/07/193](#)

Application title: Impact of providing CBT in Emergency Department for Frequent Attenders
NHS Application Number: 15/LO/0497

Your NHS Ethics application and approval conditions have been considered by the Faculty Research Ethics Committee on behalf of the University. It has been given ethical approval to proceed with the following conditions:

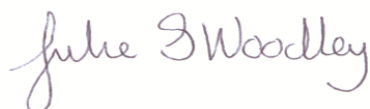
- You comply with the conditions of the NHS Ethics approval.
- You notify the Faculty Research Ethics Committee of any further correspondence with the NHS Ethics Committee.
- You must notify the Faculty Research Ethics Committee in advance if you wish to make any significant amendments to the original application.

- If you have to terminate your research before completion, please inform the Faculty Research Ethics Committee within 14 days, indicating the reasons.
- Please notify the Faculty Research Ethics Committee if there are any serious events or developments in the research that have an ethical dimension.
- Any changes to the study protocol, which have an ethical dimension, will need to be approved by the Faculty Research Ethics Committee. You should send details of any such amendments to the committee with an explanation of the reason for the proposed changes. Any changes approved by an external research ethics committee must also be communicated to the relevant UWE committee.
- Please note that any information sheets and consent forms should have the UWE logo. Further guidance is available on the web:
<http://www1.uwe.ac.uk/aboutus/departmentsandservices/professionalservices/marketingandcommunications/resources.aspx>
- Please note that the University Research Ethics Committee (UREC) is required to monitor and audit the ethical conduct of research involving human participants, data and tissue conducted by academic staff, students and researchers. Your project may be selected for audit from the research projects submitted to and approved by the UREC and its committees.

Please note that your study should not commence at any NHS site until you have obtained final management approval from the R&D department for the relevant NHS care organisation. A copy of the approval letter(s) must be forwarded to Leigh Taylor in line with Research Governance requirements.

We wish you well with your research.

Yours sincerely



Dr Julie Woodley
Chair
Faculty Research Ethics Committee

c.c. *James Byron Daniel*



Health Research Authority

NRES Committee London - Bromley

Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421390
Fax: 01173420445

04 August 2015

Miss Samantha L Gibson
Specialist Psychologist
Dorset Healthcare University Foundation Trust
Royal Bournemouth Hospital, Dept of Liaison Psychiatry Education Centre
Post Point F49, Castle Lane East Royal Bournemouth Hospital,
Bournemouth
BH7 7DW

Dear Miss Gibson

Study title:	Investigating the impact of providing a cognitive behavioural therapy intervention for frequent attenders at the Emergency Department with medically unexplained symptoms.
REC reference:	15/LO/0497
Protocol number:	1
IRAS project ID:	144246

Thank you for your letter of 15th July 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Miss Georgina Castledine, nrescommittee.london-bromley@nhs.net.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management

permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [ndemnity letters UMAL CT 14-15.pdf]		16 July 2014
Interview schedules or topic guides for participants [Script for Telephone Interviews]	1	10 February 2015
Interview schedules or topic guides for participants [Script for Telephone Interviews]	2	01 July 2015
IRAS Checklist XML [Checklist_13072015]		13 July 2015
IRAS Checklist XML [Checklist_15072015]		15 July 2015
Letters of invitation to participant [participant+letter]	2	02 March 2015
Other		01 August 2014
Other [indemnity letter]		01 August 2014
Other [registration of research project]	2	28 November 2013
Other [RD1 approval]	1	07 March 2014
Other [Progression Outcome Report]	1	23 May 2014
Other [Progression Exam Confirmation]	1	23 May 2014
Other [RBH ED approval letter]	1	10 February 2015
Other [Liaison Psychiatry RBH Approval letter]	1	18 November 2013
Other [PGH Letter of Approval]	1	10 February 2015
Other [Response letter]		
Participant consent form [consent form]	2	01 July 2015
Participant information sheet (PIS) [participant information sheet v2]	3	15 June 2015
REC Application Form [REC_Form_04032015]		04 March 2015
Research protocol or project proposal [research protocol v4]	4	10 February 2015
Research protocol or project proposal [research protocol v5]	5	15 July 2015
Summary CV for Chief Investigator (CI) [CV-SGv1]	1	02 February 2015
Summary CV for supervisor (student research) [CV-JBDv1]	1	03 February 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Reporting requirements

The attached document “*After ethical review – guidance for researchers*” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

<http://www.hra.nhs.uk/hra-training/>

15/LO/0497

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project. Yours

sincerely



Ms
Carol
Jones

Chair

Email: nrescommittee.london-bromley@nhs.net

Enclosures: “After ethical review – guidance for researchers” *[SL-AR2]*

Copy to: Ms Leigh Taylor
Mrs Caroline Jamieson-Leadbitter, The Royal Bournemouth and
Christchurch Hospitals NHS Foundation Trust

10.1136/emered-2013-203113.2

Objectives & Background We identified that there is a cohort of people who attend our Emergency Department (ED) extremely frequently (>24 times per year) or who have frequent admissions (>12 per year). Analysing hospital clinical records identified that in many cases medically unexplained symptoms (MUS) drive the frequent presentation. The needs of these patients were not being met by a traditional dualistic approach in which people are seen in either physical or mental health settings. Indeed, despite frequent medical investigations/treatments, their symptoms persist, their problems are not resolved, they frequently complain and they keep coming back. This carries risk and distress for the patients, and heavy use of resources for the hospitals involved.

Methods Each month we looked at attendance data for the previous 3 months (this identified people who in an acute phase of repeat presentations). By accessing patients clinical records, we determined the main factors which appeared to drive their frequent attendance and admissions and identified those who presented with MUS. Care plans were developed and each patient was contacted and offered weekly Cognitive Behavioural Therapy (CBT) sessions to help them manage their symptoms. This was part of a case management approach in which coordinated, multidisciplinary reviews were undertaken resulting in an individualised care plan.

Results Thus far the pilot has seen a reduction in attendances at ED for 100% of patients included in study (N=20). Crucially, all now attend less than once per month. In total 245 attends were saved after the CBT interventions

Conclusion Providing a psychological intervention to this patient cohort is effective in reducing hospital costs by containing the most frequent attenders. CBT and care plans have reduced attendance to under once per month and subsequently reduced medical interventions and prescribing costs.

A PILOT PROJECT TARGETING FREQUENT ATTENDERS AT THE EMERGENCY DEPARTMENT WITH MEDICALLY UNEXPLAINED SYMPTOMS

866 Emerg Med J 2013;30(10):866–880

Theme	Subtheme	Code	Subcode
1.		Mismatch of Psychiatric treatment and physical symptoms	Doctor sent me I left when they gave me lots of forms No why would I have gone there No that's where I went before they didn't understand what I was going through Probably not because I was in so much pain Just asked about me wanting to kill myself They discharged me coz I kept cancelling
2.		Proximity to hospital Familiarity	There all the time Easy for me (location) I live close So far from me (psych) Always there
3.		Help seeking Negative emotions felt	I'd try anything to get better Nothing to lose Cope better (help me) Glad to see someone Called Samaritans – they are great when I can't cope Wasn't happy

Theme	Subtheme	Code	Sub code
1.		confusion	P10 Confused really, didn't know who she was or anything. P4 Well if I'm honest, I wasn't happy about it. But then I didn't really know what it was about. P7 I didn't know what it was but (said name of community matron) said I should go. P2 Found the term frequent flyers confusing and was not sure what to expect.
		Just another appointment	P5 Just thought it was another appointment. I was always there for

			<p>something so didn't really thing anything about it.</p> <p>P1 No particular thoughts specifically – just another medical appointment.</p>
2.		Relief to have an appointment	<p>P8 Thank goodness, I think.</p> <p>P3 Relief to have an appointment.</p>
3.		Unhappy about appointment	<p>P4 Well if I'm honest, I wasn't happy about it. But then I didn't really know what it was about.</p>
Theme	Subtheme	Code	Sub code
1.		Empowered - I try to do something before it gets really bad	<p>Don't ignore stuff</p> <p>Go to my doctor and get is sorted early</p> <p>Learnt not to ignore it and make it all worse</p> <p>Deal with my stress</p> <p>Do something</p> <p>Better organised</p> <p>Deal with it differently</p> <p>Learnt to just get on with things – you know</p>
2.		Accepting/resignation of uncertainty	<p>Just time you know</p> <p>Nothing they can do</p> <p>Nothing – just gotta learn to live with it</p>
5.		Trust in health service – see other themes??	<p>Hospital staff are wonderful – they know best</p> <p>GP has been great</p>
4.		Managing emotions - Accepting - live with it	<p>I know it was my worry</p> <p>Deal with my stress</p>

Cognitive Behavioural Therapy Interventions for Medically Unexplained Symptoms: A critical review of the treatment studies

Abstract

MUS has been used to describe a collection of conditions that present as physical symptoms but no organic pathology can be found. Crayford and Hotopf (2002) identified that patients with MUS accounted for double the financial cost of investigations than that of other groups of service users. But this over testing leads to very dissatisfied patients who view their needs as remaining unmet (Hahn, Thompson, Wills, Stern and Budner, 1994). To address this problem, clinicians and researchers have been developing and evaluating Cognitive Behaviour Therapy (CBT) interventions by utilising an empirical framework of case formulation, intervention and evaluation. This review attempts to synthesise this research and has identified that there is good support for CBT interventions but there still appears to be a diversity of who is delivering these interventions and what they are calling CBT.

1. Introduction

The Condition

Whilst the term medically unexplained symptoms (MUS) which is sometimes referred to as medically unexplained physical symptoms (MUPS) may be relatively new (Henningesen, Fink, Hausteiner-Wiehle and Rief, 2011); the reporting of physical illness/symptoms that may be negatively impacted by psychological distress is not. From ancient Egypt to ancient Greece evidence of its existence have been reported (Woolfolk and Allen, 2007). In medieval Persia, Ahmed ibn Sahl al-Balkhi (AD 934)

documented his observation that if a person becomes ill they lose their enjoyment of life and conversely, when the mind lacks joy the body becomes ill. Additionally, in the early 20th century Groddeck (1925, cited in Schoenberg 1991) documented his theory that illness was determined by an 'unconscious factor' and could thus be addressed with psychotherapy. This was followed by Alexander's work that began to treat patients with what was deemed psychosomatic medical disorders (such as ulcerative colitis and asthma) with psychoanalysis. Alexander (1968, Schoenberg, 1991) argued that stressful life events created a biological reaction which targeted vulnerable parts of the body. Nevertheless, this work has been criticised on three counts. Firstly, psychological distress was not always evident in patients. Secondly, psychoanalysis did not appear to remove or impact on the physical symptoms. Finally, different disease pathologies have been discovered within disorders such as in inflammatory bowel disease with the discovery of Crohn's disease differing greatly to ulcerative colitis (Taylor, 1989 cited in Schoenberg 1991).

Today MUS has been used to describe a collection of conditions that present as physical symptoms but no organic pathology can be found. This is despite the patients (and often the clinician) attributing the symptoms to a medical cause (Brown, 2004). A group of conditions has been suggested by Brown (2006) that includes Functional Somatic Syndromes, Somatised Mental Disorders, Hypochondriasis, Somatoform Disorder, Dissociative Conversion Disorders or indeed any organic illness where disability is greater than expected. However, any definitive definitions are not without criticism (Henningesen, 2007). Indeed, even the term medically unexplained symptoms have caused disagreement as critics believe it does not adequately account for symptom severity or recognise non - medical

explanations (Henningesen, 2007; Henningesen et al, 2011). Additionally, the term somatoform has proved unacceptable to patients as it implies its origin is a purely psychogenic one. However, it has been noted that the term appears less contentious in Germany than it does in the United Kingdom and the United States of America (Henningesen et al, 2011) and this perhaps needs to be researched in the near future. Further criticism of the terms has come from Creed, Guthrie, Fink, Henningesen, Rief, Sharpe, and White (2010) who contend that they encourage the continuation of the dualism of mental and physical health domains to remain in healthcare services. Adding, they may give clinicians a non-committal diagnostic term but this is viewed negatively by patients who, it is claimed view the labels as ambiguous or stigmatising. Nonetheless, it is contended that MUS provides a neutral label for professionals that covers the diversity of symptoms often presented; but recognises that it may be better if descriptions rather than labels were used in clinical practice (Brown, 2006).

Henningesen et al's thoughtful and provocative paper published in (2011) argued for the introduction of another term to replace MUS given its ambiguity. They argued that Bodily Distress Syndrome was a more positive term as it does not imply any aetiology of the symptoms and is utilises an 'anti-dualistic' language. Even so, a definitive psychiatric definition for MUS is currently under review for inclusion into DSM-V (expected 2013). Obviously, this suggested inclusion has not been without its own criticism. For example, Creed & Barsky (2004) have argued that proposers of a distinct diagnosis of MUS have continually failed to distinguish or prove that symptom clusters equal a discrete psychiatric disorder.

Regardless of the term or label used; the patients presenting at healthcare providers continue to seek a cure from their symptoms whilst constantly seeking an 'explaining' diagnosis. It has been well documented that MUS has been identified as a major problem in healthcare because of increased health service use (Kolk, Schagen and Hanewald, 2004; Rief and Broadbent, 2007; Brown, 2006 among others). For example, MUS costs in the USA were estimated to be in excess of \$100 billion per year (Kroenke, 2007). Whilst in the UK it has been quoted that 'at least' 20% of attendees at Emergency departments are MUS patients (Rief & Broadbent, 2007). Furthermore, in a retrospective cohort study of the South Thames (West) NHS region, Reid, Wessely, Crayford and Hotopf (2002) identified that patients with MUS accounted for double the financial cost of investigations than that of other groups of service users. Indeed, one of the most frequently quoted figures for the cost of healthcare utilisation for this patient group is around 16 percent of total budgets in western industrialised societies (Barsky, 2005).

In the United Kingdom this would equal approximately £8.5 billion per annum.

However, given that this does not include any social care, disability and housing benefits to patients and carer costs; it must be concluded that this estimate is very conservative indeed. Whilst the cost to the rest of the world is unknown, it has been reported that MUS appears with similar symptoms, disability and prevalence across large and diverse cultural settings (Sumathipala, Siribaddana, Abeysingha, De Silva, Dewey, Prince and Mann, 2008). One reason for this over utilisation has been proposed by Salmon (2007) who has contended that clinicians are failing to recognise the role of psychosocial factors in influencing physical symptoms.

Therefore, they attempt to 'rule out' organic causes with extensive investigations

which not only increases the cost to the hospital but also reinforces the patient's belief that they have an 'undiagnosed' physical illness (Salmon, 2007).

It is further contended that this over testing leads to very dissatisfied patients who view their needs as remaining unmet (Hahn, Thompson, Wills, Stern and Budner, 1994) and reporting lower levels of satisfaction with the information they receive from their clinicians (Jackson, Kincey, Fiddler, Creed and Tomenson, 2004). Furthermore, not only are these patients dissatisfied, cost more and utilise more services than other attendees but they are also more likely to cause their clinicians stress and anxiety and be labelled as 'frustrating' (Hahn et al, 1994).

Indeed, research has highlighted that as many as 70% of people with medically unexplained physical symptoms also suffer from depression and/or anxiety disorders. Worryingly, those diagnosed also report poorer quality of life than people with given a medical diagnosis for their symptoms (Nimnuan, Hotopt & Wessely, 2001). Moreover, of a study by the European Consultation Liaison Psychiatry Workgroup (ECLW) studied European inpatient data for 34500 patients. They identified that approximately 4830 or 14% of the cohort had somatoform disorders but only 61 were referred to the liaison psychiatry service (Fink, Burton, De Bie, Sollner and Fritzsche, 2011). However, this link had previously been disputed in a literature review conducted by Burton (2003). The review declared that many patients with MUS had no clear psychological illness on assessment.

Nevertheless, it must be remembered that there is still a large problem engaging patients in psychological interventions given that a considerable proportion considers

their symptoms to be physical in nature seeing any referral as a rejection by their treating practitioner. In addition, as previously mentioned, the European study found that very low patient numbers are referred on from medical specialities for a psychotherapeutic intervention (Fink et al, 2011). Therefore, not only are patient viewing mental health referrals as inappropriate or unacceptable but practitioners are also.

It has also been reported that if a referral does take place the refusal and drop out numbers are large (Barsky and Ahern, 2004). Importantly, one approach to tackle this has been presented by Speckens, van Hemert, Spinhoven, Hawton, Bolk, and Rooijmans (1995). They highlighted that interventions conducted in the medical setting known to patients (e.g. GP surgery or hospital outpatients) appear to improve the engagement process.

Different levels of MUS have been identified (old Hartman, Borghuis, Lucassen, van de Laar, Speckens and van Weel, 2009; Creed, van der Geltz-Cornelis, Guthrie, Henningsen, Rief, Schroder & White, 2011 among others) with the onset of symptoms defined as important component for successful treatment (old Hartman et al, 2011). They have highlighted that the DSM IV definitions are unhelpful at present at identifying potential treatment groups given that the threshold for somatisation disorder is very high whilst undifferentiated somatisation disorder probably too low.

Nevertheless, screening tools such as the Patient Health Questionnaire – 15 (PHQ-15) are available and whilst simplistic in its nature; it has been noted that the 10-20% of top scorers correlate well with the severe end of the spectrum (Kroenke, Spitzer

and Williams, 2002). Creed et al (2011) have speculated that patients can be defined by the likelihood of symptoms becoming chronic. They reported three groups for MUS patients' low, intermediate and high risk.

1. 'Low risk' for example, would see good outcomes as patients only experience symptoms for a short while and are prepared to consider that psychosocial factors may be impacting them (if given the chance).
2. 'Intermediate risk' patients presented at health providers with comorbidity of other symptoms or psychiatric diagnosis. Problems may occur if they are treated in isolation e.g. only physical symptoms receive medical treatment. Thus, if patients are provided with a treatment that looks at the presentation holistically the prognosis is deemed good for the future.
3. 'High risk' group are those with persistent symptoms that they view as disabling. They are more likely to have numerous admissions for diagnostic testing or surgical procedures and have poor relationships with clinicians that lead to seeking second opinions. They may be in the midst of legal claims or in receipt of disability pensions.

This hierarchy is supported by Barsky (1996) who noted that early identification of people with MUS is important as the more they are investigated and referred the more difficult it becomes to help them. Plus, old Hartman et al (2009) stated that a more severe condition led to a worse clinical outcome. However, Guthrie's (1996) review concluded that CBT studies had thus far not targeted this group of patients.

Certainly, there have been differences in severity reported between those attending secondary and primary care which is easily explained by the way most western healthcare services are set up e.g. Specialist Consultants receive referrals from the

General Practitioner if they are unable to resolve the issue (Fink et al, 2011).

However, it must be remembered that a proportion of those with MUS symptoms will see them resolve spontaneously.

The Intervention

To address this problem, clinicians and researchers have been developing and evaluating Cognitive Behaviour Therapy (CBT) interventions by utilising an empirical framework of case formulation, intervention and evaluation. The aim has been to define cognitions, emotions, biological/physiological changes and subsequent behaviours to identify a holistic overview of MUS presentations (Nezu, Nezu and Lombardo, 2001). Thus, cognitive behavioural therapy encompasses the bio-psycho-social model. In summary,

- CBT proposes that an interaction of biological, behavioural, social and psychological factors maintains illness.
- Thus, it does not threaten an individual's illness belief or offer a cure; but proposes that it has the potential to improve coping by changing cognitions and recognising behaviours that may negatively impact an individual's symptoms.

Why it is important to do this review?

Fundamental to any CBT/MUS intervention model is a holistic approach or bio-psycho-social construct. However, to date the health care services do not incorporate this. Indeed, this represents a challenge to the majority of healthcare setups built on the dualism where symptoms are perceived and treated as either

mental or physical. Without understanding or a willingness to adapt to the construct that all presentations have components of both success may be limited.

The Department of Health (UK) publication of 'no health without mental health' (2011) is seeking to attempt to move this patient cohort to psychological therapy services. Improving Access to Psychological Therapies (IAPT) have been charged with potentially providing MUS services throughout the UK and have developed pilot sites to develop care pathways and provide therapeutic interventions for this patient group (IAPT, 2012). This would, at first look, make it appear that dualism remains alive and well. Research has already shown that the most severe and costly do not accept mental health referrals (Barsky and Ahern, 2004) therefore, they may end up just treating the 'low risk' patient group (Creed, 2011) leaving the more severe untreated and over utilising the already stretched health care services. Thus, it would appear useful to look if levels/severity of MUS were considered in the CBT interventions thus far reported and if so how severe (or difficult to engage patients) were recruited. As differences and treatment resistance have been noted stating that earlier onset of symptoms led to worse outcomes after interventions (old Hartman et al, 2011). It would be useful to note if this pattern existed for other studies in the genre.

Additionally, it would be useful to verify if treatment situation impacts outcome as reported by (Speckens et al, 1995) and that treating them in their usual treatment setting can improve results. This may mean introducing MUS/CBT clinics in outpatients and emergency departments by taking the expertise to where the patients are.

Although thus far there have been previous reviews looking at psychological interventions with MUS populations (see Table 1 for summary) they have previously compared CBT to other psychological approaches or concentrated on treatment effects. As previously highlighted, it is necessary to understand the look at the who, what and where of the treatments.

The aims of the review were to identify the following:

1. Did the location of the treatment intervention impact the outcomes?
2. Were risk levels/severity of MUS documented in the CBT interventions? And if so, how were the patients recruited?
3. Who provided the interventions? What training/qualifications did they have/receive?
4. Did they use treatment manuals/protocols?
5. Were there differences in outcomes for the type of intervention (individual, group or guided self-help?)

Table 1. Summary of findings of previous reviews conducted.

Author (s)	Symptoms	Interventions	Outcomes	Conclusion
Kleinstauber, Witthoft & Hiller (2011)	Multiple MUS	Short term Psychotherapy	Disorder specific, Depressive symptoms & psychopathology, functional impairment	Small but stable effects found across symptom relief.
Kroenke (2007)	Somatoform Disorders	CBT, antidepressants, consultant letter, writing disclosure, St. John's wort, Exercise, hypnosis	Treatment type,	CBT was most effective with benefit also from consultation letter.
Sumathipala (2007)	Somatoform Disorders	Psychological therapy, CBT, pharmacological therapy, management	Treatment type, Physical symptoms, psychological distress, disability.	CBT was most efficacious treatment
Smith et al (2003)	MUS	Any intervention in treatment group to inform development of primary care protocol	Overviews of research	Simple cognitive behavioural techniques could be used for primary care non-complex patients
Looper & Kirkmayer (2002)	Somatization Disorder	CBT, Consultation letters, meditation & relaxation	Symptom severity Medical costs	Consultation letters may reduce health costs
Allen, Escobar, Lehrer, Gara & Woolfolk (2002)	MUS	Psychosocial interventions	Reduction of physical discomfort & disability	Large methodological flaws in research. No lasting benefits.
Nezu et al (2001)	MUS	CBT	Physical symptoms, Psychological Distress	CBT is effective in symptom reductions in both areas
Guthrie (1996)	Somatisation Disorders	CBT, psychodynamic therapy	Recovery rates, physical symptoms, beliefs & behaviours	Brief therapy provided delayed or long term therapeutic benefits.

2. Method

The strategy utilised for the search was adapted from The Cochrane Handbook of Systematic Reviews of Interventions (2011).

2.1. Identification of question

An important component of any synthesis of research should include clearly identified question. To following were used to assess the effects of cognitive behavioural therapy for medically unexplained symptoms in adult populations in primary and secondary healthcare settings and to guide this review.

Who provides effective CBT treatment, what protocols did they follow if any and did the treatment location impact outcomes.

2.2 Literature Selection criteria

The **PICO** model (**P**opulation, **I**ntervention, **C**omparison & **O**utcome) was used to initially develop the literature selection criteria (Booth and Fry-Smith, 2004) for this review. **P**opulation to be included was defined as male or female adults (> 18 years). The reason the population was limited to an adult only group was that differences between the groups had been reported. It would appear that children and adolescents MUS symptoms differed by type of symptom and often remitted completely in adulthood (Eminson, 2007). However, interestingly it has been reported that children with MUS were more likely to suffer from psychiatric disorders in adulthood. But if this was successfully treated symptoms reduced spontaneously (Hotopf, Carr, Mayou, Wadsworth, and Wessely, 1998).

The Intervention looked at was cognitive behavioural therapy interventions. There were no restrictions on the type i.e. group, individual or guided self-help or on the length of the intervention provided. Likewise, Comparison was not limited, if there was a control group (passive or active) or the intervention was measured against an alternative intervention the studies were included. Similarly, Outcomes were not specified as long as pre and post quantitative results were included.

2.3 Search Protocol

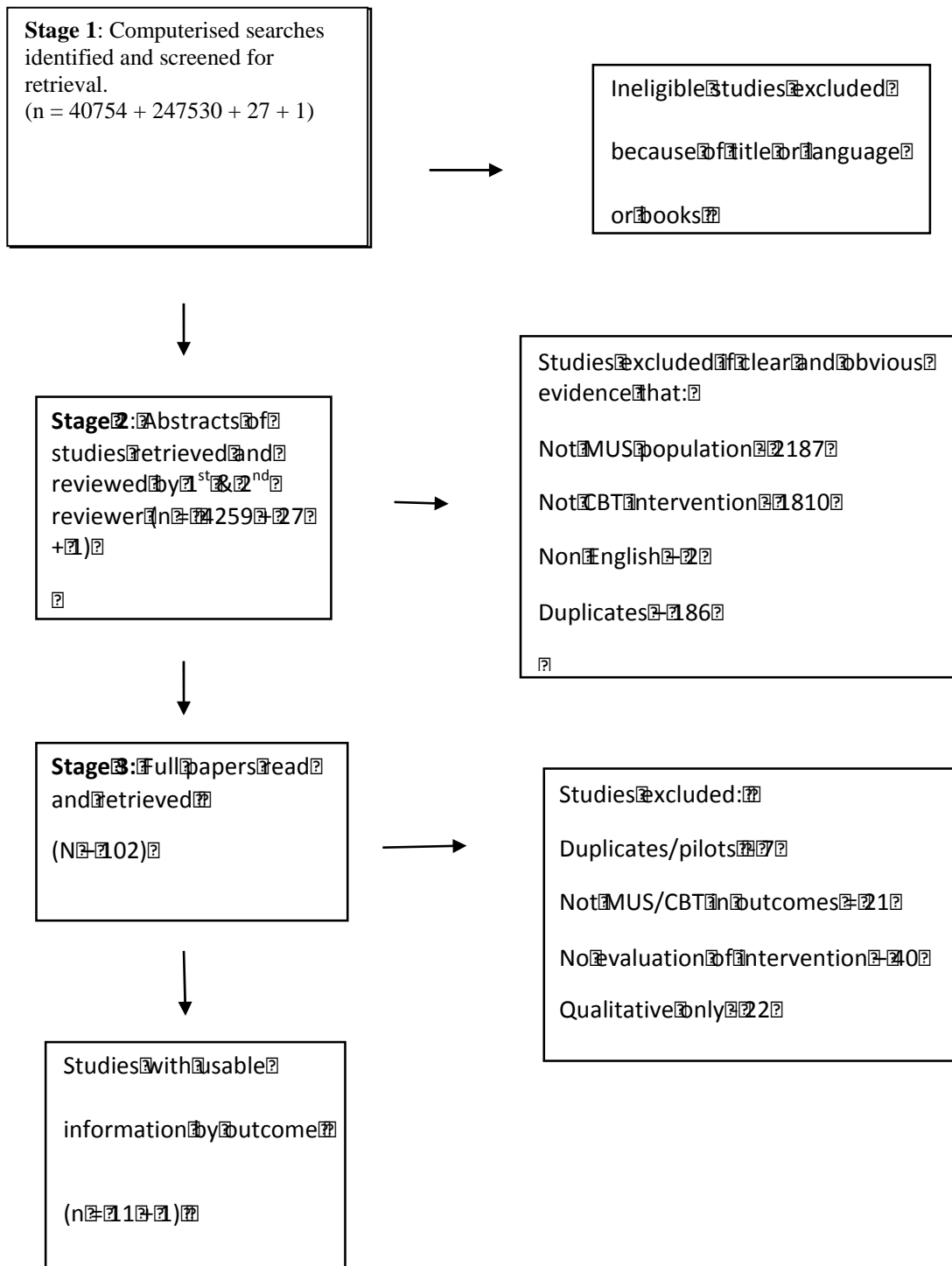
A multi-phase search was conducted. Firstly electronic searches were conducted utilising the following data bases: MEDLINE, PsychINFO, the Cochrane Library; EMBASE; PubMed, ClinicalTrials.gov, ProQuest Digital Dissertations. Symptoms specific key words were used as follows: Medically Unexplained Symptoms or MUS; Medically Unexplained Physical symptoms or MUPS; Medically Unexplained Symptom Syndrome or MUSS; Unexplained Physical Symptom; Bodily Distress Syndrome; Somatoform Disorder; Multi Somatoform Disorder; Somatisation /Somatization Disorder; Somatising /Somatizing Patients. All papers included a single diagnosis of fibromyalgia, irritable bowel syndrome or chronic fatigue syndrome were excluded as these have (already and/or current reviews in progress) been reported as separate diagnosis within Cochrane Reviews (for example Zijdenbos, de Wit, van der Heijden, Rubin & Quartero, 2009; Bernardy, Klose, Busch, Choy, Häuser, 2012; Williams, Eccleston, Morley S, 2012 & Price, Mitchell, Tidy, Hunot, 2009). The electronic search resulted in a large number of hits for the symptoms specific search: MEDLINE up to 1276 hits, PsychINFO up to 82888 hits, the Cochrane Library up to 1103 hits; EMBASE up to 12760 hits; PubMed up to 14068 hits, ClinicalTrials.gov up to 52, ProQuest Digital Dissertations 11.

The Intervention key words utilised were: Cognitive Behaviour/Behaviour Therapy or CBT; Cognitive Therapy or CT; Behavior/Behaviour Therapy. The electronic search also resulted in a large number of hits for the symptoms specific search: MEDLINE up to 172111 hits, PsychINFO up to 18278 hits, the Cochrane Library up to 3767 hits; EMBASE up to 1082; PubMed up to 49083, ClinicalTrials.gov up to 3155, ProQuest Digital Dissertations 27.

In the next phase a hand search of previous reviews, papers and book chapters for eligible publications. Plus two CBT for MUS continuing professional development training days were attended to see if grey literature could be obtained. Finally, emails were sent requesting any unpublished studies to experts in the field. The response rate was sadly 5%. All relevant studies published up to August 2nd 2011 were included. However, due to translation difficulties only English language studies accepted. The multi-phase search resulted in 102 paper titles.

The quorum flow chart (figure 1) displays the process of article selection. Stage 1 consisted of removing ineligible studies e.g. biological interventions etc. The remaining abstracts were independently reviewed by two researchers (see appendix 2 for screen form). Full copies of papers were then retrieved and were again independently reviewed by two researchers and specifically designed data extraction forms that documented the inclusion criteria (see appendix 3) were used (again by two researchers) to extract relevant data and verify inclusion in final paper. Any disputes between the two researchers were negotiated for agreement. However, if unable to reach an agreement a 3rd researcher had the final say.

Figure 1. Quorum Flowchart



**Table 2.
Included
studies**

Authors	Type of Study	Setting	Participant number	Drop out number	Follow up in months	Jadad
Schroder et al (2012)	Randomised Controlled Trial	Secondary Care	120	9	4, 10, 16	3
Sharpe et al (2011)	Randomised Controlled Trial	Secondary Care	127	2	3 6	3
Sumathipala et al (2008)	Randomised Controlled Trial	Primary Care	150	22	3, 6, 9 12	3
Martin, Rauth, Fichter & Rief (2007)	Randomised Controlled Trial	Primary Care	140	22	6	3
Allen & Woolfolk (2006)	Randomised Controlled Trial	Primary Care	84	7	9 15	3
Bleichhardt, Timmer & Rief (2004)	Randomised Controlled Trial	Secondary Care	191	5	12	3
Speckens et al (1995)	Randomised Controlled Trial	Secondary Care	79	77	6 12	3
Escobar, Gara, Diaz-Martinez, Interian, Warman, Allen, et al. (2007)	Randomised Controlled Trial	Primary Care	187	44	6	2
Arnold,De Waal, Eekhof, Assendelft, Spinhoven &	Controlled Trial	Primary Care	65	55	6 12	1

van Hemert, (2009).						
Ehlert, Wagner & Lupke (1999)	Controlled Trial	Secondary Care	42	Not recorded	Not recorded	2
Lidbeck (1997, 2003)	Controlled Trial	Primary Care	33	2	6 18	2
Tyrer, Tyrer & Lovett (in press) Ehlert, Wagner & Lupke (1999)	Cohort Study	Secondary Care	444	62 (incl. of death-rates)	24	2

Table 2. Included Studies (continued)

Results

Quality of the included studies was assessed utilising the scale developed in 1996 by Jadad (see table 2, column 1996). The scale incorporates three items as follows; was the study randomised, were dropout/attrition rates reported and finally if the study was described as double blind. These were included in the screening tool worded to elicit a yes/no answer with a point awarded for each positive answer (max score achieved = 3, minimum = 0). However, given the intervention being tested was cognitive behavioural therapy the third question was changed as it would not be possible to blind participants to the condition. So, included instead was 'did the study include a structured interview and/or diagnostic testing?' This question has previously been used in a review of psychological therapy (see Kleinstauber et al, 2011) highlighting the importance of differentiating between MUS and anxiety and depressive symptoms to ensure the appropriateness of treatments offered (Melville, 1987 cited in Kleinstauber et al, 2011).

Table 3. Individual CBT Interventions

Authors	Session no's	Protocol/manual	Outcomes	Comments
Sumathipala et al (2008)	3	OWN	Symptoms, psychological & utilisation	No improvements in any outcomes for treatment group
Martin et al (2007)	1	Sharpe (1992)	Symptoms, psychological, utilisation, medication & sick leave	Utilisation & medication reduced
Allen & Woolfolk (2006)	10	Woolfolk & Allen	Symptoms, costs, utilisation, functional	Costs Symptoms reduced Improvement in functional
Speckens et al (1995)	Mixed 1 – 20	Salkovskis (1989), Sharpe (1992)	Symptoms, psychological, utilisation, medication	Medication reduced Small gains in other measurements
Escobar et al (2007)	10	Woolfolk & Allen	Symptoms, psychological & medication	Short term gains in all area but not sustained at follow up
Arnold et al (2009).	5	Sharpe (1992)	Symptoms, beliefs, psychological, functional	No significant improvements
Ehlert et al (1999)	Not reported	NO	Symptoms, psychological	Improvements in both areas measured
Tyrer et al (in press)	Mean of 7.3	Not reported	Costs, utilisation.	Costs & utilisation greatly reduced.

Table 4. Group & other CBT

Interventions					
Authors	Intervention	Session no's	Protocol/manual	Outcomes	Comments
Schroder et al (2012)	Group	9	STreSS	Symptoms, functional and vitality	Long term effects of symptom reduction
Lidbeck (1997, 2003)	Group	8	OWN	Symptoms, beliefs, psychological, medication & vitality.	Small improvements but reduced at follow up to 1 area only (beliefs)
Sharpe et al (2011)	Guided Self Help	N/A	Sharpe (1992)	Symptoms, psychological	Significant in all areas but results not maintained at follow up
Bleichhardt et al (2004)	Inpatient Treatment	MIXED	Bleichhart et al	Symptoms, psychological & utilisation	Utilisation & symptom reduction

Treatments Intensity in the Studies

The treatment intensity for the intervention groups could be collected from 10/12 studies (inpatient study could not be calculated accurately as various groups and individual sessions were offered at varying rates for participants, one study was for self-help and the third did not report the frequency of sessions). The mean of the included studies was 7.7 sessions with a range of 1-20. The subjects in the control arms were assigned to wait list in one study with another 12 providing treatment as usual.

Secondary Study Characteristics

Of the 12 studies included, 2 were conducted in The Netherlands (Arnold et al, 2009; Speckens et al, 1995)., 2 from USA (Allen & Woolfolk, 2006; Escobar et al, 2007), 3 from Germany (Bleichhardt et al, 2004; Martin et al 2007; Ehlert et al, 1999), 2 in the UK (Sharpe et al, 2011; Tyrer et al, in press) and 1 in Sri Lanka (Sumathipala et al, 2008), Denmark (Schroder et al, 2012) and Sweden (Lidbeck, 1997, 2003) respectively. Eleven studies provided demographics allowing analysis. The mean age for participants in the treatment groups was 37.23 years with a mean of 39.12 years in controls. Additionally, Female to male ratios were 79% female in the treatment conditions with an 81% female population in control groups. Race and ethnicity were reported in only one study from USA with a median of 19% minorities included (range 10% - 36%). Likewise, two studies reported on education status but the differentials in reporting made any overall estimate difficult to achieve.

Drop Out, Exclusion and Refusal Rates

Twelve studies reported drop-out rates (Ehlert et al, 1999 excluded as no result reported). From the original participant numbers of 1823, 309 failed to complete the studies or approximately 1 in 6 but the range varied greatly (2 – 77). However, eight studies also included exclusion criteria (Martin et al, 2007; Sumithapala, 2008; Schroeder et al, 2012; Escobar et al, 2007; Allen et al, 2006; Sharpe et al, 2011; Speckens et al, 1995; Arnold, 2009). Exclusion criteria included age, psychiatric diagnosis, severe current medical conditions, substance dependence or legal issues. Total participant numbers in the 8 studies were 1018. However, exclusion numbers totalled 1078. Furthermore, of eight studies documenting refusal rates, the take up of participation was 1201 but original refusal rates were 564 potential participants or 46.96%. there were 3/6 studies primary care (Sumathipala et al, 2008; Escobar et al, 2007 and Arnold et al, 2009) and 4/6 secondary care (Schroder et al, 2012; Sharpe et al, 2011; Speckens et al, 1995 and Ehlert et al,1999).

Measured Outcomes

The two largest outcome groups were Psychological measurements and reported physical symptoms which were recorded in ten studies each. Psychological outcome measures were the utilised by the majority of studies (10/12). Only one study used their own designed questionnaire (Speckens et al, 1995) In all other studies, valid and reliable measurement tools were used. For example, Arnold et al (2009) included the Hospital Anxiety and Depression Scale (HADS), Escobar et al (2007) Hamilton Rating Scale for Depression (HAM-D), Ehlert (1999) Zung Self Rating Depression Scale. Lyles et al (2003) Centre for Epidemiological Studies Depression Scale (CESD) and Speilberger

State Anxiety Scale (SSAS), Martin et al (2007) measured changes using Beck Depression Inventory (BDI), Sharpe et al (2011) utilised the Whiteley Index for anxiety and finally Bleichhardt et al (2004) went for the HADS.

In addition, reductions in reported physical symptoms were documented as outcomes in ten studies with varying results. Sumathipala et al (2008) and Arnold et al (2009) did not report any improvement in the treatment group when compared to controls; whilst small but non-significant results were reported by Lidbeck et al (2003). However, Allen (2006), Elhert (1999), Escobar (2007), Sharpe (2011) reported improvements in symptoms at outcome but the reductions in reported symptoms were not maintained when follow up by Escobar (2007), Sharpe (2011). In opposition, Schroeder's study showed that symptoms reduced with time and reported that the reductions in symptoms were maintained at follow-up. But, once again it is hard to equate the reported changes as a vast variety of measurement tools were used for measuring physical symptoms. Allen et al (2006) used the Global Impression for somatic Disorder (GSI-SD). Escobar et al (2007) utilised the PHQ-15 and Composite Diagnostic Interview (CIDI) visual analogue score (VAS) plus the Clinical Global Impression Scale (CGI) for physical symptoms. In addition, Bleichhardt et al (2004) administered the Screening for Somatic Symptoms (SOMS), Schroeder (2012) the Short Form Health Measure (SF-36) and 90 item Symptom Checklist – Revised Soma Scale; Elhert et al (1999) Frielburg Complaint List; Sharpe (2011) PHQ-15 adapted to 13 questions; Lidbeck used the Illness Behaviour Questionnaire (IBQ); Arnold et al (2009) Physical Symptom Checklist (PSC) and the VAS; Sumathipala (2008) GHQ-30; Bradford Somatic Inventory and Martin the Brief Symptom Checklist and Derogah's Symptom Checklist and finally, Speckens et al (1995) developed their own questions.

Healthcare utilisation was recorded as an outcome measure in six studies. Tyrer et al (in press) saw a dramatic reduction in hospital bed days and Emergency Department visits ($P = 0.007$ and $P = 0.002$) which reduced further over the second year of the study. Blichhardt (2004), measured GP visits and a reduction of 39% was seen in the treatment group over the following year. Whilst, Martin et al (2007) saw the biggest reduction for GP visits with their intervention. However, this was not the same for visits to specialists which remained static. This result was replicated by Speckens et al (1995) and Allen et al (2006). Sumathipala et al (2008) looked at GP visits only and whilst they did not achieve significant results for the intervention in the treatment group; they reported that both the Treatment and control groups improved on follow up.

Onset of symptoms before study was reported in six papers (Arnold,2009; Lidbeck, 2003; Schroeder, 2012; Sumathipala, 2008; Sharpe, 2011 and Martin, 2007) with a mean of 82.8 months for treatment intervention (range 40.6 – 141.6) and 85.2 mean months (range 43 – 120) in the control groups from onset of symptoms. The lowest onset was recorded by Sumithapala, with 40.6 controls treatment and 43months control and the longest was in Arnold (2007) with means of 110 months for treatment and 141.6 mean months for the controls.

Additional Results

Location was split evenly between the studies. Secondary care studies (Schroeder et al 2012; Tyrer et al in press, Bleichhardt et al 2004; Ehlert, 1999, and Sharpe, 2011) all

reported significant results in outcome measures although Sharpe failed to maintain these at follow up. In the six studies from primary care, Allen et al (2006) and Martin et al (2007) reported statistical significant results in outcomes that were maintained in follow up. Escobar et al (2007) were also able to provide in outcomes when compared to the control condition but these were not maintained over the longer term. However, Lidbeck et al (1995) achieved only minimal improvements with their intervention and Arnold et al (2009) and Sumathipala (2008) did not achieve any improvements in any area.

Protocols utilised in 11 studies with one not reporting (Tyrer, in press) and another describing intervention without protocol (Ehlert, 1999). Four studies used Sharpe (1992), two used Woolfolk & Allen, one used STreSS. Finally, three studies developed their own model for the intervention. However, comparisons are difficult as one was a GSH, one provided only 1 session another 5 and finally Speckens provided between 1 & 20.

Qualifications and training of practitioners providing the intervention arms of studies was recorded in 11/12 studies. Blichhardt, (2004) failed to report, however, the study was conducted in a specialist inpatient facility. Three studies reported practitioners who would meet the BABCP criteria: Martin et al (2009) stated licenced CBT therapist; Elhert et al (1999) a qualified CBT therapist; Schroeder (2012) used a psychiatrist with over two years CBT training. Whilst Escobar (2007) had doctoral level psychologists, Tyrer et al (in press) used a physician 'experienced in CBT', Sharpe et al (2012) reported a psychologist and nurse 'trained in CBT' and Speckens et al (1995) had a Behaviour Therapist (no accreditation or qualifications were stated). Additionally, Arnold et al (2009) and Sumathipala (2008) trained family physicians (20hrs and 5 sessions respectively) in

what were described as the principles of CBT. Finally, Lidbeck's study used a physician who specialised in 'internal, family and social medicine' who was trained in 'stress relaxation' with no mention of CBT.

Of the interventions that were successful, the best results were in reducing psychological distress and symptom reduction (obviously very important to the patient group) and in reducing health care utilisation and costs (important to health care providers). The studies that stood out by not only achieving these reductions but also included good methods. In particular, Allen et al (2006) and Escobar (2007) not only used protocols (enabling replication) but also ensure the intervention sessions were recorded and reviewed in supervision after each session. This enabled them to ensure that treatment protocols were adhered to and that it was uniform throughout.

Discussion

The needs of Individuals experiencing medically unexplained symptoms are not being met by a traditional medical approach. It has been highlighted that their own psychopathology and the nature of health services combine to make their experience of the health care unsatisfactory. Indeed, despite frequent medical investigations/treatments, their symptoms persist, their problems are not resolved, they frequently complain and they keep coming back. Researchers have recognised this and are attempting to address the problem by providing CBT interventions.

A detailed search of the literature in this area provided 12 studies attempting to resolve this status quo. Although the intention of the search was to be thorough regarding

inclusion, as with any literature review, there were limitations identified. Perhaps most notably by the exclusion of qualitative studies and it is acknowledged that this may prove significant. Also, only one grey literature study included. However, with regard to publication bias, it must be noted that two of the published results were highlighting non-significant results. Even so, a standard meta-analytical approach was not utilised. This was because of the high heterogeneity of studies, symptoms and measurement tools utilised. Moreover, many studies produced such loose definitions of their primary outcomes or failed to pre-specify the sample size needed to adequately test for them.

However, the synthesis of results across the studies did highlight the broad success of cognitive behavioural interventions in reducing psychological and physical symptoms in the majority of participants. More pleasingly, these results were maintained in follow up in over half of the studies measuring them. In addition, studies the majority of studies did utilise evidence based measurements and two monitored the quality of interventions by recoding them.

Positively, external validity was well documented in the studies overall. Unfortunately, this was usually done by acknowledging (or alluding to) small sample sizes or biased opportunistic sampling. Thus, external validity of the studies is limited for generalisability. This was particularly true with the way the majority of studies excluded large numbers from participating because of previous mental health or co-morbid medical diagnosis (conditions that impact vast numbers of the general population).

Whilst most authors reported that the 'refined' selection procedures to reduce confounding variables; they failed to state that this may have impacted the outcomes and limited the external validity (especially to those groups who were excluded). Whilst it is not possible to reduce selection bias in a self-selecting participant pool, the demographics of those refusing to participate should be included to ensure or perhaps design interventions with them in mind or simply acknowledge that the intervention is untested in this area. Certainly, the lack in defining ethnicity was a noticeable missing and unreported demographic. Thus, the generalisability of the interventions cannot be made across different races and ethnic groups. Moreover, with regards to gender the vast majority of participants were female and without documentation of declines and exclusions we cannot be sure that this is simply because they are the ones who opt in

Nevertheless, the internal validity of all 11/12 studies (Tyrer in press = cohort study) was increased by the inclusion of a control group. The 'confound' of attention (therapeutic effect) given to the treatment groups was not considered. Additionally, although the studies did use specific measurement tools; the lack of consistency with the tools utilised (some even using non-validated 'own' measurements) could be seen as problematic.

Using such a diversity of measures made comparison of the evidence difficult.

Furthermore, rationales provided as to the choice of tool and the evidence base supporting its choice of utilisation was limited or non-existent.

With regard to the original search questions the review has provided some insight. When looking at whether the location of the treatment intervention impacted the outcomes?

Surprisingly, the most consistent results came from secondary care studies where one

might expect to see the most severe MUS patients. However, this is not conclusive as 2 of the 6 primary studies were reporting null hypothesis. With regard to severity, it was hoped to define if risk levels/severity of MUS were documented in the CBT interventions? Severity (that has been linked to onset, see old Hartman et al, 2011) but the two least effective studies were from the lowest and highest ranges which leaves four studies with similar outcomes in the middle. So, it is not that clear cut if onset impacted outcome.

In addition, it was felt important to look at the who and what of the interventions. Who provided the interventions? And what training/qualifications did they have/receive highlighted that those trained and qualified practitioners achieved the best results in terms of outcomes and longevity. Those who had the least training (Sumathipala et al, 2008; Arnold et al, 2008) produced the worst. With regard to using protocols and manualised therapy, comparisons between manuals are difficult as all were using them at different durations e.g. one was a GSH, one provided only 1 session another 5 and another provided between 1 & 20. Therefore, how much of the manual was used has to be questioned. Nevertheless, studies using no manual or who developed their own did not do as well in-patient outcome measures. With regard to the objective to verify if there were differences between outcomes for the type of intervention (individual, group or guided self-help). Again, it is not possible to compare as there were too few studies to make a comparison. However, GSH provided good results initially but this tapered off and only one study was included. Group therapy included 2 studies that produced completely opposite results (short term results but no long term – no short term non-significant but long-term reductions for outcomes reported).

However, the review has highlighted some concerns that could be addressed in future research studies. For example, the vast array of measurement tools is problematic. In both symptoms and psychological outcomes so many are being used that it is problematic for anyone wanting to replicate. It may be worthwhile if they were compared and evidenced based 'best' measurements were defined. This is the same for protocols, maybe protocols could be compared/tested against each other in future research? In addition, we saw GP visits reduced but no change in hospital utilisation. However, this may have been as the result of current health care set up's, with outpatient appointments given as standard rather than when needed. But without further investigation this remains an anomaly.

In conclusion, this review has been limited by its focus on a small quantity of studies. But it has highlighted some good support for CBT interventions and some good practice (recording interventions). However, there still appears to be a diversity of who is delivering these interventions and what they are calling CBT.

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MINIMUM TRAINING STANDARDS for The Practice of Cognitive Behavioural Psychotherapy

In September 1997 BABCP published its Minimum Training Standards detailing the minimum level of training, experience and practice that therapists applying for Accreditation with BABCP must have attained. These have been updated several times since 1997 and the current set of Minimum Training Standards has the aims of:

- Providing people seeking further training with the core standards they will be expected to meet within their overall training in cognitive and behavioural psychotherapies
- Providing training courses with a guide to the training needs which will need to be met by their training programme
- Providing the Accreditation and Registration Committee (A&R) of BABCP with a standard against which to decide if an applicant has received the desired level of training necessary to practice
- Providing employers with a benchmark of standards in cognitive and behavioural psychotherapies

1. BASIC REQUIREMENTS

- 1.1 All therapists are considered on an individual basis but they will usually have an approved basic professional qualification in an appropriate profession (e.g. psychology, psychiatry, nursing, counselling, occupational therapy, social work, education). They will usually be registered with a professional regulatory body and have undertaken a minimum period of two years post qualification training and experience
- 1.2 Therapists being considered for Accreditation will have sufficient experience in working in a therapeutic role with clients
- 1.3 Therapists must be able to demonstrate personal qualities that make them suitable for the practice of cognitive and/or behavioural psychotherapy
- 1.4 Therapists will be using cognitive and/or behavioural psychotherapy in a systematic way as their main, or one of their main therapeutic models

2. LENGTH OF TRAINING

- 2.1 Training, including basic professional training and experience and relevant cognitive and/or behavioural psychotherapy training, will have been over at least a four year period

3. THEORETICAL AND SKILLS TRAINING

- 3.1 The period of training will include the acquisition of a critical understanding of the relevance of studies of human development, psychopathology, psychology, social issues and evidence-based practice
- 3.2 Specialist courses in a particular model of cognitive and/or behavioural psychotherapy, or in a specialist area of its application may focus on a specific area of interest. However, all therapists

will have covered a minimum curriculum that will provide a broad-based understanding of the theoretical basis of cognitive and/or behavioural psychotherapies and their application across a range of problem areas

- 3.3 Skills training is an essential component of the acquisition of knowledge and experience and should not be less than 50% of a therapist's total training programme. Theoretical knowledge and skills will have been acquired through structured teaching and prescribed self-directed study. The minimum number of hours study required for the cognitive/behavioural elements of training is 450 hours of which 200 hours should be provided (taught) directly by recognised C/BP trainers through a recognised course or other programme of study
- 3.4 A training log must specify the length of study, number of taught hours and a record of the lecturers, tutors or mentors participating in a therapist's training
- 3.5 Therapists should achieve the skills to be able to understand and interpret research relevant to the outcome and effectiveness of cognitive and/or behaviour therapy

4. SUPERVISED CLINICAL PRACTICE

- 4.1 Therapists will have conducted 200 hours of supervised assessment and therapy during training in addition to that specified in 3.4 above
- 4.2 All therapists will have received supervision during the period of training for both assessment and therapy, carried out by a cognitive and/or behavioural psychotherapist who meets the BABCP criteria for Accreditation. Supervision will consist of regular feedback and discussion. Close supervision will involve the use of live, audio or video materials in supervision, using a skills assessment tool
- 4.3 A minimum of eight clients will be treated during the period of training from assessment to completion or termination of treatment before a therapist is regarded as having completed their training. These cases should all be regularly supervised, of at least five sessions in length (although most should be significantly more). These cases will cover at least three types of problems, and three cases will have been closely supervised as defined above
- 4.4 Details of supervised clinical practice and case mix will be recorded in a training log

5. PERSONAL DEVELOPMENT

- 5.1 Therapists must ensure that they can identify and manage appropriately their personal involvement in the process of cognitive and/or behaviour therapy
- 5.2 Therapists must have developed an ability to recognise when they should seek other professional advice

6. ACCREDITATION OF COGNITIVE AND/OR BEHAVIOURAL PSYCHOTHERAPISTS

- 6.1 To apply to be Fully Accredited by BABCP as Cognitive and/or Behavioural Psychotherapist, therapists must: have two years experience since qualification in their core profession; meet the Minimum Training Standards; maintain an agreed level of continuing professional development in cognitive and/or behaviour psychotherapy; receive regular C/BP clinical supervision; and adhere to the BABCP "Standards of Conduct, Performance and Ethics for Members"

7. ASSESSING MINIMUM TRAINING STANDARDS

- 7.1 Therapists are expected to demonstrate an understanding of the theoretical aspects of cognitive and/or behavioural psychotherapy and its application by the production of a formal assessment essay, exam or research project
- 7.2 An understanding of evidenced-based practice should be evaluated by (i) the production of an extended case report that critically discusses the research evidence or (ii) a relevant research

dissertation; or (iii) a research paper to which they have contributed, published in a peer review journal

7.3 Supervised practice will be subjected to formal assessment with four case studies written up (2000 – 4000 words), which meets the academic standards stated by BABCP Registration and Accreditation Committee; “Criteria for Evaluating Academic Case Studies, 2007” (available from BABCP)

7.4 The above assessments are usually required in most recognised post qualification cognitive and/or behaviour therapy course. For candidates who are not pursuing a training route through such a course it is important that they agree an independent programme of study and assessment with a cognitive and/or behavioural psychotherapist who meets the BABCP criteria for Accreditation

Rod Holland

Chair BABCP Training and Accreditation Committee

June 2006 (updated June 2011)

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Appendix 2.

STUDY NUMBER =	YES / NO	NOTES
DOES IT INCLUDE MUS (SEE LIST) SYMPTOMS?		
IS THE INTERVENTION CBT? (SEE INTERVENTION LIST)		
IS INDEPENDENT STUDY (NOT A REVIEW OF OTHERS WORK)?		
ACCEPT IN STUDY?		

Appendix 3

STUDY NO:

Authors

Year.....Journal

(Circle/Highlight Correct

Answer)

JADAD

Were participant attrition rates reported? YES=1 NO=0
 Was the trial randomised? YES =1 No= 0
 Did it include a structured clinical interview &/or diagnostic testing? YES =1 No = 0

Population: Is the study based on adult population? YES NO
 Number of participants? Pre..... Post..... Follow.....
 Was recruitment described? YES NO

What was the Experimental Design? Randomised CT Controlled Trial
 Cohort study Case report

Economic Evaluation

What is the care setting of the study? Secondary Primary
 Was a Control Group included? YES NO
 Intervention: Cognitive Behav* therapy? YES NO
 Were co-interventions used? YES NO

What were they?.....

Was depression and/ or anxiety measured? YES NO
 How many sessions of intervention were provided?.....

How was the therapy provided? Individually Group Computerised

Did they describe the CBT treatment protocol/manual utilised? YES NO PARTLY

What was it?.....

Did they describe WHO provided intervention? YES NO PARTLY

Were their qualifications/accreditations described? YES NO

What were they?.....

Was the Hypothesis clear & justified?	YES	NO	PARTLY
Were baseline measurements provided?	YES	NO	PARTLY
Were post intervention measurements provided?	YES	NO	PARTLY
Were follow-up measurements provided?	YES	NO	PARTLY

What was length of follow up?.....

What were outcomes measured?	Symptoms	Psychological	Functional
	Attendance	Beliefs	
Costs	Medication		
Other.....			

Your general overview of study?.....

CONTINUE TO INCLUDE IN STUDY?	YES	NO
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