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ABSTRACT

Individuals with autism spectrum disorder (ASD) commonly experience comorbid anxiety disorders, but there are no treatment guidelines specifically for this population. The purpose of the study was to determine whether cognitive behavioural treatment (CBT) is effective in treating adults with ASD and comorbid anxiety and to compare different treatment protocols. The electronic database from a large and comprehensive secondary mental healthcare provider in London was also utilized to evaluate the relationship between the number of sessions and favourable outcome. Patients who were diagnosed with ASD and comorbid anxiety, and have also received CBT treatment with Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) performed pre- and post-therapy comprised the sample, retrieved by the SLaM Case Register Interactive Search (CRIS) system. A total of 37 eligible participants were analysed, 32 receiving CBT and medication for anxiety at the same time, and 5 receiving CBT only. The results provide preliminary evidence suggesting that CBT administered within SLaM’s services may be effective at reducing general psychological distress in patients with ASD and comorbid anxiety disorders, who were at the same time undergoing pharmacological treatment. However, the same was not recorded for patients who were receiving CBT only. It was also demonstrated that the increase in CBT sessions may affect the reliable improvement as measured by reliable change in CORE global distress score at post-therapy. However, due to the very small sample size all results need to be interpreted with caution. Clinical relevance and research implication of the findings are further discussed.

Keywords: ASD, comorbid anxiety, CBT, pharmacological treatment, CORE-OM
# TABLE OF CONTENTS

ABSTRACT .......................................................................................................................... 3

1 INTRODUCTION .............................................................................................................. 5
  1.1 Autism spectrum disorder ......................................................................................... 5
  1.2 Anxiety ...................................................................................................................... 6
  1.3 Anxiety and autism spectrum disorder ...................................................................... 7
    1.3.1 Prevalence ........................................................................................................... 7
    1.3.2 Phenomenology and clinical issues ...................................................................... 8
  1.4 Treatment of anxiety ................................................................................................. 8
    1.4.1 Cognitive behavioural therapy ........................................................................... 8
    1.4.2 Pharmacological treatment ................................................................................ 8
    1.4.3 Monotherapy versus combination treatment protocol ....................................... 9
  1.5 Treatment of anxiety in patients with ASD ............................................................. 10

2 METHOD .......................................................................................................................... 13
  2.1 Study setting and population ................................................................................... 13
  2.2 Procedure .................................................................................................................. 14
  2.3 Sample ...................................................................................................................... 16
  2.4 Measures .................................................................................................................. 18
    2.4.1 Outcome measure .............................................................................................. 18
    2.4.2 Individual characteristics .................................................................................. 19
  2.5 Statistical analysis ..................................................................................................... 19

3 RESULTS .......................................................................................................................... 20
  3.1 CORE-OM analysis ................................................................................................. 20
  3.2 Subscales of CORE-OM analysis ............................................................................. 21
  3.3 “Reliable change” ................................................................................................... 21
  3.4 “Clinical change” ..................................................................................................... 22
  3.5 Binominal logistic regression ................................................................................... 23

4 DISCUSSION .................................................................................................................... 25
  4.1 Limitations of this study .......................................................................................... 27
  4.2 Strengths of this study ............................................................................................. 29

5 REFERENCES .................................................................................................................... 33
1  INTRODUCTION

Autism spectrum disorder (ASD) is a lifelong neurodevelopmental disorder. Clinically significant functional impairment is led by several specific deficits distinctive for ASD, which present themselves in early childhood. Prevalence rates of ASD have been increasing greatly over the past several years. Evaluations from 2014 indicate that one in every 68 American children has been identified with the disorder (Christensen et al., 2016). Equivalently high prevalence rates have also been indicated outside of the United States of America (Brugha et al., 2012; Kim et al., 2011). Furthermore, considerable additional burden is added to many individuals diagnosed with ASD by severe symptoms of comorbid anxiety. Despite this, treatment guidelines for comorbid anxiety and ASD are still in their infancy. This dissertation focuses on whether cognitive behavioural therapy (CBT) is successful in anxiety treatment among adult individuals with ASD, using anonymised information from the Trust’s clinical records. Additionally, it tries to determine which intervention protocol, if any, should be preferred.

1.1  Autism spectrum disorder

It is nowadays widely accepted that ASD is a complex neurodevelopmental disorder, heterogeneous in its presentation, outset and aetiology. It is defined by variable difficulties in social interaction and communication challenges, as well as repetitive and restrictive behaviours (American Psychiatric Association, 2013).

Since the primary observations documented by Kanner (1943), there has been an extensive debate regarding the diagnoses, the diagnostic threshold and sub-types that relate to what is now known as ASD. The complex history has hence been reflected in constant redefinition of the disorder, from ‘infantile autism’ to the current ASD diagnosis. Defining the condition by the diagnostic norms in the widely used International Classification of Diseases (10th ed.; ICD-10; World Health Organization, 1992) ASD comes under the umbrella term of pervasive developmental disorders. According to the presence or absence of various aspects such as intellectual disability and developmental language delay, and the scope of symptoms, an individual can be classified as having one of the diagnostic subtypes, namely autistic disorder/childhood autism, atypical autism, Asperger’s syndrome, other pervasive developmental disorders or pervasive developmental disorders – unspecified, (Wilson et al., 2013).
As mentioned above, ASD diagnosis is based on three domains; atypical communication, difficulties with interaction in social settings, alongside narrow interest and repetitive behaviours. The symptomatology of the disorder is comprehensive and omnipresent, accompanied by an onset apparent in early childhood (age 2-3 years old), that could be regarded as a dimensional process. Symptoms of the disorder are furthermore linked to impairment across multiple domains of functioning, which can vary greatly.

1.2 Anxiety

The research has unequivocally demonstrated that ASD usually does not occur in isolation (Joshi et al., 2010; Kohane et al., 2012; Simonoff et al., 2008) and the presence of comorbid disorders can highly increase impairment beyond core ASD symptoms. Anxiety disorders have been recognised as one of the significantly overrepresented comorbid psychopathologies in ASD in a Kohane et al. (2012) study, that outlined comorbidities of more than 14 thousand autistic participants and highlighted the strain of comorbidity across multiple health care systems.

Anxiety disorders describe a heterogeneous group of illnesses, whose core phenomenology is anxiety, excessive fear and accompanying behavioural disturbances. Anxiety is composed by multiple components (Moskowitz et al., 2017) involving affective states (subjective fear), cognitions (thoughts, beliefs), behavioural patterns (avoidance), and associated physiological arousal (heart palpitation, fatigue). The diagnostic schema for anxiety disorders in the ICD-10 (World Health Organization, 1992) recognizes the following subgroups of anxiety disorders under the general term “Neurotic, stress-related and somatoform disorders”; phobic anxiety disorders (e.g. agoraphobia, social phobias, specific phobias), other anxiety disorders (e.g. panic disorder, generalized anxiety disorder (GAD)), obsessive compulsive disorder (OCD) and those disorders that develop as a reaction to severe stress (e.g. post-traumatic stress disorder (PTSD), adjustment disorder) among others.

All anxiety disorders share physiological and psychological manifestation of anxiety. Common anxiety psychological symptoms include concentrating difficulties, trepidation feelings and
restlessness; whilst trembling, heart palpitations and fatigue manifest as physical symptoms frequently. Furthermore, distinctive symptoms are associated with each specific anxiety disorder in addition to common symptoms (Barton, Karner, Salih, Baldwin, & Edwards, 2014).

1.3 Anxiety and autism spectrum disorder
Anxiety and ASD have been associated since the earliest description of what later became known as ASD. Both Leo Kanner and Hans Asperger had noted the presence of generalized worry, social fear, obsessiveness, need for sameness, and phobias in their earliest reports (Kanner, 1943; Uljarevic, Nuske, & Vivanti, 2016).

1.3.1 Prevalence
3 - 8% of youth is expected to meet criteria for anxiety disorder in general population (McConachie et al., 2014), however, estimates from a recent systematic review indicated the presence of clinically significant degree of anxiety in 40% of 2,121 ASD individuals (van Steensel, Bögels, & Perrin, 2011). Experience of significant levels of anxiety disorders in childhood have been reported to range anywhere between 11% and 84% (Simonoff et al., 2008; White, Oswald, Ollendick, & Seahill, 2009) and comparable results have been well documented in adults as well (Hofvander et al., 2009; Joshi et al., 2013). Research so far also demonstrates higher levels of anxiety in ASD individuals compared not only to typically developing individuals (Uljarevic et al., 2016), but also when compared with different clinical groups, including people with conduct disorder (Green, Gilchrist, Burton, & Cox, 2000), Down syndrome (Evans, Canavera, Kleinpeter., Maccubbin, & Taga, 2005) and learning disabilities (Gadow, Devincent, Pomeroy, & Azizian, 2005).

Despite inconsistent findings, specific phobias, generalized anxiety disorder, obsessive compulsive disorder, social phobia and separation anxiety disorder appear to be the most prevalent anxiety conditions in individuals with autism (de Bruin, Ferdinand, Meester, de Nijs, & Verheij, 2007; Evans et al., 2005; Gadow et al., 2005; Weisbrot, Gadow, DeVincent, & Pomeroy, 2005).
1.3.2 Phenomenology and clinical issues

The description of feeling anxious explained by many individuals with ASD resembled those reported in the typical developing individuals. Nonetheless, expression of anxiety in ASD individuals might vary greatly from its manifestation in people without ASD or might be less clear. One of the underlying factors for these differences might be the overlap of core symptoms between both conditions. Furthermore, prime ASD impairments might affect the expression of anxiety symptoms. One of the clinical issues is also the atypical presentation of symptoms of anxiety in individuals with ASD (Uljarevic et al., 2016).

1.4 Treatment of anxiety

1.4.1 Cognitive behavioural therapy

Suggested treatment approach for anxiety disorders is decided according to the presumed underlying cause of the specific disorder and includes psychological therapy, pharmacological treatment or combination of both. NICE (2012) guidelines recommend evidence based psychological intervention such as CBT as a first-line treatment in preference to pharmacological protocols for mild to moderate presentations of the disorder.

CBT is a cooperative and directive therapy approach, with specific and transparent aims. Its primary focus is to recognise, understand, and change the thinking and behaviour patterns. The patients are heavily involved in their own recovery, as keeping records between the appointments, and completing homework assignments is typically a part of the therapy. Consequently, individuals learn skills that are useful in their day to day life (Bystritsky, Khalsa, Cameron, & Schiffman, 2013). CBT has been proven to be efficient for anxiety disorders in adulthood in multiple meta-analysis of randomised controlled trials and systematic reviews (Hofmann & Smits, 2008; Norton & Price, 2007).

1.4.2 Pharmacological treatment

For individuals whose symptoms of anxiety do not improve or have severe presentation of the disorder, a pharmacological treatment in line with the stepped care model is prescribed. NICE (2012) recommends use of selective serotonin reuptake inhibitors (SSRIs) as the first-line
pharmacotherapy agents of choice for anxiety disorders, considering the balance of efficiency and rather low incidence of adverse effects (Koen & Stein, 2011).

The leading feature of SSRIs is the inhibition of the serotonin reuptake or reabsorption which leaves more serotonin available and thus improves mood. Escitalopram, citalopram, fluvoxamine, fluoxetine, paroxetine, and sertraline belong under this drug class (Baldwin, Waldman, & Allgulander, 2011). Whilst they are considered an effective treatment for all anxiety disorders, there are several reported side effects; the most common being sexual dysfunction, sleep problems and weight gain.

Typical second-line medication treatment include serotonin-norepinephrine reuptake inhibitors (SNRIs), benzodiazepines, tricyclic antidepressants and second generation antipsychotic drugs among others (Baldwin et al., 2011; Bystritsky et al., 2013).

1.4.3 Monotherapy versus combination treatment protocol

Whilst NICE guidelines for treatment of anxiety disorders advise the least intrusive and most effective intervention first, there have been mixed results in regards to which treatment is most successful and if either monotherapy or combination treatment should be favoured (Bystritsky et al., 2013). A review by Roshanaei-Moghaddam et al. (2011) showed great heterogeneity in patient’s responsiveness to either CBT or medication within the anxiety disorders. CBT was superior in comparison to medication in individuals with panic disorder only. Conversely, patients diagnosed with social anxiety disorder were more susceptible to pharmacological treatment. Another meta-analysis confirmed superiority of combination treatment in panic disorder only, whilst showing equal efficiency of both monotherapy protocols in general (Bandelow, Seidler-Brandler, Becker, Wedekind, & Rüther, 2007). Mixed results show that the advantage of a combined treatment versus either pharmacological or psychological therapy across anxiety disorders varies greatly, and more research is needed (Black, 2006; Bystritsky et al., 2013; Foa, Franklin, & Moser, 2002).
1.5 Treatment of anxiety in patients with ASD

Guidelines from NICE recommend psychological interventions such as CBT should be offered for comorbid mental health disorder in adults with ASD. Recommendations for adults with comorbid anxiety are however the same as for anyone else without ASD. Suggested adaptations to standardised CBT protocols in treatment of comorbid mental health conditions are focused on children and young people only and are directed at patients’ cognitive and social-communication needs. Increased emphasis is given to behavioural rather than cognitive change and involvement of a carer in therapy is encouraged. More structured approach with use of visual support is utilized (NICE, 2012).

Previous research involving children and adolescents with ASD shows great promise (Wood et al., 2015) and the evidence that supports the effectiveness of CBT for youth with comorbid anxiety disorders is prevailing (Reaven, Blakeley-Smith, Culhane-Shelburne, & Hepburn, 2012; Storch et al., 2013; Wood et al., 2015). Moreover, independently from the diagnosis of ASD, CBT has consistently been categorized as a sound treatment for anxiety in children and adults (Nadeau et al., 2011), as already mentioned above. Nevertheless, studies examining the effect of CBT on anxiety levels in adults with ASD are lacking, despite anxiety being a common and impairing problem in ASD individuals and a wealth of evidence for effectiveness of CBT in children with ASD. Deficiency of evidence based psychological therapies for adults with ASD and comorbid psychopathologies has also been emphasised by two reviews (Binnie & Blainey, 2013; Spain, Sin, Chalder, Murphy, & Happé, 2015). Nonetheless, very recent results published in Sizoo & Kuiper's (2017) study indicate association between CBT and reduction in anxiety and depressive symptoms among adults with ASD. Furthermore, improvements in social anxiety in adults with ASD were also noted in a review by Spain, Sin, Harwood, Mendez, & Happé (2017). However, generalizability of the results was restricted by a very small number of available studies. A very novel research by Blainey (in press) has also been investigating the effectiveness of psychological therapy for adults with ASD and comorbid mental health disorders in routine clinical practice. Although the research has not been focused on comorbid anxiety disorders only, anxiety disorders were in fact the most prevalent co-occurring disorders in their sample. Extremely promising results are suggesting that the majority of the clients undergoing CBT improved, with 36.9% of individuals exhibiting reliable change. Scarce research is hence revealing the potential of CBT in managing comorbid anxiety disorders in adult individuals with ASD.
The effectiveness of treating anxiety in ASD with medication agents has been explored by a very limited number of studies. Whereas some evidence has been indicating the success of SSRIs in treating comorbid anxiety in ASD population (Couturier & Nicolson, 2002; Namerow, Thomas, Bostic, Prince, & Monuteaux, 2003), the research by Martin, Koenig, Anderson, & Scahill (2003) rejected such evidence and found no change in symptoms of anxiety. Moreover, considerable harmful effects have been found in all three studies. Ultimately, other authors have noted experience of reduction of anxiety symptoms in 70% of ASD individuals, aged between 6 and 17 years, after being administered an anti-anxiety therapeutic (Buitelaar, van der Gaag, & van der Hoeven, 1998). It is worth noting that the aforementioned studies had relatively small samples and further high quality research is thus essential.

Large scale multisite clinical trials demonstrate the effectiveness of combination of SSRIs and CBT treatments for typically developing children with anxiety disorders (Walkup et al., 2008), but comparable treatment studies for comorbid anxiety disorders in individuals with ASD are also needed (Vasa et al., 2014). Moreover, there is a vast deficiency of large scale and long term randomised controlled trials examining psychopharmacological and non-psychopharmacological treatments for anxiety in adult population with ASD, since the evidence for the effectiveness of SSRIs in adults with ASD are mixed (Williams, Wheeler, Silove, & Hazell, 2010).

Whilst the evidence suggests that psychological intervention can benefit adults with ASD and comorbid mental health disorders (Binnie & Blainey, 2013; Blainey, in press; Spain et al., 2015) and the indication for the effectiveness of pharmacological treatment is tentative, evidence of efficiency in routine clinical practice is still lacking. To extend the findings from children to adults and to tackle the issues with the credibility of the control conditions and concerns about appropriate measurements, this study used anonymised data from South London and Maudsley’s (SLaM) clinical records. King’s College London and SLaM hospitals have pioneered the transformation to “Big Data” through the Clinical Records Interactive Search (CRIS) system. They have developed a computer system which helps to carry out research using patient records that contain individual’s medical information. The information
stored in those records are very valuable in helping with individual’s personal clinical care, but the system also empowers researchers to look at a large number of people in real life situations and is designed to improve the quality of research data and produce faster, more focused results, from large and complex clinical, genomic, proteomic and neuroimaging data. In practice the search system CRIS allows requirements or criteria of a cohort of interest to be defined (for instance, all of those with a specified diagnosis, or everyone with a certain key word in their records in a given time window) and also brings back any other additional variables of interest, such as ethnicity, age, gender, specific dates. Database of individuals who meet specific criterion are then brought back by the CRIS application.

This study thus sought to assess the effectiveness of CB intervention for comorbid anxiety disorders in adults with ASD, using anonymised information from SLaMs’ clinical records. It was hypothesised that there will be a significant relationship between CBT and anxiety in adults with ASD. The records were additionally explored for differences in effectiveness of various treatment protocols. We hypothesised that there will be a greater reduction in the anxiety symptoms of adults with ASD undergoing combined treatment, in comparison to those who are undergoing pharmacological or CBT treatment alone. Furthermore, the higher the exposure to CBT, the lower the anxiety levels in adults with ASD post-therapy.
2 METHOD

2.1 Study setting and population

SLaM is a National Health Service (NHS) and one of the Europe’s largest mental health trusts. It provides secondary and tertiary mental health care to approximately 1.3 million people residing across four highly populated and diverse boroughs of London (Lambeth, Southwark, Lewisham and Croydon). Across all SLaM services electronic health records have been used thoroughly since 2006 and CRIS system which has been developed in 2008, provides anonymised information in regards to secondary and tertiary mental health-care services from those clinical records. This permits research workers to examine and retrieve entire clinical reports for purposes of research. The description of a process of converting source medical records to CRIS can be seen in Figure 1. At present, there are more than 260,000 individual patients represented on the system, from which the patient cohort for this study was assimilated, and the register continues to grow with roughly 20,000 new cases added yearly, in addition to extension of follow-up for current cases. CRIS was approved as a dataset for secondary analysis by Oxfordshire Research Ethics Committee C (reference 08/H0606/71+5), with further details of the case register described in publicly accessible publications (Perera et al., 2016; Stewart et al., 2009). Right of access to conduct this project was granted by SLaM NHS Foundation Trust and the ethical approval had been obtained by nominated manager/project supervisor through King’s College London.

![Figure 1. Diagrammatic description of the CRIS technological architecture in addition to external data linkage and GATE (General Architecture for Text Engineering) language processing (Perera et al., 2016).](image-url)
It is important to note that there are no specific appropriate measures for anxiety in people with ASD to use in a routine clinical practice, even though administration of outcome measures used in typically-developing adults with anxiety disorders may be less than satisfactory, especially in individuals with ASD who are lower-functioning. This is why the main outcome of this study was the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2000), as it is also a routinely collected outcome measure for all patients who undertake psychological therapy by any psychological therapy service in SLaM. CORE-OM is a generic self-report measure of psychological distress and it is utilized to illustrate general adversities that clients present with. Measures should be completed, as a minimum, at the beginning and end of treatment, nevertheless these may be collected more regularly, allowing data to be included even in the case of an unexpected drop out of a client.

2.2 Procedure
A CRIS search was carried out to distinguish patients with ASD, depended on structured WHO ICD-10 diagnostic codes as diagnoses in SLaM are catalogued in accordance with ICD-10 (World Health Organization, 1992). This study cohort consisted of SLaM patients who were diagnosed with ICD-10 F84.0 (autistic disorder/childhood autism), F84.1 (atypical autism), F84.5 (Asperger’s syndrome), F84.8 (other pervasive developmental disorder) and F84.9 (pervasive developmental disorder - unspecified) and comorbid anxiety disorders (F40-F43) entered between January 2007 and May 2017. This was supplemented by a natural language processing application which was developed with the utilization of Generalised Architecture for Text Engineering (GATE) to extract any text strings associated with a diagnosis statement in order to supplement the existing structured fields. Study participants were included if they have had minimum of 3 CBT sessions and were at least 18 years old at the beginning of the treatment. The information on specific pharmacological treatment for anxiety in clients with ASD was also elicited, based on a consultation with a psychiatrist from SLaM adult outpatient neurodevelopmental clinic. Certain SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), second generation antipsychotic drugs (misulpride, aripiprazole, clozapine, lurasidone hydrochloride, olanzapine, paliperidone, quetiapine, risperidone), benzodiazepines (diazepam, temazepam, lorazepam, midazolam), tricyclic antidepressants (amitriptyline hydrochloride, clomipramine hydrochloride, dosulepine hydrochloride, doxepin, imipramine hydrochloride, lofepramine, nortriptyline, trimipramine), tricyclic-related antidepressants (mianserin hydrochloride, trazodone hydrochloride) and other antidepressant
drugs (agomelatine, duloxetine, flupentixol, mirtazapine, reboxetine, venlafaxine, vortioxetine) were included. The patients were thus divided into two separate groups based on the management of anxiety method – first group receiving CBT in conjunction with any medication from the list and second group receiving CBT only. Our primary goal was to focus on patients with no other structured ICD-10 diagnosis apart from ASD and anxiety, but as the search yielded very scarce results, we were forced to include people with other diagnoses as well. The clinical records of the patients with other diagnoses were hence manually reviewed and the ones who were in the past diagnosed with conditions for which they could have received the same medication or psychological therapy as for anxiety were excluded (e.g. bipolar affective disorder, depression, psychosis, borderline personality disorder). It was allowed for people with diagnosis such as eating disorder or person with feared health complaint in whom no diagnosis is made, mental disorder not otherwise specified, attention deficit hyperactivity disorder to be included in our sample. The utilization of CRIS front end followed as the overall and subscale CORE-OM scores were then pulled out for everyone in our sample. However, although CORE outcome measure was previously reported to be routinely collected for everyone undergoing psychological therapy in SLaM, the results showed numerous inconsistencies and lack of reporting the scores altogether. People with only one recorded CORE-OM measure or missing scores were excluded, since at least two documented instances were needed for the comparison.
2.3 Sample

The primary sample of ASD patients with anxiety diagnosis generated from the SLaM’s BRC case register consisted of 94 people who had CBT treatment and medication, and 19 people who underwent CBT only and have not been taking any pharmacological agents at the same time. After manually reviewing the data as described in “Procedure” section only 32 (34.04%) patients in the first group and 5 (27.78%) in the second group met our inclusion criteria and had complete records. The descriptive statistics are reported for both groups together to protect patient’s anonymity as it is theoretically possible that someone could recognize any individual due to a very small number in our second group (only 5). Furthermore, due to a very small sample size it is also important to be aware that it may not be entirely representative of all patients with ASD and anxiety receiving cognitive behavioural therapy.

Within both groups of the study sample the mean age at the start of psychological therapy was 28.65 years (SD = 10.09) with minimum age being 19.18 and maximum 57.69 years old. Mean number of CBT sessions received was 32.8 (SD = 34.04) with minimum 3 sessions and
maximum 173 sessions. There were 34 males (91.9 %) and 3 females (8.1 %), which is in line with the gender balance typically seen in studies with individuals with pervasive developmental disorders (Fombonne, 2009). 28 patients (75.7 %) were White British, 2 (5.4 %) Indian, with the rest of the individuals recorded as belonging to other ethnic groups (18.9 %, \( N = 7 \)). As illustrated in Figure 2 the most common diagnosis of ASD was Asperger’s syndrome (\( N = 19; 51.4 \% \)).

![ASD Diagnosis](image)

*Figure 3.* Distribution of autism spectrum disorder diagnosis across the study sample, as recorded in patients’ clinical records.

The most common diagnosis of anxiety – OCD 48.7 % (\( N = 18 \)) and others are exhibited in Figure 4. 21 (56.8 %) patients from our sample also had other structured diagnosis in addition to anxiety, such as an eating disorder, person with feared health complaint in whom no diagnosis is made, mental disorder not otherwise specified, and attention deficit hyperactivity disorder.
2.4 Measures

2.4.1 Outcome measure

The CORE-OM (Evans et al., 2000) is a 34 item generic self-report measure designed to capture patients’ global distress. The measure can be separated into four domains or subscales: subjective well-being (4 items), commonly experienced problems or symptoms (12 items), social/life functioning (12 items), and risk to self and others (6 items). The measure is scored on a five-point scale ranging from 0 to 4 (0 = ‘not at all’; 4 = ‘all the time’) and can be prorated with up to 3 missing items.

Total and mean or clinical scores can be worked out for all items together (global distress) and for each of the four subscales separately. The recommended clinical cut-off for the overall general distress CORE is a clinical score of 10 (mean score of 1.0 times 10). Individuals scoring above this threshold are considered to present clinical caseness. This was identified from the distributions of a wider population sample and a clinical one (consisting of primary and secondary care, in addition to both outpatient and community settings). In order for a patient to exhibit “reliable change” over time there should be an overall CORE-OM score change of at least five; with reliable change meaning that an individual change in scores could not have occurred due to a random measurement error. If therapy moves someone from the range of the
dysfunctional population (clinical case) to the range of the typical population, that is called a “clinical change” and it is indicated by a patient moving from a clinical CORE-OM overall score of ten or greater, to a clinical global distress score of less than ten (Connell et al., 2007; Evans et al., 2000).

CORE-OM is designed as a pan-theoretical and pan-diagnostic measure, but it has not yet been validated particularly within the individuals with ASD (Barkham et al., 2001). Nevertheless, it is sensitive to change with good reliability and convergent validity with other measures used in psychiatric and psychological settings (Evans et al., 2002). Barkham et al. (2001) noted that CORE correlates most highly with measures of symptoms (Spearman’s Rho $> 0.80$), but it is also highly correlatable with the Beck Anxiety Inventory (Spearman’s Rho $= 0.65$).

2.4.2 Individual characteristics

Several other variables, including gender, ethnicity, date of birth, number of therapy sessions, ASD and anxiety diagnosis, when were the diagnoses received, the presence of other co-morbid disorders, whether they have been taking medication or not and the latest prescription date were extracted from the electronic records.

2.5 Statistical analysis

All statistical analyses were carried out using STATA SE (version 12) and the significance level was set as 0.05. Having checked normality assumptions, paired sample t-test and its non-parametric equivalent (Wilcoxon signed rank test) were used to assess pre- and post-therapy difference in CORE-OM score for both groups separately. A t-test was also performed for the subscale pre- and post-therapy score change analysis. Descriptive statistics regarding reliable and clinical change were presented. Furthermore, binominal logistic regression was chosen to investigate whether higher number of CBT sessions can predict reliable improvement (decrease in score for at least 5) after the therapy. The assumptions were tested beforehand and after visual inspection of the scatter plot 6 outliers were removed. Independent sample t-test and Fisher’s exact test were employed to check for group differences between people who exhibited reliable change and the ones who did not. Q-Q plots and Levene’s test for equality of variance were examined beforehand.
3 RESULTS

3.1 CORE-OM analysis

Parametric analysis was conducted to compare the difference in means for the clinical CORE-OM score measured at the beginning and at the end of CBT treatment on the same set of subjects – group 1 (CBT + medication). All of the 32 participants were included in the analysis. The skewness - kurtosis test for the variables of score pre- and post-therapy demonstrated that the p-values were not under the standard significant threshold of 0.05. As it was not possible to reject the null hypothesis for normality it was thus concluded that at this time there was not enough evidence to view the variables from this model as being something other than normally distributed. Further assessment of normality using a Shapiro-Wilk’s tests and visual inspection of histograms, normal Q-Q plots and box plots did not illustrate large deviations from the normal distribution for the CORE-OM score before and after therapy.

Paired sample t-test that was carried out as a result, demonstrated that the clinical global distress scores were significantly lower post-therapy (M = 14.98, SD = 8.34) than pre-therapy (M = 19.37, SD = 7.01) (t(31) = 4.67, p < 0.0001), illustrating an average change of -4.39 in clinical CORE-OM score. This equates to a medium effect size of Cohen's d = 0.57 (Cohen, 1992).
Figure 5. Total clinical CORE-OM score change pre- and post-therapy for individuals receiving CBT and medication at the same time; illustrating significant change in means.

Non-parametric test for paired samples was employed to compare the difference in means of score measured at the beginning and at the end of CBT treatment in second group (CBT only), due to a very small sample size (N = 5). A Wilcoxon Signed-Ranks test indicated that the post-therapy ranks were not statistically lower than pre-therapy ranks Z = -0.674, p = 0.5002.

3.2 Subscales of CORE-OM analysis

Paired sample t-test also illustrated a significant decrease in clinical global distress scores for group 1 (CBT + medication) in all subscales; Wellbeing: t(31) = 5.003, p < 0.001, CI: 4.57-10.86; Problems/Symptoms: t(31) = 3.58, p = 0.0012, CI: 1.66-6.08; Functioning: t(31) = 3.58, p = 0.0012, CI: 1.91-6.97 and Risk subscale: t(31) = 3.45, p = 0.0017, CI: 1.34-5.22. The results are illustrated in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Subscale</th>
<th>n</th>
<th>Pre-therapy Score</th>
<th>Post-therapy Score</th>
<th>p-value (significant on a 0.5 level)</th>
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<td></td>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
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<td>Wellbeing Subscale</td>
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<td>21.35 (7.93)</td>
<td>16.90 (9.03)</td>
<td>0.0012</td>
</tr>
<tr>
<td>Risk Subscale</td>
<td>32</td>
<td>7.08 (7.60)</td>
<td>3.80 (6.23)</td>
<td>0.0017</td>
</tr>
<tr>
<td>Total Score</td>
<td>32</td>
<td>19.37 (7.00)</td>
<td>14.98 (8.34)</td>
<td>&lt; .0001</td>
</tr>
</tbody>
</table>

3.3 “Reliable change”

At the beginning of therapy 31 patients from our first group fell into the ‘clinical’ category (i.e. met criteria for caseness on first session with a clinical overall CORE general distress score ≥
10). Out of those, 80.7% improved from first to last session. More than half of patients reliably improved (51.6%), with a reliable change described as an increase or decrease in clinical score of 5 or more. Of the patients who improved, 29.1% did not experience a large enough change to be classified as reliable. A smaller proportion (12.9%) of patients experienced deterioration from first to last session, although only 1 patient deteriorated reliably. There was no change in clinical CORE-OM score in one patient.

In our second group 4 out of 5 patients were classified as clinical cases based on their overall CORE-OM score before the start of the therapy. Only 1 (20%) of them improved, but not reliably. Of 3 (60%) clients who experienced deterioration one deteriorated reliably. Summary of results available in Table 2.

<table>
<thead>
<tr>
<th>Reliable Change</th>
<th>Group 1 (CBT + medication)</th>
<th>Group 2 (CBT only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliable improvement</td>
<td>51.6% (N = 16)</td>
<td>0</td>
</tr>
<tr>
<td>Non-reliable improvement</td>
<td>29.1% (N = 9)</td>
<td>40% (N = 2)</td>
</tr>
<tr>
<td>Non-reliable deterioration</td>
<td>12.9% (N = 4)</td>
<td>40% (N = 2)</td>
</tr>
<tr>
<td>Reliable deterioration</td>
<td>3.2% (N = 1)</td>
<td>20% (N = 1)</td>
</tr>
<tr>
<td>No change at all</td>
<td>3.2% (N = 1)</td>
<td>0</td>
</tr>
</tbody>
</table>

### 3.4 “Clinical change”

As already mentioned a clinical change is indicated by a patient moving from a clinical CORE-OM score of ten or more, to a clinical general distress score of less than ten. 25.8% (N = 8) of the individuals who met criteria for caseness at their first session experienced clinical change in the first group (CBT + medication), whilst 74.2% (N = 23) did not show clinical change in general distress post-therapy. As summarised in Table 3 in our second group (CBT only) none of the patients experience clinical change.
Table 3

Clinical change results for both groups

<table>
<thead>
<tr>
<th>Clinical Change</th>
<th>Group 1 (CBT+medication)</th>
<th>Group 2 (CBT only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical to non-clinical</td>
<td>25.5% (N = 8)</td>
<td>0</td>
</tr>
<tr>
<td>Remain clinical</td>
<td>74.2% (N = 23)</td>
<td>100% (N = 4)</td>
</tr>
</tbody>
</table>

3.5 Binominal logistic regression

Binominal logistic regression was chosen to investigate whether reliable improvement (decrease in score for at least 5) after the therapy can be predicted by higher number of CBT sessions. Of the 37 original participants from both groups together, only 31 were included in the logistic regression model. The assumptions that underpin logistic regression were tested beforehand and after the visual inspection of scatter plots 6 outliers were removed due to a very high number of CBT sessions received. Of those outliers, all were from the first group (CBT + medication). The sample hence consisted of 16 individuals receiving CBT + medication (3 females and 23 male) and 5 receiving CBT only (all males). Descriptive statistics for this group are summarized in table 4.

Table 4

Descriptive statistic for a group with excluded outliers

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Min-Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>31</td>
<td>29.70</td>
<td>10.85</td>
<td>19.97 – 57.69</td>
</tr>
<tr>
<td>N of CBT sessions</td>
<td>31</td>
<td>20.45</td>
<td>11.46</td>
<td>3 – 42</td>
</tr>
<tr>
<td>CORE-OM start</td>
<td>31</td>
<td>18.92</td>
<td>6.5</td>
<td>7.9 – 33.5</td>
</tr>
<tr>
<td>CORE-OM end</td>
<td>32</td>
<td>15.64</td>
<td>8.03</td>
<td>0.6 – 34.4</td>
</tr>
</tbody>
</table>

Binominal logistic regression was then performed to investigate whether reliable improvement post-therapy can be predicted from the number of CBT sessions the patient has received. The decrease in post-therapy CORE-OM score for at least 5 thus represented the dichotomous
dependent variable (“reliable change”, “no reliable change”). Duration of CBT therapy (number of sessions) was the independent variable. The results showed that with every additional session of CBT the patient is 1.08 times more likely to score a reliable change on CORE-OM at post-therapy (OR = 1.085, p = 0.038, 95% CI: 1.0046 - 1.1709).

It is important to note that due to the sample size being so small it was not possible to introduce any interaction terms even though some factors might increase or decrease the effect of number of CBT sessions on the outcome. Nonetheless, to at least obtain an indication of the possible confounders the group differences for age and gender separately were checked for.

Inspection of Q-Q plots revealed that age was normally distributed for both groups (the ones who exhibited reliable change at post-therapy and the ones who did not) and that there was homogeneity of variance as assessed by Levene's test for equality of variances. Therefore, an independent sample t-test was employed on the data with a 95% confidence interval for the mean difference. It was determined that there is a significant difference between the means of age at the beginning of CBT for individuals who exhibited reliable change over time at post-therapy (M = 25.19, 95% CI 20.18-30.19) and individuals who did not (M = 33.42, 95% CI 27.62-39.23), conditions; t(29) = 2.24, p = 0.033.

To test how likely it is that the distribution of females and males in each group (reliable change over time at post-therapy or not) is due to chance, the Fisher Exact test was chosen since there was not enough data to perform Pearson's chi-square test (cell count of less than 5 for females). The results exhibited no significant difference between gender and reliable improvement after the therapy (p = 0.562), but it is important to note that there were only 3 women in this sample.
4 DISCUSSION

This study aimed to investigate the effectiveness of CBT on anxiety in adults with ASD and to compare SLaM’s clinical records for differences in effectiveness of various treatment protocols. Furthermore, it was intended to assess the relationship between the number of sessions and favourable outcome, based on the information obtained from CRIS. The results provide preliminary evidence suggesting that CB interventions administered within SLaM’s services may be effective at reducing general psychological distress in adults with ASD and co-morbid anxiety disorders, who were at the same time undergoing pharmacological treatment. This is in line with the findings of previous research in children (Reaven et al., 2012; Storch et al., 2013; Wood et al., 2015) and adults (Blainey, in press; Sizoo & Kuiper, 2017; Spain et al., 2017). The same was not recorded for participants who were receiving CBT only, however the sample size for this group was too small to conduct any separate statistical analysis. It was also demonstrated that the increase in CBT sessions may affect the reliable improvement as measured by change in the CORE global distress score at post-therapy.

Due to the nature of this research it was not known in advance what kind of data will be available in the clinical records and slight changes hence had to be made in regards to initially set hypotheses. It was expected that there would be reports on specific anxiety measures for everyone recorded as having anxiety (and ASD) and starting any kind of treatment or not, but that was not the case. CORE-OM (Evans et al., 2000) was the singular routinely collected measure in SLaM’s services for patients who commenced psychological therapy and it was thus necessary to adjust the analysis to work with information that was available. This ultimately meant that we were not able to obtain any information for people who did not receive any CBT and thus had no control group (non-treatment group). Therefore, the first hypothesis, which considered significant relationship between CBT and anxiety in adults with ASD, was impossible to test.

Nevertheless, based on the available information the results showed that there was a significant decrease in CORE-OM global distress score and in all subscales of the measure (Wellbeing, Problems/Symptoms, Functioning and Risk) across the entire group of people who had received CBT and medication therapy at the same time. More than 80 % of the patients improved from first to last session, over half of them improved reliably and only 1 person (3.2
% relied deteriorated. However, only 25.5% individuals showed clinically reliable decrease in general distress score. It is likely that residual distress noted in our study is reflected by ASD symptoms itself and difficulties they cause in everyday life. Hirvikoski and Blomqvist (2015) have demonstrated association between autistic traits and higher subjective distress and stress in comparison to typical developing individuals. The same was noted in Blainey's (in press) study, where only 18.5% of the participants showed clinically reliable reduction in overall CORE-OM score, even though she found that three-quarters of patients improved after the therapy. The significant decrease in CORE-OM score overall and in all subscales in her study is also comparable to our results. It is important to note that Blainey's (in press) research comprised data collected in a specialist ASD service and the results could hence not be generalizable to psychological therapy offered in mainstream services. In present study all the participants but one came from a non-specialist service, which aids to the understanding of the effectiveness of CBT irrespective of the services’ nature. It is stated in the Autism Act (Parliament UK, 2009) that mainstream services should offer approaches suitable for individuals with ASD, therefore the confirmation of efficacy of psychological therapies in non-specialist services is very valuable.

However, disparate results were detected for people who undertook CB intervention only and did not consume any medication at the same time. Out of five patients only two improved but not enough to present reliable change. Two of them deteriorated, with one exhibiting reliable deterioration at post-therapy. None of them showed clinical change. Those results are suggesting that there might be a difference between different treatment protocols as hypothesised in our second hypothesis, which predicted a greater reduction in the anxiety symptoms of adults with ASD undergoing combined treatment, in comparison to those who underwent pharmacological or CBT treatment alone. However, due to a distinct study design, it was not possible to obtain information regarding the specific anxiety symptoms and CORE outcome measure of general distress was used instead. Information on patients who were undergoing pharmacological treatment protocol only was also missing as they have not started the psychological therapy and CORE-OM was thus not performed. A very small sample in the second group (N = 5) also prevented any additional between group analysis to be conducted so the results must be interpreted with great caution.
Although it was not possible to test our third hypothesis, stating that longer duration of therapy can predict lower anxiety levels in individuals with ASD, the obtained results demonstrated that the odds of showing a reliable change (decrease in general distress score for at least 5) in post-therapy increases by 8% with each CBT session. These crude results imply that additional CBT sessions can ameliorate general distress in patients with ASD and anxiety and that perhaps additional funding should be provided for those clients if needed as it can lead to reliable improvement. Previous research has also suggested that this clinical population may benefit from a protracted period of treatment (Blainey, in press; Walters, Loades, & Russell, 2016). Considering very small sample size it was unfortunately not possible to introduce any other interaction variables in to the model, as multiple regression would lead to considerable reduction in the power of the analysis. Nevertheless, additional separate analysis revealed that reliable improvements in general psychological distress were in fact independent of gender, showing that the reliable change at post-therapy for adults with ASD is not affected by being female or male. It is thus unlikely that this variable interacts with the data in our sample. There were however statistically significant group differences determined for age between patients who exhibited reliable change at post-therapy and patients who did not. The individuals who improved reliably after finishing CBT were on average younger by 8.42 years at the beginning of therapy in comparison to clients who were not exhibiting reliable change at the end. The interaction between variables is thus possible and further multiple models should be tested. Given the results, it is clear that quick access to appropriate care is important and reasonable adjustment for patients with ASD should thus be made. Still, due to a very small sample one has to take caution when interpreting the results.

4.1 Limitations of this study

Lack of comparison group, consisting of adults with ASD and anxiety who have not received any treatment, is one of the biggest limitations of this study. It is thus not possible to determine whether the changes in CORE-OM scores at post-therapy resulted from the CBT offered or were caused by other circumstantial factors and simply represent a change over time. Furthermore, a very small sample is another considerable limitation of this research, especially in the second group (CBT only) which captured only 5 patients, and thus any conclusions drawn from this paper should be treated with high vigilance.
Lack of appropriate measures for anxiety in ASD population or in fact any outcome measure designed for a routine clinical practice with adults with ASD is also considered as disadvantageous. Although CORE-OM is a pan-theoretical measure and it does cover anxiety it was not possible to compare a reduction in anxiety symptoms, as first hypothesised. As the measure was not designed to detect distress specific for any disorder and is in fact assessing a very wide spread of problems, a client with relatively low general distress score could still be potentially experiencing a lot of anxiety. However, CORE-OM is consequently able to provide a more rounded view of the change accomplished by the patients at post-therapy, whilst disorder or symptom specific measures may not reveal the state of other areas outside of the disorder, especially social and functioning aspects of a patients’ everyday life.

Furthermore, as also noted in Blainey (in press), use of outcome measures in this population may be made more challenging due to alexithymia. It has been recorded that people with ASD have more difficulties recognizing and understanding their internal states including thoughts and emotions (Bird & Cook, 2013). Therefore, reporting of these for clients with ASD may present great difficulties, which can potentially contribute to symptom underestimation. It is possible that through CB intervention a patient starts to recognize and understand their feelings, which leads to a more accurate reporting and increase in CORE-OM scores post-therapy. It is important to note that there is also a possibility of ceiling or floor effects of the CORE outcome measure (Shepherd et al., 2005). This means that patients who obtained lowest scores can only get worse and clients with high scores at pre-therapy can only improve.

Main characteristics of ASD – communication and social difficulties – may also affect answers on the CORE-OM or other similar measures (Berthoz & Hill, 2005; Mazefsky, Kao, & Oswald, 2011). Even though the CORE-OM is presuming that the patient will be able to comprehend at times unclear language, this may pose a problem for individuals with ASD. For instance, ASD clients may perceive some of the items on the scale in a very literal or factual way. Moreover, rigidity of thinking may present a further challenge when completing outcome measures as words such as ‘sometimes’ may be hard to comprehend for ASD individuals, who could have a difficulty understanding exactly how frequent that is. It is possible that this might have led to a very small number of complete CORE-OM scores found in the clinical records in current study, since patients did not complete the measure fully due to described challenges.
High self-report outcome results, due to not being able to understand questions fully also poses a threat to the authenticity of such clinical data. Previous studies have resolved this problem by using multiple measures and an observer measure in conjunction with that (Russell et al., 2013), but due to the nature of the study design it was not possible to correlate CORE-OM scores with observational information.

Moreover, even though practice-based data such as current study has the advantage to understand the patients and significance of contextual factors that may influence results, there are certain disadvantages (Cahill, Barkham, & Stiles, 2010). For example, the delivery of the treatment is evaluated as it occurs naturally in the setting, so there is no verification of CBT being conducted in accordance to the protocol. It is however worth noting that available NICE guidelines (NICE, 2012) recommend working with adult ASD individuals should be similar to what is offered to people with intellectual disability. Considering that people with ASD do have better cognitive capabilities (Wilson et al., 2014) in comparison to intellectually-disabled individuals, this extrapolation may not be reasonable and specific protocols for working with adults should be developed. There are no recommendations for how to work in regards to specific comorbid disorders, such as anxiety, in adults with ASD.

It cannot be emphasized enough, that due to a very small sample and the lack of no treatment comparison group those results should be interpreted with immense caution and only serve as an encouragement for future research. It should also be taken into account that there are also numerous other contextual factors that can affect the change in ASD patients with anxiety at the end of the therapy, regardless of the treatment protocol. Nonetheless, it should not be forgotten that the analysed database was established for the purpose of administration in routine clinical practice, rather than research. Incomplete or missing information on offer in thus not surprising and should be taken into account at the start of a project.

### 4.2 Strengths of this study

CRIS is being increasingly used for research and through linkages to external data the depth of information is being expanded even more. Nonetheless, this study showed that not all research questions are appropriate for this particular study design. Irrespective of the volume of
information that is available, it is important to bear in mind that it is highly dependent on what information is actually recorded by clinical staff members.

Given the small sample size it would probably be more reasonable to conduct this study in one particular service, where collection of specific outcome measures would be regularly prompted. However, as this research draw directly from clinical records it provided “real world” data, which demonstrated numerous flaws in how the work with patients with ASD and anxiety is being conducted and recorded. For instance, it exposed the need for validated outcome measures for this population and measures for specific comorbid disorders as well, which would be administered regularly. The evidence highlights the need for clinicians to be aware of the implications that electronic health records and their content, or the lack of it, can have for research.

4.3 Clinical relevance of results

Mentioned results contribute to the growing body of evidence, which has tentatively supported CBT as effective treatment for comorbid anxiety disorders in patients with ASD. While the data presented here do not demonstrate changes in anxiety disorders specifically, it does suggest that in general combined CBT and medication based treatment protocol is helpful in ameliorating psychological distress in adult patients with ASD and comorbid anxiety. Therefore, results of the current study indicate that SLaM’s mainstream mental health services are able to relatively successfully treat clients with ASD and comorbid anxiety disorders with CBT and medication. The appropriate therapy should thus be more accessible and offered routinely. Further findings suggest that higher number of CBT sessions do imply favourable outcome at post-therapy, which might be helpful for funding bodies to consider when allocating additional funding for such therapies. The age at which ASD individuals start therapy has also been proven to play a role in patients’ improvement. Therefore, immediate access to the appropriate service should be assured, with clear pathways from Children and Adolescents Mental Health Services (CAMHS) to adult services. Information should be normalised, easy to find and reliable - similar to the information on physical health. Health checks in local general practitioner services could also be an important way for people with ASD to get their mental health needs checked out routinely and if needed obtain referral for the appropriate service as quickly as possible.
Individuals with ASD are reported to experience very high rates of comorbid anxiety disorders (Simonoff et al., 2008; White et al., 2009) and yet often find it very difficult to access mental health services (National Development Team for Inclusion, 2012). This may happen as a result of diagnostic overshadowing, where diagnostic relevance of symptoms that would otherwise indicate a comorbid psychological illness may be diminished by the existence of ASD and hence considered as untreatable. It is also possible that work with ASD population may pose difficulties for staff working in services not specialised for neurodevelopmental disorders, even though Autism Act and Strategy in England state that mainstream services should make themselves accessible for people with neurodevelopmental differences (Parliament UK, 2009). Additional education on how to work with and support this population may thus contribute to CBT being offered more consistently (Dillenburger, McKerr, Jordan, & Keenan, 2016). It is essential that appropriate training is provided so that staff feel capable of offering CBT interventions to individuals with ASD. The development of clinical guidelines for this particular group of people, covering issues of appropriate psychological and pharmacological treatment for specific comorbid disorder – especially highly prevalent anxiety, might be of great importance, as well.

4.4 Future research

Current study adds to the scarce evidence of effectiveness of CBT in adults with ASD and comorbid anxiety disorders, and offers several implications for further research.

It is suggested that there is a clinical impetus for further studies on CBT in patients with ASD and anxiety to be undertaken, employing more robust trial designs, with additional measures collected to ascertain change in anxiety symptoms. However, given that there are overlaps in the anxiety and ASD symptom profiles, it is important to establish how best to measure these comorbid symptoms, as well as the relative success of treatment. Furthermore, described challenges with self-reporting in ASD individuals are also pressing for appropriate measures of therapeutic change in this population. The possibility of supporting clients with ASD to develop their own personal scales to measure a change and incorporate their special interest might also be worth exploring. Comparison between different treatment protocols with additional no treatment control group would definitely be of use, in order to understand whether CBT should be preferred to any other approach. To obtain information on how generalizable
CBT is for individuals with more impaired language skills or higher pervasive developmental delay often associated with ASD, it would be wise for future research to investigate IQ and other prerequisite skills that are necessary for CBT to be carried out successfully. Moreover, it would also be useful to better understand the mediating and moderating components of CBT for individuals who have both ASD and anxiety.

Finally, even though using the SLaM BRC Case Register was not the best choice for this particular study, it has been previously employed for an extensive range of investigations, in addition to audit projects and service evaluations, and consequently numerous publications have arisen (Perera et al., 2016). Electronic patients’ clinical records hence provide potentially transformative information on mental health and outcomes in routine clinical care and present important opportunities to contribute to research in the field of ASD and comorbid anxiety. Data drawn from electronic health records could also potentially allow enhanced and more effectively targeted recruitment of specific clinical population – individuals with ASD, for randomised controlled trials and other intervention evaluations, as well as permitting efficiency planning and modelling before trial. Accordingly, future research projects with patients with ASD and anxiety should employ “big data” such as CRIS system and use the vast amount of information that is available. However, the research needs to be carefully tailored, so that it takes into account the nature and quality of the source information.
5 REFERENCES


