Maria Megalogeni

#### Case Study 1: An Evidence-Based Practice Review Report

# Theme: School (setting) based interventions for children with special educational needs (SEN)

How effective is CBTp in improving psychotic symptoms and functioning in adolescents and young people below the age of 25?

## 1. Summary

Psychosis is a life-altering mental health condition that can present early in life and impact children and young people (CYP) at a time of great developmental change. Cognitive Behavioural Therapy for psychosis (CBTp) is recommended as a psychological intervention for CYP, though evidence on CBTp use in non-adult populations is scarce. During CBTp, the CYP develops a therapeutic alliance with the therapist where psychotic incidents and the beliefs the CYP holds about them are explored and ultimately replaced by more adaptive beliefs and behaviours. The goal of CBTp is to reduce the distress associated with delusions and hallucinations, with the aim of enhancing symptomatic relief and functional recovery. This review sought to explore the current literature and evaluate the effect of CBTp on psychosis and functioning in CYP under the age of 25. A systematic literature search identified five studies for review and a combination of small to large effect sizes supporting CBTp efficacy were found. Study findings and future research needs are discussed.

## 2. Introduction

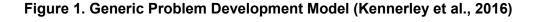
## **CBTp:** from theory to practice

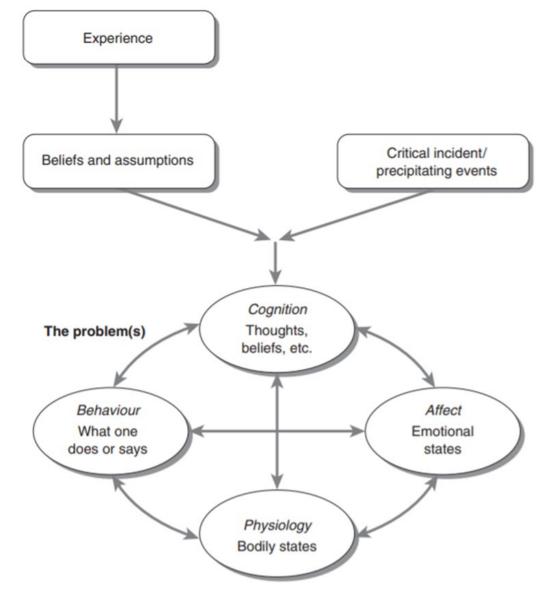
Cognitive Behavioural Therapy for Psychosis (CBTp) evolved from Beck's cognitive model of depression (1979) which views pathology as a product of four interacting systems: our thoughts, emotions, behaviour and physiology. CBT suggests that it is the person's interpretation of an event that affects how they feel and behave, rather than the event itself (cognitive principle), while also explaining that what a person chooses to do (behavioural principle) will in turn affect how they feel and think (Kennerley et al., 2016) (Figure 1). For example, an inaccurate belief may lead a person to avoid a certain experience, which can in turn reduce their opportunities for reality testing, thus reinforcing the original inaccurate belief, contributing to pathology.

But where does pathology originate from? The guiding theory behind both CBT and CBTp is that bio-psycho-social factors such as early childhood experiences develop our core beliefs and structures of the world, which can be functional and adaptive or maladaptive. Beck et al. (1990) explained that these maladaptive schemas develop over the years and 'await' to be triggered by critical incidents in life, in turn evoking dysfunctional behaviours or emotional states such as anxiety. On this basis, CBT 'helps people identify and change thinking and behavior patterns that are harmful or ineffective, replacing them with more accurate thoughts and functional behaviours'' (VandenBos, 2015).

Similarly, CBT models of psychosis propose that psychotic-like experiences are influenced by maladaptive appraisals of neutral or anomalous experiences, which in turn cause stress that heightens the occurrence and severity of the psychotic incident (Phiri et al., 2017). Morrison et al. (2021), advocates of the cognitive model of psychosis (Morrison, 2001), explain that it is not the psychotic incident itself that causes distress and disability, but rather the person's interpretation and response to it. As such, the goal of CBTp is to reduce the distress associated with delusions and hallucinations, with the aim of enhancing symptomatic relief and functional recovery (Addington & Gleeson, 2005).

While several approaches to applying CBTp have developed over the years, the therapeutic process typically consists of the following steps: engagement, assessment, formulation, goal setting, interventions and relapse prevention. Engagement is key to building rapport and patient commitment to therapy, and involves techniques such as ambivalence resolution and normalisation of experiences (i.e. people who are not schizophrenic can also hear voices if they are stressed or sleep deprived). During assessment, the therapist aims to gather detailed information on factors such as the person's beliefs, symptoms and life experiences, to guide formulation. Formulation aims to "connect" these factors to construct a model that explains how the psychotic symptoms developed and are maintained, and to produce an alternative explanation that is less stigmatising and more adaptive. Interventions depend on the client's goals but can involve client and family psychoeducation on psychosis, identifying and reducing triggers (i.e. avoiding alcohol), reality testing exercises and cognitive restructuring (i.e. viewing voices as thoughts or worries). During relapse prevention work, the context, triggers and impact of relapse are identified and preventative strategies are developed collaboratively (Landa, 1987).





## **Rationale and relevance**

CBT has been gaining recognition over the last 20 years as a potential therapy for people with psychosis (Cormac et al., 2002) and is now recommended by UK NICE guidelines (2016) as a non-pharmacological intervention for CYP experiencing psychosis. However, this recommendation is guided by the continuously growing evidence-base supporting CBTp use in adult populations (Naeem et al., 2014) and not CBTp research in CYP, which is shockingly scarce (Stafford et al., 2015).

Early onset psychosis which is defined as the presence of a first-episode of psychosis before the age of 18 is thought to affect approximately 6 in 100,000 people in the UK (Boeing et al., 2007). Symptoms are divided into positive (e.g. delusions, hallucinations) and negative (e.g. emotional and social withdrawal, poverty of speech) (Andreasen, 1982; Passby & Broome, 2017).

Arguably one of the most life-impacting mental health conditions, onset of psychosis at a time when young people are developing socially, biologically and cognitively can leave CYP at their most vulnerable. Indeed, studies report much poorer outcomes for this group compared to those first experiencing psychosis in adulthood (Fleischhaker et al., 2005; Hollis, 2000; Immonen et al., 2017), signifying the necessity for a multidisciplinary approach to treatment during this time. Young people's chances of remission are lower at this age (Clemmensen et al., 2012), educational and social functioning is impaired (Hollis, 2000), while suicide risk is higher compared to their peers (Falcone et al., 2010). Though early intervention in psychosis is associated with better outcomes (DHSC, 2001) and both CAMHS and Early Intervention for Psychosis Services in the UK are available for support, waiting times are high and access to psychological interventions is particularly low (HQIP, 2016). Furthermore, there is concern that adolescents experience comparably longer periods of untreated psychosis (Schimmelmann et al., 2007).

With the latter in mind, Fuggle and Dunsmuir's (2013) statement on the 'significant advantages in accessing psychological therapies in the school setting' could not be more accurate or relevant. CBTp trained Educational Psychologists (EP) following

#### Doctorate in Educational and Child Psychology

Dunsmuir and Hardy's (2016) guidance on delivering psychological therapies in schools could play a significant and evidently needed role in augmenting available support, at the benefit of CYP. However, as EPs are responsible for considering the evidence before adopting therapeutic interventions (HCPC, 2016), an exploration of the effectiveness of CBTp in CYP needs to take place first.

With people up to the age of 24 considered as youth by the WHO and neuroimaging studies revealing that brain growth continues into the twenties (Johnson et al., 2009), studies including young people up to the age of 25, an age group supported by EPs as per the SEND Code of Practice (2015), were included in this review. Functional improvement has been found to be independent to psychotic symptom remission, and has been highlighted as an area of more importance to young people than symptomatic relief (Iyer et al., 2011; Ramsay et al., 2011). As such, the review aims to look into both psychopathology and functional outcomes following CBTp.

## **Review Question**

How effective is CBTp in improving psychotic symptoms and functioning in adolescents and young people below the age of 25?

## 3. Critical Review of the Evidence Base

## Literature Search

A systematic literature search utilising the Scopus, Web of Science and PsycInfo databases was carried out between the 26<sup>th</sup> and 28<sup>th</sup> of January 2022. A list of search terms, including the electronic search strategy that was performed can be found below.

#### Table 1. Electronic Search Strategy

1. Adolescent schizophrenia 16. Cognitive behavioural therapy

- 2. Adolescent Psychosis 3. **Psychotic-like experiences** 4. Early onset psychosis 5. Early onset schizophrenia 6. Child schizophrenia Children psychosis 7. 8. Unusual experiences 9. Child psychosis 10. Children schizophrenia 11. First episode psychosis 12. Early psychosis 13. VEOS 14. Psychosis 15. Schizophrenia 6 OR 7 OR 8 OR 9 OR 10 OR

31. 1 OR 2 OR 3 OR 4 OR 5 OR

11 OR 12 OR 13 OR 14 OR 15

33. 31 AND 32

- 17. CBT
- 18. Cognitive behavioral therapy
- 19. Psychological intervention
- 20. Psychological interventions
- 21. Cognitive Behavioural Treatment
- 22. Cognitive Behavioral Treatment
- 23. Psychological Treatment
- 24. Psychological Treatments
- 25. Psychosocial intervention
- 26. Psychosocial interventions
- 27. Psychosocial Treatment
- 28. Psychosocial Treatments
- 29. Cognitive behaviour therapy
- 30. Cognitive behavior therapy
- 32. 16 OR 17 OR 18 OR 19 OR 20
- OR 21 OR 22 OR 23 OR 24 OR 25
- OR 26 OR 27 OR 28 OR 29 OR 30

## Study screening: eligibility criteria

A total of 1,688 articles were identified following the aforementioned search strategy,

with 779 articles remaining after duplicate removal. All articles were screened at title

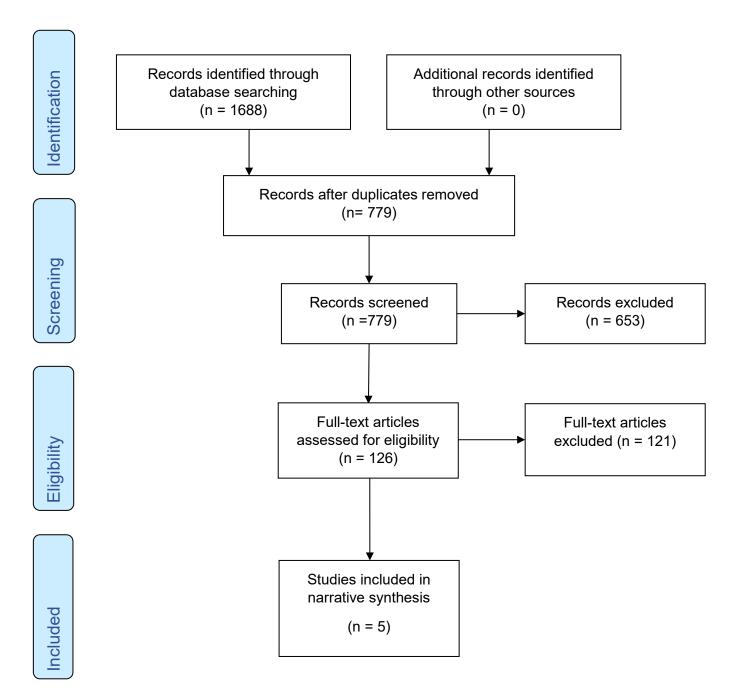
and abstract level against the eligibility criteria found in Table 2, with 126 screened at

full text where a clear decision at abstract level could not be made. A PRISMA flow

diagram summarising the screening process can be found below.

A total of five articles, referenced in Table 3, were included in the review.

## Figure 2. Prisma Flow Diagram (Moher et al., 2009)



## Table 2. Eligibility Criteria

Criterion	Inclusion	Exclusion	Rationale
1. Type of publication	The article has been published in a peer- reviewed journal	The article has not been published in a peer-reviewed journal	The article has been subjected to quality control by experts in the field
2. Study design	RCT with pre- and post- intervention measures	Non-RCT (i.e. Quasi- experimental studies, systematic reviews and meta-analyses, case experimental studies, qualitative studies	RCTs minimise the risk of confounding factors influencing the trial results and are considered to provide the most reliable evidence on the effectiveness of interventions
3. Language	Article is written in English	Article is not written in English	Author accessibility to article
4. Intervention	Trials investigating CBT- based interventions	Trials not investigating CBT- based interventions	This review seeks to evaluate the efficacy of CBT-based interventions on psychosis and functioning in those aged ≤25 years of age
5. Population	Article contains data from participants aged ≤25 that can be differentiated from and extracted from adult data (>25 years) for the purposes of calculating effect sizes	Article does not contain data from participants aged ≤25 that can be differentiated from and extracted from adult data (>25 years) for the purposes of calculating effect sizes	This review seeks to evaluate the efficacy of CBT-based interventions on psychosis and functioning in those aged ≤25 years of age
6. Diagnosis	Participants have an ICD or DSM diagnosis of psychosis, including active psychotic symptoms at screening	Participants do not have an ICD or DSM diagnosis of psychosis and they did not have active psychotic symptoms at screening	This review seeks to evaluate the efficacy of CBT-based interventions on psychosis, therefore active psychotic symptoms at the time of the intervention are a requirement
7. Outcomes	Measures evaluating psychotic symptoms (positive and/or negative) and/ or functioning	Measures do not evaluate psychotic symptoms (positive and/or negative) or functioning	This review seeks to evaluate the efficacy of CBT-based interventions on psychosis and functioning in those aged ≤25 years of age

RCT= Randomised Controlled Trial; CBT= Cognitive Behavioural Therapy, ICD= International Classification of Disorders (WHO, 1992); DSM= Diagnostic and Statistical Manual (APA, 1994)

Note: a list of excluded trials can be found in Appendix A

#### Table 3. References of included articles

**1.** Browning, S., Corrigall, R., Garety, P., Emsley, R., & Jolley, S. (2013). Psychological interventions for adolescent psychosis: A pilot controlled trial in routine care. *European Psychiatry*, *28*(7), 423-426. <u>https://doi.org/10.1016/j.eurpsy.2013.05.008</u>

**2.** Francey, S. M., O'Donoghue, B., Nelson, B., Graham, J. R., Baldwin, L., Yuen, H. P., Kerr, M. J., Ratheesh, A., Allott, K. A., Alvarez-Jimenez, M., Fornito, A., Harrigan, S., Thompson, A., Wood, S. J., Berk, M., & McGorry, P. D. (2020). Psychosocial Intervention With or Without Antipsychotic Medication for First-Episode Psychosis: A Randomized Noninferiority Clinical Trial. *Schizophrenia Bulletin Open*, *1*(1). <u>https://doi.org/10.1093/schizbullopen/sgaa015</u>

**3.** Jackson, H. J., McGorry, P. D., Killackey, E., Bendall, S., Allott, K., Dudgeon, P., Gleeson, J., Johnson, T., & Harrigan, S. (2008). Acute-phase and 1-year follow-up results of a randomized controlled trial of CBT versus Befriending for first-episode psychosis: the ACE project. *Psychological Medicine*, *38*(5), 725–735. <u>https://doi.org/10.1017/S0033291707002061</u>

**4.** Morrison, A. P., Pyle, M., Maughan, D., Johns, L., Freeman, D., Broome, M. R., Husain, N., Fowler, D., Hudson, J., Maclennan, G., Norrie, J., Shiers, D., Hollis, C., James, A., Morrison, A. P., Pyle, M., Maughan, D., Johns, L., Freeman, D., James, A. (2020). Antipsychotic medication versus psychological intervention versus a combination of both in adolescents with first-episode psychosis (MAPS): a multicentre, three-arm, randomised controlled pilot and feasibility study. *The Lancet Psychiatry*, *7*(9), 788-800 <u>https://doi.org/10.1016/S2215-0366(20)30248-0</u>

**5.** Müller, H., Kommescher, M., Güttgemanns, J., Wessels, H., Walger, P., Lehmkuhl, G., Kuhr, K., Hamacher, S., Lehmacher, W., Müller, K., Herrlich, J., Wiedemann, G., Stösser, D., Klingberg, S., & Bechdolf, A. (2020). Cognitive behavioral therapy in adolescents with early-onset psychosis: a randomized controlled pilot study. *European Child & Adolescent Psychiatry, 29*(7), 1011–1022. <u>https://doi.org/10.1007/s00787-019-01415-4</u>

## Weight of Evidence

All studies under review have undergone a quality and relevance assessment based on The Gough Weight of Evidence Framework (2007). Quality appraisal judgments were made based on three characteristics and used to calculate an overall weight of evidence score (WoE D): methodological quality (WoE A), methodological relevance (WoE B) and topic relevance (WoE C).

The Jadad Scoring Scale (Jadad et al., 1996), an empirically-evidenced scoring system widely used for assessing the methodological quality of randomised clinical trials was used to calculate WoE A. Studies are judged for their method of randomisation, double blinding status and their description of participant withdrawals and dropouts. The scale was selected among the many tools used to evaluate the quality of RCTs, as it is user-friendly, it offers a numerical score with a subsequent interpretation, and importantly, it presents with the strongest evidence for reliability and validity (Olivo et al., 2008).

Gough's WoE B and C were evaluated using author-designed criteria, with Gersten's Essential and Desirable Quality Indicators for experimental research articles (2005) used to drive the selection of the review's WoE B criteria. Rationale for the criteria selected, including information on each WoE coding protocol can be found in Appendix B. The overall weight of evidence score for each study (WoE D) can be found in Table 4, below.

Study	<b>WoE A</b> : Methodological Quality	<b>WoE B</b> : Methodological Relevance	<b>WoE C</b> : Topic Relevance	<b>WoE D</b> : Overall WoE
Browning et al (2013)	1 - Low	2.16 - Medium	1.66 - Medium	1.60 - Medium
Francey et al. (2020)	3 - High	2.33 - Medium	2 - Medium	2.44 - Medium
Jackson et al. (2008)	2 - Medium	2.83 - High	2.66 - High	2.49 - High
Morrison et al. (2020)	2 - Medium	2.66 - High	2.66 - High	2.44 - Medium
Muller et al. (2020)	2 - Medium	2.66 - High	3 - High	2.55 - High

<u>Note</u> ≤1.4: low 1.5-2.4: medium

≥2.5: high

## **Mapping the Field**

A narrative synthesis of the five included studies has been conducted to address the review question. A table detailing the main characteristics of each study can be found below.

## Table 5. Study if harasteriating Child Psychology

References/ Country	Study Type	Diagnosis	Interventions (N)	Intervention Design	Age/ Sample Size <i>(n)</i>	Measures	Main Findings	WoE D
Browning et al. (2013) U.K.	Pilot RCT	Psychotic disorder, ICD-10	Intervention CBTpA+Standard Care (n=10) Comparison Group(s) Family Therapy (FTpA) + inpatient Standard Care (SC). Duration: 5h long sessions over 4–10 weeks (n=10) Standard Care (SC) (n=10)	CBTpA: 10 half-hour sessions, twice a week - duration was patient length of stay in setting (M=65.5 days)	14 - 17 n= 30	a) Affective and psychotic symptoms (BPRS) b) Psychosocial functioning (C- GAS)	No significant difference between therapy group comparisons (CBTpA vs FTpA). Improvement in symptoms and psychosocial functioning found in CBTpA group compared to SC group. Significant within group improvements over time in symptoms and functioning for both therapeutic groups. Post- intervention improvements only in symptoms but not functioning for the SC group.	1.60 - Medium

References/ Country	Study Type	Diagnosis	Intervention (N)	Intervention Design	Age/ Sample Size (n)	Measures	Main Findings	WoE D
Muller et al. (2020) Germany	Pilot RCT	Current diagnosis of schizophrenia, schizophreniform, schizoaffective or delusional disorder (DSM- IV) according to the SCID-PD	Intervention (N) CBTpA + Treatment as Usual (TAU) (n= 13) Comparison Group(s) (N) Treatment as usual (TAU) (n= 12)	9 months (20 individual sessions) of CBTpA + TAU	14-20 n= 25	<ul> <li>a) PANSS- positive subscale</li> <li>b) PANSS - negative subscale</li> <li>c) Auditory</li> <li>Hallucinations</li> <li>(PSYRATS)</li> <li>d) Delusions</li> <li>(PSYRATS)</li> <li>e) Depression</li> <li>(CDSS)</li> <li>f) Functioning</li> <li>(GAF)</li> <li>g) Quality of life</li> <li>(MSQoL-R)</li> </ul>	Between-group effect sizes at post-treatment were trivial (d= 0.04) for the PANSS-positive subscale and lacked statistical significance. However, small between-group effect sizes in favour of CBT+TAU were seen for the PANSS negative subscale, delusions, depression, psychosocial functioning and QoL. Between-group effect sizes at 2-year follow up were still trivial (d= 0.02) for the PANSS-positive subscale and lacked statistical significance. However, small between- group effect sizes in favour of CBT+TAU were seen for the "material quality of life" subscale, the PANSS negative subscale, auditory hallucinations, depression, psychosocial functioning and QoL. Large within group effect sizes were seen in both groups	2.55 - High

References/StudyCountryType	Diagnosis	Intervention (N)	Intervention Design	Age/ Sample Size (n)	Measures	Main Findings	WoE D
Morrison et al. (2020) U.K. RCT		Intervention CBT + optional family intervention (OFI) (n=18) Comparison Group(s) Antipsychotic monotherapy (n=22) Antipsychotic monotherapy + CBT (+OFI) (n=21)	Up to 26 1h CBT sessions over 6 months, plus up to four booster sessions (once a week). Optional family intervention incorporated up to six sessions over 6 months (once a month)	14-18 n= 61	a) Positive and negative symptoms (PANNS) b) Psychotic Experiences (SPEQ) c) Depression (HADS)	There were no significant <b>between group</b> differences in either positive or negative symptoms (PANNS) at 6 months, indicating no superiority of any treatment. At 12 months, CBT+OFI+meds showed slightly higher improvement in PANNS symptoms compare to CBT+OFI only. <b>Within group</b> improvements in PANNS were seen for all treatment groups at 6 and 12 months, with improvements seen in remaining outcome	2.44 - Medium

References/ Country	Study Type	Diagnosis	Intervention (N)	Intervention Design	Age/ Sample Size (n)	Measures	Main Findings	WoE D
Jackson et al. (2008) Australia	RCT	Psychotic symptoms, Structured Clinical Interview for DSM-IV TRAxis 1 Disorders – Patient Edition (SCID)	Intervention CBT (Active Cognitive Therapy - ACE) + TAU (n=31) Comparison Group(s) Befriending +TAU (n=31)	Up to 20 CBT sessions within 14 weeks, 45 mins per session	15-25 n=62	a) Psychotic Symptoms – Psychotic Subscale of the BPRS b) Negative Symptoms (SANS) c) Functioning (SOFAS)	Between Group: ACE outperformed Befriending by lowering negative and positive symptoms of psychosis and improving functioning at mid- treatment, and to a smaller extent lower negative symptoms and improve functioning at end of treatment Following the mid- treatment stage, Befriending caught up with the ACE group and there were no significant differences in any outcome measures at 1- year follow-up	2.49 - High

References/ Country	Study Type	Diagnosis	Intervention (N)	Intervention Design	Age/ Sample Size (n)	Measures	Main Findings	WoE D
Francey et al. (2020) Australia	Non- inferiority RCT	DSM-IV psychotic disorder, including schizophrenia, schizophreniform disorder, delusional disorder, brief psychotic disorder, major depressive disorder with psychotic symptoms, substance- induced psychotic disorder, or psychosis not otherwise specified (NOS)	Intervention CBCM + non- active ingredient placebo (n=46) Comparison Group(s) CBCM + antipsychotic medication (n=44)	Mean of 14 CBCM sessions by 6- month trial endpoint	15-25 (n=90)	a) Functioning (SOFAS) b) Quality of Life (QLS) c) Positive symptoms (BPRS-4) d) Negative symptoms (SANS) e) HAMD- Depression f) HAM-Anxiety	Both with and without medication CBT groups improved in their functioning post-treatment (6 months), including on all measures of psychopathology. No between group differences were seen to indicate a discernible advantage to receiving medication. No between group differences at 12 and 24 months, with the exception of negative symptoms at 12 months where the medication group had significantly less symptoms.	2.44 - Medium

Note: RCT=Randomised Controlled Trial, ICD=International Classification of Diseases, CBTpA=Cognitive Behavioural Therapy for Adolescents with Psychosis, FTpA=Family Therapy for Adolescents with Psychosis, SC=Standard Care, BPRS=Brief Psychiatric Rating Scale, C-GAS=Children's Global Assessment Scale, DSM=Diagnostic and Statistical Manual of Mental Disorders, SCID-PD=Structured Clinical Interview for DSM-5 Personality Disorders, TAU=Treatment As Usual, CBT=cognitive behavioral therapy, PANSS-POS=positive and negative syndrome scale-positive scale, PANSS-NEG= positive and negative syndrome scale-negative scale, PSYRATS= Psychotic Symptoms Rating Scales, CDSS=Calgary Depression Scale for Schizophrenia, GAF=Global assessment of functioning scale, MSQoL=Modular System for Quality of Life, OFI= Optional Family Intervention SPEQ= Specific Psychotic Experiences Questionnaire, HADS= Hospital Anxiety and Depression Scale, ACE= Active Cognitive Therapy, SANS=Scale for the Assessment of Negative Symptoms, SOFAS= Social and Occupational Functioning Scale, CBCM= Cognitive Behavioural Case Management, QLS= Heinrich Quality of Life Scale, HAMD-Depression= Hamilton Depression Scale, HAM-Anxiety= Hamilton Anxiety Scale

Maria Megalogeni

## Participant and study characteristics

A total of 268 participants of which 55% were male, took part in the five studies. The median sample size was n=61 (range 25 to 90), while the participant mean age was 18.2 years (range 16.3 to 22.3). All participants shared an ICD-10 or DSM-IV diagnosis of psychosis and had active psychotic symptoms upon study entry. In their majority, participants were outpatients in specialist psychosis or adolescent services across the U.K. (Morrison et al., 2020), Australia (Francey et al., 2020; Jackson et al., 2008) and Germany (Muller et al., 2020), however Muller et al. (2020) also recruited from an inpatient unit and a residential home, while Browning et al. (2013) recruited patients residing in an Adolescent Psychiatric Unit (U.K.).

All trials, bar Browning et al. (2013), provided data on their participants' education status, with 44% of the sample indicating they were still in education. The studies were evaluated in WoE C based on their mention of several participant characteristics, such as use of antipsychotic medication and receipt of private psychotherapy. Browning et al. (2013) received WoE C penalties for providing limited information on patient demographic, diagnosis and therapy data, raising concerns as to the probability of external factors influencing their findings. The remaining trials received medium (Francey et al., 2020) and high scores (Jackson et al. 2008; Morrison et al. 2020; Muller et al. 2020) in this area.

A variety of tools were used across the five trials to measure psychopathology and functioning. The Brief Psychiatric Rating Scale-BPRS (Overall & Gorham, 1962; Ventura et al., 1993) was used in three trials (Browning et al., 2013; Francey et al., 2020; Jackson et al., 2008) as a measure of psychotic symptoms, while The Positive and Negative Syndrome Scale-PANNS (Kay et al., 1987) which incorporates the 18-

#### Doctorate in Educational and Child Psychology

item BPRS scale, was adopted by two of the trials (Morrison et al., 2020; Muller et al., 2020). Though the authors did not provide current or historical sources on the psychometric quality of the tools other than references to their origin, both the BPRS and PANNS are established measures, used internationally in both a clinical and research capacity, with information on their reliability and validity being readily available. Their psychometric properties, in particular strong inter-rater reliability (Bell et al., 1992; Kay et al., 1989; Kopelowicz et al., 2008; Ligon & Thyer, 2000; Yehya et al., 2016) and validity (Andersen et al., 1989; Dingemans et al., 1995; Kay et al., 1987; Khan et al., 2013; Leucht et al., 2005; van Beek et al., 2015) are evidenced by a number of trials, with the PANNS thought to be superior to the BPRS when it comes to clinical predictive validity (Bell et al., 1992).

The Scale for the Assessment of Negative Symptoms-SANS (Andreasen, 1989), the Psychotic Symptoms Rating Scales—PSYRATS (Haddock et al., 1999) and the Specific Psychotic Experiences Questionnaire-SPEQ (Ronald et al., 2014) were used as secondary measures in Francey et al. (2020), Muller et al. (2020), and Morrison et al. (2020), respectively, with the SANS scale used as a primary measure (alongside the BPRS) in the Jackson et al. (2008) trial. As with the PANNS and BPRS, evidence on the reliability and validity of the SANS measure is readily available (Alonso et al., 2008; Andreasen et al., 1991; Rabany et al., 2011), with the tool being one of the most widely used for measuring negative symptoms in psychosis. However, concerns exist around the validity of the measure, in particular its inclusion of items that are not considered part of the negative syndrome of psychosis (Kirkpatrick et al., 2006; Lader, 2000).

#### Doctorate in Educational and Child Psychology

Though a fairly new measure, the SPEQ has been found to have good convergent validity, test-retest reliability, and internal consistency (Ronald et al., 2014, Zavos et al., 2014). Data on the psychometric properties of the PSYRATS are also positive, with research supporting the tool for re-test and inter-rater reliability and validity, in particular, internal consistency and sensitivity to change (Drake et al., 2007; Favrod et al., 2012; Hatton et al., 2005; Mortan Sevi et al., 2016).

Francey et al. (2020) utilised the Heinrich Quality of Life Scale-QLS (Heinrichs et al., 1984) and the Social and Occupational Functioning Scale-SOFAS (APA, 1994) to measure functioning, with the latter also used to assess functioning in the Jackson et al. (2008) trial. Muller et al. (2020) assessed functioning with the Global Assessment of Functioning Scale-GAF (APA, 1994), while Browning et al. (2013) used the Children's Global Assessment Scale-C-GAS (Shaffer et al., 1983).

Both the SOFAS and GAF have been found to have excellent inter-rater reliability and convergent validity, with evidence supporting the GAF's validity as a measure of global psychopathology, and the SOFAS validity as a measure of interpersonal, occupational and social functioning (Hilsenroth et al., 2000; Patterson & Lee, 1995). Evidence on the psychometric properties of the C-GAS is also available, with the tool found to have good inter-rater reliability, discriminant validity and test-retest reliability (Shaffer et al., 1983; Steinhausen, 1987). The QLS, which is typically used in conjunction with other measures of psychopathology rather than as a standalone tool, is reported to have good inter-rater reliability (Heinrichs et al., 1984), criterion-related validity (Ascher-Svanum et al., 2012) and convergent validity (Lehman et al., 1993).

Maria Megalogeni

## Study design

Study design was evaluated against WoE A and B criteria. Each study followed a randomised controlled trial design, a gold standard for investigating cause-effect relationships by stratifying participants into 'equally' comparable groups, while minimising bias by blinding researchers and/ or participants to treatment (Hariton & Locascio, 2018). Stratified, computer-generated (Francey et al., 2020; Morrison et al., 2020; Muller et al., 2020) or statistician-assisted randomisation (Jackson et al., 2008) was employed in all studies except in Browning et al. (2013) where allocation was conducted according to date of admission, thus receiving a lower WoE A score.

Parallel forms of outcome measures capturing psychopathology and functioning were taken pre- and post-treatment in all trials, increasing the trials' power in detecting change. Follow-up periods of 1 to 2 years were also adopted in four trials, except Browning et al. (2013), earning them higher WoE scores as they allowed for intervention effect(s) over time to be captured. All studies adopted an 'active' control-group design which allowed for the control of variables external to the intervention (e.g. therapist exposure) from influencing findings and for an estimate of change caused by the intervention rather than *regression to the mean* to be made. This randomised, pre-test-post-test, control group design earned all trials higher scores for a number of WoE B criteria, while allowing for both within-group and between-group changes to be measured.

Given the nature of the intervention under investigation, participant blinding to CBT allocation was not possible. None of the trials, bar Francey et al. (2020), met Jadad requirements for double-blind status, with Francey et al. (2020) scoring higher on WoE A due to participant concealment to antipsychotic treatment rather than to CBT.

#### Doctorate in Educational and Child Psychology

Though this increased risk of bias for the four remaining trials and relevant points were deducted, the studies minimised bias from further influencing findings by either blinding their outcome measure raters to treatment allocation (Jackson et al., 2008; Morrison et al., 2020; Muller et al., 2020) or ensuring they were independent to CBT delivery (Browning et al., 2013; Francey et al., 2020).

All five studies provided information on their withdrawal and drop-out rates where they occurred. As missing or incomplete outcome data increase the risk of attrition bias by minimising group comparability, different methods were adopted by the studies to adjust for missing data. Muller et al. (2020) used the Last-Observation-Carried-Forward method, while Jackson et al. (2008) used multiple imputation (MI) methods. Francey et al. (2020) employed *used-mixed effects* modelling, but received WoE B penalties alongside Morrison et al. (2020) due to a high proportion of missing outcome data at follow-up.

#### Intervention

All CBT models employed in the five studies were manual-based. Intervention delivery time ranged from 10 to 26 CBT sessions lasting 30-60 minutes each, with treatment periods ranging from 4-10 weeks to 9 months. Browning et al. (2013) utilised Fowler, Garety and Kuiper's CBTp manual (1995) which focuses on changing appraisals, testing biases, re-evaluating schemas and relapse prevention, among other elements. Muller et al. (2020) adopted Klingberg's (2009; 2010; 2018) approach while supplementing it with strategies from Fowler's manual (Fowler et al., 1995). Morrison et al. (2020) used their own published therapeutic protocol (Morrison, 2017) which focuses on normalisation and re-appraisal of psychotic experiences. Jackson et al. (2008) and Francey et al. (2020) utilised CBT manuals specifically developed for early

psychosis (Bendall et al., 2005; Orygen Youth Health Research Centre, 2010). All trials scored high in WoE C for offering information and/ or references to comprehensive descriptions of their therapeutic manuals, allowing for replicability and efficacy testing by future trialists.

Two of the studies (Browning et al., 2013; Muller et al., 2020) were awarded for adapting their therapeutic protocols to the developmental needs of adolescents and young people, contributing to the currently scarce evidence-base on CBTp protocols for CYP. Browning et al. (2013) utilised their service's experience of working with youth to make adaptations such as using visuals (i.e. cartoon-faces) to label emotions during therapy and reduced their sessions from 60 to 30 minutes. Similarly, Muller et al. (2020) utilised 'lessons learnt' from the Browning et al. trial (2013) including advice from an expert committee of CYP therapists, and adjusted their manual to incorporate youth-friendly materials such as comics.

Fidelity to and quality of the intervention were captured by WoE B and C. Jackson et al. (2008) and Morrison et al. (2020) received high scores for providing a treatment fidelity protocol. Therapy sessions were audiotaped and judged for integrity by raters using a Cognitive Therapy Rating Scale (Young & Beck, 1988). In addition, sessions were carried out by trained therapists in receipt of supervision, and adherence to treatment data were methodically kept. Session attendance was also captured in the Muller et al. study (2020) with CBTp delivered by therapists experienced in the treatment of psychosis who were regularly supervised and trained in the study's CBTp manual. The trial however received penalties as neither the quality of the sessions nor the therapist(s) adherence to the manual were formally assessed. Francey et al. (2020) received WoE B penalties for the same reason. Browning et al. (2013) received penalties in both WoE B and C; no information was provided on the therapist's CBT training, the quality of the sessions nor on treatment adherence, significantly impacting the reliability of their research findings.

## Findings

Though there was heterogeneity between the trials when it came to their primary and secondary aims, psychotic symptoms and functioning were explored in all. Most studies reported between-group effect sizes for their treatment phases, however within-group calculations were not commonly provided. Where the magnitude of treatment effect was not reported or calculated as a *Cohen's d* standardised mean difference (SMD), the formulae found in Appendix C were used for the calculation.

CBTp plus 'treatment as usual' (TAU), the latter typically consisting of antipsychotic treatment and case management by a psychiatrist, was compared against TAU and/ or another non-pharmacological intervention in three trials (Browning et al., 2013; Jackson et al., 2008; Muller et al., 2020).

Browning et al. (2013) did not find any significant differences when comparing CBT to Family Therapy post-treatment, however when compared to standard treatment (TAU), small to medium effect sizes in favour of CBT+TAU were seen in psychosocial functioning and psychotic symptoms. Diligence however should be given when interpreting the results, as the trial's WoE ranged from medium to low. Furthermore, the length of treatment exposure between the two comparison groups varied, violating the study's assumption of a normal distribution.

When comparing CBT+TAU (or else ACE) to Befriending+TAU, Jackson et al. (2008) found that ACE outperformed Befriending in improving functioning and reducing positive and negative symptoms mid-treatment, and to a smaller extent in lowering negative symptoms and improving functioning post-treatment. Befriending appeared

to 'catch up' with ACE post-treatment and no significant differences were seen between the groups in these measures at the 1-year follow up.

Muller et al. (2020) found trivial between-group differences on the PANNS positive subscale post-treatment and at follow-up when comparing CBT+TAU to TAU. However, post-treatment reductions in delusions, negative symptoms and depression, including a reduction of auditory hallucinations (but not delusions) at follow-up were seen in the CBT+TAU group compare to TAU. Functioning and quality of life were also improved with small between-group effect sizes in favour of CBT+TAU seen at post-treatment and follow-up.

In place of TAU, participants in the Morrison et al. (2020) trial received CBT with optional monthly family therapy (OFI). The group was compared to an antipsychotics only group (AP) and a CBT+OFI+AP group. Though no significant differences were found between the groups in PANNS positive or negative symptoms post-treatment, the group receiving both medication and psychological therapy showed slightly higher improvement in their PANNS scores at 12-months, compared to those receiving CBT+OFI only.

In contract to the aforementioned trials, Francey et al. (2020) conducted a noninferiority trial, investigating whether CBT for first-episode psychosis was inferior to CBT with antipsychotic medication. No between-groups differences were found indicating either intervention to be superior to the other at post-treatment or follow-up, with the exception of negative symptoms at 12-months where the CBT+AP group showed significantly less symptoms. Small to large effect sizes were seen in both CBT groups post-treatment and at follow-up. Participants presented with reductions in depression, anxiety and positive and negative symptoms, while improvements were seen in their functioning and quality of life measures.

Within-group improvements in functioning and psychopathology at post-treatment and follow-up were seen in all five trials for participants receiving CBT. Given the trials received medium to high WoE D scores, relevant merit should be given to the findings and their importance to the review question. However, it is important to highlight that the trials were not powered for efficacy testing and as such their findings should be interpreted with caution.

A summary of main findings, measures and effect sizes can be found below.

## Table 6. Study Findings

References/ Country/ N	Outcome measures	Effect Size (Cohen's d)	*Descriptor (Cohen, 1992)	Main Findings	WoE D
Browning et al. (2013)	Between Groups: CBTpA vs SC			Improvement in symptoms and psychosocial functioning found in <b>CBTpA group compared to</b>	
U.K.	Pre-treatment to post- treatment:			SC group.	
I	Affective and psychotic	Cohen's d= 0.6	Medium	No significant difference	
Intervention ( <i>N</i> )	symptoms (BPRS) Psychosocial Functioning (C-	Cohen's d= 0.2	Small	between therapy group comparisons (CBTpA vs	
(/•)	GAS)		Ontai	FTpA).	1.60 -
CBTpA, n=10					Medium
Comparison	**Within CBTpA Group:			Significant within group improvements over time in	
Group(s) ( <i>N</i> )	Pre-treatment to post-			symptoms and functioning for	
	treatment (M=65.5 days):			both therapeutic groups. Post-	
FTpA, n= 10 SC, n= 10	Affective and psychotic	Cohen's d= 2.5	Large	intervention improvements only in symptoms but not	
00,11-10	symptoms (BPRS)			functioning for the SC group.	
	Psychosocial Functioning (C-GAS)	Cohen's d= 1.7	Large		

References/ Country/ <i>N</i>	Outcome measures	<b>Effect Size</b> (Cohen's d)	* <b>Descriptor</b> (Cohen, 1992)	Main Findings	WoE D
Muller et al. (2020) Germany Intervention (N) CBTpA+TAU, n=13 Comparison Group(s) (N)	Between Groups: CBT+TAU vs TAU         Pre-treatment to post-treatment (9 months):         PANSS - negative subscale         Delusions (PSYRATS)         Depression (CDSS)         Functioning (GAF)         Quality of life (MSQoL-R)         Pre-treatment to 2-year follow up:         PANSS - negative subscale         "Material quality of life" subscale	Cohen's d= 0.39 Cohen's d= 0.46 Cohen's d= 0.31 Cohen's d= 0.44 Cohen's d= 0.39 Cohen's d= 0.56 Cohen's d= 0.73	Small Small Small Small Small Medium Medium	Between-group effect sizes at post-treatment were trivial (d= 0.04) for the PANSS-positive subscale and lacked statistical significance. However, small between-group effect sizes in favour of CBT+TAU were seen for the PANSS negative subscale, delusions, depression, psychosocial functioning and QoL.Between-group effect sizes at 2- year follow up were still trivial (d=	
TAU, n=12	(MSQoL-R) Auditory hallucinations (PSYRATS) Functioning (GAF) Quality of life (MSQoL-R) Within CBT Group <u>Pre-treatment to post-treatment (9</u> <u>months):</u> PANSS - positive subscale PANSS - negative subscale Auditory Hallucinations (PSYRATS) Delusions (PSYRATS) Depression (CDSS)	Cohen's d= 0.38 Cohen's d= 0.35 Cohen's d= 0.43 Cohen's d= 0.61 Cohen's d= 0.41 Cohen's d= 0.54 Cohen's d= 0.92 Cohen's d= 0.33	Small Small Small Medium Small Medium Large Small	<ul> <li>0.02) for the PANSS-positive subscale and lacked statistical significance. However, small between-group effect sizes in favour of CBT+TAU were seen for the "material quality of life" subscale, the PANSS negative subscale, auditory hallucinations, depression, psychosocial functioning and QoL.</li> <li>Large within group effect sizes were seen in both groups</li> </ul>	2.55 - High
	Functioning (GAF) Quality of life (MSQoL-R) <u>Pre-treatment to 2-year follow up:</u> PANSS - positive subscale PANSS - negative subscale Auditory Hallucinations (PSYRATS) Delusions (PSYRATS) Depression (CDSS) Functioning (GAF) Quality of life (MSQoL-R)	Cohen's d= 1.20 Cohen's d= 0.68 Cohen's d= 0.45 Cohen's d= 0.45 Cohen's d= 0.47 Cohen's d= 0.57 Cohen's d= 0.32 Cohen's d= 1.37 Cohen's d= 0.81	Large Medium Small Small Medium Small Large Large	were seen in bour groups	

References/ Country/ N	Outcome measures	Effect Size (Cohen's d)*Descriptor (Cohen, 1992)		' Main Fingings		WoE D	
Morrison et al. (2020)	**Within group Pre-treatment to end of treatment	CBT+OFI	CBT+OFI+meds			There were no significant <b>between</b> <b>group</b> differences in either positive or negative symptoms (PANNS) at	
U.K. Intervention (N)	(6 months): Psychotic and negative symptoms (PANNS)	Cohen's d= 1.11	Cohen's d= 0.90	Large	Large	6 months, indicating no superiority of any treatment. At 12 months, CBT+OFI+meds showed slightly	
CBT+OFI, n=18	HADS-Depression HADS-Anxiety SPEQ-paranoia	Cohen's d= 0.61 Cohen's d= 0.39 Cohen's d= 0.60	Cohen's d= 0.72 Cohen's d= 0.73 Cohen's d= 1.22	Medium Small Medium	Medium Medium Large	higher improvement in PANNS symptoms compare to CBT+OFI only.	
Comparison Group(s) (N)	SPEQ-hallucinations	Cohen's d= 1.27	Cohen's $d= 1.22$ Cohen's $d= 2.25$	Large	Large	Within group improvements in	2.44 - Medium
Antipsychotic monotherapy	Pre-treatment to 1 year follow up: Psychotic and negative symptoms (PANNS)	Cohen's d= 1.07	Cohen's d= 1.40	Large	Large	PANNS were seen for all treatment groups at 6 and 12 months, with improvements seen in remaining	
(meds), n=22	HADS-Depression HADS-Anxiety	Cohen's d= 1.12 Cohen's d= 1.14	Cohen's d= 1.17 Cohen's d= 1.95	Large Large	Large Large	outcome measures too	
CBT+OFI+meds, n=21	SPEQ-paranoia SPEQ-hallucinations	Cohen's d= 0.33 Cohen's d= 1.14	Cohen's d= 1.64 Cohen's d= 2.80	Small Large	Large Large		

References/ Country/ <i>N</i>	Outcome measures	<b>Effect Size</b> (Cohen's d)	* <b>Descriptor</b> (Cohen, 1992)	Main Findings	WoE D
Jackson et al. (2008)	Between Groups: ACE vs BF			Between Group: ACE outperformed Befriending by	
Australia	Pre-treatment to mid-treatment (6 weeks): Functioning (SOFAS)	Cohen's d= 0.5	Medium	lowering negative and positive symptoms of psychosis and	
Intervention (N)	Positive Symptoms (BPRS) Negative Symptoms (SANS)	Cohen's d= 0.23 Cohen's d= 0.28	Small Small	improving functioning at mid- treatment, and to a smaller extent lower negative symptoms and	
ACE+TAU, n=31	Pre-treatment to end of treatment			improve functioning at end of treatment	
Comparison Group(s) (N)	( <u>12 weeks):</u> Functioning (SOFAS) Negative Symptoms (SANS)	Cohen's d=0.39 Cohen's d= 0.18	Small Small	Following the mid-treatment stage,	
BF+TAU, n=31	**Within ACE Group			Befriending caught up with the ACE group and there were no significant differences in any outcome	
	Pre-treatment to mid-treatment (6 weeks):			measures at 1-year follow-up	2.49 - High
	Functioning (SOFAS)	Cohen's d= 0.76	Medium		-
	Positive Symptoms (BPRS)	Cohen's d= 1.15	Large		
	Negative Symptoms (SANS)	Cohen's d= 0.56	Medium		
	Pre-treatment to end of treatment (12 weeks):				
	Functioning (SOFAS)	Cohen's d= 0.82	Large		
	Positive Symptoms (BPRS)	Cohen's d= 1.02	Large		
	Negative Symptoms (SANS)	Cohen's d= 0.44	Small		
	Pre-treatment to follow-up (1-year):				
	Functioning (SOFAS)	Cohen's d= 0.89	Large		
	Positive Symptoms (BPRS)	Cohen's d= 1.08	Large		
	Negative Symptoms (SANS)	Cohen's d= 0.69	Medium		

References/ Country/ N	Outcome measures	Effect Size (Cohen's d)		* <b>Descriptor</b> (Cohen, 1992)		Main Findings	WoE D
Francey et al. (2020)	**Within group Pre-treatment to post-treatment (6	CBMC+meds	CBMC+placebo			Both with and without medication CBT groups improved in their functioning post-treatment (6	
Australia	<u>months)</u> : Functioning (SOFAS)	Cohen's d= 0.63	Cohen's d= 0.48	Medium	Small	months), including on all measures of psychopathology.	
Intervention (N)	Quality of Life (QLS) Positive symptoms (BPRS-4)	Cohen's d= 0.16 Cohen's d= 1.36	Cohen's d= 0.33 Cohen's d= 2.25	Small Large	Small Large		
CBCM+placebo, n=46	Negative symptoms (SANS) HAMD-Depression HAM-Anxiety	Cohen's d= 0.43 Cohen's d= 0.93 Cohen's d= 0.72	Cohen's d= 0.46 Cohen's d= 0.79 Cohen's d= 0.99	Small Large Large	Small Medium Large	No <b>between group differences</b> were seen to indicate a discernible advantage to receiving medication.	
Comparison Group(s) (N)	Pre-treatment to follow-up (12 months):					No between group differences at 12 and 24 months, with the exception	
CBCM+meds, n=44	Functioning (SOFAS) Quality of Life (QLS)	Cohen's d= 0.87 Cohen's d= 0.76	Cohen's d= 0.46 Cohen's d= 0.46	Large Large	Small Small	of negative symptoms at 12 months where the medication group had significantly less symptoms.	2.44 - Medium
	Positive symptoms (BPRS-4) Negative symptoms (SANS) HAMD-Depression	Cohen's d= 1.97 Cohen's d= 0.97 Cohen's d= 1.35	Cohen's d= 1.83 Cohen's d= 0.45 Cohen's d= 0.93	Large Large	Large Small	significantly iess symptoms.	
	HAM-Anxiety	Cohen's d= 1.35 Cohen's d= 1.43	Cohen's $d= 1.12$	Large Large	Large Large		
	Pre-treatment to follow-up (2-years): Functioning (SOFAS)	Cohen's d= 1.10	Cohen's d= 0.72	Large	Medium		
	Quality of Life (QLS) Positive symptoms (BPRS-4)	Cohen's d= 0.80 Cohen's d= 1.97	Cohen's d= 0.72 Cohen's d= 2.16	Large Large	Medium Large		
	Negative symptoms (SANS) HAMD-Depression HAM-Anxiety	Cohen's $d = 0.84$ Cohen's $d = 1.50$ Cohen's $d = 1.19$	Cohen's d= 0.74 Cohen's d= 0.97 Cohen's d= 1.04	Large Large	Medium Large		
				Large	Large		

\*Note: Effect size descriptors can be found in Appendix D

\*\* Cohen's *d* calculated by author as not reported in article. Calculation details found in Appendix C

SC=Standard Care, CBTpA=Cognitive Behavioural Therapy for Adolescents with Psychosis, FTpA=Family Therapy for Adolescents with Psychosis, BPRS=Brief Psychiatric Rating, Scale, GoGAS; Cobal Assessment Scale, SCID-PD=Structured Clinical Interview for DSM-5 Personality Disorders, TAW=Treatment As Usual, CBT=cognitive behavioral therapy, PANSS-POS=positive and negative syndrome scale-positive scale, PANSS-NEG= positive and negative syndrome scalenegative scale, PSYRATS= Psychotic Symptoms Rating Scales, CDSS=Calgary Depression Scale for Schizophrenia, GAF=Global assessment of functioning scale, MSQoL=Modular System for Quality of Life, OFI= Optional Family Intervention SPEQ= Specific Psychotic Experiences Questionnaire, HADS= Hospital Anxiety and Depression Scale, ACE= Active Cognitive Therapy, BF= Befriending, SANS=Scale for the Assessment of Negative Symptoms, SOFAS= Social and Occupational Functioning Scale, CBCM= Cognitive Behavioural Case Management, QLS= Heinrich Quality of Life Scale, HAMD-Depression= Hamilton Depression Scale, HAM-Anxiety= Hamilton Anxiety Scale

## 4. Conclusions and Recommendations

To our knowledge this is the first systematic literature review looking into CBTp efficacy in people under the age of 25. Previous reviews of RCT in CYP with psychosis have looked into psychosocial interventions in general, with one review (Stafford et al., 2015) not identifying any trials at the time, while the other (Anagnostopoulou et al., 2019) only identifying one trial on CBT (Browning et al., 2013). Our review provides positive but preliminary evidence on CBTp efficacy on psychosis and functioning in CYP under the age of 25.

Within-group improvements in functioning and psychopathology were seen post CBT treatment in all five trials, with effect sizes ranging from small to large. Where followup data were collected, intervention effects were still evident at one- and two-year timepoints, however attrition rates were high in two of the four trials adopting a followup design (Francey et al., 2020; Morrison et al., 2020) therefore this data should be interpreted with caution. Between-group data were also promising. CBT+TAU was found to be superior to standard care in two trials (Browning et al., 2013; Muller et al., 2020) and superior in improving functioning and lowering negative symptoms post-treatment when compared to a psychological intervention (Jackson et al., 2008). Findings however were mixed, with no significant between-group differences seen in positive or negative symptoms post-treatment in Morrison et al. (2020) nor in functioning and psychotic symptoms in Francey et al. (2020).

Though the latter two trials did not find any between-group differences when comparing CBT to their comparison groups (CBT+AP or AP only), they did however provide valuable preliminary data against the conventional wisdom that antipsychotics should be used in all cases of psychosis. Indeed, their within-group data showed that

#### Doctorate in Educational and Child Psychology

#### Maria Megalogeni

CBTp without antipsychotic medication can be effective in reducing psychotic symptoms and improve functioning in some young people with psychosis following treatment, with small to large effect sizes still evident at follow-up. Though further safety and efficacy trials replicating this data are undoubtedly needed, managing psychosis through non-pharmacological interventions would perhaps be a welcome option for many. Antipsychotic medication use in CYP is currently associated with a range of adverse effects such as weight gain (Correll et al., 2009), stigma (Murphy et al., 2015), cardiovascular risk and movement disorders (Haddad & Sharma, 2007), while their risk-benefit ratio has been found to be poor (Stafford et al., 2015).

Given differences such as length of intervention exposure, participant characteristics and of course sample size between the trials, there was heterogeneity in both effect sizes and sustainability of treatment effect across the studies. For example, while in Jackson et al. (2008) between-group effect sizes in favour of ACE did not last beyond mid-treatment, this was not the case in Muller et al. (2020) where effects lasted beyond CBT therapy. Furthermore, CBTp appeared to have a larger effect on functioning in Muller et al. (2020) compared to Browning et al. (2013). These differences could be attributed to a number of factors such as the different focus of the CBT protocols used in each trial (i.e. one may have focused more on positive symptoms, while another on functioning), heterogeneity in participant comorbidities and severity of psychosis, and of course the duration of treatment exposure. While participants in the Browning et al. (2013) trial were exposed to treatment for approximately two months, CBT therapy in Muller et al. (2020) lasted nine months. Future trials in this area should take this heterogeneity into consideration, and questions in relation to the optimal number and duration of CBT sessions depending on participant comorbidity and symptom severity should be addressed.

NICE guidelines (2016) recommend a combined treatment of antipsychotic medication and psychological intervention (CBT and family intervention) for CYP with psychosis. Given the significant lack of evidence from non-adult populations, they also call for research in this area. The review provides preliminary evidence that CBTp can augment standard care and benefit CYP under the age of 25 who are experiencing psychosis. Given methodological limitations such as the small sample size of each reviewed trial, we conclude that these results are not yet generalisable, and suggest that larger scale, efficacy powered RCTs on CBTp in those under the age of 25 are conducted. Given the current constraints seen in CAMHS and EIP services in the UK (HQIP, 2016), the importance of early intervention and the stigma connected to receiving a psychosis diagnosis (Murphy et al. 2015), CBTp trained EPs can play a valuable role enhancing multidisciplinary treatment, while offering therapeutic support in an environment considered non-stigmatizing; the school (DfE, 2016). Though CBT can be delivered outside the clinic, feasibility alongside efficacy testing of CBTp in the educational setting would first need to take place.

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Zavos, H. M., Freeman, D., Haworth, C. M., McGuire, P., Plomin, R., Cardno, A. G., & Ronald, A. (2014). Consistent etiology of severe, frequent psychotic experiences and milder, less frequent manifestations: a twin study of specific psychotic experiences in adolescence. *JAMA Psychiatry*, *71*(9), 1049–1057.

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# Appendix A

# **Excluded Trials**

Due to the large number (>100) of trials that could not be screened by title and abstract

only, a small number of trials excluded following full text screening are offered as an

example, below.

# Table 1: List of Trials Excluded at Full Text Screening

<b>Reference</b> Singer, A. R., Addington, D. E., Dobson, K. S., & Wright, C. (2014). A pilot study of cognitive behavior therapy for depression in early psychosis. <i>Cognitive and Behavioral Practice</i> , <i>21</i> (3), 323–334. <u>https://doi.org/10.1016/j.cbpra.2013.08.004</u>	<b>Exclusion Criterion</b> 2 Study did not adopt an RCT design
Chung, Y., Yoon, K., Park, T., & Yang, J., & Oh, K. (2013). Group Cognitive- Behavioral Therapy for Early Psychosis. <i>Cognitive Therapy and Research,</i> <i>37,</i> 403-11. 10.1007/s10608-012-9460-9	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Fowler, D., Hodgekins, J., Painter, M., Reilly, T., Crane, C., Macmillan, I., Jones, P. (2009). Cognitive behaviour therapy for improving social recovery in psychosis: A report from the ISREP MRC Trial Platform study (Improving Social Recovery in Early Psychosis). <i>Psychological Medicine,</i> <i>39</i> (10), 1627-1636. doi:10.1017/S0033291709005467	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Drake, R. J., Day, C. J., Picucci, R., Warburton, J., Larkin, W., Husain, N., Reeder, C., Wykes, T., & Marshall, M. (2014). A naturalistic, randomized, controlled trial combining cognitive remediation with cognitive- behavioural therapy after first-episode non-affective psychosis. <i>Psychological Medicine</i> , 44(9), 1889–1899. <u>https://doi.org/10.1017/S0033291713002559</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest

Sönmez, N., Romm, K. L., Østefjells, T., Grande, M., Jensen, L. H., Hummelen, B., Tesli, M., Melle, I., & Røssberg, J. I. (2020). Cognitive behavior therapy in early psychosis with a focus on depression and low self-esteem: A randomized controlled trial. <i>Comprehensive Psychiatry</i> , <i>97</i> , 152157. <u>https://doi.org/10.1016/j.comppsych.2019.152157</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Lepage, M., Bowie, C., Montreuil, T., Baer, L., Percie du Sert, O., Lecomte, T., & Malla, A. (2022). Manualized group cognitive behavioral therapy for social anxiety in first-episode psychosis: A randomized controlled trial. <i>Psychological Medicine</i> , 1-10. doi:10.1017/S0033291721005328	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Kumari, V., Premkumar, P., Fannon, D., Aasen, I., Raghuvanshi, S., Anilkumar, A. P., Antonova, E., Peters, E. R., & Kuipers, E. (2012). Sensorimotor gating and clinical outcome following cognitive behaviour therapy for psychosis. <i>Schizophrenia Research</i> , <i>134</i> (2-3), 232–238. <u>https://doi.org/10.1016/j.schres.2011.11.020</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Steel, C., Hardy, A., Smith, B., Wykes, T., Rose, S., Enright, S., Hardcastle, M., Landau, S., Baksh, M. F., Gottlieb, J. D., Rose, D., & Mueser, K. T. (2017). Cognitive-behaviour therapy for post-traumatic stress in schizophrenia. A randomized controlled trial. <i>Psychological Medicine</i> , <i>47</i> (1), 43–51. <u>https://doi.org/10.1017/S0033291716002117</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Tarrier, N., Yusupoff, L., Kinney, C., McCarthy, E., Gledhill, A., Haddock, G., & Morris, J. (1998). Randomised controlled trial of intensive cognitive behaviour therapy for patients with chronic schizophrenia. <i>BMJ (Clinical research ed.), 317</i> (7154), 303–307. https://doi.org/10.1136/bmj.317.7154.303	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Vallina-Fernández, O., Lemos-Giráldez, S., Roder, V., García-Saiz, A., Otero-García, A., Alonso-Sánchez, M., & Gutiérrez-Pérez, A. M. (2001). Controlled study of an integrated psychological intervention in schizophrenia. <i>The European Journal of Psychiatry, 15</i> (3), 167–179.	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest

Haddock, G., Tarrier, N., Morrison, A. P., Hopkins, R., Drake, R., & Lewis, S. (1999). A pilot study evaluating the effectiveness of individual inpatient cognitive-behavioural therapy in early psychosis. <i>Social</i> <i>psychiatry and Psychiatric Epidemiology</i> , <i>34</i> (5), 254–258. <u>https://doi.org/10.1007/s001270050141</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Granholm, E., Loh, C., Link, P., & Jeste, D. (2010). Feasibility of Implementing Cognitive Behavioral Therapy for Psychosis on Assertive Community Treatment Teams: A Controlled Pilot Study. <i>International</i> <i>Journal of Cognitive Therapy, 3,</i> 295-303. 10.1521/ijct.2010.3.3.295	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Husain, M. O., Chaudhry, I. B., Mehmood, N., Rehman, R. U., Kazmi, A., Hamirani, M., Kiran, T., Bukhsh, A., Bassett, P., Husain, M. I., Naeem, F., & Husain, N. (2017). Pilot randomised controlled trial of culturally adapted cognitive behavior therapy for psychosis (CaCBTp) in Pakistan. <i>BMC Health Services Research</i> , <i>17</i> (1), 808. <u>https://doi.org/10.1186/s12913-017-2740-z</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Farhall, J., Freeman, N. C., Shawyer, F., & Trauer, T. (2009). An effectiveness trial of cognitive behaviour therapy in a representative sample of outpatients with psychosis. <i>The British Journal of Clinical Psychology</i> , <i>48</i> (1), 47–62. <u>https://doi.org/10.1111/j.2044-8260.2009.tb00456.x</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Husain, M. O., Chaudhry, I. B., Mehmood, N., Rehman, R. U., Kazmi, A., Hamirani, M., Kiran, T., Bukhsh, A., Bassett, P., Husain, M. I., Naeem, F., & Husain, N. (2017). Pilot randomised controlled trial of culturally adapted cognitive behavior therapy for psychosis (CaCBTp) in Pakistan. <i>BMC Health Services Research</i> , <i>17</i> (1), 808. <u>https://doi.org/10.1186/s12913-017-2740-z</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest

O'Donoghue, B., Francey, S. M., Nelson, B., Ratheesh, A., Allott, K., Graham, J., Baldwin, L., Alvarez-Jimenez, M., Thompson, A., Fornito, A., Polari, A., Berk, M., Macneil, C., Crisp, K., Pantelis, C., Yuen, H. P., Harrigan, S., & McGorry, P. (2019). Staged treatment and acceptability guidelines in early psychosis study (STAGES): A randomized placebo controlled trial of intensive psychosocial treatment plus or minus antipsychotic medication for first-episode psychosis with low-risk of self- harm or aggression. Study protocol and baseline characteristics of participants. <i>Early Intervention in Psychiatry, 13</i> (4), 953–960. <u>https://doi.org/10.1111/eip.12716</u>	7 No data yet available from study
Peters, E., Landau, S., McCrone, P., Cooke, M., Fisher, P., Steel, C., Evans, R., Carswell, K., Dawson, K., Williams, S., Howard, A., & Kuipers, E. (2010). A randomised controlled trial of cognitive behaviour therapy for psychosis in a routine clinical service. <i>Acta Psychiatrica Scandinavica,</i> <i>122</i> (4), 302–318. <u>https://doi.org/10.1111/j.1600-0447.2010.01572.x</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Turkington, D., Kingdon, D., Turner, T., & Insight into Schizophrenia Research Group (2002). Effectiveness of a brief cognitive-behavioural therapy intervention in the treatment of schizophrenia. <i>The British</i> <i>Journal of Psychiatry, 180</i> , 523–527. <u>https://doi.org/10.1192/bjp.180.6.523</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest
Dellazizzo, L., Potvin, S., Phraxayavong, K., & Dumais, A. (2020). Exploring the Benefits of Virtual Reality-Assisted Therapy Following Cognitive- Behavioral Therapy for Auditory Hallucinations in Patients with Treatment-Resistant Schizophrenia: A Proof of Concept. <i>Journal of</i> <i>Clinical Medicine</i> , <i>9</i> (10), 3169. MDPI AG. Retrieved from <u>http://dx.doi.org/10.3390/jcm9103169</u>	5 Article contains data from participants over the age of 25 that cannot be removed from age group of interest

# Appendix B

### Weight of Evidence A: Methodological Quality Criteria

### Table 1. Summary of the Jadad Scoring Scale (Jadad et al., 1996)

1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)?

2. Was the study described as double blind?

3. Was there a description of withdrawals and dropouts?

#### Scoring the items:

#### Either give a score of 1 point for each "yes" or 0 points for each "no". There are no in-between marks.

Give 1 additional point if:	For question 1 the method to generate the sequence of randomisation was described <b>and</b> it was <b>appropriate</b> (table of random numbers, computer generated, coin tossing, etc).
and / or:	If for question 2 the method of double-blinding was described <b>and</b> it was <b>appropriate</b> (identical placebo, active placebo, dummy, etc).
Deduct 1 point if:	For question 1 the method to generate the sequence of randomisation was described <b>and</b> it was <b>inappropriate</b> (patients were allocated alternately, or according to date of birth, hospital number, etc).
and / or:	For question 2 the study was described as double-blind but the method of blinding was <b>inappropriate</b> (e.g., comparison of tablet vs. injection with no double dummy).

#### **Guidelines for Assessment**

#### 1. Randomisation

A method to generate the sequence of randomisation will be regarded as appropriate if it allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which treatment was next. Methods of allocation using date of birth, date of admission, hospital numbers or alternation should not be regarded as appropriate.

#### 2. Double-blinding

A study must be regarded as double-blind if the word double-blind is used. The method will be regarded as appropriate if it is stated that neither the person doing the assessments nor the study participant could identify the intervention being assessed, or if in the absence of such a statement, the use of active placebos, identical placebos or dummies is mentioned.

#### 3. Withdrawals and drop outs

Participants who were included in the study but did not complete the observation period or who were not included in the analysis must be described. The number **and** the reasons for withdrawal must be stated. If there were no withdrawals, it should be stated in the article. If there is no statement on withdrawals, this item must be given no points.

**Note**: A Jadad score of  $\leq 2$  qualifies as a low quality, a score of 3 qualifies as adequate (medium) quality, while a score of  $\geq 4$  qualifies as a high quality study.

### Table 2. Weight of Evidence A: Jadad Score Across Studies

ltem	Browning et al. (2013)	Francey et al. (2020)	Jackson et al. (2008)	Morrison et al. (2020)	Muller et al. (2020)
Was the study described as randomized (this includes words such as randomly, random, and randomization)?	1	1	1	1	1
Was the method used to generate the sequence of randomization described and appropriate (table of random numbers, computer-generated, etc)?	0	1	1	1	1
Was the study described as double blind?	0	1	0	0	0
Was the method of double blinding described and appropriate (identical placebo, active placebo, dummy, etc)?	0	1	0	0	0
Was there a description of withdrawals and	1	1	1	1	1
dropouts?					
Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (e.g. patients were allocated alternately, or according to date of birth, hospital number).	-1	0	0	0	0
Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g. comparison of tablet vs. injection with no double dummy).	0	0	0	0	0
*Jadad Score=	1 - low	5 - High	3 - Medium	3 - Medium	3 - Medium
<u>Note</u> ≤2: low					
3: medium					
≥4: high					
Weight of Evidence A Score= *To allow for a WoE D estimate to be calculated, Jadad evaluations of <i>low, medium and high</i> were converted to WoE A numerical scores of 1, 2 and 3 respectively	1 - Low	3 - High	2 - Medium	2 - Medium	2 - Medium

# Weight of Evidence B: Methodological Relevance Criteria

# Table 3. Weight of Evidence B: Evaluation criteria for the methodological relevance of each study to the review question

Criteria	Low - 1	Medium - 2	High - 3	Rationale
Study design	Non experimental design	Quasi- experimental or cohort study with no randomization to groups	Randomised Controlled Trial	RCTs were favoured as randomisation minimises bias and they are the gold standard for effectiveness research (Hariton & Locascio, 2018)

Comparisons	Single group design with no control group	At least one 'no intervention' comparison group (i.e. on waiting list)	A minimum of one 'active' comparison group receiving an alternative intervention or attention placebo (i.e. standard care)	This allows for an estimation of change caused by regression to the mean and the control of variables not related to the intervention (Barnett et al., 2005)
Implementation of the Intervention	Limited or no information offered on quality of and fidelity to intervention	Fidelity to or quality of intervention (CBT) is captured and described	Fidelity to and quality of intervention (CBT) is captured and described	Inconsistent implementation and inaccurate treatment delivery will lead to ambiguous interpretations of research findings (Gersten et al., 2005)
Data Collection Timepoints	Outcome measures are taken at pre- and post-treatment but they may not be parallel forms	Parallel forms of outcome measures are taken pre- and post-treatment but there is no follow- up	Parallel forms of outcome measures are taken pre- and post-treatment, including at follow-up	This allows researchers to compare groups and capture true intervention effects, including whether intervention effects last over time (Baldwin, 2018)
Rater Bias	Administered by assessor with role in CBT delivery and not blind to treatment allocation OR no information provided	Administered by assessor independent of CBT delivery but not blind to treatment allocation	Administered by assessor independent of CBT delivery and blind to treatment allocation	Blinded outcome assessment is recommended in open- "label" trials to reduce rater bias influencing study findings (Kahan, 2014)
Data analysis	Study was not powered for efficacy testing but had high attrition data at post-treatment and/ or follow-up data (where applicable)	Study was not powered for efficacy testing but had no or low attrition data for post-treatment and follow-up data (where applicable)	Power analysis has taken place and study was appropriately powered for efficacy testing with no or low attrition data	The likelihood of a true effect being detected (should it exist) increases in sufficiently powered trials (Jones et al., 2003)

Criteria	Browning et al. (2013)	Francey et al. (2020)	Jackson et al. (2008)	Morrison et al. (2020)	Muller et al (2020)
Study design	3	3	3	3	3
Comparisons	3	3	3	3	3
Implementation of the Intervention	1	2	3	3	2
Data Collection Timepoints	2	3	3	3	3
Rater Bias	2	2	3	3	3
Data analysis	2	1	2	1	2
Weight of Evidence B Score:	- 2.16 - Medium	2.33 - Medium	2.83 - High	2.66 - High	2.66 - High
<u>Note</u> ≤1.4: low					
1.5 - 2.4: medium					
≥2.5: high					

### Table 4: Weight of Evidence B Score across studies

# Weight of Evidence C: Topic Relevance Criteria

Table 5. Weight of Evidence C: Evaluation criteria for the topic relevance of each study to the review question

Criteria	Low - 1	Medium - 2	High - 3	Rationale
Participant characteristics	Limited demographic, illness and therapy data provided	Demographic, illness and therapy data provided	Detailed demographic, illness and therapy data provided	Intervention effects can be attributed to the intervention rather than to external factors. Results can be generalised to other populations were participant characteristics are clear
Therapists	No information provided on therapist(s) CBT training	CBT based intervention delivered by individual in training and supervised by trained therapist	CBT based intervention delivered by trained therapist	Correct delivery of the intervention allows for a true investigation of intervention effect(s)
Intervention model	Limited or no information provided on the CBT intervention model used	CBT intervention model is described and based on an evidence-based protocol tailored to the needs of people with psychosis but not CYP	CBT intervention model is described and based on an evidence-based protocol that has been adapted to the needs of CYP people with psychosis	A thorough description of an effective CBTp model for CYP offers ease of intervention adoption and replicability by other trialists or therapists

			-		
Criteria	Browning et al. (2013)	Francey et al. (2020)	Jackson et al. (2008)	Morrison et al. (2020)	Muller et al. (2020)
*Participant characteristics	1	2	3	3	3
Therapists	1	2	3	3	3
Intervention model	3	2	2	2	3
Weight of Evidence C Score	- 1.66 - Medium	2 - Medium	2.66 - High	2.66 - High	3 - High
<u>Note</u> ≤1.4: low					
1.5 - 2.4: medium					
≥2.5: high					

### Table 6. Weight of Evidence C score across studies

\*See Table 7 for a description of participant characteristics and the calculation of average scores

### Table 7: Participant Characteristics across the studies

	Browning et al. (2013)	Francey et al. (2020)	Jackson et al. (2008)	Morrison et al. (2020)	Muller et al. (2020)
Participant Characteristics					
Psychosis diagnosis	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Psychotic symptoms active upon study entry	✓	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Age	√	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Gender	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Ethnicity			$\checkmark$	$\checkmark$	
Psychosis due to a medical condition			$\checkmark$	$\checkmark$	$\checkmark$
Substance-induced psychosis		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Treatment from private psychiatrist/psychologist			$\checkmark$	$\checkmark$	$\checkmark$
Dose of antipsychotic medication (where relevant)		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
CBT adherence data		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Education Status		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Total:	4	8	11	11	10
<b>Score:</b> 0-4 = low 1	1 - Low	2 - Medium	3 - High	3 - High	3 - High

5-8 = medium 2

9-11 = high 3

# Appendix C

### Formulae

The following formulae, taken from Cohen's (1988) calculations, were used to calculate effect sizes in trials where the aforementioned data was not provided.

Cohen's  $d = (M_2 - M_1) / SD_{pooled}$ 

SDpooled=  $\sqrt{[(s_1^2 + s_2^2) / 2]}$ 

For within group calculations where sample sizes changed over time due to participant withdrawals or drop-outs, the <u>Psychometrica</u> calculator was used to adjust the calculation of the pooled standard deviation with weights for the sample sizes.

# Appendix D

Table 1. Cohen's <i>d</i> Effect Size Thresholds (Cohen, 1992)	
Effect Size	Descriptor
0.2 0.5 0.8	Small Medium Large