A randomised controlled trial of Acceptance and Commitment Therapy for anxious adolescents: Effectiveness and mechanisms for change

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Thesis by publication

This Doctor of Philosophy (PhD; Clinical Psychology) dissertation reflects a "thesis by publication" submission to The University of Newcastle, NSW, Australia. The Rules Governing Research Higher Degrees (Rule 000830) allow for a thesis to be submitted in the form of a series of published papers. The details of the thesis by publication rules are provided at Appendix A. This thesis submission follows the formatting guidelines provided therein.

Statement of collaboration/authorship

I hereby certify that this thesis is submitted in the form of a series of published papers of which I am a joint author. The PhD research formed part of a large randomised controlled trial conducted in collaboration with other researchers, and carried out at The Children's Hospital Westmead (CHW), Sydney, NSW, Australia. The major components of the research project involved recruitment, data collection, structured clinical interviewing and assessment (at three time points), delivery of group therapy, statistical analysis and write up. As the PhD student involved with a small team of researchers, I undertook a key role in all aforementioned components of the research. This involved assuming a lead role in recruitment drives to maximise identification of suitable adolescent participants, assessment of children/adolescents and their parents at all three time points, as well as taking the co-therapist and lead therapist role across two group therapy programs; Acceptance and Commitment Treatment (ACT) and Cognitive Behavioural Therapy (CBT). I was also active in formulating statistical planning and consulting with CHW Biostatistician to ensure the appropriateness of the planned analyses, the lead author in four of the five publications included within this thesis, and second author on the remaining paper. Included at Appendix B is a written statement from each co-author, endorsed by the Faculty Assistant Dean (Research Training), attesting to my contribution to the joint publications.

Statement of originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and – notwithstanding the collaborations described above – to the best of my knowledge and belief, contains no material previously

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published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968, following an Embargo period of twelve months to allow for the final journal articles to be published ahead of this thesis being made available.

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Swain, J., Hancock, K., Hainsworth, C. & Bowman, J. (2014*).* Mechanisms of change: Exploratory outcomes from a randomised controlled trial of Acceptance and Commitment Therapy for anxious adolescents. *Journal of Contextual Behaviour Science.* Advance online publication. http://dx.doi.org/10.1016/j.jcbs.2014.09.001

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Swain, J., Hancock, K., Dixon, A., & Bowman, J. (2014). *Acceptance and Commitment Therapy for children: A systematic review of intervention studies.* Manuscript submitted for publication.

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Contents

Précis

The conduct of a randomised controlled trial (RCT) at The Children's Hospital Westmead (CHW), Sydney, NSW, Australia, is central to the research reported within this PhD thesis. This trial aims to examine the effectiveness of Acceptance and Commitment Therapy (ACT) and traditional Cognitive Behaviour Therapy (CBT), relative to a waitlist control (WLC), in the treatment of anxiety disorders among children aged 7-17 years. The PhD research reported focuses on a subgroup of the participants within this trial; adolescents (aged 12-17 years). The overarching objective of the thesis is to examine the utility of ACT in the treatment of adolescent anxiety and to conduct and exploratory evaluation of the elements of the intervention that operate as mechanisms for change among these participants.

The PhD thesis by publication is comprised of an *Introductory overview*, five chapters – each comprised of an original journal article – and a *Concluding statement*. The *Introductory overview* aims to contextualise the papers within an established body of knowledge. The prevalence and impact of anxiety disorders for children is explored alongside the psychological interventions available for children with anxiety disorders. The current status and limitations of CBT as the first-line evidence based intervention for anxiety disorders is discussed; tempered by the lack of evidence for alternative interventions. ACT is introduced as a "third wave" behaviour therapy. Its underpinning philosophy of science (functional contextualism), theory (relational frame theory), as well as the ACT hexaflex model of psychological flexibility are explored, with reference to the application of ACT approaches to anxiety. The similarities and differences of ACT and CBT as two therapeutic modalities falling under the greater behavioural and cognitive therapy umbrella are reviewed, with reference to their divergent theoretical underpinnings and emphasised outcomes. The existing evidence (ahead of current research) for treating children with anxiety with ACT is explored; considering the impact of therapeutic format (individual, group or family focused) on outcomes. The thesis establishes the importance of providing an empirical account for the basis of psychotherapeutic effects – the "mechanisms of change" – to foster parsimonious clinical practice and optimise the sensitivity and specificity of interventions. From an exploratory study perspective, it elucidates the need to identify mediators of change, as an important precursor to identifying mechanisms.

Chapter 1 is comprised of a systematic review of the published and grey literature undertaken with the aim of examining the utility of ACT in the treatment of anxiety. Outcomes of interest include reductions in clinician- and self-report anxiety measures, diagnostic remission rates, clinically significant/statistically reliable change and long term treatment outcomes. A narrative synthesis approach is adopted to examine the methodological quality and results of 38 studies covering the spectrum of *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* anxiety disorders (alongside test and public speaking anxiety). This review identified only one published article on children (a case study) that was excluded from the review due to methodological inadequacies, highlighting the paucity of research evidence for this high prevalence condition among children.

An extension of the body of knowledge of ACT in the treatment of adult psychopathology is conducted in *Chapter 2* through a discussion of the adaptation and suitability of ACT techniques among child and adolescent populations. *Chapter 2* aims to examine the evidence for using ACT to treat children. A systematic review of published and unpublished child population literature is undertaken to support clinical decision making for the use of ACT. A narrative synthesis approach is employed for the 21 studies meeting inclusion criteria, with studies covering a spectrum of presenting problems. It also reports the results of a methodological quality assessment.

These early chapters set the scene for an overview of the full trial methodology and research protocol, provided in *Chapter 3*. This chapter describes the study design, participants, inclusion/exclusion criteria, procedure as well as main (clinical) outcomes, secondary (quality of life; QOL) outcomes, and putative mediator (process) variables/outcomes. It presents details of the interventions, including a session-by-session description of the ACT protocol designed at CHW as well as treatment fidelity assessment and statistical analysis approaches, including power calculations. *Chapter 4* reports the results of clinical and QOL outcomes of the RCT of the three groups (ACT, CBT and WLC). It reports changes in clinician-, self- and parent-reported clinical measures (anxiety, depression and child behaviour), QOL measures (anxiety

interference, self-efficacy as well as psychosocial and physical health-related QOL) and a measure of acceptance/defusion, gathered at pretreatment, posttreatment and 3-month follow-up (3MFU). Self-efficacy and psychosocial/physical QOL measures were limited to younger children (7-11 years) and, as such, are beyond the scope of the PhD investigation. Anxiety life interference was examined as the QOL outcome of interest among adolescents. Outcomes were only significantly different for younger children (aged 7-11 years) and adolescents (aged 12-17 years) on clinician-rated anxiety severity, in that adolescents evidenced higher mean clinical severity ratings. Despite this difference in severity, outcomes indicated the same pattern of results for younger children and adolescents in terms of main effects for group, time and the interaction. This is in line with a recent review that found no clinical or demographic factors moderated or predicted treatment outcome among children and adolescents (Nilsen, Eisemann, & Kvernmo, 2013). In light of these findings, and to increase statistical power, results for the full sample are presented with the exception of clinical severity ratings, which are presented by age. *Chapter 4* also discusses treatment adherence, credibility and therapist competency evaluations.

Upon establishment of significant changes at therapy cessation, *Chapter 5* provides a preliminary exploration of the ACT "mechanisms of change" for clinical and QOL outcomes. This is conducted via an analysis of theoretically postulated mediators of change, or process variables, which may statistically explain the relationship between therapy and outcome, among the adolescent participants. Research suggests ACT fosters psychological flexibility via six interrelational core processes – putative mediators of change – that form a "hexaflex" model: acceptance, defusion, mindfulness, self-as-context, committed action and valued living. The treatment specificity of these processes is examined through comparison of changes in these measures observed among ACT, CBT and WLC participants. Findings are discussed and contextualised within the existing mediation research conducted among adults with anxiety.

The *Concluding statement* draws together the key findings from each of the preceding chapters, as well as outlining limitations and future research directions. Finally, the *Appendices* include the aforementioned thesis by publication rules (Appendix A), the respective

"Statements from co-authors" for each of the five papers (Appendix B) and the complete ACT protocol "ProACTive" developed at CHW (Appendix C).

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Abstract

Anxiety disorders affect approximately 10-30% of children and adolescents. While traditional Cognitive Behaviour Therapy (CBT) is the first-line psychosocial treatment for children with anxiety, a significant proportion are nonresponsive or exhibit residual symptomatology at treatment cessation. Acceptance and Commitment Therapy (ACT) has been found to be effective among adults with anxiety disorders and children with other psychiatric conditions. ACT fosters psychological flexibility via putative mediators of change that form a "hexaflex" model: acceptance, defusion, mindfulness, self-as-context, committed action and valued living. This research examined ACT versus CBT in the treatment of anxiety disorders among children and adolescents. Among adolescents, an exploratory investigation of ACT mediators for change was undertaken. One-hundred-and-ninety-three children were block randomised to a manualised 10-week group format ACT or CBT program, or to waitlist control (WLC). Repeated clinical – clinician/self/parent-reported anxiety, depression and problem behaviours – and quality of life (QOL) measures – anxiety interference, psychosocial and physical health-related QOL – were taken pretreatment, posttreatment and 3-month follow-up (3MFU). Completers were 157 children, 58% female, with a mean age of 11 years ($SD = 2.8$). Completer and intention-to-treat (ITT) analyses revealed ACT and CBT were both superior to WLC across outcomes, reflecting statistically and clinically significant differences, with gains maintained at 3MFU. While WLC improved significantly on some outcomes at posttreatment, improvements were not clinically significant. Both completer and ITT analyses found ACT and CBT to produce similar outcomes. However, on ITT 3MFU results, CBT evidenced significantly lower scores on clinician-, but not self- or parent-reported outcomes. Mediation results were mixed. The hexaflex mediated the relationship between treatment and clinician-rated anxiety severity for ACT only; with treatment common effects observed for depression and self-reported anxiety. Acceptance and defusion emerged as specific mediators and evidenced the same pattern of effects, with clinician-rated anxiety effects treatment common. Hexaflex effects were accounted for by acceptance and defusion, as all other process measures were nonsignificant. Mediation analyses for parent-rated and QOL outcomes were nonsignificant. Few changes in process measures were observed post to 3MFU and mediation effects were nonsignificant. In conclusion, ACT and CBT are both effective in improving clinical and QOL outcomes among

children with anxiety. Despite mixed results, there was some evidence for acceptance and defusion as treatment common change mediators. Limited support was obtained for the hexaflex model, the processes of valued action and mindfulness/self-as-context and the treatment specificity of mediation effects. ACT may be a viable alternative evidence based treatment option for clinicians working with children with anxiety disorders. Despite their differences ACT and CBT may be underpinned by analogous mechanisms.

<div align="center">**Introductory overview**</div>

Anxiety disorders: Prevalence and impact among children and adolescents

Whilst fear may function as an adaptive response to threatening stimuli, some fears fail to dissipate with time, and instead are reinforced to persist well beyond their protective value (Ollendick, Grills, & Alexander, 2001). Childhood and adolescence has been described as a period of increased risk for the development of anxious symptoms and syndromes, which span from transient subclinical presentations to diagnosable anxiety disorders (Beesdo, Knappe, & Pine, 2009). Several studies have estimated the prevalence of anxiety disorders among children at 10-20% (American Psychiatric Association, 2000; Essau, Conradt, & Petermann, 2000; Semple & Lee, 2008) and as high as 30% among adolescents (Woodward & Fergusson, 2001). Despite this, young people with anxiety have been typically underrepresented in clinical research and anxiety in children is often minimised by health professionals. This is potentially due to a common perception that in this population anxiety is developmental, transient and innocuous (Hirshfeld-Becker et al., 2010; Piacentini & Roblek, 2002). While transitory fears in childhood have been associated with a typical developmental course (Carr, 2006) and many children diagnosed with an anxiety disorder achieve diagnostic remission (Essau, Conradt, & Petermann, 2002), research consistently demonstrates that for a large proportion of children, anxiety disorders follow a chronic course (e.g. Essau et al., 2002; Last, Perrin, Hersen, & Kazdin, 1996).

Adolescence is a period of rapid developmental change that includes physical maturation, neurological changes that support altered affect regulation, peer influence and intimacy in relationships (Cameron, 2004; Dahl, 2004; Wolfe & Mash, 2006). It is a vital period of transition from familial identification and dependence to individuation and autonomy (Dahl, 2004; Wolfe & Mash, 2006). Adolescent maturation, however, can contribute to the emergence of behavioural and emotional problems (Bokhorst & Westenberg, 2011; Oort, Greaves-Lord, Verhulst, Ormel, & Huizink, 2009). Estimates suggest approximately one in five adolescents have a psychiatric disorder with anxiety disorders found to be among the most prevalent diagnoses in adolescence, second only to drug abuse/dependence (Costello, Copeland, & Angold, 2011). A

recent review of 19 studies across 12 countries suggests the prevalence of psychiatric problems in young people may be rising (Bor, Dean, Najman, & Hayatbakhsh, 2014). This review identified comparatively increased depressive symptoms among adolescents compared a decade ago, with some studies finding 30-50% of adolescent girls experience anxiety and depression (Bor et al., 2014). Longitudinal evidence indicates that the trajectory of anxiety symptoms typically decreases in early adolescence and increases from middle to late adolescence (Oort et al., 2009). Others have found that diagnosis at an older age is associated with increased likelihood of anxiety persistence (Essau et al., 2002).

Problems of anxiety in children and adolescents in accordance with the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) include panic disorder and/or agoraphobia, specific phobia, social phobia, obsessive compulsive disorder, generalised anxiety disorder, posttraumatic stress disorder, and separation anxiety (American Psychiatric Association, 2000). Whilst each reflects a unique disorder, the anxiety disorders are typified by thoughts that are intrusive and/or disturbing, intense psychophysiological arousal, highly negative appraisals of private experience, and behavioural disturbances (e.g. Essau, Olaya, & Ollendick, 2012; Greeson & Brantley, 2008; P. C Kendall, Hedtke, & Aschenbrand, 2006). Anxiety disorder diagnoses are linked with high levels of internal distress, impaired emotional regulation, diminished self-esteem, and life interference in areas such as school functioning, leisure and socialisation (e.g. Brumariu, Obsuth, & Lyons-Ruth, 2012; Essau et al., 2000, 2002; Rapee, Schniering, & Hudson, 2009). Indeed, both prospective and retrospective studies have found that anxiety disorders in childhood and adolescence are associated with an increased likelihood of anxiety and/or other psychiatric disorders in later life (e.g. Essau et al., 2000; Rapee et al., 2009; Semple & Lee, 2008; Woodward & Fergusson, 2001) at a rate significantly greater than children and adolescents without such diagnoses (Last et al., 1996). Comorbidity of the anxiety disorders among children is also commonplace and some researchers have found that comorbidity increases the likelihood of poor outcomes in later life (Essau et al., 2002; Woodward & Fergusson, 2001). Findings are mixed as to whether comorbidity is predictive of treatment success (Compton et al., 2014; Kley, Heinrichs, Bender, & Tuschen-Caffier, 2012).

Treatment of anxiety among children: CBT the first line psychosocial approach

A substantial body of literature attests to the effectiveness of traditional CBT in improving clinical outcomes among children with anxiety in several RCTs as well as in naturalistic settings; referred to as the current first line psychosocial intervention (Butler, Chapman, Forman, & Beck, 2006; Compton et al., 2004; James, James, Cowdrey, Soler, & Choke, 2013; Reynolds, Wilson, Austin, & Hooper, 2012; Seligman & Ollendick, 2011). Whilst improved clinical outcomes with CBT have been observed for children with anxiety (Barrett, Duffy, Dadds, & Rapee, 2001; P. C. Kendall, Safford, Flannery-Schroeder, & Webb, 2004; Saavedra, Silverman, Morgan-Lopez, & Kurtines, 2010), the lack of control conditions in these studies limits the extent to which results can be attributed to treatment over the long term. Furthermore, research has found that a high proportion of those treated with traditional CBT are nonresponsive or exhibit residual symptomatology upon treatment cessation (Compton et al., 2014; Hudson, 2005). This is estimated at between 33% and 50% of those treated (Cartwright-Hatton, Roberts, Chitsabesan, Fothergill, & Harrington, 2004; Compton et al., 2014; Hudson, 2005; Seligman & Ollendick, 2011). In terms of diagnostic remission, one large study of children and adolescents observed that just 20-46% of those treated with CBT no longer met criteria for an anxiety disorder (Ginsburg et al., 2014). A long term follow-up, at a mean of six years after randomisation, found that less than half (46.5%) were in remission (Compton et al., 2014; Ginsburg et al., 2014). Despite this, CBT remains the "gold standard" psychotherapeutic approach for children with anxiety, primarily due to a scarcity of evidence for alternative approaches, rather than findings that other therapies are ineffective (APS, 2010).

As a so called "second wave" behaviour therapy, CBT has attracted some criticism. While cognitive approaches have clear pragmatic value, researchers have argued that they have demonstrated a somewhat tenuous linkage to underlying cognitive science in terms of cognitive processes and structures (Brewin, 1989; S. C. Hayes, Luoma, Bond, Masuda, & Lillis, 2006; S. C. Hayes, Villatte, Levin, & Hildebrandt, 2011). Moreover, traditional CBT approaches rested upon the mediational role of cognitive change in therapeutic outcome, and substantial research has not supported this assumption (e.g., Dobson & Khatri, 2000; S. C. Hayes, 2004; Longmore & Worrell, 2007). Several component analysis studies have found that the addition of cognitive

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techniques added nothing to the effectiveness of behavioural interventions (e.g. Dobson &

Khatri, 2000; Gortner, Gollan, Dobson, & Jacobson, 1998; Jacobson et al., 1996; Ruiz, 2012).

Although more contentious, others have argued that clinical improvement is often observed

among patients prior to the implementation of cognitive approaches in CBT (S. C. Hayes, 2004;

Ilardi & Craighead, 1999). Finally, research began to indicate that first order control orientated

approaches (to manage psychological phenomena) paradoxically increased their frequency

(Levitt, Brown, Orsillo, & Barlow, 2004) and/or perceived intensity (Christenfeld, 1997; Eifert &

Heffner, 2003).

In summary, whilst CBT has been found to be effective for the treatment of anxiety disorders

among children and adolescents, there is limited evidence that it is more effective than

alternative interventions, or active controls with a substantial proportion of children exhibiting

residual symptomology at treatment cessation. More research is warranted among young

people to address these concerns and to investigate the effectiveness of alternative

approaches.

Acceptance and Commitment Therapy (ACT): A "third wave" behaviour therapy

Reflecting a synthesis and reformulation of concepts underpinned by the prior waves of

behaviour therapy and cognitive behaviour therapy, "third wave" approaches such as ACT were

conceived to address such empirical anomalies and to optimise therapeutic outcomes (Arch &

Craske, 2008). ACT is founded upon functional contextualism, a philosophy of science that

aims to precisely predict, and subsequently influence, human behaviour with reference to the

historically and situationally defined contexts in which it occurs (Flaxman, Blackledge, & Bond,

2011; S. C. Hayes, 2004; Ruiz, 2012). Reflecting an extension of radical behaviourism, ACT

takes a functional approach to the truth and meaning of psychological phenomena – thoughts,

feelings and sensations – with such phenomena viewed as a product of their contingencies

(Coyne, McHugh, & Martinez, 2011; S. C. Hayes, Levin, Plumb-Vilardaga, Villatte, & Pistorello,

2013). As such, in ACT the primary focus is on the context and function of psychological

phenomena as the target of change interventions, rather than directly changing the form,

frequency or validity, as typified by second wave traditional CBT approaches (Blackledge, Ciarrochi, & Deane, 2009; S. C. Hayes, 2004; S. C. Hayes et al., 2011).

ACT is underpinned by relational frame theory (RFT), a behavioural research platform focused on language and cognitive processes (for a review see S. C. Hayes, 2004; S. C. Hayes et al., 2006; S. C. Hayes et al., 2011). These processes are associated with many psychopathologies (Williams, 2001). The theory is derived from basic learning principles, such as reinforcement and punishment, and has several implications for the practitioner in helping clients. RFT purports "the core of human language and cognition is the learned and contextually controlled ability to arbitrarily relate events mutually and in combination, and to change the functions of specific events based on their relations to others" through learned derivation (S. C. Hayes et al., 2006, p. 5). Whilst such learning offers several evolutionary advantages, this creates a propensity for relational responding to events on the basis of their verbally ascribed relationship to other events, rather than on the unique properties of each event as it occurs (S. C. Hayes et al., 2006; Luoma, Hayes, & Walser, 2007). Thus, psychopathology is construed as the consequence of reactive relationships to relationally derived distressing internal experiences (Roemer & Orsillo, 2005). In turn this elicits experiential avoidance; behavioural attempts to avoid or escape distress (S. C. Hayes et al., 2011). Whilst providing short term negative reinforcement, chronic reliance on experiential avoidance strategies has been argued to create secondary distress and preclude the development of more adaptive coping (Luoma et al., 2007), diminishing the capacity for action in line with one's values and decreasing QOL (S. A. Hayes, Orsillo, & Roemer, 2010; S. C. Hayes, 2004). As such, the overarching aim of ACT is to facilitate psychological flexibility, which is the antithesis of experiential avoidance. Psychological flexibility is "the ability to contact the present moment more fully as a conscious human being, and to change or persist in behaviour when doing so serves valued ends" (S. C. Hayes et al., 2006, p. 7). This is achieved via six interrelational core therapeutic processes that form a hexaflex model; acceptance, cognitive defusion, mindfulness, self-as-context, committed action, and valued living (Luoma et al., 2007). These approaches are deployed to foster the attainment of increasingly flexible methods of managing challenging cognitions, emotions or

sensations, thereby diminishing their deleterious behavioural consequences (Arch & Craske, 2008).

ACT and traditional CBT: A snapshot of similarities and differences

Both ACT and CBT are behavioural and cognitive therapies (Forman & Herbert, 2009; S. C. Hayes et al., 2013). These two therapeutic modalities view thoughts as observable and separate from the self, facilitate heightened identification of psychological phenomena and may incorporate behavioural approaches such as activation and exposure (Gaudiano, 2011). Core differences, however, include underpinning theories of psychopathology, therapeutic techniques, putative mechanisms of change, and emphasised outcomes (Gaudiano, 2011).

CBT has been described as being guided by a philosophy of science know as elemental realism, which purports that the world is independent of our perceptions and is organised into individual components (Herbert, Gaudiano, & Forman, 2013). Elemental realism suggests that our descriptions of the world can be objectively true or false relative to their actual reflection of reality (Herbert et al., 2013). As there is no unified model of CBT, there is no singular theory that underpins it. Rather, CBT is better viewed as a broad term that encompasses an array of theoretical standpoints. Some include common elements while maintaining unique features – such as the learning theories of classical vs operant conditioning – and the salience of particular approaches in terms of optimal treatment is the subject of greater professional conjecture (Herbert et al., 2013). In accordance with the cognitive model, in CBT psychopathology is construed as a consequence of faulty information processing that results in an array of cognitive distortions, dysfunctional beliefs and associated schemas (Beck, 2005). These distortions and beliefs are subsequently considered to interact with the environment producing feelings and behaviour. Intervention efforts emphasise the direct first order change of thoughts and feelings via therapeutic techniques such as cognitive identification, disputation and restructuring (Twohig, Woidneck, & Crosby, 2013). In CBT the explicit aim is symptom amelioration, arguably with the implicit assumption that QOL will improve in line with a reduction or remission of symptoms (Twohig et al., 2013). In CBT, cognitive change is considered to play a key mediational role in therapeutic outcome (Longmore & Worrell, 2007).

Rather than emphasising symptom reduction as a prerequisite to QOL (CBT), ACT supposes that QOL is possible regardless of the presence of symptoms, provided the client responds to their symptoms with mindfulness (Harris, 2006). ACT rejects the notion that thoughts and emotions cause psychopathology, instead emphasising the maladaptive reactions to these psychological phenomena, rather than the phenomena itself (S. C. Hayes, 2008). With its foundation in functional contextualism and RFT, ACT posits psychopathology is a consequence of entanglement in the content of thoughts (fusion), associated loss of contact with the present moment, and experiential avoidance in the presence of psychological phenomena, that leads to a rigid, psychologically inflexible, nonvalued way of living (S. C. Hayes et al., 2013; S. C. Hayes et al., 2011; Luoma et al., 2007). Rather than attempting to directly alter psychological phenomena, drawing from the radical pragmatism of functional contextualism, ACT focuses on valued living and workability in altering relationships individuals have with this phenomena – via the hexaflex model and its component core processes, described above – in order to support improved QOL (S. C. Hayes, 2008).

Operationalising treatment success: Clinical and quality of life outcomes (QOL)

Whilst there is little consensus on an apt all-encompassing definition, it is widely acknowledged that therapeutic effectiveness is typically operationalised in clinical outcome terms, as the amelioration of psychological symptomology. Although a return to "normal" functioning is a salient concern for clinicians and consumers alike, this definition of health and disease may be overly narrow, in that it does not account for the gamut of health outcomes that may be impacted by psychological concerns and subsequent intervention efforts (Gladis, Gosch, Dishuk, & Crits-Christoph, 1999; Jacobson, Roberts, Berns, & McGlinchey, 1999). QOL allows for the examination of symptom derived impairment on functioning and wellbeing (Mendlowicz & Stein, 2000). In contrast to the clinician perspective on treatment effectiveness, which typically emphasises clinical outcomes, QOL may be more indicative of the consumer's perspective, arguably reflecting the clinical significance of changes (Gladis et al., 1999; Kazdin, 1977; Safren, Heimberg, Brown, & Holle, 1996). In this way, QOL, rather than clinical status, may influence treatment motivation, engagement, adherence, and the likelihood of completion

(Wolf, 1978). Thus, effectiveness evaluations in psychotherapy might be augmented through an examination of both clinical and QOL outcomes.

QOL and anxiety. Research suggests a range of QOL indices are markedly impaired among individuals with anxiety disorders. A review and meta-analysis of 23 clinical studies of individuals with mixed anxiety disorders observed these conditions were associated with significantly compromised QOL across all investigated domains - physical health, mental health, work, social, home and family – relative to control comparison, a difference of large effect size (Olatunji, Cisler, & Tolin, 2007). Among children, anxiety disorders have been associated with impaired overall QOL outcomes (Varni, Limbers, & Burwinkle, 2007) as well as specific impairments observed in self-efficacy/wellbeing (Messer & Beidel, 1994; Muris, 2002; Stein & Kean, 2000), psychosocial health (Ginsburg, La Greca, & Silverman, 1998; Weitkamp, Daniels, Romer, & Wiegand-Grefe, 2013), physical health related QOL (Clark & Kirisci, 1996; Varni et al., 2007) and anxiety life interference (Last, Hansen, & Franco, 1997), among others.

Treatment success in CBT: Research evidence. The empirically established efficacy of CBT in the treatment of children with anxiety has almost exclusively emphasised clinical outcomes such as diagnostic remission and symptom reduction (Greco, Blackledge, Coyne, & Ehrenreich, 2005). There is a dearth of research, however, on the impact of CBT on children's QOL (Greco et al., 2005; Safren et al., 1996), specifically in terms of the aforementioned QOL areas (global QOL, self-efficacy/wellbeing, psychosocial health, physical health related QOL and anxiety life interference). Research has found CBT to produce improvement in global functioning, self-efficacy, social competence and coping capacity (e.g., Heyne, Sauter, Van Widenfelt, Vermeiren, & Westenberg, 2011; P. C. Kendall et al., 1997; P. C. Kendall, Hudson, Gosch, Flannery-Schroeder, & Suveg, 2008; Ollendick, 1995; Segool & Carlson, 2008). Mixed evidence has been found with respect to life interference in accordance with rater (e.g. child, parent or clinician) group and sex. CBT was found to reduce parent-, but not child-reported measures in a recent case study (Lundkvist-Houndoumadi & Thastum, 2013). A further study found that female adolescents, but not

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males – whose parents completed CBT – evidenced lower anxiety life interference than a control condition 11 years later (Rapee, 2013). Taken together, these studies suggest research is accumulating on the effectiveness of CBT in improving QOL outcomes. However, evidence is mixed and others have countered that observed improvements following CBT cessation continue to reflect scores below the normal population (Safren et al., 1996). Furthermore, it has been suggested that poor QOL indicators following positive response to CBT among individuals with anxiety disorders may be risk factors for subsequent relapse (Olatunji et al., 2007).

Treatment success in ACT: Research evidence. ACT challenges the goals of most Western psychological therapies, such as traditional CBT, that emphasise clinical outcomes with the assumption that symptom amelioration is a necessary precursor to living a better life. ACT takes a radically different stance. It assumes that (a) QOL is primarily dependent upon mindful, values guided action, and; (b) this is possible regardless of the presence, or number, of symptoms – provided that symptoms are responded to with mindfulness (Harris, 2006). Indeed, improvements in QOL outcomes have been observed for ACT in the treatment of adults with social anxiety disorder (Dalrymple & Herbert, 2007) and generalised anxiety disorder (S. A. Hayes et al., 2010), among others. Whilst symptom reduction is not the primary aim of ACT, several studies (e.g. Arch, Eifert, et al., 2012; Forman, Herbert, Moitra, Yeomans, & Geller, 2007; Forman, Shaw, et al., 2012; Roemer & Orsillo, 2007; Twohig, Hayes, et al., 2010) have found that ACT improves anxious symptomatology among adults. In explanation for this, relative to the overarching aim of ACT, it is argued that by focusing on QOL and therefore getting on with what is important, anxiety symptoms become less of a focus and, as a by-product, symptoms reduce (Harris, 2006).

There are currently no published studies on the impact of ACT for QOL outcomes among children with anxiety. However, emerging evidence suggests ACT produces positive outcomes on the aforementioned QOL indices among children with other concerns. Health related QOL and life interference were found to improve among children with debilitating longstanding pain treated with ACT over time and in comparison to a multidisciplinary

treatment approach in one study (Wicksell, Melin, Lekander, & Olsson, 2009). Another case study of ACT for paediatric sickle cell disease showed improvements on self and parent reported daily physical functioning and health related QOL at posttreatment with further improvements at follow-up (Masuda, Cohen, Wicksell, Kemani, & Johnson, 2011). A pilot study among adolescents with depression found significant improvements on emotional and behavioural functioning posttreatment for ACT and a treatment-as-usual (TAU) comparison group, with further improvement observed for ACT and not TAU at 3-month follow-up (L. Hayes, Boyd, & Sewell, 2011). Likewise, ACT was associated with improvements in social competence relative to TAU among adolescents with high risk sexualised behaviour (Metzler, Biglan, Noell, Ary, & Ochs, 2000). In a study of ACT for posttraumatic stress among a mixed sample of community-dwelling adolescents and adolescent inpatients, with posttraumatic stress and a comorbid eating disorder (Woidneck, Morrison, & Twohig, 2014), statistical analysis of QOL outcomes was not reported. However raw scores indicated improved QOL at posttreatment, with gains maintained or further improved at 3-month follow-up (Woidneck et al., 2014). Finally improvements in school attendance, emotion focused avoidance and general/physical functioning were observed in a case study involving an adolescent with idiopathic pain (Wicksell, Dahl, Magnusson, & Olsson, 2005).

Although evidence for ACT in producing improved QOL outcomes among children is sparse, and few studies have compared ACT QOL outcomes to alternative interventions, preliminary evidence across an array of clinical presentations supports its utility in this area in line with its therapeutic emphasis. Furthermore, burgeoning research also attests to the effectiveness of ACT in improving clinical outcomes for the anxiety disorders. CBT has also demonstrated effectiveness in improving clinical outcomes among children with anxiety in line with its overarching objectives. Although not its primary focus, evidence is also accruing for the effectiveness of CBT in increasing QOL among children with anxiety. Thus, despite their differential foci, preliminary research suggests ACT and CBT are both effective in achieving clinical and QOL improvements.

ACT applied to the anxiety disorders

From an ACT perspective, it is the struggle to be free of anxious distress (e.g. cognitions, physiological sensations and memories) and the experiential avoidance this evokes, rather than anxiety itself, that is at the core of anxiety disorders (Codd, Twohig, Crosby, & Enno, 2011; Eifert et al., 2009; S.C Hayes, 2004). In other words, the perception of anxiety as distressing and intolerable can lead to the idea that it is vital not to experience anxiety (S. C. Hayes, 2004). Paradoxically this "fear of fear" fuels anxiety the next time the anxiety producing stimulus is encountered, leading to the development of increasing rigid patterns of behaviour (Eifert & Forsyth, 2005). Agoraphobic avoidance, for example, is conceptualised as avoidance of distressing psychological phenomena that arise and are linked with panic in public places, rather than avoidance of the places themselves (Friman, Hayes, & Wilson, 1998). Similarly, in obsessive compulsive disorder, avoidance of touching certain objects associated with contamination fears is construed as avoidance of the distress that arises when touching the object rather than the fear of being contaminated (Friman et al., 1998). ACT suggests experiential avoidance continues due to its negative reinforcement value; the short-term mitigation of acute anxious distress (Eifert & Forsyth, 2005).

Anxiety is ubiquitous with the human condition, our innate biological alarm system that works to facilitate survivability. From this perspective, the aim to ameliorate anxiety seems nonsensical. Building from this idea, ACT focuses on building skills to support the observation and acknowledgement of anxious distress as it emerges to allow for increasingly flexible behaviour repertoires that involve engagement with, rather than avoidance of, valued action (Codd et al., 2011; Eifert & Forsyth, 2005; Eifert et al., 2009; Twohig et al., 2013). In accordance with Eifert and Forsyth (2005), ACT supports clients to (a) recognise the "control agenda" in that their inflexible attempts to minimise, avoid or escape anxiety are ineffectual and paradoxically lead to increased distress over the long term; (b) adopt acceptance as an alternative to the control agenda when anxious experience occurs, and in the circumstances that elicit these responses; (c) develop mindfulness and willingness to experience the full gamut of emotional and cognitive experiences as they are and; (d) redefine what is really important, what is valued, without doing so from the standpoint of anxiety being intolerable and the restrictions this imposes on living.

While, like CBT, ACT treatment may involve exposure exercises, the reduction of anxiety is not the emphasis in ACT, but rather supporting clients to live life in line with their values, thereby increasing QOL.

ACT empirical research outcomes

Several reviews and meta-analyses have concluded that ACT is effective in the treatment of an array of problems over time and evidences significantly superior outcomes in comparison to control conditions (S. C. Hayes et al., 2006; Ost, 2008; Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009). Fewer studies have examined the effectiveness of ACT relative to alternative active treatments (Levin & Hayes, 2009; Powers et al., 2009). A more recent meta-analysis of ACT versus CBT however, found ACT outperformed CBT to some degree in 11 out of 16 outcome studies (Ruiz, 2012). In spite of its high prevalence there remains a paucity of anxiety specific studies among those included in the aforementioned reviews and many of those operationalised as "anxiety" have addressed stress or general distress. This classification concern resulted in the latter review concluding that there were no significant differences between ACT and CBT in the treatment of anxiety problems (Ruiz, 2012). Reanalysis of the results of this review however, which included only five anxiety specific studies, revealed ACT was superior to CBT in all but one study. A number of other studies support this finding, having observed large improvements in anxiety clinical outcomes for both ACT and CBT over time, with no significant differences observed between the two treatments (Arch, 2009; Arch, Eifert, et al., 2012; Block, 2002; Block & Wulfert, 2000; Forman, Shaw, et al., 2012; Twohig, Whittal, Cox, & Gunter, 2010). A recent meta-analysis on ACT for anxiety and obsessive compulsive disorder (OCD) spectrum disorders on nine RCTs also supports the above findings, showing that ACT was equally effective as manualised treatments such as CBT (Bluett et al., 2014).

ACT in the treatment of child populations

Relational Frame Theory (RFT) posits that when we develop language we constantly derive relations, or engage in relational framing, because people around us reinforce such relating (S. C. Hayes et al., 2006). Learned derivation is observable from early childhood (S. C. Hayes, 2004). During early language training interactions for example, children are often shown objects

and asked to repeat their names. A mother may then clap her hands and smile, or say "That's right, that's a car!," reinforcing that the word "car" is the same as the name of the object, car. The child may also be taught the name of the car, so object-word and word-object relation is explicitly trained. Enough repetitions of this training will lead to derived relational responding. For example, a child begins to generalise that the spoken word car also refers to a toy car, and to the printed words "toy car", and vice-versa: the printed word refers to a toy car, which refers to the spoken words toy car. Over time seeing a photo of a car might generate an image of a toy car and a real car outside the child's home. RFT explains how language develops and can dominate experience, that is, we often trust our own thoughts even when our experience tells us otherwise, even though it may be unhelpful (Ciarrochi & Bailey, 2008; S. C. Hayes, Barnes-Holmes, & Roche, 2001)

Research on the ACT core processes and their relation to QOL, psychosocial outcomes and wellbeing among children suggests that these processes operate in a similar way to that of adults (for a review see Coyne et al., 2011). Feasibility studies also offer support for the utility of mindfulness based approaches, such as ACT, with children (Burke, 2010). It has been argued that as children think less literally than adults, and as such, the employment of metaphors and experiential approaches may allow children to grasp abstract concepts through experience (O'Brien, Larson, & Murrell, 2008). Preliminary research with children as young as four years provides some evidence for this assertion (Heffner, Greco, & Eifert, 2003). Furthermore, it has been purported that children have had less time to adopt more entrenched patterns of experiential avoidance and as such, ACT may operate to achieve both the remediation, and prevention, of the emergence of inflexible patterns of psychological responding (Greco et al., 2005). Such approaches may also be well suited to adolescents as they assist in rapport building and are less instructive (Greco et al., 2005). ACTs focus on experiential, or personal learning, approaches support autonomously driven behaviour that may be particularly appropriate for adolescents desiring increased independence who may be nonresponsive to adult direction (Hadlandsmyth, White, Nesin, & Greco, 2013).

ACT approaches have been adapted for use among child and adolescent populations (Greco, Blackledge, Coyne, & Ehrenreich, 2005). There are two existing reviews of ACT for children (Coyne et al., 2011; Murrell & Scherbarth, 2006). These are subject to several limitations however, including nonscientific approaches and the inclusion of purely theoretical studies or those not subjected to peer-review. At the time of the publication of the most recent review, few empirical studies had been conducted and those that were available were predominantly case studies or uncontrolled pilots (Coyne et al., 2011). In the past few years, since the conduct of these reviews, the ACT literature has seen a proliferation of studies involving child and adolescent populations. These include published studies of ACT in the treatment of children with posttraumatic stress (Woidneck et al., 2014), stress (Livheim et al., 2014), pain (Gauntlett-Gilbert, Connell, Clinch, & McCracken, 2013; Ghomian & Shairi, 2014), trichotillomania (Fine et al., 2012), and depression (Livheim et al., 2014). In the main, these studies have evidenced improvements in clinician-, parent- and self-rated measures of symptoms, QOL outcomes and/or psychological flexibility, with many observing additional gains at follow-up assessment. However, several methodological caveats limit conclusions. For example there are currently only four existing RCTs and just one study that compares ACT to another active treatment. Additional research in this area is warranted to address these concerns and consolidate findings.

ACT in the treatment of children with anxiety

Prior to the current investigation, to the author's knowledge, there have been three published studies of ACT in the treatment of anxiety symptoms or DSM-IV anxiety disorders among children, the first was a case study (Soo, Tate, & Lane-Brown, 2011). The second included a sample of three (Armstrong, Morrison, & Twohig, 2013) and a third study (*N*=7) addressed PTSD/posttraumatic stress (PTS) symptoms among community dwelling adolescents, as well as a sample of inpatient adolescents with eating disorders and comorbid PTS (Woidneck et al., 2014). While these studies make an important contribution to the field, several caveats limit the generalisability of findings. The first study made limited use of psychometrically evaluated assessment tools, instead relying on anecdotal evidence to determine the impact of treatment on outcomes, and the intervention was not conducted in line with the initial treatment protocol. All three studies were subject to issues of small sample size (and therefore questionable

sample representativeness), a lack of control or alternative treatment comparison and random allocation to treatment. The generalisability of the PTS study is also limited in its employment of a mixed community and inpatient sample, the latter of whom were receiving concurrent treatment for a primary eating disorder diagnosis. Clearly, these findings highlight the relative dearth of studies from which to support evidence based clinical practice with children and adolescents. Additional research of sound methodological rigour is required to evaluate the utility of ACT among children and adolescents with anxiety.

Group versus individual treatment: State of the evidence

The benefits of psychotherapy delivered in a group format include optimising the costs and time of health care provision, adaptive modelling and feedback opportunities, the fostering of support networks both during and beyond therapy cessation as well as opportunities for interpersonal in-vivo exposure (Barrett, 1998; Silverman et al., 1999). Several studies have demonstrated that group CBT is effective in the treatment of anxiety disorders among children, with superior outcomes relative to control conditions – in terms of outcomes such as diagnostic remission, symptom severity and clinically significant change – on clinician-, parent- and self-report measures (e.g. Barrett, 1998; Shortt, Barrett, & Fox, 2001; Silverman et al., 1999).

Outside of the present investigation, three published studies of ACT group based treatment for children were identified. The first was an interdisciplinary residential program for 98 adolescents experiencing chronic pain (Gauntlett-Gilbert et al., 2013). Improvements were observed across measures of acceptance, pain anxiety, depression, catastrophizing, social/physical functioning, development, and objective physical measures, with the exception of pain intensity. Across two pilots, Livheim et al. (2014) observed significant improvements of large effect size in depression among ACT participants and ACT was found to outperform TAU on a measure of perceived stress. Whilst these studies reflect encouraging preliminary results for the application of ACT in group format for children, several caveats limit findings. In the first study the lack of a control group and the use of an interdisciplinary multicomponent approach may confound the extent to which changes in measures can be attributed to ACT. The residential nature of the program may also limit the generalisability of the findings. Limitations

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of both pilots (Livheim et al., 2014) include the sole reliance on self-report measures, which are inclined towards social desirability biases in respondents. The vast majority of participants in both studies were female, which impacts on the capacity to generalize the result to male populations. Neither study included follow-up assessment to examine the durability of observed outcomes. Finally therapist competence and adherence to the protocol were not examined, given the therapists were relatively inexperienced in the use of ACT this is an important consideration in determining whether the program was ACT consistent.

Whilst there is a paucity of evidence for group based ACT in the treatment of children, group based ACT has been found to be effective in producing improvements in clinician- and self-rated measures among adults with generalised anxiety disorder (Orsillo, Roemer, & Barlow, 2003; Sachs, 2005), panic disorder (Karekla, 2005), social anxiety disorder (Block, 2002; Block & Wulfert, 2000; England, 2011; Goldfarb, 2010; Kocovski, Fleming, & Rector, 2009; Ossman, Wilson, Storaasli, & McNeill, 2006) and mathematics anxiety (Brown et al., 2011). Clearly, more studies are warranted to expand upon this research.

Mechanisms of change in psychotherapy

Establishment of the effectiveness of interventions has been the focus of decades of clinical research, fostering the evolution of increasingly sophisticated knowledge of the utility of various psychotherapeutic approaches for disorder and population-specific intervention (Arch, Wolitzky-Taylor, Eifert, & Craske, 2012; Kazdin, 2007). Despite this, we are yet to establish a consolidated empirical explanation for the basis of therapeutic effects. That is, why and how even our most well researched psychotherapies work, the processes through which interventions foster positive outcomes; the "mechanisms of change" (Ciarrochi, Bilich, & Godsell, 2010; Kazdin, 2007). Understanding which factors are critical in achieving therapeutic change creates flexibility for clinicians to provide tailored interventions that are adapted to an array of patient variables. Identification of treatment specific mechanisms of change has been sought to support parsimonious clinical practice, optimising clinician patient encounters to facilitate shorter term interventions delivered with improved sensitivity and specificity (Kazdin, 2007).

Determining the effectiveness of therapy involves the investigation and assessment of the processes through which interventions affect change in clinical outcomes of interest, which essentially begins with a search for mediated effects (Weersing & Weisz, 2002). Mediation requires the identification of relationships between intervention, mediator and outcome measure. Change must first be established in outcome measures in order to demonstrate therapeutic effectiveness. Change in putative mediators must be observed with treatment and therapeutic effects must be able to be accounted for via process measures (Weersing & Weisz, 2002).

Highly controlled laboratory based component studies provide some support for the ACT hexaflex as well as each of the core processes that make up the model as mediators of change with larger effect sizes observed for theoretically postulated outcomes such as QOL (Levin, Hildebrandt, Lillis, & Hayes, 2012). Preliminary research in naturalistic settings offers mixed support for components of the ACT hexaflex model as mechanisms for change for the anxiety disorders among adults (Ciarrochi et al., 2010; Forman et al., 2007; S. C. Hayes et al., 2006). Whilst support has been obtained for cognitive defusion ("defusion"; Arch, Wolitzky-Taylor, et al., 2012; Forman, Chapman, et al., 2012; Forman et al., 2007) and committed action (Forman, Chapman, et al., 2012) mediation effects were not treatment specific, but treatment common to ACT and CT/CBT. Acceptance, however, has been found to be an ACT specific mediator for change in symptom intensity in one study (Forman, Chapman, et al., 2012) Other studies have lacked comparison conditions, which therefore preclude a consideration of the treatment specificity of mediation effects. Among such studies, one did not find support for mindfulness as a predictor of change (Kocovski et al., 2009). Another found that acceptance, but not valued action, significantly predicted posttreatment QOL (S. A. Hayes et al., 2010).

The existing ACT mediation literature for anxiety is subject to several methodological limitations, which may offer some explanation for the mixed findings. There is a general paucity of overall published studies as well as conceptual and operational issues that limit validity and delineation between causes, processes, mediators, and mechanisms for change (Ciarrochi et

al., 2010; Forman, Chapman, et al., 2012; Kazdin, 2007). Among those studies that have been conducted there is substantial heterogeneity in study design, sample, data collection schedule, outcomes and measurement tools, treatment protocol and statistical techniques; factors that impact on the capacity to draw meaningful conclusions. Few studies have compared ACT to another active psychotherapy to determine whether proposed processes are ACT specific or treatment common (Arch, Wolitzky-Taylor, et al., 2012). ACT proponents indicate that there is no specified order for working through the core processes and elements can be tailored to the individual (Ciarrochi et al., 2010; Luoma et al., 2007). To date however, it is unclear from the literature whether particular elements of ACT are more critical in terms of therapeutic outcome or whether specific techniques within the model are more effective for disorder specific or population specific samples to provide an evidence base for clinical decision making in this area (Ciarrochi et al., 2010). Furthermore, despite the burgeoning research into ACT processes, little is known about whether these processes are equivalently observable among child populations or whether therapy works to affect change differently in young people.

Research design, aims and hypotheses

The RCT described within this thesis is a prospective three (group: two intervention and one control) by three (time: pretreatment, posttreatment, and three months posttreatment; 3MFU) repeated measures factorial design. This research aimed to examine the effectiveness of a manualised ACT group therapy program in the treatment of anxiety disorders among children and adolescents. The PhD research formed a subsection of the broader RCT, specifically focused upon the adolescent participants. It was hypothesised that:

1. ACT would be at least as effective in the treatment of anxiety disorders in these populations relative to a manualised CBT group therapy program. This will be measured by no significant differences between the two treatments on clinician-, parent- and self-report clinical and QOL outcome measures.

2. ACT would be more effective in the treatment of anxiety disorders in this population relative to WLC at both immediate posttreatment and 3MFU on the aforementioned outcome measures.

3. Larger effect sizes would be observed for theoretically specified outcomes – clinical for CBT; QOL for ACT.

The secondary aim of the research was to examine the ACT hexaflex model, and the specific effects of the core processes as putative mediators for therapeutic change among adolescents. The specificity of observed mediation effects to ACT were identified through comparison to CBT. In light of their theoretical importance in ACT, the hexaflex and its component core processes were expected to operate as mediators for change in QOL, with mediation effects anticipated to be treatment specific to ACT. While clinical outcomes such as symptom remission or amelioration are not the focus in ACT, research indicates that ACT also produces change in these outcomes. As such, the final hypothesis was:

4. Both QOL and clinical outcomes would be mediated by the ACT hexaflex model and its core component processes for ACT, but not CBT or WLC participants.

A detailed description of the research design is provided in *Chapter 3*. However, since the publication of this paper, a number of minor changes were made to the study protocol. Firstly, the "MindChill" program detailed in *Chapter 3* has been renamed "ProACTive". Secondly, analyses pertaining to one of the assessment measures, the Family Assessment Device (FAD), were nonsignificant and these were omitted from *Chapter 4.* Thirdly, on the basis of subject matter expert consultation, a modification to the statistical approach was adopted in *Chapter 5* relative to the "statistical analysis" section outlined in *Chapter 3*, with respect to the mechanism of change hypotheses. Whilst a regression based approach was adopted, as described in *Chapter 3*, receiver operating curves were not examined. Instead Ordinary Least Squares (OLS) regression with bootstrapping was employed to conduct exploratory mediation analyses. OLS regression is a multiple mediation approach that examines the direct, indirect effects and total indirect effects of several putative mediators (Preacher & Hayes, 2008). Bootstrapping is a nonparametric resampling approach that yields percentile based confidence intervals for both the aforementioned total and specific indirect effects (for a discussion see A. F. Hayes, 2009). It is advocated as a supplement to regression analyses in mediation studies with small samples as it makes no assumptions about the normality of the distribution (Preacher & Hayes, 2008).

This approach has been previously utilised in mediation analyses of ACT in other populations such as those with psychosis (Gaudiano, Herbert, & Hayes, 2010) and epilepsy (Lundgren, Dahl, & Hayes, 2008). One further change was made to the assessment measures detailed in *Chapter 3.* Finally, while growing literature attests to the effectiveness of ACT, far fewer studies have examined the processes of change underpinning treatment success and the literature is in its infancy in terms of the current availability of valid, reliable measurement tools that tap each of the hexaflex core processes. On the basis of subject matter expert feedback on the specificity of process measures and the complexity produced through the inclusion of multiple measures assessing the same construct, we modified our protocol to incorporate only the most optimal measure for each core process. Full details of this approach are described in *Chapter 5.*

Chapter 1 – Acceptance and Commitment Therapy in the treatment of anxiety: A systematic review

Swain, J., Hancock, K., Hainsworth, C., & Bowman, J. (2013). Acceptance and Commitment Therapy in the treatment of anxiety: A systematic review. *Clinical Psychology Review, 33,* 965-978.

Chapter 2 – Acceptance and Commitment Therapy for children: A systematic review of intervention studies

Swain, J., Hancock, K., Dixon, A., & Bowman, J. (2014). *Acceptance and Commitment Therapy for children: A systematic review of intervention studies.* Manuscript submitted for publication.

Chapter 3 – Acceptance and Commitment Therapy for anxious children and adolescents: Study protocol for a randomised controlled trial

Swain, J., Hancock, K., Dixon, A., Koo, S., & Bowman, J. (2013). Study protocol: A randomised controlled trial of Acceptance and Commitment Therapy for anxious children and adolescents. *Trials, 40,* 140-152.

Chapter 4 – Acceptance and Commitment Therapy versus Cognitive Behaviour Therapy for children with anxiety: Outcomes of a randomised controlled trial

Hancock, K., **Swain, J.**, Hainsworth, C., Dixon, A., Koo, S., & Munro, K. (2014). *Acceptance and Commitment Therapy versus Cognitive Behaviour Therapy for children with anxiety: Outcomes of a randomized controlled trial.* Manuscript submitted for publication.

Chapter 5 – Mechanisms of change: Exploratory outcomes from a randomised controlled trial of Acceptance and Commitment Therapy for anxious adolescents

Swain, J., Hancock, K., Hainsworth, C. & Bowman, J. (2014*). Mechanisms of change: Exploratory outcomes from a randomised controlled trial of Acceptance and Commitment Therapy for anxious adolescents. *Journal of Contextual Behaviour Science.* Advance online publication. http://dx.doi.org/10.1016/j.jcbs.2014.09.001

Concluding Statement

This PhD thesis by publication examined the utility of ACT in the treatment of anxiety disorders among young people. An exploratory evaluation of the elements of the intervention that functioned as mechanisms for change was also undertaken among the adolescent participants.

In a systematic review of the published and grey literature, *Chapter 1* found ACT to be effective in the treatment of anxiety disorders and other problems of anxiety. Over 92% of the 38 included studies ($n = 959$) evidenced positive clinical outcomes for ACT. Studies typically showed significant improvements in anxiety of moderate to large effect sizes. There was also some evidence that a substantial proportion achieve clinical/reliable change and/or full remission at treatment cessation. Among those studies that compared ACT to CBT, both treatments were found to produce broadly equivalent outcomes. Among the 21 ACT studies that evaluated follow-up outcomes, 90.48% attained significant results indicating that effects are maintained for some time after treatment cessation. Findings provided preliminary support for ACT in the treatment of the spectrum of anxiety conditions. Findings held across clinical and nonclinical populations and for both individual and group therapy format. Despite anxiety disorders being among the prevalent psychiatric afflictions affecting children and adolescents, just two studies included in this review – including a total of just six participants for one anxiety disorder; OCD – were conducted among child populations. This highlighted the need for additional research in this area.

The ACT "hexaflex" and its core processes – acceptance, defusion, mindfulness, self-as-context, committed action and valued living – have been linked to quality of life/psychosocial and wellbeing among children, with research indicating they operate among young people in a similar way to that of adults (see Coyne et al., 2011). Increased attention among researchers over the past decade has also been directed toward the adaptation, and assessment of the suitability, of ACT approaches among child and adolescent populations (Greco, Blackledge, Coyne, & Ehrenreich, 2005). To examine the evidence base for the utility of ACT among child populations, in *Chapter 2* a systematic review of 21 identified studies was undertaken ($n =$

707). Studies covered a spectrum of presenting issues and obtained preliminary evidence for ACT in improving in the majority of clinical outcome measures among children, in accordance with both clinician-, parent- and self-report. However, the majority of presenting problems were examined in one or two studies and for several conditions, including the majority of anxiety disorders, ACT remained untested. Furthermore, despite the theoretical emphasis on QOL outcomes in ACT, few studies employed QOL specific outcomes. Among the four studies that did employ these measures, all found improvements over time, with the exception of the study on stress (Livheim et al., 2014), which was underpowered to detect effects. Less than 50% of included studies examined changes in the ACT core processes among children, and the evidence amongst them was mixed. In those studies that examined changes in avoidance and fusion 50% indicated improvements at post or follow-up. Positive changes were observed in acceptance across two studies, but not in a third, which was underpowered. Evidence for valued living and committed action was limited to one or two studies, with positive improvements observed among participants treated with ACT.

These opening chapters established the empirical basis for ACT in both the treatment of anxiety disorders and child populations. It highlighted the current paucity of research evidence specific to children with anxiety disorders. Despite the emphasis on QOL outcomes in ACT, studies have not routinely examined the impact of treatment beyond assessment of clinical outcomes. To address this gap, *Chapter 3* described the research protocol/methodology of the RCT conducted at CHW. The PhD research formed a subsection of this trial, with a focus on adolescents. However, statistical analysis of the differences between younger children and adolescents revealed these were limited to higher mean anxiety Clinical Severity Ratings (CSR) among adolescents (with the same pattern of main effects obtained). As such, to increase statistical power, results for the full participant sample are presented in *Chapter 4*. It was hypothesised that 1) ACT would be at least as effective in the treatment of anxiety disorders in these populations relative to a manualised CBT group therapy program, as measured by no significant differences between the two treatments on clinician-, parent- and self-report clinical and QOL outcome measures, and; 2) ACT would be more effective in the treatment of anxiety disorders in this population relative to WLC at both immediate

posttreatment and 3MFU, across measures. It was also purported that 3) larger effect sizes would be observed for theoretically specified outcomes – clinical for CBT; QOL for ACT.

Results of the RCT, presented in *Chapter 4*, obtained support for the first hypothesis. In terms of clinical measures, no significant differences (statistically or clinically) were observed between ACT and CBT on anxiety CSR means over time overall, with very large effect sizes obtained for within group change in CSR across both treatments. Similarly the average number of anxiety diagnoses reduced from three to one for both ACT and CBT, a finding of very large effect size. Both ACT and CBT produced significant within group improvements on self and parent-reported anxiety (MASC-C/P). Likewise both treatments showed significant improvement in depression symptoms (CDI) and parent-rated total and anxious/depressed behaviours (CBCL) over time and there were no significant differences between ACT and CBT. This pattern at posttherapy was maintained at the 3MFU. In terms of QOL outcomes, ACT (and not CBT) evidenced significantly less child-reported anxiety interference (CALIS-C) over time; however, when adjustments were made due to ACT having higher interference CALIS-C scores, post differences between ACT and CBT no longer remained.

Partial support was obtained for the second hypothesis. At posttreatment ACT and CBT were superior to WLC on the primary outcome CSR (completer analyses), differences of very large effect size. Both treatment groups outperformed WLC on recovery rates. The treatment groups were superior to WLC on self-reported anxiety (MASC-C), depression symptoms (CDI) and life interference (CALIS) at posttreatment. In contrast to predictions, CBT, and not ACT, obtained significant greater improvements than WLC on parent-rated anxiety (MASC-P) at posttreatment. Parent-reported total problems / anxious depressed behaviour data (CBCL) indicated that statistically all three groups improved from pretreatment to post, with no between-group differences observed. However, effect sizes for the treatment groups were moderate to large, with a small effect size for WLC. Arguably changes on the CBCL among the treatment groups reflected clinically significant change, in that they saw a movement from the borderline clinical diagnosis to the normal range, whereas the WLC scores continued to place them in the borderline clinical range. Parent ratings of their child's internalising problems, such as anxiety,

have been found to be influenced by maternal anxiety. One study observed mothers with increasing anxiety levels were more likely to perceive their child to exhibit greater internalising problems than those with mothers with lower anxiety, despite nil differences on clinician-rated measures (Cobham, Dadds, & Spence, 1999). As maternal anxiety was not examined in the current investigation, this cannot be ruled out as an explanation for the aforementioned MASC-P and CBCL findings.

As CBT aims to support a reduction or remission of clinical symptomology, whereas ACT emphasises QOL outcomes, the third hypothesis was that these treatments would obtain superior effect sizes on outcomes linked to these theoretical underpinnings. Evidence to support this hypothesis was limited, in that few significant treatment differences in outcome measures were observed, as described above. Where differences were observed, they were of small effect size, and in the expected direction. Across clinical outcomes CBT was superior to ACT on self-reported anxious symptoms (MASC-C) at posttreatment, although both treatment groups exhibited scores in the normal range. At 3MFU, using the intention-to-treat (ITT) sample, CBT was superior to ACT on CSR. No differences were observed between the two treatments on CSR completer analyses. On QOL outcomes ACT had larger effect sizes than CBT on both child and parent-reported anxiety interference (CALIS-C/P).

Upon establishment of changes in clinical and QOL outcome measures across time for the treatment groups, our secondary aim – reflected in *Chapter 5* – was to examine the ACT hexaflex model and its core processes as putative mediators for change. As such, the final hypothesis was that 4) the hexaflex and its component core processes would operate as mediators for treatment related change in clinical and QOL outcomes, with mediation effects expected to be treatment specific to ACT. Findings were mixed and provided limited support for this hypothesis. Treatment related change in process measures over time revealed change in acceptance and defusion (AFQ-Y) across both treatment groups, and not the WLC, with ACT (and not CBT) evidencing further increases from post to 3MFU. In contrast to predictions however, the mindfulness/self-as-context and valued action components of the ACT hexaflex model (CAMM-20 and VLQ), did not evidence significant within group change for either ACT or

CBT at post. These unexpected findings may be underpinned by several factors such construct inconsistency, the suboptimal capacity of these measures to track change over time, response bias, or reduced statistical power. However, our findings are in line with the mixed results observed among those few studies – as discussed in *Chapter 2* – that have examined changes in the core processes among both child and adult populations.

In terms of clinical outcomes, multiple mediation analyses revealed the hexaflex model mediated the relationship between treatment and CSR for ACT only, in partial support of our hypothesis. Treatment common mediation effects for the hexaflex were observed for depression (CDI) and self-reported anxiety (MASC-C). Acceptance and defusion (AFQ-Y) emerged as specific mediators and evidenced the same pattern of effects, also treatment common. No significant mediators emerged for parent-rated measures, which may be explained by poor agreement often observed between parent and child reports on anxiety (Baldwin & Dadds, 2007; Klein, 1991) or the difficulties for parents to accurately rate all components of internalising disorders such as anxiety. Effects of the hexaflex model as a whole were accounted for by the specific role of acceptance and defusion, as all other process measures were nonsignificant.

Mediation analyses for QOL outcomes were nonsignificant, in contrast to predictions. Likewise, few changes in process measures were observed post to 3MFU and mediation effects were nonsignificant. However, this is in line with research that has found that while the mediational role of psychological flexibility in ACT on a broad level has been identified, only modest support has been obtained for the anxiety disorders (S. C. Hayes et al., 2006). Alternatively 3MFU may not have offered sufficient time to observe changes in QOL. Some support for this assertion can be gleaned from the literature of ACT for children, in which several studies observed that treatment gains were either not fully evident at posttreatment (or initial follow-up) or that greater improvements for ACT were obtained some months after therapy cessation (e.g. L. Hayes et al., 2011; Metzler et al., 2000; Wicksell, Melin, & Olsson, 2007).

Limitations and directions for future research

Both systematic reviews highlighted that the evidence base for ACT among those with anxiety, and among children with other psychiatric concerns, is characterised by several methodological inadequacies and overall low study numbers, suggesting further research is warranted to consolidate findings. Just four RCTs were identified in the anxiety-specific literature, with the same proportion identified in the child-focused literature. In addition, a high proportion of identified studies were unpublished. There is a relative paucity of studies that have compared ACT to control, and alternative active treatments, among children, and most presenting problems are limited to one or two studies.

There is also some evidence that the methodological rigour observed in studies of ACT has not developed to the same extent of CBT. Likewise, the ACT for children literature lags behind that of ACT for anxiety in terms of methodological stringency. Thus, despite a proliferation in research over the past several years, the ACT empirical base is still in its infancy. However, given the comparative newness of ACT compared to CBT, this is not a surprising situation.

Caveats of the current RCT (described in detail below) included the:

1) Psychometric properties of the measures used to tap the hexaflex constructs and the developmental appropriateness of these measures for child populations has not been widely examined.

2) Differential attrition rates between treatments and design flaws in relation to examination of formal mediation limits the generalisability of findings.

3) Small sample size for the mediation analysis and the overlapping nature of the hexaflex core processes may affect the validity of findings.

4) Comparison of two manualised programs that incorporated overlapping behavioural components such as exposure (although employed with divergent emphasis), social skills training and problem solving. Thus, the extent to which these behavioural components alone contributed to outcomes is difficult to determine.

While measures of clinical outcomes are abundant in existing research, there is a relative dearth of research designed to examine processes of change (Twohig, Field, Armstrong, & Dahl, 2010). The literature is in its infancy in terms of the current availability of valid, reliable measurement tools that tap each of the hexaflex core processes, with some processes more thoroughly examined than others. Some constructs are not consistently operationalised, and our understanding of the way in which these processes operate in young people is limited. The employment of these measures across a wide age spectrum is also a drawback, with potential implications for the developmental appropriateness of measures. In support of the measures employed however, in the area of values for example, research suggests that observations from childhood broadly emulate the trends in adult populations (Cohen & Cohen, 1996), A further limitation is that the interrelating nature of ACT processes of change may produce resultant discriminative validity concerns in measurement tools, an area for future research. Additionally, as this study was designed to measure ACT putative mediators for change, and required completion of a large battery of assessments to provide coverage for the ACT hexaflex, CBT putative mediators (e.g. catastrophising, etc.) were not examined. A comparison of the various ACT and CBT putative mediators would add to the broader mediation literature, as this may offer additional evidence for the possibility of shared mechanisms underpinning treatment outcomes, a further consideration for future research.

The generalisability of the findings may also be limited in that the present investigation was conducted at one clinical site. This limitation, however, is balanced by the methodological stringency afforded in the use of one site, such as the employment of the same assessment methods, consistency of therapists and the conduct of the research in a real life tertiary care setting. Rates of attrition were identified to vary by treatment group, with a greater number of ACT participants having dropped out. Whilst this may raise concerns of possible bias, the rationale for dropouts was pragmatic, rather than treatment related or motivationally based, and completer analyses were done in addition to ITT to account for this.

In order to cover the breadth of clinical, QOL and process outcomes, the current research protocol incorporated multiple psychometrically reliable and valid outcome/process measures,

which resulted in increased time for participants to complete assessment batteries. The conduct of session-by-session repeated measures was therefore unfeasible as it was considered to be overly taxing to young participants. Instead, reassessment was limited to three time points (pre, post and 3MFU). As process measures were obtained in concert with main outcome measures, a formal examination of causal mediation was not possible. Similarly changes in clinical and QOL outcomes between post and 3MFU were observed, which precluded longitudinal mediation analyses. Thus, the precise nature of the relationship between process and outcome variables in this investigation is difficult to delineate. Future research should utilise repeated multiple process and outcome measures at midtreatment, rather than follow-up, to circumvent this difficulty.

Regarding the limitation of the use of multiple behavioural components in both treatments, ACT typically includes behavioural methods as part of its model and protocols. Exposure is done in the context of increasing the clients' willingness to experience anxiety based on the goal of living a valued life. This is an exploratory study and future research could refine the elements of the program that are essential.

Implications

Findings indicated ACT is effective in improving the majority of clinical and QOL outcomes among young people (aged 7-17 years) with anxiety disorders. This research provides further evidence for the utility of ACT in the treatment of anxiety disorders (to date primarily obtained from adult samples) and ACT in the treatment of child populations with a spectrum of other psychiatric concerns.

Statistically and clinically significant changes were observed over time and relative to WLC, with results broadly comparable to that obtained by the current "gold standard" treatment, CBT. This is particularly important in light of the high proportion of children treated with CBT who are nonresponsive or exhibit residual symptomatology upon treatment cessation and suggest ACT is a viable alternative for clinicians. These observations are also in line with those from the largest study of ACT in the treatment of adults with mixed anxiety disorders (Arch, Eifert, et al.,

2012), whereby equivalent reductions on clinician- and self-rated anxiety measures and clinical/reliable change rates were found. This study also found that despite their differential aims in terms of treatment outcome, both studies were effective in producing improvement in clinical and QOL outcomes. Although this RCT does not suggest ACT should replace CBT, it does provide evidence that ACT is effective in treating anxiety symptoms in children and adolescents, with similar outcomes obtained.

The developmental appropriateness of ACT approaches for children has been a subject of much debate and there is currently a paucity of research conducted with adolescent samples over 14 years. This research expanded upon the existing literature through the inclusion of a sample aged up to 17 years and observed similarly efficacious outcomes for younger children and adolescents. Whilst findings also supported the observations of other researchers that older age has been associated with increasing anxiety severity (Oort et al., 2009), treatment outcomes did not differ by age in the present investigation. These findings challenge the common clinical misperception that adolescent engagement precludes treatment success and suggest ACT approaches are developmentally appropriate in this age group, in line with the considerations of other researchers (Coyne et al., 2011; Greco et al., 2005).

While emergent literature attests to the effectiveness of ACT, far fewer studies have examined the processes of change pivotal to treatment outcomes. Whilst results varied on the outcome under consideration, acceptance and defusion emerged as the only two hexaflex processes to mediate treatment effects. While acceptance and defusion are theorised to mediate treatment outcome among ACT participants, a rationale for these processes in mediating outcomes in CBT is less well understood. Acceptance is the antithesis of avoidance, a key factor in the maintenance of anxiety disorders, and CBT emphasises exposure and brave behaviour in relation to fears, which necessitates changes in experiential avoidance. However, the ACT approach of defusion is an alternative to the CBT technique of cognitive restructuring, and as such changes in this measure are unexpected. Despite their deviation from theoretically based hypotheses, these findings are in line with outcomes from other studies comparing ACT and CBT in the adult literature (Arch, Eifert, et al., 2012; Forman, Shaw, et al., 2012) and may

suggest these two differential approaches operate via similar mechanisms. Further research is required to replicate and expand upon the findings of this exploratory study to refine the aspects of treatment fundamental to outcome.

Conclusion

This RCT was the first to compare ACT with CBT and WLC in children and adolescents (7-17 years) with mixed anxiety disorders. ACT was found to be a viable treatment available to clinicians, and a feasible alternative to traditional CBT for these populations. Notwithstanding the aforementioned limitations, this study bolstered the ACT literature among children and provides an empirical base for its clinical application among those with anxiety disorders. Despite mixed results, some evidence was obtained for the hexaflex processes of acceptance and defusion as mediators of treatment related outcomes for CBT and ACT, suggesting that, despite their differences, these two therapeutic approaches may be underpinned by analogous mechanisms. Whilst the mediation effects gleaned in the current investigation require further replication, these exploratory findings suggest ACT interventions with young people should ensure a focus on the components of acceptance and defusion for the achievement of optimal clinical and QOL outcomes.

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Appendix A – Rules governing the RHD thesis by publication

Office of Graduate Studies
Information Sheet
Thesis by Publication

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

The Rules Governing Research Higher Degrees (Rule 000830) allow for a thesis to be submitted in the form of a series of published papers.

> **Rule 53.** A thesis submitted in the form of a series of published papers shall conform to the following:
>
> **a)** a full explanatory overview shall be included to link the separate papers and to place them in the context of an established body of knowledge;
>
> **b)** a literature review shall be included;
>
> **c)** if detailed data and descriptions of methods are not otherwise given, they shall be included as appendices;
>
> **d)** the papers must be published, in press or submitted to scholarly media only, i.e. refereed publications classified by national journal rankings and refereed conference papers, however at least 50% of the papers must have been published. Papers published up to three years prior to enrolment may be included provided they were published in scholarly media and do not represent more than 50% of the total papers;
>
> **e)** publications submitted for another degree by the student may only be referred to in the literature review;
>
> **f)** the number of papers submitted should be sufficient for the body of work to constitute a significant and original contribution to knowledge;
>
> **g)** the candidate must be the lead author in at least 50% of the papers written in the time of their formal Research Higher Degree candidature. Any published paper of which the candidate is a joint author may only be included in the thesis provided the work done by the candidate is clearly identified. The candidate must include in the thesis a written statement from each co-author attesting to the candidate's contribution to a joint publication included as part of the thesis. These statements must be endorsed by the Pro Vice-Chancellor (or nominee);
>
> **h)** the Head of School or Pro Vice-Chancellor may seek the approval of the Deputy Vice-Chancellor (Research) to include a paper that is outside the scope of these rules.

Issues to consider

- **Each discipline area will have different issues to consider in the decision to submit a thesis in the form of a series of published papers.**

- **It is essential that you discuss your options carefully with your supervisor(s). The thesis must reflect a sustained and cohesive theme, an integrated whole that sits logically in the context of the available literature. Overall the material presented for examination needs to equate to that which would otherwise be presented in the traditional thesis format.**

- **Some journals take a long time to finalise the review process and waiting for papers to be accepted can delay thesis submission. Time management and selection of journals/publishers is critical. Focusing on**

publication rather than research may lead to candidates being tempted to publish sections of their work prematurely and missing opportunities to fully capitalize on the significance of the work.

- **You need to consider the thesis from the examiners' view point - if the publications do not have a clear cohesion and the contribution to knowledge is not clearly demonstrated, then the thesis may attract criticism and be rejected by examiners. The content of the thesis remains a matter of professional judgment for the supervisor(s) and candidate.**

- **As per rule 53 g) any published paper of which the candidate is a joint author may only be included in the thesis provided the work done by the candidate is clearly identified. The candidate must include in the thesis a written statement from each co-author attesting to the candidate's contribution to a joint publication included as part of the thesis. The statement/s need to be signed by the Faculty Assistant Dean (Research Training) (Pro Vice-Chancellor nominee). A sample statement is provided below.**

- **We strongly advise you to arrange for the signatures from co-authors to be collected as soon as the paper is prepared or submitted for publication rather than trying to collect them at the time of thesis submission.**

- **There is no minimum or maximum requirement on the number of papers. Of equal, or perhaps more importance than quantity, is the quality of the journals.**

_____

Other options

As discussed above, you need to consider if your publications will form a sufficient body of work to meet the requirements of thesis by publication. You may wish to consider the other option of including publications within a standard thesis format, either in the body or as an appendix, as per rule 50 c) below.

51. A thesis:

c) may include publications arising as a consequence of the research undertaken for a thesis. When the candidate includes a co-authored published paper or co-authored scholarly work, or a substantive component of a co-authored published paper or co-authored scholarly work in the body of the thesis, the candidate must include in the thesis a written statement attesting to their contribution to the joint publication. This statement must be endorsed by the supervisor. A statement is not required when publications are included as an appendix.

_____

Suggested format

1. **Title Page**

2. **Declaration**
"I hereby certify that this thesis is submitted in the form of a series of published papers of which I am a joint author. I have included as part of the thesis a written statement from each co-author; and endorsed by the Faculty Assistant Dean (Research Training), attesting to my contribution to the joint publications.".

3. **Acknowledgements**

4. **List of publications included as part of the thesis**

   4.1   List all of the included published work with the full bibliographic citations in the order they appear in the thesis.

   4.2   Provide a statement to indicate that where necessary permission regarding copyright has been obtained from copyright owners. For example, the statement may say "I warrant that I have obtained, where necessary, permission from the copyright owners to use any third party copyright material reproduced in the thesis (e.g. questionnaires, artwork, unpublished letters), or to use any of my own published work (e.g. journal articles) in which the copyright is held by another party (e.g. publisher, co-author)."

5. **Statement of Contribution of Others**
Include in the thesis a written statement from each co-author attesting to the candidate's contribution to a joint publication included as part of the thesis. The purpose of this statement is to summarise and clearly identify the nature and extent of the intellectual input by the candidate and any co-authors.

   5.1   Sample co-author statement

   I, (insert co-author's name in full), attest that Research Higher Degree candidate (insert name) contributed (insert outline of contribution) to the paper/publication entitled (insert reference details).

   (Signature of Co-Author)

   (Full Name of Co-Author)

   Date:

   (Signature of Candidate)

   (Full Name of Candidate)

   Date:

   (Signature of Assistant Dean Research Training (ADRT))

   (Full Name of ADRT)

   Date:

6. **List of additional publications**
    List additional publications and conference presentations which have relevance to the thesis,
    but are not included in it. List these alphabetically and chronologically.

7. **Table of Contents**

8. **Abstract**
    An abstract of approximately 300 words is required to describe the content of the thesis.

9. **Overview**
    A full explanatory overview is required to link the published papers to the research thesis. This may include sections for Literature Review, Research Design and Review/Discussion. Not all of these sections may be necessary. Choose the format that underpins the academic argument so that the contents of the thesis are established as a substantial and significant body of work, but without unnecessary repetition.

10. **Published papers**
    Each chapter should have an introduction to explain how it contributes to the overall body of knowledge. Where the candidate is relying on publications, the author's final version of the paper (the version of the paper accepted by the journal for publication, including all modifications from the publishing per review process) would normally be included. It is not necessary to reformat published works in the thesis. Publications can be included in full or in parts thereof, where appropriate, to substantiate the contribution to knowledge.
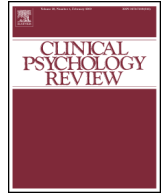
11. **Appendices**
    Appendices may include permission letters regarding copyright, evidence supporting refereed status of publications such as conference papers, and acceptance of papers which have not yet appeared in print.

12. **Bibliography**
    List all references cited in the thesis.

Appendix B – Statements from co-authors

Appendix C – "ProACTive" treatment manual

Acceptance and Commitment Therapy in the treatment of anxiety: A systematic review

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HIGHLIGHTS

- ACT has been empirically evaluated for the spectrum of anxiety disorders.
- Several methodology caveats exist, but initial evidence for ACT is promising.
- More research is needed to examine comparative effectiveness and consolidate findings.
- More studies are required to extrapolate findings to children and older adults.

ARTICLE INFO

ABSTRACT

With a lifetime prevalence of approximately 17% among community-dwelling adults, anxiety disorders are among the most pervasive of contemporary psychiatric afflictions. Traditional Cognitive Behaviour Therapy (CBT) is currently the first line evidence-based psychosocial intervention for the treatment of anxiety. Previous research, however, has found that a significant proportion of patients do not respond to traditional CBT or exhibit residual symptomatology at treatment cessation. Additionally, there is a paucity of evidence among child populations and for the comparative effectiveness of alternative interventions. Acceptance and Commitment Therapy (ACT) has a growing empirical base demonstrating its efficacy for an array of problems. A systematic review was conducted to examine the evidence for ACT in the treatment of anxiety. PsycInfo, PsycArticles, PsycExtra, Medline and Proquest databases were searched, reference lists examined and citation searches conducted. Two independent reviewers analysed results, determined study eligibility and assessed methodological quality. Thirty-eight studies met inclusion criteria (total n = 323). The spectrum of DSM-IV anxiety disorders as well as test and public speaking anxiety were examined. Studies were predominantly between-group design and case studies, with few employing control comparisons. Several methodological issues limit conclusions; however results provide preliminary support for ACT. Larger scale, methodologically rigorous trials are needed to consolidate these findings.

Contents

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1. Introduction

1.1. Anxiety: Prevalence, impact and psychosocial intervention

Anxiety disorders are characterised by symptoms of thoughts that are intrusive and/or disturbing, intense psychophysiological arousal, and highly negative appraisals of private experience (Greeson & Brantley, 2008). A systematic review of the international published literature on anxiety between 1980 and 2004 estimated the lifetime prevalence of anxiety disorders in the general population at 16.6% (Somers, Goldner, Waraich, & Hsu, 2006). In recent reviews of the best available evidence for the treatment of psychological disorders, traditional Cognitive Behaviour Therapy (CBT) was found to be the first line evidence-based psychosocial intervention for the treatment of anxiety disorders in adults (Otte, 2011; The Australian Psychological Society [APS], 2010). Arguably, in part, this is a consequence of insufficient evidence for alternative interventions (APS, 2010) rather than findings indicating other treatments are unsuitable. Furthermore, whilst traditional CBT is considered to be the "gold standard" for treatment for anxiety in adults, among children its effectiveness has not been established for some anxiety disorders, and was found to be variable across others (APS, 2010). Furthermore, research has found that many adults with social anxiety disorder (Dalrymple & Herbert, 2007) and generalised anxiety disorder (Hayes, Orsillo, & Roemer, 2010) either do not respond to traditional CBT or exhibit residual symptomatology and substantial impairment at treatment cessation.

1.2. Acceptance and Commitment Therapy: A "third wave" cognitive behaviour therapy

In an attempt to address such empirical and therapeutic anomalies so-called "third wave" cognitive behaviour therapy approaches, such as Acceptance and Commitment Therapy (ACT), have emerged (S. C. Hayes, 2004). Founded upon functional contextualism (for detailed review see Flaxman, Blackledge, & Bond, 2011; Hayes, 2004; Ruiz, 2012), ACT emphasizes the context and function of psychological phenomena (thoughts, feelings and sensations) as the target of change interventions, rather than the direct change of their form, frequency or validity, as typified by traditional CBT approaches (Blackledge, Ciarrochi, & Deane, 2009; Hayes, 2004; Hayes, Villatte, Levin, & Hildebrandt, 2011). In ACT psychopathology is construed as the consequence of reactive relationships to psychological phenomena that are perceived as distressing and intolerable, rather than the direct experience of these phenomena themselves (Luoma, Hayes, & Walser, 2007). Negative perceptions of psychological phenomena in turn elicit experiential avoidance, diminish an individual's capacity to respond to events as they unfold, and produce rigid patterns of behaviour that are in the service of achieving freedom from suffering rather than in line with personal values for living (Hayes et al., 2011; Roemer & Orsillo, 2005). Thus, the overarching aim of ACT is to facilitate psychological flexibility; "the ability to contact the present moment more fully as a conscious human being, and to change or persist in behaviour when doing so serves valued ends" (Hayes, Luoma, Bond, Masuda, & Lillis, 2006, p. 7). In ACT this is achieved via six interrelational core therapeutic processes that form a "hexaflex" model; acceptance, cognitive defusion, mindfulness, self-as-context, values and committed action (Luoma et al., 2007). Deployed as alternative to the direct change interventions typified by traditional CBT (e.g. cognitive restructuring), these approaches foster the attainment of increasingly flexible methods of managing psychological phenomena thereby diminishing their deleterious behavioural consequences (Arch & Craske, 2008).

Several previous reviews examining the efficacy of ACT in the treatment of a range of problems have consistently observed that whilst the ACT literature is characterised by several methodological caveats (Ost, 2008; Ruiz, 2010), ACT is more effective than control conditions (Hayes et al., 2006; Ost, 2008; Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009). Two reviews concluded that additional evidence is needed to determine the relative effectiveness of ACT in comparison to established treatments (Levin & Hayes, 2009; Powers et al., 2009). However, a more recent meta-analysis of studies on ACT versus CBT found that ACT outperformed CBT to some degree in 11 out of 16 outcome studies (Ruiz, 2012). Overall these reviews identified few anxiety-specific studies, and among those operationalized as anxiety within these publications were studies addressing stress or general distress. For example, Ruiz (2012) identified nine studies on problems of anxiety that compared ACT with CBT and observed no significant differences in anxiety primary outcome measures. However, one third of studies classified as "anxiety" involved the treatment of stress/general distress (Bond & Bunce, 2000; Flaxman & Bond, 2010; Lappalainen et al., 2007). A further study (Forman, Herbert, Moitra, Yeomans, & Geller, 2007) was analysed by Ruiz (2012) in accordance with a general measure of psychological functioning, rather than the specific anxiety measure

collected in this research, which limits this conclusion. Closer analysis of the results from the remaining five studies of anxiety problems revealed that ACT was superior to CBT in all but one study (Brown et al., 2011). This meta-analysis was also limited in that studies not employing a CBT comparison group were excluded. Likewise, another review was conducted to examine the effectiveness of ACT for the treatment of anxiety in the general population (Soo, Tate, & Lane-Brown, 2011). However, this review was limited to studies of RCT or single case study designs and, as a consequence, just seven studies met inclusion criteria, meaning a substantial body of the ACT for anxiety literature was unaccounted for. Furthermore, whilst changes in our current approach to the classification of mental disorders is imminent (and likely to include a reconceptualization of anxiety), with the uptake of a newly released diagnostic manual in May 2013, three of the studies (42.86%) included within the Soo et al review involved treatment of *Diagnostic and Statistical Mental of Mental Disorders — Fourth edition* (DSM-IV; American Psychiatric Association, 2000) "Impulse-control problems" – trichotillomania and skin picking – diagnoses made only if an individual does not meet criteria for another disorder, such as an anxiety disorder (American Psychiatric Association, 2000).

Taken together, whilst various reviews have been conducted, the literature lacks a comprehensive review of the efficacy of ACT specific to anxiety disorders and in the treatment of anxious symptoms that account for the gamut of research available to date. To address this gap, the current paper presents a broad systematic review of the empirical research for ACT in the treatment of anxiety, covering both the published and the unpublished literature regardless of study design or comparison condition. The main aim is to examine the utility of ACT in the treatment of anxiety. To the author's knowledge, this is the first systematic review to specifically focus upon anxiety.

2. Method

2.1. Search and screening procedures

The PsycInfo, PsycArticles, PsycExtra and Medline databases were electronically searched for the published literature up to October 2012. To identify unpublished literature the Proquest – dissertations and theses – database was searched applying this same time period. A list of keywords and terms was developed to identify studies (see Appendix A) and was adapted for use in each database. For each included study manual searches of reference lists were conducted and citation searches undertaken to locate additional potential studies for inclusion.

The title and abstracts of citations attained from initial searches and via secondary examination of reference lists were subjected to the below inclusion and exclusion criteria by two independent reviewers. Where reviewers disagreed on eligibility judgement, the study was jointly reassessed to achieve a unanimous result. In the event that this could not be reached, a third independent reviewer was available to make a determination. Full papers were retrieved and resubjected to inclusion and exclusion criteria in the same manner as titles and abstracts.

2.2. Inclusion criteria

Inclusion criteria for the current review included:

a) Intervention studies of Acceptance and Commitment Therapy (ACT) employing a minimum of two of the following ACT core processes: mindfulness, acceptance, cognitive defusion, self-as-context, values and committed action. This was to facilitate sufficient breadth of the review, whilst ensuring that included studies detailed more than a single technique described within the ACT model, as previous reviews have already been conducted on particular processes such as mindfulness [e.g. Baer (2003).]

b) Studies that specifically aimed to treat an anxiety disorder (as defined by the *Diagnostic Statistical Manual of Mental Disorders*; *DSM*; American Psychiatric Association, 2000) problem of anxiety or anxiety symptoms

c) Studies with outcome measures designed to identify remission or reduction of anxiety symptoms

d) Outcome measures of established psychometric quality

e) Articles prepared in English.

Intervention studies of all design types, from randomised controlled trials (RCT) to case studies, were included within this review. No population or setting criteria (adult, child, inpatient, outpatient, age, sex, etc.) or control/comparison condition specifiers were employed and both published and unpublished literature, where retrievable, were included within the review to maximise breadth. Studies were included regardless of timeframe to follow-up.

2.3. Exclusion criteria

Exclusion criteria for the current review included studies:

a) Utilising mindfulness-based stress reduction, as for the purposes of the current review the construct "stress" was differentiated from "anxiety". A thorough review has also previously been completed in this area [see (Toneatto & Nguyen, 2007)];

b) Employing mindfulness-based cognitive therapy as this intervention has a differential, increased focus on mindfulness practice beyond that employed within ACT and often incorporates cognitive change strategies that do not fit within the ACT model.

2.4. Eligible studies

The initial search produced 302 citations (after de-duplication). Additional 21 citations were identified through examination of reference lists. Three-hundred-and-twenty-three studies were subjected to inclusion and exclusion criteria. Sixty-six of these were deemed to have met initial inclusion criteria after 100% agreement was met by the two independent reviewers. Full papers were retrieved for these 66 citations and were again examined by two reviewers independently to determine whether the study met full inclusion criteria. See Fig. 1 for an overview of the study selection process.
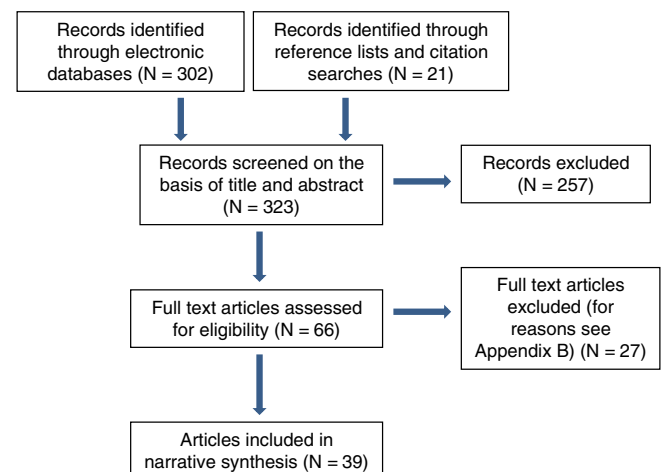

Fig. 1. Selection of studies.

2.5. Data extraction, synthesis and quality assessment

A standardised coding sheet was developed and data was extracted to this sheet for all studies meeting inclusion criteria. Data extracted included population characteristics, setting, research design, treatment conditions, treatment duration, outcomes and ACT core processes involved in the intervention. Outcomes of interest included: 1) reductions in clinician-rated and self-report anxiety measures; 2) diagnostic criteria met for a given anxiety disorder; 3) reductions in anxiety deemed to be clinically significant as determined by the criteria of Jacobson and Truax (1991) in relation to postintervention functioning that is either − a) outside the range of the dysfunctional population; b) within the range of the functional population; or c) mean scores nearer to the functional than the dysfunctional population; 4) reductions in anxiety deemed to evidence statistically reliable change as defined by Jacobson and Truax (1991) during the course of therapy; 5) whether the effects of treatment held at a follow-up evaluation. Due to the heterogeneity of studies that met the inclusion criteria, a narrative synthesis approach was deemed to be the most appropriate method for the review.

Quality assessment information was evaluated against the 22-item 'Psychotherapy outcome study methodology rating form' (POMRF) devised by (Ost, 2008). This scale examines 22 individual methodological elements including sample characteristics, the psychometric properties of outcome measures, research design, controls as well as therapist training and therapeutic modality adherence. Each item is rated on a 3-point scale from 0 to 2, where 0 = *Poor* and 2 = *Good*. Overall POMRF scores range from 0 to 44, with higher overall scores indicative of greater methodological rigour. In terms of psychometric properties the POMRF was found to have good internal consistency (0.86) and interrater reliability within the range 0.50–1.00 with a mean of 0.75 (Ost, 2008). Quality assessment data were extracted by two independent reviewers to a second coding sheet developed for this purpose. Where quality assessment judgement was subject to discrepancy the study was jointly reassessed by the two reviewers to gain a unanimous result. Where this could not be reached a third independent reviewer was available to make a determination. As the majority of studies included in this review did not report effect sizes, it was not possible to perform a more sophisticated analysis beyond POMFR scores and a narrative approach.

3. Results

Thirty-nine articles were deemed eligible for this review, after they were found to meet full inclusion criteria. These were comprised of 38 unique studies and one article (Forman et al., 2012) that reported follow-up outcomes of an included study (Forman et al., 2007). The reasons for exclusion of the 27 studies that met initial inclusion criteria, but were excluded after full review, are summarised in Appendix B. The primary reasons for exclusion at this stage related to the minimum number of ACT core processes not being met and the paper not reflecting an intervention trial (i.e. reviews or meta-analyses).

3.1. Overview of included studies

Table 1 provides an overview of the 38 included studies. Studies included a total of 959 participants and covered the full spectrum of *DSM-IV* (American Psychiatric Association, 2000) anxiety disorders as well as populations presenting with anxiety symptoms or with comorbid conditions. The majority of studies were published journal articles ($n = 22$; 57.89%) with a lesser proportion made up of unpublished university theses ($n = 16$; 42.11%).

3.2. Sample characteristics

Studies predominantly recruited adults with a specific anxiety disorder or problem of anxiety. Social anxiety disorder (including four with

specific phobia relating to public speaking) was the most commonly investigated condition ($n = 10$; 26.32%), followed by obsessive–compulsive disorder (OCD; $n = 7$; 18.42%), generalised anxiety disorder (GAD; $n = 5$; 13.16%), general anxiety symptoms ($n = 4$; 10.53%), posttraumatic stress disorder (PTSD; $n = 3$; 7.89%) and panic disorder with/without agoraphobia ($n = 2$; 5.26%). Five studies recruited participants with multiple anxiety problems (13.16%) and two with test anxiety/mathematics anxiety (5.26%). Comorbidity of anxiety disorders was commonplace. Predominantly participants were clinical outpatients ($n = 31$; 81.58%) and studies were undertaken in the United States of America ($n = 33$; 86.84%). The sample size ranged from 1 to 128 participants (median 16). Studies were relatively gender balanced. The majority of studies were conducted with adults ($n = 35$; 92.1%). Two were conducted with children (Armstrong, 2011; Yardley, 2012) and one focused on older adults (Wetherell et al., 2011).

3.3. Study design and treatment conditions

There were 16 between-group, ten within-group designs (five including multiple baseline measures) and an equivalent number of case studies, case series and RCTs ($n = 4$). Most studies reported that the treatment employed was ACT ($n = 32$; 84.21%). Whilst other studies met the inclusion criteria for ACT as described within this review, these were referred to as Acceptance-based Behaviour Therapy ($n = 4$; 11.43%). One study described the treatment being investigated as "Acceptance-enhanced Panic Control Treatment and Mindfulness and Acceptance-based Group Therapy". The majority of studies involved individual treatment ($n = 25$; 65.79%), with a lesser proportion undertaken in group format ($n = 13$; 34.21%). All studies involved the delivery of therapy with the exception of two where the intervention was a self-help protocol where participants were issued with ACT reading material (Beharry, 2008; Muto, Hayes, & Jeffcoat, 2011). High heterogeneity was observed in terms of treatment duration. Two studies involved a single intervention session, with one lasting 2 hours (Brown et al., 2011) and the other just 15 minutes (Goldfarb, 2010). Individual therapy ranged from 6 to 21 sessions, with 3–21 sessions for groups.

3.4. Control comparison and random assignment

The majority of studies did not utilise a control comparison group ($n = 30$; 78.95%), including two-thirds of between-group studies. Of the eight studies that did employ a control group 50% utilised a waitlist, 25% no treatment, 12.5% psychoeducation and 12.5% treatment as usual. Overall, 17 (44.74%) involved random assignment of participants to treatment.

3.5. Comparison to other active treatments

Sixteen (42.11%) studies compared ACT with another active treatment. The most common comparison conditions were CBT ($n = 9$; 23.68%) – representing the most methodologically stringent comparison condition to use (Ost, 2008) – and progressive relaxation training ($n = 2$; 5.26%). Other comparison conditions included panic control treatment, schema plus emotion-focused therapy, exposure with habituation and systematic desensitisation.

3.6. Primary outcome measure assessment tools

Several anxiety symptom assessment tools were utilised among the reviewed studies, with most employing multiple measures. Overall, the Anxiety Disorders Interview Schedule − Fourth edition (ADIS-IV; Silverman & Nelles, 1988), the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) and the Beck Anxiety Inventory (BAI; Beck & Steer, 1990) were the most commonly used scales. They were reflected within 28.95%, 23.68% and 18.42% of studies,

Table 1
Overview of included studies by anxiety problem.

Study	N	Age	Mean Age	% f	Pop.	Country	Design	Control	R/A	Treatment	Format	Length
Anxiety symptoms												
Forman et al. (2007, 2012)	101	18–52	27.87	80.20%	C, O	USA	BG	–	Y	ACT vs CBT	I	Av. = 15 × 1 h
Muto et al. (2011)	70	20–26	23.6	63%	NC, O	USA	BG	WL	Y	ACT	I	8 wks
Ovchinikov (2011)	38	18–67	–	84%	NC, O	USA	WG	–	Y	ACT	I	12 wks
Lassen (2011)	20	24–62	41.86	39.30%	C, I	USA	RCT	TAU	Y	ACT + TAU vs TAU	G	4 × 1 h
GAD												
Orsillo et al. (2003)	4	25–45	32.5	25%	C, O	USA	CSer	–	–	ACT	G	9 × 1 + 1 h
Roemer and Orsillo (2007)	16	19–58	36.44	56.30%	C, O	USA	WG	–	N	ACT	I	4 × 1.5 + 12 × 1 h
Roemer et al. (2008)	31	–	33.59	71%	C, O	USA	RCT	WL	Y	ACT	I	5 × 1.5 + 12 × 1 h
Sachs (2005)	8	27–54	35	–	C, O	USA	BG	WL	–	ACT+	G	8 × 2.5–3 h
Wetherell et al. (2011)	16	60+	70.8	47.50%	C, O	USA	RCT	BC	Y	ACT vs CBT	I	12 × 1 h
Mixed anxiety problems												
Arch (2009)	36	–	34.54	47.22%	C, O	USA	BG	–	Y	ACT vs CBT	I	12 × 1 h
Arch et al. (2012)	128	19–60	38	52%	C, O	USA	BG	–	Y	ACT vs CBT	I	12 × 1 h
Codd et al. (2011)	3	19–60	36	66.66%	C, O	USA	CSer	–	–	ACT	I	9–13 × 1–1.5 h
Eifert et al. (2009)	3	19–60	44.6	33.33%	NC, U	USA	CS	–	–	ACT	I	12 × 1 h
Jourdain and Dulin (2009)	1	19–60	68	0%	C, O	NZ	CS	–	–	ACT	I	7 × 1 h
OCD												
Main-Wegielnik (2010)	6	23–58	40.5	17%	C, O	USA	CSer	BC	–	ACT	I	12 × 1 h
Twohig (2007)	34	19–66	42	50%	C, O	USA	BG	–	Y	ACT vs. PRT	I	8 × 1 h
Twohig et al. (2006)	4	19–63	33.5	50%	C, O	USA	CSer	–	–	ACT	I	9 × 1 h
Twohig et al. (2010a)	79	18–67	37	61%	C, O	USA	BG	–	Y	ACT vs PRT	I	10 × 1 h
Twohig et al. (2010b)	6	23–36	30.2	67%	C, O	USA	BG	–	–	ACT vs ERP vs CBT	I	12 × 1 h
Yardley (2012)	3	10–11	10.33	33.33%	C, O	USA	WG	BC	–	ACT	I	9 × 50 min
Armstrong (2011)	3	12–13	12.33	33.33%	C, O	USA	WG	BC	–	ACT	I	8–10 × 50 min
Panic disorder/agoraphobia												
Karekla (2004)	22	18–65	34.95	77%	C, O	USA	BG	–	Y	APCT vs PCT	G	10 × 1.5 h
Lopez (2000)	1	28	28	0%	C, O	Spain	CS	–	–	ACT	I	12 × 1 h
PTSD												
Braekkan (2007)	22	50–59	55.83	0%	C, O	USA	BG	NTC	–	ACT	G	24 × 1.5 h
Twohig (2009)	1	43	43	100%	C, O	USA	CS	–	–	ACT	I	21 × 1 h
Williams (2007)	15	56–67	59.9	0%	C, O	Australia	BG	–	N	ACT vs. ACTDIS	G	10 × 3 + 3 h
Social anxiety disorder												
Beharry (2008)	8	21–50	28.5	77%	C, O	NZ	MB	–	–	ACT	I	8–16 wks
Block (2002)	39	18–43	–	67%	NC, O	USA	BG	NTC	SMR	ACT vs CBT	G	3 × 1.5 h
Block and Wulfert (2000)	11	–	–	63.64%	C, O	USA	BG	WL	SMR	ACT vs CBT	G	4 × 1.5 h
Goldfarb (2010)	45	17–21	19	86.60%	NC, U	USA	RCT	P.Ed	Y	ACT vs CBT	G	1 × 15 min
Dalrymple (2006)	16	–	31	52.80%	C, O	USA	MB	–	–	ACT	I	12 × 1 h
Dalrymple and Herbert (2007)	19	–	31	52.80%	C, O	USA	MB	–	–	ACT	I	12 × 1 h
Kocovski et al. (2009)	29	18–63	34.17	69%	C, O	Canada	WG	–	–	ACT	G	12 × 2 + 2 h
Ossman et al. (2006)	12	31–56	44	50%	C, O	USA	WG	–	–	ACT	G	10 × 2 h
Yuen et al. (2010)	24	19–63	35	25%	C, O	USA	WG	–	N	ACT	I	12 × 1 h
England (2010)	45	19–63	31.93	80%	C, O	USA	BG	–	Y	ACT vs. HAB	G	6 × 2 h
Test/mathematics anxiety												
Brown et al. (2011)	16	–	20.2	68.80%	NC, O	USA	BG	–	Y	ACT vs CBT	G	1 × 2 h
Zettle (2003)	24	–	30.9	81.01%	NC, O	USA	BG	–	Y	ACT vs SD	I	6 × 1 h

Note: Percentage female (% f); Average (Av.); Population — Clinical (C), Inpatient (I), Non-clinical (NC), Outpatient (O), Self-Help (SH), University (U); Design — Case series (CSer), Case Study (CS), Between Group (BG), Multiple Baseline (MB), Randomised Controlled Trial (RCT), Within Group (WG), Control condition — Baseline Control (BC), No-Treatment Control (NTC), Psychoeducation (P.Ed), Treatment-As-Usual (TAU), Wait List (WL); R/A = Random allocation; SMR = Semi-random; Treatment: Acceptance and Commitment Therapy (ACT), Cognitive Behaviour Therapy (CBT), Treatment As Usual (TAU), Progressive Relaxation Training (PRT); Exposure and Response Prevention (ERP); Acceptance-enhanced Panic Control Treatment (APCT), Panic Control Treatment (PCT), Acceptance and Commitment Therapy without the 'Distancing the self' component (ACTDIS), Habituation (HAB), Systematic Desensitisation (SD); Format — G = Group; I = Individual.

respectively. The validity and reliability of these measures have been established and they are among the most widely utilised anxiety measures. Studies involving disorder-specific interventions tended to use assessment tools designed for populations with that disorder. For example studies on obsessive–compulsive disorder typically utilised the Yale Brown Obsessive Compulsive Scale (YBOCS; Goodman et al., 1989).

3.7. Assessment of methodological quality

Results of the assessment of methodological quality revealed a high level of variability among included studies across POMRF items (see Table 2). Overall POMRF scores ranged from 4 to 31 out of a total of 44

points, with the average score 17.29 (SD = 7.53). As Ost (2008) did not include cut-off scores for the POMRF, the current review employed standard deviations (SD; rounded to the nearest whole number) to enable the calculation of a POMRF rating to compare methodological quality between studies. Studies more than one SD below the mean POMRF score were rated "well below average" (range 0–9), those within one SD of the mean "below average" (10–17), "above average" (18–26), and "well above average" (27+). As shown in Table 2, in accordance with these definitions, eight studies (21.05%) were determined to be of well below average methodological rigour. There were equal numbers of studies scored in the below average and above average range ($n = 12$; 31.58%) and six studies (15.79%) were well above

Table 2
POMRF and outcomes for included studies by anxiety problem.

Study	N	POMRF score	POMRF rating	Outcomes
Anxiety symptoms				
Forman et al. (2007, 2012)	101	27	Well above average	↓CR (ES = 0.34), ↓SR (ES = 0.68), CSC overall sample 55%, ACT = CBT; FUP ↓SR overall sample (ES = 0.22), ACT = CBT, CSC: ACT 56% vs. CBT 72.7%
Muto et al. (2011)	70	10	Below average	↓SR (ES = 0.89–1.37/1.33–2.01), ACT > WLC (severe anxiety), CSC: ACT 59% vs. WLC 10%, RC: ACT 15% vs. WLC 6%
Ovchinikov (2011)	38	9	Well below average	↓BAI
Lassen (2011)	20	14	Below average	SR ns., ACT = TAU
GAD				
Orsillo et al. (2003)	4	9	Well below average	↓CR ↓SR, 75% TR, 55% HEF
Roemer and Orsillo (2007)	16	24	Above average	↓CR (ES = 0.76/0.64), ↓SR (ES = 0.70–0.71/0.49–0.55), TR 75%/50%, HEF 62%/58.3%
Roemer et al. (2008)	31	27	Well above average	↓CR (ES = 2.97/2.83/2.34), ↓SR (ES = 1.23–1.77/1.47–1.95/1.30–1.86). At post ACT 76.92% vs. 16.67% WLC ≠ diagnosis, 75% TR, ACT > WLC
Sachs (2005)	8	29	Well above average	↓CR (ES = 6.06/7.22), ↓SR (ES = 1.03–2.24/1.07–3.36), BAI ns. At post 33.33% ≠ diagnosis, ACT > WLC on ADIS-IV (ES = 4.93)
Wetherell et al. (2011)	16	25	Above average	ACT↓PSWQ, HAMA ns.; CBT↓HAMA, PSWQ ns.; FUP: All outcomes ns[a]
Mixed problems of anxiety				
Arch (2009)	36	13	Below average	↓CR; ACT = CBT. At post 100% ≠ diagnosis
Arch et al. (2012)	128	31	Well above average	↓CR (ES = 0.82–0.93), ↓SR (ES = 0.13–0.26), ACT = CBT (ITT) at post & FUP. At FUP CSR ACT > CBT (completers; ES = 1.1)
Codd et al. (2011)	3	8	Well below average	↓CR & SR post & FUP. At post 100% ≠ diagnosis
Eifert et al. (2009)	3	9	Well below average	↓CR & SR. At post 100% ≠ diagnosis
Jourdain and Dulin (2009)	1	4	Well below average	↓SR (non-clinical levels) post & FUP
OCD				
Main-Wegielnik (2010)	6	12	Below average	CR & SR ns
Twohig (2007)	34	28	Well above average	↓CR (ES = 2.08/1.93), ACT > PRT (ES = 0.97/0.63), CSC: Post 55% ACT vs 12% PRT (ES = 1.01) & FUP 62.5% ACT vs 26.6% PRT (ES = 0.89)
Twohig et al. (2006)	4	11	Below average	↓CR & SR post & FUP; CSC OCI post & FUP
Twohig, Hayes et al. (2010)	79	29	Well above average	↓CR (ES = 0.77/1.10), ACT > PRT (ES = 0.84)
Twohig et al. (2010b)	6	17	Below average	↓CR, ACT = ERP = CBT[b]
Yardley (2012)	3	16	Below average	↓CR, SR obsession freq. & intensity ↓ among 2/3 P's. Overall frequency 21.95% ↓ & intensity 25.02% ↓[b]
Armstrong (2011)	3	17	Below average	↓CR & SR (exc. COIS-R). Overall SR compulsion frequency↓ 40.4–64.5%; CY-BOCS↓ 28.2%. 66.6% ≠ diagnosis[b]
Panic disorder/agoraphobia				
Karekla (2004)	22	25	Above average	↓CR (ES = 0.46–0.73), ↓SR (except PAS) at FUP. APCT = PCT; APCT > PCT on interference, severity and panic symptoms at FUP
Lopez (2000)	1	4	Well below average	ACT↓SR outcomes (exc. FQ)
PTSD				
Braekkan (2007)	22	15	Below average	↑SR auto thoughts at 3mths. All other CSR and SR ns
Twohig (2009)	1	9	Well below average	↓CR & SR
Williams (2007)	15	16	Below average	↓ Symptoms & general health, PTSD checklist ns., ACT > ACTDIS on PCL-M at FUP (ES = 0.31)
Social anxiety disorder				
Block (2002)	39	20	Above average	↓ Social phobia, avoidance & SUDS at post & FUP. FQ ↓ FUP; At post ACT > NTC & ACT > CBT on avoidance, CBT > ACT on social interaction anxiety, CBT > NTC on FQ; FUP ACT ↓SR (exc. Social Interaction), ACT = CBT
Beharry (2008)	8	6	Well below average	↓SR (ES = 0.38–0.57)
Block and Wulfert (2000)	11	17	Below average	↓SR, ACT > WLC, ACT = CBT[b]
Goldfarb (2010)	45	14	Below average	↓SR, ACT = P.Ed = CBT
Dalrymple (2006)	16	21	Above average	↓CR & SR (ES = 1.01–1.04), CSC 56.3%, RC 62.5%, RC & CSC 37.5%, 44% ≠ diagnosis
Dalrymple and Herbert (2007)	19	20	Above average	↓CR & SR (ES = 0.72–3.86/0.72–3.86) excl. worry, 44% ≠ diagnosis
Kocovski et al. (2009)	29	23	Above average	↓SR (ES = 1.00–1.11/1.00–1.17), RC 68.97%/43%
Ossman et al. (2006)	12	18	Above average	↓SR (ITT ES = 0.56–0.66) at post & FUP
Yuen et al. (2010)	24	22	Above average	↓CR (ES = 2.32), ↓SR (ES = 1.23–1.99), 54% ≠ diagnosis
England (2010)	45	9	Well below average	↓CR (ES = 0.64–0.7), ↓SR (ES = 0.43–56) exc. SSTAI, ACT = HAB. Results maintained at FUP, 100% ACT completers ≠ diagnosis
Test/mathematics anxiety				
Zettle (2003)	24	18	Above average	↓SR, ACT = SD (exc. trait anxiety SD > ACT), CSC (ACT = SD), Math anxiety ACT 83.33% vs. SD 91.66%; trait/test anxiety ACT 41.66% vs SD 50%. FUP CSC ACT 0% vs. SD 66.66%, SD > ACT. FUP↓ ACT maths anxiety, all other outcomes ns., SD ↓ test anxiety, all other outcomes ns., ACT = SD.
Brown et al. (2011)	16	20	Above average	↓SR (exc. state anxiety); ACT = CBT except ACT > CBT performance (ES = 0.39)

Note: Psychotherapy Outcome Methodology Rating Form (POMRF); Outcome measures — Anxiety Disorders Interview Schedule (ADIS-IV), Beck Anxiety Inventory (BAI), Child Obsessive Compulsive Impact Scale — Revised (COIS-R), Fear Questionnaire (FQ), Hamilton Anxiety Measurement Assessment (HAMA), Panic and Agoraphobia Scale (PAS), Penn State Worry Questionnaire (PSWQ), Posttraumatic Stress Disorder Checklist — Military Version (PCL-M), Speilberger's State Trait Anxiety Inventory (SSTAI); Outcomes — Acceptance and Commitment Therapy (ACT), Acceptance and Commitment Therapy without the 'Distancing the self' component (ACTDIS), Acceptance-enhanced Panic Control Treatment (APCT), Cognitive Behaviour Therapy (CBT), Clinician-Rated (CR), Clinical Recovery (CRec); Clinically Significant Change (CSC), Effect size (ES); Exposure and Response Prevention (ERP); Habituation (HAB), High End-state Functioning (HEF), Intention To Treat (ITT), No-Treatment Control (NTC), Not Significant (ns), Obsessive Compulsive Inventory (OCI), Panic Control Treatment (PCT), Progressive Relaxation Training (PRT); Psychoeducation (P.Ed), Reliable Change (RC), Self-Report (SR), Subjective Units of Distress (SUDS), Treatment As Usual (TAU), Treatment Responders (TR); Systematic Desensitisation (SD).

[a] Sample size meant BS comparisons could not be made.
[b] No statistical tests conducted.

average, translating to relatively high methodological rigour. In terms of the specific problems of anxiety, each problem was characterised by studies of varying methodological quality.

Some aspects of methodological quality were widely ignored; for example, only five studies (13.16%) described the use of a power analysis (Dalrymple, 2006; England, 2010; Lassen, 2011; Muto et al., 2011; Twohig, Hayes, Plumb, Pruitt, Collins, et al., 2010). Eight (21.05%) employed inadequate statistical analyses or omitted aspects of the obtained data. Predominantly clinical significance was not discussed ($n = 24$; 63.16%) and the same proportion did not report disorder severity/chronicity or employed subsyndromal samples. Six studies handled attrition to a "good" standard (Arch et al., 2012; Armstrong, 2011; Block, 2002; Forman et al., 2007; Ossman, Wilson, Storaasli, & McNeill, 2006; Yardley, 2012). The training of researcher assessors was specified well in only two (5.26%) included studies (Roemer, Orsillo, & Salters-Pedneault, 2008; Sachs, 2005) and none examined the impact of therapist on outcome. Furthermore, checks for treatment adherence were conducted in 39.47% and the remainder did not report any checks to ensure interventions were conducted in line with study protocol. It is necessary to ensure adherence to treatment protocol is ascertained by independent assessors in order that treatment effectiveness be determined (Ost, 2008).

Most studies were subject to biased treatment assignment ($n = 23$; 60.53%). In terms of design, more studies (60.53%) were scored as poor as they included a waitlist comparison or vaguely detailed treatment-as-usual (TAU) group, rather than comparing ACT to an alternative empirically documented intervention. Regarding sample representativeness, 14 (36.84%) of the studies received a "poor" rating as they were either case study designs or involved fewer than 10 participants. Of the remaining 24 studies, the majority ($n = 21$; 87.5%) included a sample somewhat representative of patients seeking treatment for the disorder, whereas in just 5 (13.16%) it was determined that efforts were taken to ensure sample representativeness (Arch et al., 2012; Brown et al., 2011; Forman et al., 2007; Kocovski, Fleming, & Rector, 2009; Twohig, 2007). Seven studies (18.42%) reported that diagnoses were made via a structured interview undertaken by a trained assessor, and detailed adequate interrater reliability. Less than one-quarter (23.68%) reported the use of blind evaluators and just one described the employment of checks to ensure that the assessor was not aware of intervention condition (Sachs, 2005).

Studies fared better in terms of specificity and reliability of outcome measures. All studies employed either specific ($n = 31$; 81.58%) or moderately specific outcome measures ($n = 7$; 17.42%). Thirty-six (94.74%) included only measures with sound psychometric properties. Two (5.26%) employed measures where the psychometric properties were largely unknown (Block & Wulfert, 2000; Twohig, Whittal, Cox, & Gunter, 2010). However, this latter finding may be explained by several studies including measures associated with ACT core processes as there are only relatively new measures available to assess these constructs. Studies predominantly employed replicable, specific treatment programmes designed for the disorder ($n = 35$; 92.11%), however three (7.89%) provided vague treatment or multiple forms of treatment without appropriate controls (Jourdain & Dulin, 2009; Orsillo, Roemer, & Barlow, 2003). Thirteen (34.21%) completed some form of check for therapist competence. For those studies employing between-group comparisons ($n = 16$), 13 (81.25%) involved an equality of therapy hours between conditions, whereas 2 involved conditions in which the therapeutic hours spent differed by more than 20% (Lassen, 2011; Roemer et al., 2008), that has implications for study internal validity.

3.8. Outcomes

Study outcomes are depicted in Table 2. Outcome data reported includes reporting of effect sizes (ES) where available at posttreatment and any follow-up undertaken. All available follow-up ES are reported directly after posttreatment ES in Table 2, and where data from multiple

assessment points was reported, these are delineated by a backslash (/). The following pages will provide a narrative synthesis of these results by anxiety problem.

3.8.1. Social anxiety disorder (SAD)

Ten studies examined SAD. More than two-thirds included a clinical outpatient sample. Of these, three examined the effectiveness of a 12-week individual ACT programme (Dalrymple, 2006; Dalrymple & Herbert, 2007; Yuen, Herbert, & Forman, 2010). In a sample of 19 participants, ACT produced significant decreases in self-reported social phobia, fear and avoidance as well as clinician-rated anxiety severity (Dalrymple & Herbert, 2007). Likewise, in an earlier pilot involving 16 participants, Dalrymple (2006) found significant improvement across all self and clinician-reported social anxiety measures posttherapy of large effect size. ACT produced clinically significant change among 56.3%, reliable change among 62.5% and both clinically significant and reliable change among 37.5% (Dalrymple, 2006). Yuen et al. (2010) employed videoconferencing as a medium in the delivery of ACT for 24 participants and found results across both clinician and self-rated performance in line with the aforementioned equivalent face-to-face therapeutic programmes, indicating that videoconferencing may be considered as another medium by which to deliver ACT interventions. At posttreatment these three studies found that 44–54% of patients no longer met diagnostic criteria for SAD. The methodological rigour of these studies in accordance with the POMRF was above average (in the range 20–22), suggesting a reasonable level of generalisability of the findings. These studies would have been strengthened by the incorporation of a control group or alternative intervention comparison.

Five studies examined the effectiveness of ACT group therapy in the treatment of SAD. Significant treatment effects for ACT on anxiety measures of large effect size were found (Kocovski et al., 2009; Ossman et al., 2006). Kocovski et al. (2009) received the highest POMRF rating of all SAD studies included within this review, within the above average range, and also found reliable change in 68.97%. Another group-based programme employed a university sample with social anxiety symptoms to compare the relative efficacy of ACT to CBT, with a wait-list control (Block & Wulfert, 2000). Findings indicated a decrease in symptoms of social phobia and fear among both intervention groups, whereas the wait-list group exhibited no change or increased anxiety. However, this study's findings are limited by sole reliance on self-report data and no statistical tests to determine significance. The POMRF score for this study was lower than most of the SAD studies, in the below average range for all studies in this review.

Two group-based intervention studies specifically considered the effectiveness of ACT on public speaking anxiety, a form of social anxiety, among nonclinical university samples (Block, 2002; Goldfarb, 2010) and a further study among a clinical outpatient sample (England, 2010). Block (2002) examined the comparative effectiveness of ACT and CBT relative to a waitlist control. ACT participants evidenced significant decreases on all anxiety measures at follow-up, with the exception of social interaction anxiety, which significantly decreased among CBT participants. However, between group comparisons revealed that ACT produced decreased avoidance relative to CBT, whereas changes in avoidance were nonsignificant for CBT participants. In an RCT, Goldfarb (2010) studied the relative effectiveness of a single 15 minute group session of ACT versus CBT with a psychoeducation control. State anxiety decreased across both intervention groups; however, no differences were identified between groups on other anxiety measures. Neither intervention was significantly more efficacious than psychoeducation. However, results of his study are severely limited by the treatment duration. This aspect, together with a below average POMRF score suggest poor external validity of these findings.

In another study, 45 participants with nongeneralised SAD – or SAD limited to one or two specific situations (i.e. public speaking) – were randomised to either an acceptance/defusion (ACT) or a habituation-focused exposure (HAB) programme (England, 2010). Results indicated

that ACT participants showed improvements on both clinician and self-rated measures of public speaking anxiety of moderate effect size but, both ACT and HAB produced equivalently significant treatment effects. In a study exhibiting substantial methodological weaknesses, Beharry (2008) examined the effectiveness of an ACT self-help workbook plus a therapist contact programme. Results showed significant reductions in anxiety (with the exception of self-reported fear) and cognitive change. However, a POMRF score in the well below average range for both of these studies suggests for that almost all indicators of methodological adequacy were not met, so results must be interpreted with caution.

In summary, results of ACT studies conducted with SAD clinical populations showed significant improvements in anxiety – moderate to large effect sizes – regardless of whether treatment was completed in group or individual format. There is also some evidence that ACT results in clinical and reliable change and that a substantial proportion of individuals achieve full remission at treatment cessation, findings that were underpinned by studies exhibiting relatively strong methodological rigour. Whilst methodological caveats were pronounced among studies of the treatment of anxiety associated with public speaking, the available research indicates that ACT may be supportive in reducing some aspects of social anxiety and produces equivalent outcomes when compared with CBT.

3.8.2. Obsessive–compulsive disorder (OCD)

Seven studies examined ACT in the treatment of OCD with all employing clinical outpatient samples and individual treatment. Three between-group studies were undertaken (Twohig, 2007; Twohig, Hayes, et al., 2010; Twohig, Whittal, et al., 2010). Of these, two compared ACT to progressive relaxation training (PRT). Both studies evidenced above average POMRF ratings and found that ACT resulted in a decrease in OCD severity of moderate to large effect size. Likewise, clinically significant change in OCD severity was observed at greater proportions in the ACT condition relative to PRT (Twohig, 2007; Twohig, Hayes, et al., 2010). In a study of 34 participants (18 ACT and 16 PRT), Twohig (2007) also found that 55% in the ACT group were treatment responders, in that they scored less than 12 on the Yale Brown Obsessive Compulsive Scale (YBOCS; Goodman et al., 1989) and evidenced a pretreatment to posttreatment decrease in score by at least six points.

The remaining four studies of OCD were conducted with small samples of just three to six participants, and all evidenced below average POMRF ratings. One compared ACT to cognitive therapy and exposure with response prevention, with only two participants in each condition (Twohig, Whittal, et al., 2010). Overall where participants reported obsessions or compulsions as problematic, a reduction in anxiety was experienced by the 83.33% regardless of treatment type – including both in ACT condition – however no statistical comparisons were undertaken. In a nonconcurrent multiple baseline study involving four participants, very large decreases in self-reported compulsion frequency were found (Twohig, Hayes, & Masuda, 2006). Twohig et al. (2006) observed clinically significant improvement among 68% of participants. However, these studies have poor external validity due to their case study nature and the participants exhibiting heterogeneous OCD presentations.

Two studies involved unpublished theses and represented the only studies in this review that explored the effectiveness of ACT among anxiety in children (Armstrong, 2011; Yardley, 2012). Both incorporated ACT without exposure in the treatment of paediatric OCD among three participants aged 10–13 years and attained POMRF scores in the below average range. Armstrong (2011) found that average compulsion frequencies decreased 28.2% and 40.4–64.5% on clinician-rated and self-reported measures, respectively. Reductions in measures were observed for all participants and two of three attained Children's Yale Brown Obsessive Compulsive Scale (CY-BOCS; Foa, Kozak, Salkovskis, Coles, & Nader, 1998) scores below the clinical mean at posttreatment. Likewise,

Yardley (2012) observed large changes in clinician-reported measures across all participants with an average decrease of 47.26% and reductions in self-reported obsessive cognitions in two of three participants. However, the small sample size and lack of control condition greatly limit the rigour of these studies.

In a study of four OCD participants with high overvalued ideation – or the lack of ability to recognise one's beliefs as irrational – no significant changes in anxiety posttherapy were found (Main-Wegielnik, 2010). However, mixed results were observed between participants. Despite this, this sample might be characterised as a treatment resistant group as three of the four participants had completed a course of CBT prior to the current study. Furthermore, high overvalued ideation is characterised by increased rigidity, identification with beliefs, earlier onset of symptoms, and poorer treatment response compared to individuals with OCD without overvalued ideation (Foa, 1979; Nezirolgu, Stevens, McKay, & Yaryura-Tobias, 2001). The POMRF for this study in the below average range and low scoring also indicated concerns with respect to methodological rigour.

In summary, the bulk of the evidence from these seven studies appears to indicate that ACT is supportive for the treatment of OCD and is associated with both statistically and clinically significant change. This finding is underlined by two studies that compared ACT to PRT, which evidenced relatively good methodological rigour, and found that the former produces superior clinical outcomes for OCD. A further two studies provided preliminary evidence for ACT in the treatment of paediatric OCD, offering initial support for the utility of ACT among child populations. However, methodological weaknesses of predominantly small samples and no comparison control group limit the generalisability of findings. The presence of possible author bias is also problematic as four of the aforementioned studies were conducted by what appears to reflect a large team of affiliated researchers.

3.8.3. Generalised anxiety disorder (GAD)

Three studies examined the utility of ACT delivered as individual treatment for GAD (Roemer & Orsillo, 2007; Roemer et al., 2008; Wetherell et al., 2011). Roemer et al. (2008) randomly assigned 31 participants to ACT or a waitlist condition. Results indicated a decrease in clinician-rated severity and self-reported GAD symptoms of large effect size. ACT was found to be superior to a wait-list group in terms of proportions of participants not meeting GAD criteria and evidencing response to treatment, a significant difference between groups. At posttherapy 75% of GAD participants were deemed to evidence clinically significant change (Roemer et al., 2008), a finding strengthened by a well above average and relatively high POMRF rating. In a second trial, 16 older adults were randomised to ACT or CBT (Wetherell et al., 2011). Whilst no between-group comparisons were conducted, within group findings produced mixed results in that ACT participants exhibited significant decreases in worry. However, changes in anxious symptoms were nonsignificant. In contrast, the CBT group evidenced significant decreases in anxious symptoms, but nonsignificant changes in worry. In a third study, Roemer and Orsillo (2007) found significant decreases overall anxiety including clinician-rated GAD severity as well as self-reported anxiety and depressive symptoms with medium to large effect sizes. Results also indicated that the majority of participants demonstrated clinically significant change. POMRF scores in the above average range represent reasonably good methodological rigour in this study.

Two studies employed a group-based treatment programme (Orsillo et al., 2003; Sachs, 2005). In a study that attained the highest POMRF of the GAD research (29/44), with the majority of criteria met for methodological rigour, Sachs (2005) randomly assigned participants to either a waitlist control or ACT incorporating elements of imaginal exposure to core schema and emotion-focused therapy. ACT participants achieved significantly improved clinician-rated anxiety severity both within-group and relative to controls, with one-third no longer meeting GAD diagnostic criteria. Whilst within-group changes were noted, no significant differences between groups were observed on

self-reported symptoms of GAD. Likewise, Orsillo et al. (2003) found that ACT produced significant reductions in anxiety with 75% determined to be treatment responders – in terms of a 20% decrease in anxiety scores across therapy – and 55% of ACT participants met criteria for high end-state functioning in that scores were in the normal range. However findings of this study are limited in external validity as evidenced by a low score in the below average POMRF score and a small sample size.

Overall, studies of GAD provide some support for the use of ACT interventions with this population. ACT was typically associated with reductions in various GAD symptoms, and a high proportion of participants deemed to evidence clinically significant change at treatment cessation. The majority of studies had above average POMRF scores, suggesting relatively good generalisability of these findings.

3.8.4. General anxiety symptoms

Four studies were conducted of the efficacy of ACT in the treatment of general anxiety symptoms, including one RCT of a group-based intervention (Lassen, 2011), one individual therapy programme (Forman et al., 2007) and two self-help interventions (Muto et al., 2011; Ovchinikov, 2011). In what is widely acknowledged to be a treatment resistant group, the impact of ACT in reducing anxiety among outpatients with a primary problem of psychosis was examined with participants randomly assigned to treatment as usual (TAU) or ACT + TAU (Lassen, 2011). Substantial heterogeneity was found among participant disorders and whilst a trend towards improved state and trait anxiety was observed among ACT participants, this was nonsignificant. However, this study attained a below average POMRF rating. It is limited by a high attrition rate (28.6%) and was underpowered to detect effects that may have been present. Other factors that may have contributed to nonsignificant results included mid to low participant satisfaction and the brief nature of treatment. In another trial, 101 outpatients with anxiety and/or depression were randomised to either ACT or CBT (Forman et al., 2007). Large, equivalent improvements were observed across both self and clinician-reported measures for both treatment groups. ACT participants evidenced significant improvement pre to posttherapy on all measures. Among the overall sample 55% exhibited clinically significant change, however it is unclear what proportion of the ACT group evidenced this change. This is one of the largest RCTs on ACT, strengthening its external validity. Whilst this study attained a well above average POMFR rating with most criteria met, findings would have been bolstered through the inclusion of breakdown of participant outcomes by anxiety or depression and by treatment group for some outcomes, as well as a lower attrition rate across groups (40%).

Two self-help interventions considered the effectiveness of ACT for 108 university students with anxiety, with treatment adherence measured via a series of quizzes. Muto et al. (2011) randomised a sample of Japanese international students to either wait-list or a Japanese translation of an ACT self-help book. ACT participants with severe anxiety showed improvement, both within and between groups, producing large effect sizes. In terms of reliable change 6% of wait-list participants improved and 2% deteriorated, whereas in the ACT condition 15% improved and 0% deteriorated. Likewise, in a within-group study over 12 weeks, a self-help ACT intervention was associated with significant reductions in Beck Anxiety Inventory (Beck & Steer, 1990) scores (Ovchinikov, 2011). However, this latter study experienced a high percentage of dropouts (68.07%) and data was only reported for the 38 participants who completed the required assessments indicating a possible response bias. Whilst the results of these self-help interventions are encouraging in terms of offering an alternative delivery to face-to-face, relatively low POMRF scores indicate limitations in the generalisability of results.

The existing research on the use of ACT among populations experiencing general symptoms of anxiety indicates that this treatment may be effective in reducing impairment. Whilst preliminary evidence indicates early support for self-help interventions for anxious symptoms these studies did not perform well in methodological evaluation – with the exception of Forman et al. (2007) – suggesting that these results should be interpreted with caution. Likewise, it remains unclear whether ACT is supportive for reducing anxiety among more treatment-resistant populations. More research of higher methodological rigour is needed to establish this, low POMFR scores in this group pose difficulty in terms of the external validity of findings.

3.8.5. Posttraumatic stress disorder (PTSD)

Two between-group studies examined group-based ACT for the treatment of PTSD among male combat veterans, obtaining mixed results (Braekkan, 2007; Williams, 2007). In an Australian study, Williams (2007) allocated 15 Vietnam War veterans with PTSD to either ACT or ACT without the 'discovering the self' phase. At treatment cessation both groups showed decreased PTSD scores, fewer symptoms and less distress. Between group differences, whilst all favouring ACT, were nonsignificant with the exception of self-reported PTSD symptoms. In a study with several methodological caveats, 12 veterans were compared to demographically matched nonPTSD community members in a nonequivalent control group design (Braekkan, 2007). Results were reported at the midpoint of the study and included no significant changes for the controls. A significant increase in automatic thoughts was observed among ACT participants. It is unclear if completing the full treatment may have impacted on observed outcomes. Furthermore, between-group findings from this study are limited given the nonequivalent design and that the control group also received no treatment. Both studies evidenced lower than average POMRF scores, translating to poor external validity.

A case study examined the impact of 21 individual ACT sessions on an adult woman with chronic PTSD and major depressive disorder who was nonresponsive to prior CBT treatment (Twohig, 2009). PTSD severity, and anxiety significantly improved across treatment to within a standard deviation of nonPTSD samples and decreases in trauma-related thoughts and beliefs were also observed. The generalisability of this study is limited by its case study design, and this is reflected in a low score in the well below average POMRF rating.

Taken together it is difficult to draw firm conclusions about the effectiveness for ACT in the treatment of PTSD at this stage due to both the low number of studies available and the methodological caveats reflected in low POMFR scores. More research is required to gain further knowledge about the suitability of ACT for this population.

3.8.6. Mixed problems of anxiety

Five studies were conducted on samples with comorbid or heterogeneous anxiety concerns.

Two between group studies were conducted, comparing a 12 session programme of ACT to CBT (Arch, 2009; Arch et al., 2012). The first included 36 participants with primary problems of panic disorder/agoraphobia, SAD or specific phobia (Arch, 2009). ACT evidenced significant decreases in clinician and self-report measures, with equivalent reductions in the former between ACT and CBT from moderate severity to subclinical severity posttherapy. The largest study within this review involved 128 participants with panic disorder and/or agoraphobia, SAD, GAD, OCD and specific phobia (Arch et al., 2012). This study was found to achieve the highest overall methodological rigour of all studies within this review on the POMRF (31/44). ACT produced equivalent reductions to CBT on both clinician and self-rated anxiety measures in the intention-to-treat sample. However, in the completer sample ACT was superior to CBT on clinician-rated outcomes. Both groups evidenced equivalent clinical/reliable change.

Three case studies/series were conducted, all indicating that ACT is supportive for the treatment of participants with comorbid anxiety presentations. The most recent of these involved three consecutive patients presenting with panic disorder with agoraphobia, comorbid SAD and GAD, and PTSD (Codd, Twohig, Crosby, & Enno, 2011). All

participants evidenced clinically significant change on the ADIS-IV (Albano & Silverman, 1996). Another study involving three individuals with panic disorder, comorbid SAD and dysthymia and comorbid OCD and panic disorder found overall significant decreases in anxiety – including sensitivity, worry, symptoms and fear related avoidance – that represented clinically significant change on both self-report and clinician-rated measures (Eifert et al., 2009). Likewise, a New Zealand case study of an older Māori man with PTSD and health-rated anxiety also found that ACT produced clinically significant decreases on all anxiety measures (Jourdain & Dulin, 2009).

Whilst the majority of studies on mixed problems of anxiety were of case study design and had low POMFR scores, the largest and most methodologically sound study within this review was represented in this group (Arch et al., 2012). Based primarily on that study evidence suggests that ACT is at least as effective as CBT in reducing self-reported anxiety, and more effective than CBT according to clinician ratings among populations with mixed/comorbid anxiety problems, often attaining diagnostic remission at therapy cessation.

3.8.7. Panic disorder with agoraphobia

There was a paucity of literature of the utility of ACT for patients with panic disorder or panic disorder with agoraphobia, with just two studies meeting inclusion criteria for the current review. One study compared panic control treatment (PCT) with ACT-enhanced PCT among 22 participants, achieving a POMRF score in the above average range (Karekla, 2004). Equivalent decreases in anxiety severity, panic distress interference and worry, number of panic attacks and panic symptoms were observed. Significant decreases were observed on agoraphobia, distress, interference, avoidance and apprehension of situations. PCT participants experienced significantly more interference and agoraphobia severity as well as avoidance than the ACT group. The second study, a case study conducted in Spain, found 12 sessions of ACT to produce clinical recovery (Lopez, 2000). Large decreases in anxiety, worry and agoraphobia symptoms were reported, but no change to self-reported fear was found. However, this study attained among the lowest POMRF ratings in the current review, which suggests that considerably more methodologically sound research and in particular those with larger samples are required to consolidate these findings.

3.8.8. Test and mathematics anxiety

Two studies examined the effectiveness of ACT in managing anxiety relating to academic pursuits. ACT was compared with systematic desensitisation (SD) for the treatment of mathematics anxiety among 24 college students (Zettle, 2003). Whilst decreases in trait anxiety were observed among 12 SD participants, the results for ACT were nonsignificant. Equivalent clinically significant reductions for math anxiety were observed across both groups. In another study, 16 university students were randomised to a single two hour group workshop of either ACT or CBT (Brown et al., 2011). Equivalent significant reductions in test anxiety, emotionality and test worry were observed. ACT participants showed greater improvement in test performance than CBT who, in contrast, demonstrated performance deterioration. These studies had above average POMFR scores, but still did not meet the majority of criteria adequately. As well, there are only two studies and one (Brown et al., 2011) involved a small sample size. These findings indicate some support for ACT in reducing anxiety associated with academic pursuits regardless of the format or treatment duration employed.

3.9. Follow-up evaluation

Predominantly, studies involved a follow-up assessment after treatment cessation ($n = 23$; 60.53%). One recently published paper (Forman et al., 2012) was identified that provided long term follow-up data, 18 months posttherapy, of an included study (Forman et al., 2007) and was also included in this analysis. The time to follow up ranged from six weeks to 18 months, with a median

of three months. Of these, two did not report follow-up data (Block & Wulfert, 2000; England, 2010). From the remaining 21 studies, 90.48% attained significant results indicating that the effects of ACT are still evident for a considerable time after treatment cessation. Of those studies that did not observe significant follow-up findings, one involved a sample broadly considered to be treatment resistant – OCD participants with high overvalued ideation the majority of whom had not benefited from a prior course of CBT – and a second was undertaken among a sample of older adults with GAD, a demographic characterised by a paucity of research. Of those studies which reported effect sizes (ES), follow-up evaluations on clinician rated measures obtained ES in the range 0.46–7.22, with self-report measures in the range 0.22–3.36.

Whilst few between-group comparisons were made at follow-up, four studies examined the utility of ACT versus CBT. Three studies involving samples of mixed anxiety problems (Arch et al., 2012), SAD (Block, 2002) and anxiety and depression (Forman et al., 2012) all attained above average POMRF ratings and found ACT to produce equivalent anxiety reductions to CBT. However, when the completer sample – rather than the intention-to-treat – was examined in the Arch et al. (2012) study, ACT was found to be superior to CBT on clinician rated measures, a difference of large effect size. Forman et al. (2012) found CBT participants exhibited increased treatment effects for depression relative to ACT. Whilst clinically significant change proportions favoured CBT over ACT on self-reported anxiety, differences were nonsignificant and in part may have reflected higher baseline anxiety scores among CBT participants. The results are tempered by the inclusion of a nondifferentiated anxiety and depression sample as well as the employment of self-report data alone at the follow-up assessment. A fourth study involving older adults with GAD obtained nonsignificant results for all follow-up outcomes (Wetherell et al., 2011). However, it was similarly limited by the sole use of self-report data, which may have impacted on the findings. In the main, there is a paucity of follow-up data attesting to the comparative effectiveness of ACT versus CBT, the current gold standard treatment for anxiety disorders. However, preliminary results derived from studies rated to be among the most methodologically sound on POMRF within this review typically indicate that ACT is at least equivalently effective.

Two studies of well above average POMRF rating found ACT to be superior to PRT, producing moderate-to-large ES, in the treatment of OCD (Twohig, 2007; Twohig, Hayes, et al., 2010). For PTSD, ACT achieved significantly improved outcomes, of small ES, than ACT without the 'discovering the self' phase at follow-up (Williams, 2007). Furthermore, another study observed ACT-enhanced PCT to be superior to PCT on interference, severity and panic symptoms among those with panic disorder with agoraphobia (Karekla, 2004). Whilst among those with mathematics anxiety, in contrast to a posttreatment finding that favoured SD on trait anxiety reductions, Zettle (2003) found no significant between group differences on any outcome measures between ACT and SD at 2-month follow-up. This finding was explained by continual decrease in trait anxiety scores among ACT participants from posttreatment to follow-up, suggesting the effects of ACT may continue to grow in the aftermath of therapy.

Few studies reported indicators of reliable and/or clinically significant change as well as end-state functioning at follow-up. However, one study found 50% of GAD participants who completed ACT were still classified as treatment responders – in that they evidenced a reduction in scores of 20% or more on 75% of outcome measures – and 58.3% demonstrated high end-state functioning – in that scores were within the normative range or reflected a score of three or less on clinician-rated severity – at 3-month follow-up (Roemer & Orsillo, 2007). Twohig (2007) also identified significant differences between ACT and PRT, of large ES, favouring ACT, in terms of clinically significant change for those with OCD. In contrast, among those with mathematics anxiety treated with ACT, Zettle (2003) found that no participants met criteria for clinically significant and reliable change. However, this study was limited by its short follow-up reassessment period of 2-months and within this time

scores on some outcomes for ACT participants improved. Thus it is unclear whether a longer follow-up may have produced different outcomes.

Overall, follow-up evaluations provided additional support for the utility of ACT in the treatment of various problems of anxiety beyond therapy cessation. Among the few studies that described clinically significant or reliable change, a high proportion of participants met these criteria at follow-up across the various problems of anxiety, with the exception of mathematics anxiety. Firm conclusions regarding the comparative effectiveness of ACT to other treatments cannot yet be established due to the early stage of this research.

4. Discussion

Overall, 38 studies (covered by a total of 39 unique articles) met inclusion criteria for the current review and all but three (92.11%) found a significant improvement in the majority of anxiety outcome measures among ACT at posttherapy. Although the majority of studies did not report ES, those that did were generally in the moderate range. This finding held across the spectrum of *DSM-IV* (American Psychiatric Association, 2000) anxiety disorders and problems of anxiety. Where nonsignificant effects were observed, two studies attained below average POMRF scores that could not be accounted for solely by a case study research design. These were also conducted among populations that are widely acknowledged to be treatment resistant, including those with a psychotic disorder (Lassen, 2011) and OCD participants with high overvalued ideation (Main-Wegielnik, 2010). The third, whilst attaining a POMRF in the above average range, involved a sample of elderly participants – a population typified by a dearth of research – and identified mixed results (Wetherell et al., 2011).

An earlier review – which included three studies of anxiety discussed within the current review – (Soo et al., 2011) concluded there was some evidence to support the use of ACT for anxiety-related conditions including OCD, mathematics anxiety as well as mixed anxiety and depression. Likewise a recent meta-analysis that involved six studies included within this review found no significant differences in anxiety primary outcome measures between ACT and CBT (Ruiz, 2012). When the results of anxiety-specific studies only were examined, rather than pooled with studies of stress or general distress, four of five found ACT produced favourable outcomes. Thus the preponderance of evidence from the current review, based on a much larger pool of studies and broadly concentrating on anxiety problems, supports and expands upon these conclusions. The bulk of this evidence suggests that ACT is superior to control conditions and, in the main, broadly equivalent to other active psychotherapeutic approaches.

Whilst this finding represents important empirical evidence for the utility of ACT for anxiety, these results are necessarily tentative, limited by the number and quality of eligible studies. Several key limitations must be taken into consideration. Little is known about the relationship between effect sizes and POMRF scores. As such, an analysis of this relationship among the studies included within this review was considered, but not pursued as several obstacles limited the utility of this. These included the large number of studies of case study design and low N. As a consequence, ES were not able to be calculated for 17/38 studies. Furthermore, such an añalysis is not recommended when reviews include studies with substantial heterogeneity. Whilst a recent metaanalysis of the effectiveness of psychotherapy for the treatment of anxiety among children found that study ES had no relationship with methodological quality (Reynolds, Wilson, Austin & Hooper, 2009), it is unclear if this finding extends to adult populations. Furthermore, the POMRF assessment of methodological rigour found the majority of studies to exhibit several rudimentary design errors (e.g. no control comparison, few RCTs [10.53%] and a predominance of case studies). The assessment of methodological rigour using a tool such as the POMFR is limited in that journal submissions are typically subjected to restrictive word counts, that may mean that a study may have the appearance of poor methodological rigour, but it may be because full methodology,

involving the assessed degree of rigour, was not reported rather than not implemented. However, other mechanisms for drawing conclusions about methodological quality are not currently available. To support consolidation of conclusions about the utility of ACT, and its relative efficacy in comparison to other active treatments, trials addressing the identified gaps in methodological stringency are warranted.

It is a challenge to draw firm conclusions about the utility of ACT in treating specific anxiety problems, as most disorders/issues were examined by only a small number of studies and employed different outcome assessment tools, making comparisons difficult. Whilst RCTs are generally considered the "gold standard" for methodological rigour, other types of studies such as those reported in this review also add to the body of knowledge in a way that the controlled conditions of RCTs do not. For example, the use of naturalistic settings or multiple baseline measures is often not possible in studies of RCT efficacy studies.

Another limitation in the research found as a result of the current review is that it is difficult to estimate the comparative effectiveness of ACT to other active psychological treatments. Within this review the most common treatment comparison was CBT and these studies generally found equivalent significant reductions in outcome measures across both active treatments. However, among those studies that did assess the relative efficacy of ACT to another treatment, they were often underpowered to detect differences or between-group analyses were not reported, which compounded this concern. Indeed Ost (2008) observed the mean POMRF for ACT RCTs was 18.1 – versus 27.8 for CBT – indicating that methodological concerns are more typical in ACT research than other therapeutic modalities. This remains an area to be addressed for future research to enable appropriate comparisons of clinical outcomes to be made.

An additional problem typical of this area of study is the diversity in therapeutic terminology. Whilst most studies were conducted with "ACT" interventions, there were several studies of treatments considered to fit the definition of ACT described by terms such as "acceptance-based behaviour therapy". It is our consideration that such heterogeneous naming of therapies, that appear to encompass the same core elements, is somewhat unhelpful in terms of building a sound research base to inform clinical decision making. Likewise, the variability in the number of core ACT processes used makes it difficult to compare "apples with apples". Furthermore, it remains unclear as to the elements of the intervention that are pivotal in producing clinical outcomes. Future research might also focus on identifying these mechanisms of change in order to support clinicians in delivering optimal therapeutic interventions focusing on these aspects.

Another difficulty in comparing studies is the variability in treatment modality. Some studies were individual face-to-face, others group, and yet others self-help bibliotherapy. Some were only brief therapies (in some cases one session) whilst others were detailed. Such variability could be a factor related to outcomes that needs to be teased out in future research. One of the strengths of most studies in this review, however, was that they had a treatment comparison condition where therapy time was comparable in both groups.

Only a minority of studies reported clinical significance or *ES*. Reporting of such would provide more evidence for the effectiveness of ACT as well as assist in quantitatively comparing studies. Clinical significance is important in determining whether ACT produces important changes such as movement from one severity level to another, or from a diagnosis to condition to no diagnosable condition.

One gap identified from this review was the lack of ACT research into young people with anxiety. Indeed, this review retrieved no eligible published studies and just two unpublished theses amounting to a total of six participants on one anxiety disorder (OCD; Armstrong, 2011; Yardley, 2012). Anxiety is the most common mental health concern afflicting young people (American Psychiatric Association, 2000; Semple & Lee, 2008), increases the likelihood of academic and social skill difficulties as well as substance abuse, can be enduring if untreated and has been found to predict mental health concerns in

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Acceptance and Commitment Therapy for children: A systematic review of intervention studies

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ABSTRACT

An emerging body of research demonstrates the effectiveness of Acceptance and Commitment Therapy (ACT) in the treatment of adult psychopathology, with several reviews and meta-analyses attesting to its effectiveness. While there are comparatively fewer empirical studies of child populations, the past few years has seen burgeoning research interest in the utility of ACT for problems in childhood. A systematic review of the published and unpublished literature was conducted to examine the evidence for ACT in the treatment of children and to provide support for clinical decision making in this area. Searches of PsycInfo, PsycArticles, PsycExtra, Proquest and the Association for Contextual Behavioral Science databases were undertaken, as well as reference lists and citation searches conducted, up to December 2014. Broad inclusion criteria were employed to maximise review breadth. Methodological quality was assessed and a narrative synthesis approach adopted. Twenty-one studies covering a spectrum of presenting problems met inclusion criteria, with a total of 707 participants. Studies were predominantly within-group designs, with a lesser proportion of case studies/series, between-group and randomised controlled trials. The preponderance of evidence suggests ACT results in improvements in clinician, parent and self-reported measures of symptoms, quality of life outcomes and/or psychological flexibility, with many studies demonstrating further gains at follow-up assessment. However, several methodological weaknesses limit conclusions, including small samples, non-randomised designs, and few alternative treatment or control comparisons. While larger scale, methodologically rigorous trials from a broader research teams are needed to consolidate these preliminary findings, emerging evidence suggests ACT is effective in the treatment of children across a multitude of presenting problems. ACT may be a viable alternative treatment option for clinicians working with young people.

Contents

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1. Introduction

Acceptance and Commitment Therapy (ACT) is a contemporary behavioural and cognitive therapy that works to foster increasing flexibility in response to thoughts, feelings and sensations through processes of mindfulness, acceptance, and behaviour change (Hayes, Levin, Plumb-Vilardaga, Villatte, & Pistorello, 2013; Wilson, Bordieri, Flynn, Lucas, & Slater, 2011). In ACT the focus of change interventions is the context in which psychological phenomena occur, rather than the direct change attempts of their content/validity or frequency, as typified by traditional cognitive behaviour therapy (CBT; Blackledge, Ciarrochi, & Deane, 2009; Hayes, 2004; Hayes, Villatte, Levin, & Hildebrandt, 2011).

ACT is underpinned by a theoretical framework, termed relational frame theory (RFT; S.C. Hayes et al., 2011). RFT focuses on human language and cognitive processes and suggests that with language development we learn to continually derive relations between events. From childhood we learn to relate events to each other on the basis of social convention and to derive meaning from events on the basis of this relating, termed in ACT "learned derivation" (Luoma, Hayes, & Walser, 2007). For example, during early language training interactions, children are often shown objects and asked to repeat their names. A mother may then clap her hands, or say, "That's right, a car!", reinforcing the spoken word "car" with the object, car. The child may also be taught the name of the car, so object-word and word-object relation is explicitly trained. With sufficient repetitions learned derivation occurs. The child is then able to generalise the spoken word car to a toy car, and to the printed words "toy car", and vice-versa.

Whilst learned derivation offers evolutionary advantages, it can also act as a hindrance. When language is taken literally this can result in a "fusion" with thinking (i.e. experience one's own thoughts and beliefs as literally true), and can lead to pain (Harris, 2009). In ACT this is termed cognitive fusion. To illustrate, fusing with the thought that "life is unbearable" might produce depressive symptoms despite the existence of various things required to live a full life, such as meaningful employment and supportive relationships (Hayes, Pistorello, & Levin, 2012). Cognitive fusion in turn leads to a whole host of reactions, known as "experiential avoidance", such as excessive use of problem solving, active efforts to escape or avoid feelings, and entanglement in thinking; methods employed as a way to solve our pain (Luoma et al., 2007). These methods result in a loss of contact with the present, belief in negative stories about ourselves, and rigidity in our way of living. Life becomes less about opening up in the pursuit of things that are important, but tends to result in an overall narrowing of living to support freedom from distress (Harris, 2009). In ACT this is termed psychological inflexibility.

ACT employs six interrelational core therapeutic processes that form a "hexaflex" model of psychological flexibility; acceptance, cognitive defusion, mindfulness, self-as-context, committed action, and valued living (Luoma et al., 2007). Acceptance is employed as the antithesis to experiential avoidance. The focus is on opening up to thoughts, feelings and sensations in order to increase the behaviour repertoire and allow for action that is in line with what is important (Hayes et al., 2012). To counteract cognitive fusion, clients learn to change the way they relate to their thoughts, and thereby decrease their attachment to these. For children, metaphors and experiential exercises help the child recognise a thought for what it is, just a bunch of words, and not what it says it is. Mindfulness is utilised to reduce problematic attentional patterns, that are past focused or future orientated (Hayes et al., 2012), in order to reduce cognitive errors such as rumination (past) or catastrophising (future). Clients are taught mindfulness approaches to increase their skills in staying present focused. Approaches may range from formal meditation exercises to deliberately averting "auto-pilot" by deliberately focusing on the here-and-now experience of activities of daily living such as breathing, walking or riding a bike (Harris, 2009). Self-as-context is best conceptualised as a perspective taken from the sense of self, or the ability of humans to consciously notice themselves doing, thinking or experiencing things whilst they are occurring. Therapeutically, contact with the self-as-context is achieved via mindfulness and perspective-taking (Hayes et al., 2012). Values identification is employed to assist in living life the way that is meaningful to each individual, supporting the identification of those tenets that may act as a compass to future action and as intrinsic reinforcers to the continuation of this behaviour (Hayes et al., 2012). For children this is working through what really matters to them at school, home and/or in their friendships for example. Committed action advocates engaging in behaviour that is in line with personal values for living, moment-by-moment, this often takes the appearance of behaviour change goals such as behavioural activation or exposure (Hayes et al., 2012). These approaches from the hexaflex are deployed to foster the attainment of increasingly flexible methods of managing challenging cognitions, emotions or sensations, thereby diminishing their deleterious behavioural consequences (Arch & Craske, 2008).

ACT has a growing evidence base in the treatment of adult psychopathology, with numerous reviews and meta-analyses demonstrating its efficacy (e.g., Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Levin & Hayes, 2009; Ruiz, 2012). There has also been considerable interest in the adaptation and assessment of the suitability of ACT approaches among child and adolescent populations (e.g., Coyne, McHugh, & Martinez, 2011; Greco, Blackledge, Coyne, & Ehrenreich, 2005; Murrell & Scherbarth, 2006). Reviews have found other psychotherapeutic approaches, such as traditional CBT, to be effective in the treatment of children with various presenting problems (AACAP, 2007, 2012; James, James, Cowdrey, Soler, & Choke, 2013; Weisz, McCarty, & Valeri, 2006). However, their effectiveness has been found to be modest (Weisz et al., 2006) and/or superior to no treatment, but not active control conditions (James et al., 2013). Finally, a recent review concluded that CBT is not necessarily the most effective form of treatment for young people, but the only one that has been researched enough to provide evidence to support its use (Creswell, Waite, & Cooper, 2014). Thus there is room for improvement and there is a need for more rigorous research into alternative treatments to support evidence based clinical practice.

Stemming from the cognitive behavioural tradition and with a strong theoretical basis, ACT has been proposed as a transdiagnostic

therapy, a unified treatment applicable to a range of presenting problems and clinical diagnoses (Hayes et al., 2012; Livheim et al., 2014). One possible mechanism through which this may occur is via ACT's focus on experiential avoidance. A recent review linked experiential avoidance to an array of psychopathology, finding experiential avoidance predicts symptom severity in specific disorders, affects relapse and can act as a mediator for psychological distress and coping (Chawla & Ostafin, 2007). If ACT were found to work effectively as a transdiagnostic approach this would reduce the load on clinicians to gain familiarity and competence with a whole host of diagnosis-specific evidence-based intervention (Farchione et al., 2012). This lends itself to the potential to work across contexts, with diverse child and adolescent populations and for clinicians to readily increase their expertise in intervention delivery.

More research incorporating ACT processes of change is required, including into experiential avoidance, to better elucidate this, particularly among children. Research on the ACT core processes and their relation to QOL, or psychosocial and well-being outcomes, among children demonstrates that these processes operate in a similar way to that of adults (for a review see Coyne et al., 2011). Feasibility studies also offer support for the utility of mindfulness-based approaches, such as ACT, with children (Burke, 2010). It has been argued that as children think less literally than adults, the employment of metaphors and experiential approaches may allow children to grasp abstract concepts through experience (O'Brien, Larson, & Murrell, 2008). Preliminary research with children as young as four suggests provides some evidence for this assertion (Heffner, Greco, & Eifert, 2003). Furthermore, it has been purported that children have had less time to adopt more entrenched patterns of experiential avoidance and as such, ACT may operate to achieve both the remediation, and prevention, of the onset of inflexible patterns of psychological responding (Greco et al., 2005). ACT approaches may also be well-suited to adolescents as they assist in rapport building and are less instructive (Greco et al., 2005). ACT's focus on experiential, or personal learning, approaches support autonomously-driven behaviour that may be particularly appropriate for adolescents desiring increased independence who may be non-responsive to adult direction (Hadlandsmyth, White, Nesin, & Greco, 2013). The emphasis on values may also be pertinent for adolescents due to the exploratory nature of, and increasing capacity for abstract thinking during, this developmental period (Greco et al., 2005).

There are two existing reviews of the ACT literature among children, however, neither have been conducted systematically. Systematic reviews of psychotherapeutic research aim to synthesise the academic literature, using a predefined scientific method to answer a specific clinical question, whilst minimising bias, and support the delivery of evidence-based treatment (Mulrow, 1994). Systematic reviews also identify and analyse the methodological rigour of included studies to support clinician's to comprehend the validity of the findings to their clients as well as support the conduct of future research endeavours (Mulrow, 1994). Both existing reviews of the ACT literature for children Murrell and Scherbarth (2006) and Coyne et al. (2011) examined 15 studies, which incorporated unpublished data from conference presentations not subjected to peer-review, parenting interventions, theoretical studies, and a study with an absence of psychometric measures. Neither examined unpublished university theses or dissertations. Whilst exclusive reliance on published literature in reviews may produce publication bias (McLeod & Weisz, 2004), potentially overstating the positive nature of treatment results, it has been argued that unpublished studies are unsuitable for systematic reviews due to their inferior methodological rigour. However, studies that have examined the rigour of grey literature, academic unpublished literature that has not been subjected to widespread peer review by the scientific community, have found that theses and dissertations may contain more, or equivalently,

stringent methodology than that found within published studies (Hopewell, McDonald, Clarke, & Egger, 2007; McLeod & Weisz, 2004). Whilst any form of unpublished academic literature might be considered to be grey literature, theses and dissertations have the advantage of undergoing peer review from a (albeit, small) number of reviewers. Therefore, it would seem that unpublished theses and dissertations have the capacity to reduce publication bias, whilst maintaining methodological quality, and strengthen the empirical base into populations for which there is a paucity of research. In this way, a systematic review supports clinicians and researchers to benefit from the synthesis of a greater wealth of research where bias is minimised to support translation into clinical and academic practice.

Evaluation of the methodological stringency of ACT research may be particularly salient, as a previous systematic review and meta-analysis of the adult literature, concluded methodological concerns are more typical in ACT research than in traditional CBT and that ACT did not met the requirements to be an "empirically supported treatment" (Ost, 2008). However, the conclusions of this review are not without contention. Gaudiano (2009) argued that the strategy utilised by Ost to compare methodological quality of ACT and CBT was mismatched, with the majority of ACT studies conducted among populations widely acknowledged to be treatment-resistant. ACT and CBT were also noted to be at markedly different stages of clinical trial research and associated grant support, favouring CBT, which was moderately correlated with methodological rigour (Gaudiano, 2009). Whilst this review was not without criticism, Ost was commended for attempting to evaluate the methodological stringency of the literature when making conclusions on its applicability for clinical practice (Gaudiano, 2009).

In summary, whilst two previous reviews of ACT for children have been conducted, these are subject to several limitations including non-scientific approaches and the inclusion of studies that are purely theoretical or not subjected to peer-review. At the time of the publication of the most recent review, few empirical studies had been conducted and those that were available were predominantly case studies or uncontrolled pilots (Coyne et al., 2011). In the past few years the ACT literature has seen a proliferation of studies involving child and adolescent populations. As an increasing number of studies are now available there is a growing need for a systematic review of the utility of ACT for children. The current investigation aims to address this gap in the literature by providing an integrated synthesis of both the published and unpublished literature for ACT in the treatment of children that incorporates both an exploration of findings and an evaluation of the methodological rigour of included studies. The diverse literature will be synthesised to elucidate generalisations, consistencies and inconsistencies in research findings to enable evidence-based clinical decision-making in this area and minimise bias (Higgins & Green, 2011; Mulrow, 1994). The analysis of the methodological rigour of included studies will also offer ecological validity information to assist clinicians in translating research into practice. To the authors' knowledge, this is the first systematic review to specifically focus upon children.

2. Method

2.1. Search and screening procedures

Electronic searches of the PsycInfo and PsycArticles and PsycExtra databases were undertaken to obtain the published literature. Whilst no date restrictions were employed, the search was conducted in December 2014 and therefore included literature available up to this time. Considered to be an international online learning and research community for researchers and clinicians with an interest in ACT, the

Association for Contextual Behavioral Science webpage (http://con textualscience.org/) was also searched, for the same time period. To minimise potential publication bias, a search of the unpublished literature was undertaken via the Proquest dissertations and theses database, up to December 2014. Search terms used were "Acceptance and Commitment Therapy" AND "child∗", or "adolescen∗", or "teen∗". Manual searches of reference lists were conducted for each included study, followed by citation searches to locate additional studies for inclusion. The title and abstracts of citations attained from initial searches and via secondary examination of reference lists were subjected to the below inclusion and exclusion criteria by the first two authors. Where there was disagreement on eligibility, the study was jointly reassessed by both authors to achieve a unanimous result. In the event that this could not be reached, the third author was available to make a determination. Full papers of retained citations were retrieved and re-subjected to the below full inclusion and exclusion criteria.

2.2. Inclusion criteria

Inclusion criteria for the current review included:

a) Intervention studies of ACT or studies that employed a minimum of two of the ACT hexaflex processes: mindfulness, acceptance, cognitive defusion, self-as-context, values and committed action.
b) Studies that treated child participants up to age 18 years.
c) Articles prepared in English.

2.3. Exclusion criteria

a) Review, meta-analysis or theoretical articles.
b) Studies that lacked at least one psychometrically validated measure.

To enable maximum breadth of the review no inclusion restrictions were placed on study design, disorder or problem of interest, setting, or control/comparison condition or timeframe to follow-up.

2.4. Eligible studies

The initial search identified 169 citations (following de-duplication). An examination of reference lists produced an additional 33 citations. Of these 202 citations, 33 met initial inclusion criteria. Full papers were retrieved for these 33 citations. See Fig. 1 for an overview of the study selection process.

Twenty papers met full inclusion criteria, detailing 21 unique studies. The first two authors were unanimous with respect to eligible studies. The reasons for exclusion of the 13 papers that met initial inclusion criteria, but were excluded after full review, are summarised in Appendix A. The primary reason for exclusion at this stage related to the paper not reflecting an intervention trial (i.e. theoretical papers or reviews etc.).

2.5. Data extraction, synthesis and quality assessment

Data was extracted to a standardised coding sheet for all studies meeting inclusion criteria. Data extracted included population characteristics, setting, disorder/concern being treated, research design, treatment conditions, treatment duration and outcomes. Outcomes of interest included: (1) reductions in clinician-rated, parent-rated, self-reported or objective measures of (a) symptoms and/or (b) QOL outcomes and/or (c) psychological flexibility and (2) maintenance of treatment gains at follow-up. Due to the heterogeneity of studies and
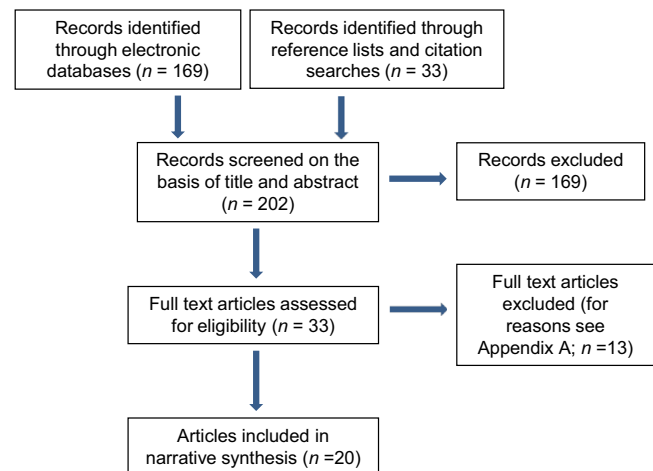
Fig. 1. Selection of studies.

few with reported effect sizes, this evaluation is limited to a narrative synthesis.

As heterogeneity of the sample studies was expected, it was important to assess methodological quality to account for likely confounding factors. Quality assessment was conducted using the 22-item "Psychotherapy outcome study methodology rating form" (POMRF) devised by Ost (2008). As discussed, the Ost (2008) review has some limitations, but his methodological critique using the POMRF has been acknowledged as an important step in progressing the field (Gaudiano, 2009). The POMRF includes 22 methodological components such as sample characteristics, the psychometric properties of outcome measures, research design, controls, therapist training and therapeutic modality adherence. Each item is rated on a 3-point scale where $0=$Poor, $1=$Fair, and $2=$Good. Each study receives an overall score between 0 and 44, with higher scores indicative of greater methodological rigour. The POMRF has good internal consistency (0.86) and interrater reliability within the range 0.50–1.00 with a mean of 0.75 (Ost, 2008). Quality assessment data were extracted by the first two authors to a second coding sheet developed for this purpose. Where quality assessment judgement was subject to discrepancy the study was jointly reassessed by the two first authors to gain a unanimous result. Where this could not be reached the third author was available to make a determination.

3. Results

3.1. Overview of included studies

Table 1 provides an overview of included studies. Studies included a total of 707 participants and incorporated treatment for children with anorexia nervosa, depression, pain, trichotillomania, sickle cell disease, tic disorders, obsessive-compulsive disorder, anxiety symptoms, posttraumatic stress disorder (PTSD)/posttraumatic stress symptoms (PTS), impulsivity/problem/sexualised behaviour, self-harm, stress symptoms, emotional dysregulation, Aspergers Syndrome, and attention deficit hyperactivity disorder. Eighty per cent of the studies were published journal articles and the remaining 20% were made up of unpublished university theses or dissertations.

3.2. Sample characteristics

Pain was the most commonly investigated condition ($n=5$; 23.81%) and studies employed predominantly clinical outpatients ($n=16$; 76.19%). The sample size ranged from 1 to 339 participants.

Table 1
Overview of included studies by anxiety problem.

Study	Problem of interest	N	Age	Mean Age	% f	Format	Pop.	Design	Control	Treatment	Format	Length
Armstrong (2013)	OCD	3	12–13	12.33	33.33	PA	C, O	WG	BC	ACT	I	8–10 × 50 min
Bencuya (2013)	Emotional dysregulation/ externalising behaviour	28	7–13	10.9	32	UD	C & NC, O	WG	WL	ACT	G	Child 6 × 1.5 h/ Parent 1 × 1.5 h + 30 min
Brown and Hooper (2009)	LD & anxiety	1	18	18	100	PA	NC, O	CS	–	ACT	I	17 Sessions
Cook (2008)	Aspergers/LD	7	16–18	17	14	UD	C, O	WG	–	ACT	G	8 × 1 h
Fine et al. (2012)	Trichotillomania	2	15–16	15.5	100	PA	C, O	CSer	–	ACT	I	12 Sessions
Franklin et al. (2011)	Tic disorders	13	14–18	15.4	15	PA	C, O	BG	–	HRT vs ACT+HRT	I	8 × HRT vs 12 × ACT+HRT
Gauntlett-Gilbert et al. (2013)	Pain	98	10–19	15.6	75	PA	C, I	WG	–	IDACT	G	90 h over 15 days
Ghomian and Shairi (2014)	Pain	20	7–12	10.45	45	PA	C, O	BG	Unspecified	ACT	Unspecified	Unspecified
Heffner et al. (2002)	Anorexia nervosa	1	15	15	100%	PA	C, O	CS	–	ACT	I	18 Sessions
S.C. Hayes et al. (2011)	Depression	30	12–18	14.9	64	PA	C, O	RCT	TAU	ACT	I	Unspecified
Livheim et al. (2014)	Depression (Australian)	66	12–18	14.6	87.88	PA	NC, O	BG	TAU	ACT	G	8 × 1.5 h
	Stress (Swedish)	32	14–15	–	71.9%	PA	NC, O	RCT	TAU	ACT	G	
Luciano et al. (2011)	Impulsivity/problem behaviour	8	12–15	13.33	100	PA	NC, U	BG	–	VDI vs VDII	I	5 Sessions
Masuda et al. (2011)	Sickle cell disease	1	16	16	0	PA	C, O	CS	–	ACT	FB	16 Sessions
Metzler et al. (2000)	Sexualised behaviour	339	15–19	17.3	68	PA	NC, O	RCT	TAU	ACT	I	5 × 1–1.5 h
Seibert (2011)	ADHD	3	6–13	9	0	UD	C, O	WG	MB	ACT-SCT	I	5 Sessions
Wicksell et al. (2005)	Pain	1	14	14	100%	PA	C, O	CS	–	ACT	I	13 Sessions
Wicksell et al. (2007)	Pain	14	13–20	17	79	PA	C, O	WG	–	ACT	I	Av 14.4 child and 2.4 parent
Wicksell et al. (2009)	Pain	30	11–18	14.8	78	PA	C, O	RCT	TAU	ACT	I	10 × 1 h (child)+ 1–2 h (parent)
Woidneck et al. (2014)	PTSD	7	12–17	14.57	71.43	PA	C, O & I	CSer	MB	ACT	I	10 × 1 h
Yardley (2012)	OCD	3	10-11	10.33	33.33	UD	C, O	WG	BC	ACT	I	9 × 50 min

Note: Problem of interest: Attention-Deficit Hyperactivity Disorder (ADHD); Learning Disorder (LD); Obsessive Compulsive Disorder (OCD); Posttraumatic stress disorder (PTSD). Design: Case series (CSer), Case Study (CS), Between Group (BG), Randomised Controlled Trial (RCT), Within Group (WG). %f: Percentage female. Format: Published article (PA); Unpublished dissertation (UD). Population: Clinical (C), Inpatient (I), Non-clinical (NC), Outpatient (O), University (U). Control condition: Baseline Control (BC), Multiple Baseline (MB), Treatment-As-Usual (TAU), Wait List (WL). Treatment: Acceptance and Commitment Therapy (ACT); ACT Self Control Training (ACT-SCT); Habit Reversal Training (HRT); Interdisciplinary ACT treatment (IDACT); Values & Defusion I protocol (VDI); Values & Defusion II protocol (VDII). Format: Family-based (FB); Group (G); Individual (I).

Overall, studies were relatively gender balanced. Participants ranged in age from 6 to 18 years, with the majority of studies conducted with adolescents (> 11 years; n=17; 80.95%), compared to younger children (< 12 years; n=4; 19.05%).

3.3. Study design and treatment conditions

There were seven within-group designs (33.33%), six case studies/series (28.57%), four between-group designs (19.04%; with two including control conditions), and the same proportion of RCTs. The majority of studies involved individual treatment (n=14; 66.67%), with a lesser proportion undertaken in group format (n=5; 23.8%). One was a family-based intervention, and another did not specify the treatment format (4.76%). High heterogeneity was observed in terms of treatment duration, with studies ranging between 5 and 90 hours.

3.4. Control/active comparison and random assignment

A large proportion of studies did not utilise a control comparison group (n=10; 47.62%). Of the eleven studies that did employ a control group, five (23.8%) used a treatment-as-usual (TAU) comparison. Two studies (n=2; 9.52%) utilised multiple baseline and, another two, baseline control. One study employed a waitlist control, and another one did not specify the form of control employed (4.76%). One study compared ACT with another active treatment, habit reversal training. Overall, only the four RCTs utilised random assignment of participants to treatment, with

one further Australian study employing a random allocation for female, but not male participants (Livheim et al., 2014).

3.5. Assessment of methodological quality

Significant variability in methodological rigour was evident with overall POMRF scores ranging from 3 to 25 out of a total of 44 points, with the average score 13.29 (SD=5.12; Table 2). As Ost (2008) did not include cut-off scores for the POMRF, standard deviations (SD; rounded to the nearest whole number) were utilised to attain a POMRF rating in order to compare studies, in line with an earlier systematic review of ACT in the treatment of anxiety (Swain, Hancock, Hainsworth, & Bowman, 2013). Swain et al. (2013) rated studies more than one SD below the mean POMRF score "well below average" (current investigation range 0–7), those within one SD of the mean "below average" (8–13), "above average" (14–18), and "well above average" (19+). See Table 2 for POMRF scores and ratings.

Many methodological components were ignored by the studies in this review and where studies did address a component, this was typically done to a "fair", rather than "good" standard. One study (4.76%) described a power analysis and two employed blind evaluators (9.52%). Four studies (19.05%) incorporated adequate controls for parallel treatment completed external to the research; all at the fair standard. Four (19.05%) involved a comparison to an alternative or well-described TAU condition and the same proportion evaluated the clinical significance of findings. Nine (42.86%) specified the assessors' training or experience with the assessment tool employed, with eight (38.1%) describing an approach for attrition handling. Whilst nine studies (42.86%) provided information on the number of

therapists involved in the intervention delivery, just one did this to a good standard and 47.61% of studies provided some information about the training/experience of therapists. Seven (33.33%) undertook treatment fidelity assessments and whilst the same proportion examined therapist competence in the delivery of treatment, this was done to a good standard by one study. Of the seven studies that compared ACT with another active treatment or TAU, inequity of therapy hours was common, with only one study attaining a "fair" rating for this item (14.29%). Studies performed better in terms of assessment time points, with 20 (95.24%) detailing fair-to-good use of reliable outcome measures. Thirteen studies (61.9%) included at least three rounds of assessment and over 95% of studies ($n=20$) had fair-to-good specificity of measures as well as a specified treatment protocol. Finally, 15 studies (71.43%) provided a fair-to-good description of the participant sample.

3.6. Outcomes

Study outcomes are depicted in Table 2. Where data from multiple assessment points was reported, these are delineated by a backslash (/). While few studies reported effect sizes (ES), reliable change or clinically significant change indices, these are reported where available. A narrative synthesis of these results ordered by POMRF rating, from most to least rigorous methodological category follows.

3.6.1. Well above average

Three studies (14.29%) were rated as well-above average in terms of methodological rigour. These included two RCTs (Hayes, Boyd, & Sewell, 2011; Metzler, Biglan, Noell, Ary, & Ochs, 2000) and one between-group study (Franklin, Best, Wilson, Loew, & Compton, 2011).

The utility of a behaviour therapy programme (including ACT approaches) vs TAU (psychoeducation) for 339 adolescents with high risk sexualised behaviour was examined in one study (Metzler et al., 2000). At 3-month follow-up, in contrast to predictions, ACT participants engaged in greater frequency of sex than TAU participants. At 6-month follow-up, ACT male participants reported significantly fewer partners than TAU males, but not females. Relative to TAU, ACT participants reported significantly fewer instances of, and improvements in, sexual contact with strangers, as well as clinician-rated social competence. Limitations of this study include low response (18%) and poor retention rate to follow-up assessment time points. The sample also evidenced significantly higher risk taking behaviours than a random sample of clients of STD clinics. Whilst this may cast doubt on the representativeness of findings, a population exhibiting more problematic behaviours might be expected to be increasingly treatment resistant, which lends further support for ACT. This may also explain the lack of significant findings at the 3-month follow-up, as it may be that participants required more time to consolidate therapeutic gains and generalise learnings to a greater number of behaviours. In contrast to predictions, there were no significant between-group differences in acceptance measures. However, this study was limited to assessment of acceptance alone and did not account for the role of other proposed change processes within the ACT hexaflex. It is unclear from this study the degree of experience of the treating therapists and this too may have impacted on the findings, as has been identified in other studies (e.g., Franklin et al., 2011). Strengths of this study include its sizable sample, treatment adherence checks and thorough analysis of interaction effects. This study attained a POMRF score of 21/44.

In another RCT, 30 depressed adolescents were randomised to TAU (manualised CBT) or individual ACT (L. Hayes et al., 2011). ACT resulted in significant improvement in depressive symptoms at posttreatment and 3-month follow-up, findings of small and large effect sizes, respectively (L. Hayes et al., 2011). Clinically reliable change was observed among 58% of ACT participants and 36% of

TAU participants. ACT achieved greater reductions in depressive symptoms than TAU at posttreatment and follow-up. At posttreatment and follow-up, 26% and 38% of ACT participants showed reliable clinically significant improvement. Strengths of this study included the use of trained therapists and psychometrically validated instruments. Therapists in this research were involved in the delivery of both ACT and TAU interventions, but a limitation of this study included a lack of information regarding treatment duration, and treatment fidelity or therapist adherence, preventing examination of contamination of treatment. This is important as, to draw meaningful conclusions about the effectiveness of treatment, treatment must be delivered as per protocol (Ost, 2008). The POMRF for this study was 20/44.

Franklin et al. (2011) undertook a trial of habit reversal training (HRT; $n=7$) vs ACT+HRT ($n=6$) among adolescents with chronic tic disorders. Results revealed significant reductions in tic severity across treatment, with no significant differences between groups. However, in terms of clinician-rated global impression ratings, superior outcomes were observed for HRT relative to ACT+HRT in terms of overall percentage improved at each time point (43% vs 40% at week 10; 86% vs 25% at week 14; 57% vs 20% at week 18 and; 71% vs 33% at one-month follow-up). Likewise, although no statistical comparisons were made on self-rated functioning, a visual inspection of scores suggested HRT performed somewhat better than ACT+HRT. Strengths of this study include the use of validated diagnostic instruments, trained assessors who were blind to treatment allocation and trained therapists. This was the only study included within this review that compared an ACT protocol with another active alternative treatment and it received the highest POMRF score in this investigation (25/44). However, a larger sample would have increased the power to enable further statistical analysis and detect significant effects. All but one of the therapists involved in this study were relatively inexperienced in ACT and had greater experience in HRT, which may have implications for treatment quality. In line with this assertion, the more experienced therapist in this study was found to achieve more substantial reductions in tic severity scores than did those therapists with minimal experience.

To date, among the child literature, the best evidence for ACT exists for the treatment of tic disorders, depressive symptoms and high risk sexual behaviour. Taken together these offer preliminary evidence for ACT in improving both self and clinician-reported outcomes. However, some improvements were not observable until follow-up, and others observed larger improvements some months after therapy cessation. ACT was superior to TAU in both studies that employed these comparisons, which suggests its utility for clinician treating children with these concerns. While, for chronic tic disorders the addition of ACT to HRT did not produce additional gains, more experienced ACT clinicians were found to achieve improved outcomes relative to those with less training. Limited evidence is currently available in the most methodologically rigorous studies on changes in the ACT core processes.

3.6.2. Above average

Seven studies (33.33%) attained above average ratings on the POMRF. Two examined the effectiveness of ACT for OCD among three children aged 10–13 years (Armstrong, 2011; Yardley, 2012). Armstrong (2011) found mean compulsion scores decreased 28.2% on clinician-rated and 40.4–64.5% on self-reported measures. All participants showed improvement across measures, with two participants achieving subclinical scores at posttreatment. In line with this, Yardley (2012) noted all participants showed large improvements across clinician-rated measures, reflecting an average drop of 47.26%. Self-reported obsessive cognitions in two of three participants also evidenced improvement. However, both

Table 2
POMRF and outcomes for included studies.

Study	Problem	N	Design	POMRF score	POMRF rating	Outcomes
Armstrong et al. (2013)	OCD	3	WG	17	Above av	↓CR & SR (exc. COIS-R). Overall SR compulsion frequency↓ 40.4–64.5%; CY-BOCS↓ 28.2%. 66.6% ≠ diagnosis\widehat
Bencuya (2013)	Emotional dysregulation/ externalising behaviour	28	WG	14	Above av	Post↓ PR child measures (emotional avoidance, behaviour prob., ADHD sympt. & metacognition deficits); ns changes in PR EA/fusion, stress, child exec. function. Post SR all ns. FUP↓PR behaviour/regulation difficulties. Parental EA & stress outcomes not maintained. Emotional regulation↓negative coping, relative to pretreatment. FUP CR↑ mindfulness, ↓EA/fusion
Brown and Hooper (2009)	LD & anxiety	1	CS	3	Well below av	↓ SR EA/fusion (mean↓1.7 points). PR indicated↓anxiety & duration of rumination as well as↑socialisation
Cook (2008)	Aspergers/LD	7	WG	12	Below av	SR↑valued living; ↓EA/fusion (ns). EA/fusion correlated with all BSI scales (exc. somatisation & phobic anxiety)
Fine et al. (2012)	Trichotillomania	2	CSer	8	Below av	↓ SR focused/autohair pulling (abstinent min 2 wks), distress & impairment. 1P relapsed & required a booster session
Franklin et al. (2011)	Tic disorders	13	BG	25	Well above av	↓ SR tic severity (ACT=HRT), functioning & CR global impression (HRT > ACT)
Gauntlett-Gilbert et al. (2013)	Pain	98	WG	11	Below av	Post SR↑acceptance social/physical functioning, development, & objective measure;↓pain anxiety, depression, catastrophizing; ns on pain intensity. Pre-FUP (ES= 0.21–1.00)↑SR acceptance, social/physical functioning, objective measures, PR school absence, PR health-care/medication;↓SR pain anxiety, catastrophizing, ns pain intensity, development & depression.
Ghomian and Shairi (2014)	Pain	20	BG	10	Below av	↓ SR & PR functional disability over time. Control ns. All PR measures ACT > control at posttreatment and 1.5 mths. Relative to pre, at 3 mths PR routine and total functional disability ACT > Control. Gains maintained post-FUP. CR physical disability ACT=control over time
Heffner et al. (2002)	Anorexia nervosa	1	CS	10	Below av	↓ SR 2/3 EDI subscales –drive for thinness & ineffectiveness subscales (clinical-nonclinical range). EDI body dissatisfaction, ns, clinical range. Weight overall↑trend; normal range at FUP. Typical menstruation resumed.
S.C. Hayes et al. (2011)	Depression	30	RCT	20	Well above av	↓ SR depressive symptoms (ES=0.38/1.45); ACT > TAU. RC: 58% ACT vs 36% TAU. ACT CSC: 26%/38%
Livheim et al. (2014)	Depression (Australian)	66	BG	12	Below av	Australian study ↓SR overall depressive symptoms (ES=0.82), dysphoria (ES=0.77), anhedonia (ES=0.89), negative self-evaluation (ES=0.67), somatic symptoms, ns; ACT > TAU. EA/fusion, ns.
	Stress (Swedish)	32	RCT	14	Above av	Swedish study ↓SR stress (ES=1.2); ACT > TAU. EA/fusion, ns. SR QOL, depression, stress, anxiety and general mental health ns. EA/fusion and mindfulness, ns.↑attendance correlated with improved QOL depression and stress ratings.
Luciano et al. (2011)	Impulsivity/problem behaviour	8	BG	12	Below av	VDII↓SR prob. behaviour, EA/fusion &↑acceptance across time maintained at FUP. High risk Ps ns ↓SR changes in EA/fusion & post↑acceptance not maintained at FUP. VDI ns across measures. VDII > VDI.
Masuda et al. (2011)	Sickle cell disease	1	CS	7	Well below av	Post ns change on SR pain. SR social anxiety & QOL in normal range pre and post, at FUP 1SD improvements on these measures. ↑PR school performance &↓EA/fusion at FUP.↑PR parent acceptance &↓distress over time.
Metzler et al. (2000)	Sexualised behaviour	339	RCT	21	Well above av	3mths: SR Freq. of sex – main effect TAU > ACT. CxG (males) TAU > ACT. All other effects ns. 6 mths: SR Number of partners – main effect ACT > TAU; CxG Males ACT > TAU (p=0.08 females); CxGxE White males/females ACT > TAU. SR Non-monogamous – main effect ACT > TAU; CxGxE White males/females ACT > TAU. Sex with strangers; ACT > TAU. Marijuana use; ACT > TAU. Social competence; ACT > TAU
Seibert (2011)	ADHD	3	WG	12	Below av	↑ CR self-control (delay to food consumption). Tolerance time ↑: 26–82 s (P1); 42–97 s (P2) &; 7–32 s (P3).
Wicksell et al. (2005)	Pain	1	CS	7	Well below av	↓ SR functional disability and pain. ↑SR emotion-focused coping (↓ emotional avoidance). Maintained 6-month FUP. SR problem-focused avoidance ns. 100% ↑PR school attendance & SR values-based goals 6-month FUP
Wicksell et al. (2007)	Pain	14	WG	15	Above av	↓ SR functional disability (ES=1.05), school absenteeism (ES=1.05), pain intensity (ES=1.53), pain interference (ES=1.27), catastrophising (ES=0.9). Results maintained 3- and 6-mth FUP. CSC Intensity: 71%/91%/73%; Interference: 86%/91%/100%
Wicksell et al. (2009)	Pain	30	RCT	17	Above av	ACT↑functioning, ↓interference & ↑QOL (ES=0.22–0.47). TAU ↑functioning &↓interference (ES= 0.21–0.55), not QOL. Across time ACT > TAU functional ability, intensity & discomfort. Catastrophizing borderline (p =0.051), & depression ns for ACT.
Woidneck et al. (2014)	PTSD	7	CSer	16	Above av	↓ SR symptoms (63-69% community & 59-81% inpatient/68-70% community & 57–84% inpatient) & EA/fusion (65% community & 57% inpatient/56% community & 42% inpatient).↓CR symptoms (57% inpatient & 61% community/ 71% inpatient and 60% community). CSC: 5 participants had PTSD pre, 100% ≠ diagnosis
Yardley (2012)	OCD	3	WG	16	Above av	↓CR, SR obsession freq. & intensity↓among 2/3P's. Overall frequency 21.95%↓& intensity 25.02% ↓\widehat

Note: Psychotherapy Outcome Methodology Rating Form (POMRF). Problem of interest: Attention-Deficit Hyperactivity Disorder (ADHD); Learning Disorder (LD); Obsessive Compulsive Disorder (OCD); Posttraumatic stress disorder (PTSD). Design: Case series (CSer), Case Study (CS), Between Group (BG), Randomised Controlled Trial (RCT), Within Group (WG). Outcomes: > (greater improvement); Acceptance and Commitment Therapy (ACT); Condition (C); Clinician-Rated (CR); Clinical Recovery (CRec); Clinically Significant Change (CSC); Eating Disorders Inventory (EDI); Effect size (ES); Ethnicity (E); Experiential avoidance (EA); Follow-up (FUP); Gender (G); Habit Reversal Training (HRT); Not Significant (ns); Participant/s (P); Reliable Change (RC); Self-Report (SR); Parent-Report (PR); Treatment-As-Usual (TAU); \widehatNo statistical tests conducted.

studies are limited in small sample size, representativeness of the sample, and non-report of control of external treatment or therapist training. These factors limit the applicability of findings.

The utility of ACT for PTSD/PTS was examined among a mixed sample of community-dwelling adolescents with PTSD/PTS and adolescent inpatients with PTSD/PTS and a comorbid eating disorder (Woidneck, Morrison, & Twohig, 2014). Results indicated reductions in the frequency and intensity of self-rated PTSD/PTS symptoms at posttreatment, reflecting reductions of 63–69% and 59–81% for the community and inpatient participants, respectively. Similar rates were found at 3-month follow-up. On clinician-rated measures at posttreatment the average reductions were 57% and 61% for the community and inpatient participants, respectively, with 71% and 60% at the 3-month follow-up. Avoidance and fusion significantly decreased at posttreatment by an average of 65% for the community and 57% for the residential participants, with further reductions at 3-month follow-up. Statistical analysis of QOL outcomes was not reported; however, visual inspection of raw scores on these measures suggested improved QOL at posttreatment, with gains maintained or further improved at 3-month follow-up. The small sample size and the mixed participant sample limits the generalisability of the findings, which may have impeded a statistical comparison between the residential and community participants. This is particularly salient as the former were also receiving intensive TAU in the residential environment for their primary diagnosis of eating disorder. As such, it is difficult to determine whether TAU may have been diluting the effects of ACT. The therapist was also known to the residential participants, prior to their commencing ACT treatment and therefore rapport levels were likely between the groups and this may have impacted on obtained findings. The lack of independent assessors in this study also may have introduced a degree of bias to the research, as the therapist also completed all assessments. The resultant POMRF score for this study was 16/44.

An ACT-based group therapy was examined among 28 children presenting with, or at risk for, emotional dysregulation and externalising behaviour (Bencuya, 2013). The sample included children adopted from foster care ($n=24$), with a lesser proportion ($n=4$) non-adopted. Forty-two per cent were medicated for psychiatric concerns. At posttreatment, parent-rated measures of child emotional avoidance, behavior problems, internalising problems (trend only), and ADHD symptoms had significantly reduced. Among non-medicated participants, parent-rated child metacognition deficits decreased and executive functioning was not significantly different. Among medicated participants, metacognition deficits had increased. Among child-reported measures there were no significant differences on cognitive emotion regulation or mindfulness at posttreatment. At follow-up, child-reported cognitive emotion regulation, mindfulness, and avoidance/fusion significantly improved, relative to pretreatment. Limitations of this study include the diverse nature of the sample as well as the unequal distribution of participants to condition. The latter may explain the lack of significant findings between participants in the waitlist and immediate treatment conditions. This study achieved a POMRF score of 14/44.

Wicksell, Melin, Lekander, and Olsson (2009) compared an ACT-based intervention with TAU (multidisciplinary plus medication approach) among 30 children with mixed idiopathic pain. ACT produced significant improvements of small effect size across all primary outcome measures (pain-related functioning, impairment, interference and health-related QOL) over time (up to 6 months post). The TAU group also improved across primary outcome measures with the exception of mental health-related QOL. At posttreatment ACT outperformed TAU on pain measures and mental health-related QOL. Incorporating all time points, ACT evidenced superior outcomes to TAU on pain outcomes. Limitations in the current study included a disproportionate number of sessions across condition (13 ACT vs 22.8 TAU), and the use of

outcome measures with unknown psychometric properties, not validated among young people. The sample were also highly diverse in terms of clinical presentations, as well as duration of condition and treatment history, which may have implications for external validity. The methodological quality of this study was rated as 17/44.

Another study among adolescents experiencing chronic pain observed functional disability and school absenteeism improved by 63% and 68%, respectively, at posttreatment (Wicksell, Melin, & Olsson, 2007). Pain intensity and interference were reduced by around 50%. Gains were maintained at follow-up. Changes were clinically significant for over 70% at posttreatment and all but one participant at 3-month follow-up. At 6-month follow-up all participants evidenced clinically significant decreases in pain interference, with 73% for intensity. At posttreatment there were significant decreases in internalising/catastrophizing, maintained at follow-up. Caveats of this study include the diverse nature of the sample and the sample size, which limits the generalisability of findings. Treatment also varied in terms of length and focus with respect to individual therapeutic goals. Although broadly reflective of clinical practice this lack of standardisation may have implications for the external validity of findings.

Livheim et al. (2014) detailed two pilot studies, completed over two countries, to examine the effectiveness of a manualised group ACT programme for adolescents with depressive symptoms (Australian study; $n=66$) and stress symptoms (Swedish study; $n=32$). The Swedish study achieved POMRF rating in the above average range, whereas the Australian study scored in the below average range. In the Swedish study, participants were randomised to ACT or TAU individual counselling with the school nurse. At posttreatment a large significant improvement was observed in self-reported perceived stress in favour of ACT, with no change for TAU. No significant differences were observed in self-reported QOL, depression, stress, anxiety (marginally significant improvement relative to TAU) or general mental health. Change in avoidance and fusion was non-significant, with change in mindfulness marginally significant for ACT relative to TAU. Greater session attendance was associated with significantly higher QOL ratings and improved depression and stress ratings. Limitations specific to this study included that the TAU intervention was completed in individual, not group format, and was not administered to all participants or in a consistent fashion. This inequity in the comparison makes it difficult to delineate the impact of factors such as the delivery format or therapeutic hours in contributing to the outcome. Whilst this study reported a power analysis, the number of participants was less than anticipated and as a consequence, it was underpowered. Thus, it is possible that significant effects that may have been present were not detected. This study attained a POMRF of 14/44.

Taken together, studies with above average methodological rigour showed ACT to be effective in achieving reductions in clinical and self-rated OCD, pain symptoms, and PTS/PTSD, at posttreatment and follow-up. Pain and OCD outcomes were consistent across two studies. Among children experiencing or at risk for emotional dysregulation ACT was also effective in improving the majority of parent-rated measures at post and follow-up. However changes in child-ratings were not apparent until follow-up. Mixed findings were observed for the effectiveness of ACT among children with stress. However this study was also underpowered, which may have impacted on findings. QOL outcomes were examined in one study on pain and one on stress. The former found significant changes over time and relative to TAU for ACT, in the latter changes were non-significant. Concerning ACT process measures, avoidance and fusion significantly reduced among children with PTS/PTSD as well as those experiencing or at risk for emotional dysregulation.

3.6.3. Below average

In accordance with POMRF ratings, eight (38.1%) studies scored below average. The utility of ACT as a treatment for trichotillomania was examined in a case series of two adolescents (Fine et al., 2012). While both participants evidenced decreases in focused and automatic hair pulling over the course of 11 treatment sessions, methodological caveats included a lack of therapist training information, checks for treatment adherence/therapist competence and an absence of a follow-up assessment. As a case study it also lacked a control group and random allocation to treatment, it attained a POMRF rating of 8/44.

The second of the pilot studies described by Livheim et al. (2014) was completed with Australian adolescents with depressive symptoms (*n*=66). This study employed a planned comparison, where girls were randomised to ACT or TAU (12-weeks monitoring by school counsellor), and a single boys group (*n*=8) received ACT. Significant improvements of large effect size in self-reported depression overall were observed among ACT participants, with no changes for TAU, at posttreatment. Effects favoured ACT across the dysphoric mood, anhedonia/negative affect and negative self-evaluation symptoms, with moderate to large effect sizes. No significant changes were observed on somatic symptoms. Changes in acceptance and defusion were only marginally significant for ACT relative to TAU. Caveats included the non-measurement of participant session attendance, which affects measurement bias. Pretreatment differences in overall depression scores were observed and thus an alternative interpretation of effects may be that changes reflected a regression to the mean (i.e., if a variable is extreme on its first measurement, it will tend to be closer to the average on its second measurement). Other limitations of this study included the sole reliance on self-report measures, which are impacted by social desirability. The vast majority of participants were female, which impacts on the capacity to generalise the result to male populations. Follow-up assessment was not included to examine the durability of observed outcomes. This is important as other studies with children have found that the effects of ACT are not immediately observable at posttreatment. Finally therapist competence and adherence to the protocol were not examined. Given the therapists were relatively inexperienced in the use of ACT this is an important consideration in determining whether the programme was ACT consistent.

In a study on chronic pain and ACT, 20 children evidencing moderate functional disability from chronic pain were allocated to ACT (*N*=10) or to an undefined control condition (*N*=10) (Ghomian & Shairi, 2014). Both child and parent reports in the ACT group evidenced significant changes in overall functional disability as well as the capacity to perform physical and daily activities. There were no significant changes for controls. Parent reports indicated ACT outperformed control across outcomes at posttreatment and 1.5 month follow-up. Relative to pretreatment, at 3 month follow-up parent reports indicated significant differences in favour of ACT, relative to control, on both routine and total functional disability. Gains were maintained between posttreatment and follow-up. On child-reported physical disability there were no significant differences between ACT and control across time, in contrast to parent-reported outcomes. However, the quality of this study is weakened by its reliance on one outcome measure. Furthermore, the limited detail on the treatment protocol in makes it difficult to determine the methodological rigour of the research (e.g., whether the treatment was delivered in individual or group format, etc.), reflected in its POMRF score of 10/44.

Another study on pain involved a three week group-based interdisciplinary residential programme with 98 adolescents (Gauntlett-Gilbert, Connell, Clinch, & McCracken, 2013). The programme consisted of physical conditioning, activity management, and ACT approaches. Results showed improvements at posttreatment, of small to medium effect sizes, in school attendance, medication and health care usage, acceptance, pain anxiety, depression, catastrophizing, social/physical functioning, development, and objective physical measures. Pain intensity did not change, in contrast to the observations of Wicksell et al. (2007). At follow-up, all measures significantly improved except pain intensity, depression, and development. Increased acceptance was related to improved physical and social functioning, objective physical measures, and all psychological variables. There are several limitations of this study, reflected by its POMRF score (11/44). The lack of a control group and the use of an interdisciplinary multicomponent approach may confound the extent to which changes in measures can be attributed to ACT. This may also explain the differences in pain intensity to that of Wicksell et al. (2007). However, as stated by the authors, results were consistent with the ACT model, in that changes occurred in functioning, in the absence of similar reductions in pain outcomes (Gauntlett-Gilbert et al., 2013). Other caveats include the lack of treatment adherence or fidelity evaluations and difficulties of generalising the results from intensive residential treatment to other settings. Furthermore, this study examined associations between changes in one ACT process measure, acceptance, and other outcomes, and did not examine the remaining ACT hexaflex processes, despite their inclusion in treatment. As a consequence it is unclear how these might be differentially related to changes in other measures.

Heffner, Sperry, Eifert, and Detweiler (2002) examined ACT in the treatment of a 15 year old with anorexia nervosa. Results showed ACT produced movement from the clinical to nonclinical range at treatment cessation on drive for thinness and ineffectiveness outcomes. However, a body dissatisfaction measure, remained within the clinical range. The participant's weight fell within the normal range at follow-up, and typical menstruation resumed. The methodological quality of this study was below average (9/44), reflective of the case design and ensuing limitations as well as lack of treatment adherence checks.

A group-based ACT protocol was examined in a group of seven adolescents with Asperger's Syndrome and/or non-verbal learning disability (Cook, 2008). At posttreatment significant improvements in valued living were observed, but changes in avoidance and fusion were nonsignificant. Correlations between change scores on avoidance/fusion and obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, paranoid ideation, and psychoticism measures were observed (Cook, 2008). Limitations of this study include the small sample, the absence of control comparison, sole reliance on self-report measures and a lack of statistical analysis of changes. The level of experience of the graduate student facilitator with ACT was unclear and treatment fidelity/adherence checks were not in place to ensure consistency with the protocol. This study scored 12/44.

Another study examined the utility of an acceptance and mindfulness "self-control training" intervention for three children with ADHD (Seibert, 2011). Following baseline stabilisation, associated with time tolerated before eating a preferred food, all participants underwent five sessions of self-control training. This involved learning acceptance and mindfulness skills in response to impulsive thoughts and bodily sensations evoked in the desire to eat a preferred food. At the conclusion of each of the five sessions, participants had access to a preferred food after a delay period of 10 times their baseline time. As predicted, all participants were able to tolerate a greater delay after self-control training and could meet the 10 times time requirement for self-control training for the majority of training sessions. Two of three participants met this for 100% of self-control training trials, and the third participant for all but one trial. Two of three participants tolerated three times their natural baseline delay to receive a large portion of their preferred food. One participant continued to be unable to tolerate this delay. Limitations of this study included the small sample, lack of control group, absence of reliability checks of diagnoses and therapist competence. Treatment involved only two of the six ACT core processes, which limits conclusions about the utility

of ACT more broadly. In line with these caveats, this study received 12/44 on the POMRF.

In another study, 15 adolescents with high self-reported problem behaviours completed a programme that included three core processes of the ACT hexaflex; values, cognitive defusion and self-as-context (Luciano et al., 2011). The study trialled a values intervention with either defusion (Defusion I) or defusion+self-as-context approaches (Defusion II). On the basis of the number of endorsed problem behaviours, participants were classified as high (score ≥ 6) or low risk (scores ≤ 5). Half of the low-risk participants received Defusion I. The remaining half of the low-risk, and all high-risk participants, received Defusion II. All participants received the values-orientated session. There were significant changes in problem behaviours and differences between groups subsequent to the values-orientated session. For Defusion I no significant differences were observed for measures of problem behaviour, experiential avoidance/fusion or acceptance across time. Low-risk participants in Defusion II evidenced significant changes across all measures with results maintained at follow-up. Four of five participants reported no problem behaviour at post and maintained this at follow-up. Results for high risk participants were equivalent, with two exceptions; experiential avoidance/fusion did not change over time, and improvements in acceptance at post were not maintained at follow-up. A comparison among low risk participants across defusion conditions revealed consistently significantly superior results for Defusion II. The authors concluded that defusion was bolstered by the inclusion of self-as-context approaches. The lack of changes in avoidance/fusion among high risk participants was unexpected. It is possible that the intervention was of insufficient duration to evidence changes on this measure among participants with more severe behavioural problems. This study was limited by the overall numbers in each group, and use of only three of the six core ACT processes. Given the low number of studies in this category and the low sample sizes used, this study scored 12/44. Further studies to examine the comparative effectiveness of ACT are warranted.

Studies scoring one standard deviation below the mean POMRF rating for methodological rigour found that ACT was effective in reducing the majority of self-reported clinical outcomes among participants with trichotillomania, depression, pain (two studies), anorexia, ADHD, and problem behaviour. Results were also consistent on parent-report in one study of children with pain conditions. Where ACT was compared with TAU, ACT achieved favourable clinical outcomes among participants with depression and pain, across time. With respect to process measures, changes in avoidance and fusion were mixed. Improvements were found among children who endorsed five or less problem behaviours, but not among those with six or more, and non-significant changes were observed among adolescents with Asperger's Syndrome. Acceptance improved among participants in one study of children with pain conditions and among those with problem behaviours. Significant improvements in valued living were observed among children with Asperger's Syndrome.

3.6.4. Well below average

Three studies (14.29%), all case studies, scored well below average on the POMRF. By their very nature, case-studies are limited in their ability to determine whether change observed was greater than chance alone. Their sample size also makes generalisation of the findings difficult. However, these studies make an important contribution to the field in that it supports the clinical-research community by providing data on a population for which there is a dearth of research. Disorder and treatment-tailored studies such as those explored in these case studies and the ability to draw conclusions from research conducted in naturalistic settings is often

not possible in large efficacy studies, thus case-studies are often a necessary precursor to appropriately designed larger-scale trials.

A study of ACT for a 14-year-old female with idiopathic pain found reductions in functional disability, pain and emotional-focused avoidance at posttreatment (Wicksell, Dahl, Magnusson, & Olsson, 2005). Improved school attendance and achievement of values-based goals was also observed with results maintained at follow-up. This study received a 7/44 POMRF rating, a reflection of its case study nature, lack of treatment adherence and competence checks, and reports of clinical significance.

Brown and Hooper (2009) examined ACT in the treatment of anxiety in an 18 year old female with a moderate-to-severe learning disorder and school refusal. Experiential avoidance had reduced at posttherapy. The participant was increasingly calm and socially confident, and had recommenced school in accordance with anecdotal parent-report. Gains were maintained at follow-up. However, several caveats limit the generalisability of findings, reflected in its POMRF score of 3/44, the lowest of all studies included within this review. One psychometrically evaluated assessment tool was employed, focused on ACT processes of change, and this study relied on anecdotal evidence to determine the impact of treatment on the clinical outcome of anxiety severity. The intervention was markedly different from protocol, as therapeutic adjustment were made throughout and the programme extended extending beyond the proposed 10 session to a 17 session intervention.

A family-based ACT intervention was completed with a 16 year old male with sickle cell disease (SCD) who experienced pain, fatigue, social apprehension and adaptive behaviour deficits in studying, socialisation and inattentiveness/inaction (Masuda, Cohen, Wicksell, Kemani, & Johnson, 2011). No significant self-reported changes in social anxiety or QOL were observed at posttreatment, although scores remained in the normal range relative to a comparative sample of SCD children. However, at follow-up, social anxiety and QOL scores improved to one standard-deviation below and above, respectively, the average in the comparison sample. Pain reports remained unchanged over time. Parent-report indicated improvements academic performance and functioning. Scores on avoidance/fusion were greater than the comparison sample at pre and posttreatment, however, large reductions were observed at 3-month follow-up. The case study nature of this study, lack of report of assessor training and treatment adherence/fidelity, are reflected in its POMRF score of 7/44.

In summary, two of these studies examined changes in clinical outcomes, with both observing improvements in self and parent reported outcomes. These studies showed some support for the processes of committed action, via the achievement of values-based goals, as well as improvements in avoidance and fusion at either post or follow-up. As described above, these studies should be interpreted with caution, given their methodological limitations. However, clinicians working with children exhibiting less prevalent conditions such as SCD or those working in disability settings may glean some utility from these findings for their populations.

4. Discussion

The past few years has seen a proliferation of ACT research in the treatment of conditions among children. While there are two existing reviews of the literature, the present investigation is the first to be conducted systematically. It involved both the published literature as well as unpublished theses/doctoral dissertations and specifically targeted studies involving treatment for children, rather than parent-based interventions. It also expands upon the findings of earlier reviews through an update of the literature completed over the past few years and the inclusion of a greater number of intervention-specific studies.

Twenty-one eligible studies were identified involving treatment for a spectrum of presenting issues. While the literature is still in its infancy, and subject to several methodological quality issues, the evidence available to date suggests that ACT produces significant improvements in the majority of self and clinician-reported clinical outcomes across presenting problems. While few studies incorporated parent-reported outcomes, where these were used, they were broadly consistent with child and clinician-rated outcomes. These findings support the argument of several researchers (e.g., Coyne et al., 2011; Greco et al., 2005; Hadlandsmyth et al., 2013) who suggest that ACT is a viable therapeutic approach for clinicians working with child populations. These outcomes also support the assertion that ACT has potential utility as a transdiagnostic approach (Hayes et al., 2012; Livheim et al., 2014), an area for future research in larger, methodologically rigorous trials with multiple clinical presentations.

There remains a relative dearth of comparisons of ACT to other active treatments. Just one study included within this review, compared ACT to another active treatment, and found the addition of ACT to another active treatment did not achieve more favourable outcomes (Franklin et al., 2011). However, a key limitation in this study is that clinicians were relatively inexperienced in the use of ACT, and expertise was associated with improved outcome (Franklin et al., 2011). ACT can be rather counterintuitive for unfamiliar clinicians and it involves several experiential exercises/metaphors that are abstract in nature. Arguably, this difficulty is intensified when delivered to adolescents, a population who may exhibit a greater spectrum of cognitive/development differences. Taken together, these findings implore the importance of skill and competence in the use of ACT prior to attempting this approach with clients for optimal outcomes.

More research is clearly warranted to establish whether ACT works better than alternative approaches. Despite this limitation, those studies comparing ACT to TAU found ACT evidenced superior outcomes among children with issues of pain, depression and sexualised behaviour. This suggests ACT should be considered by clinicians working with children with these presenting concerns and may achieve more optimal outcomes that typical treatments. Several studies found that treatment gains were either not fully evident at posttreatment (or initial follow-up) or that greater improvements for ACT were obtained some months after therapy cessation (e.g., L. Hayes et al., 2011; Metzler et al., 2000; Wicksell et al., 2007). Thus the inclusion of follow-up time points is an important consideration for future research.

Few presenting problems have been investigated among children by more than one or two studies, and this is also important for future research to consolidate the evidence base. At this stage the most widely researched condition is pain, with studies consistently observing that ACT results in improvements in functional disability and interference. Although studies differed in methodological rigour, outcomes were consistent in this area. Thus, there is encouraging support for clinicians to employ ACT approaches with young people presenting with pain concerns. However, as the majority of these studies were conducted by a group of affiliated researchers possible author bias cannot be ruled out. As such, it is recommended other researchers in different settings test and replicate these findings. This links in with the concept of therapist allegiance, which potentially affects outcomes in psychotherapy research. For instance, allegiance bias may occur with study results being contaminated or distorted by the investigators' preferences towards a treatment or theory (Luborsky, Singer, & Luborsky, 1975). In a meta meta-analysis of 30 meta-analyses (Munder, Brutsch, Leonhart, Gerger, & Barth, 2013) it was concluded that the researcher alliance outcome association is substantial and robust. For example, a researcher's enthusiasm towards a therapy might result in superior training and supervision of the therapists implementing that treatment, as opposed to a less preferred comparative treatment. It is also possible that greater experience and skill in a preferred treatment could, however inadvertently, result in better performance of this treatment over a non-preferred intervention. Thus the importance of reporting allegiances and considering the potential for such bias to occur should be addressed in future research.

Despite the focus of ACT on QOL outcomes, few studies included within this review examined changes in QOL specific measures. Thus, the research base is currently limited in the ability to draw meaningful conclusion on the impact of therapeutic changes on children's day-to-day living. Future research should augment clinical outcomes with those specific to QOL, which have been argued to reflect the clinical significance of changes (Gladis, Gosch, Dishuk, & Crits-Christoph, 1999; Kazdin, 1977; Safren, Heimberg, Brown, & Holle, 1996). Studies that did employ these measures all found improvements over time, with the exception of the study on stress (Livheim et al., 2014), which was underpowered to detect effects. In line with findings on clinical outcomes, the latter study observed superior outcomes among ACT participants, relative to TAU. Taken together, these findings offer preliminary evidence for the utility of ACT in improving both clinical and QOL outcomes among children.

Limited evidence is currently available on changes in the ACT core processes among children, particularly in the most methodologically rigorous studies, and the evidence available is mixed. Avoidance and fusion was the most commonly investigated process. Among eight studies 50% indicated improvements at post or follow-up. Others observed a nonsignificant positive trend (Cook, 2008), found improvements were limited to presentations of lower severity (Luciano et al., 2011) or saw no improvements (Livheim et al., 2014). Positive changes were observed in acceptance across two studies, but not in a third, which was underpowered to detect effects. Evidence for valued living and committed action was limited to one or two studies, with positive improvements observed among participants treated with ACT. Investigation of the ACT core processes is important due to their hypothesised role in increasing psychological flexibility. Increased research effort in this domain is likely to support knowledge development into processes through which ACT fosters positive outcomes, typically termed "the mechanisms of change" (Ciarrochi, Bilich, & Godsell, 2010; Kazdin, 2007; Kraemar, Wilson, Fairburn, & Agras, 2002). This in turn is likely to foster parsimonious clinical practice, optimising clinician-patient encounters to facilitate shorter term interventions delivered with improved sensitivity and specificity (Kazdin, 2007; Kraemar et al., 2002).

Overall methodological quality assessment identified a number of strengths among eligible studies. Most employed sufficiently detailed treatment protocols as to allow for replication, assessment of outcome was examined at follow-up time points, and most utilised specific outcome measures that were also valid and reliable. Future research should continue to adhere to these practices. However, several caveats were identified and should be addressed in ongoing studies, including heterogeneity in treatment duration between groups and a lack of consideration for the clinical significance of findings. Most studies did not report therapist training, checks for treatment adherence or therapist competence. An effect size calculation was not possible in many studies due to the methodological limitations such as low sample size. A comparison of average POMRF ratings in the current investigation ($M=13.29$), relative to a recent review of ACT for anxiety with predominantly adult studies ($M=17.29$; Swain et al., 2013) also suggests the methodological quality of studies involving child samples presently lags behind that of the adult literature. In explanation for this finding, there was a predominance of small heterogeneous samples, few conditions were investigated by more than one study, and designs that typically lacked control or alternative treatment comparisons, limiting conclusions. However, such studies may offer greater validity for clinicians working in real-world contexts than randomised efficacy trials due to the employment of naturalistic

settings and multiple baseline measures. Thus the contribution of case studies or those in naturalistic settings to the scientific body of knowledge should not be disregarded, especially for clinicians working with children from low prevalence clinical populations.

Areas needing investigating in future research include an examination of the role of demographic factors in outcomes, as several studies found outcomes varied by factors such as gender and race, and others still observed medication status was associated with divergent results. The expansion of studies to children of different age groups and those experiencing comorbid problems, is also indicated. Clinicians should note that there is currently a dearth of evidence for ACT among children under 12 years and in ACT treatment delivered in group or family-based formats. In many studies the ACT intervention employed was delivered as a component of a broader intervention and thus it is difficult to determine the contribution of non-ACT therapeutic components to outcomes. Findings must be replicated and examined relative to control conditions as well as active treatment alternatives. For the majority of disorders/conditions specific effectiveness is currently limited to one or two studies. Taken together, these findings suggest such additional methodologically stringent research is warranted taking these observed pitfalls into consideration. Despite the methodological inadequacies identified in the research reviewed, it is encouraging to see the rate at which ACT research in children is increasing, as is the scientific rigour.

5. Conclusion

Emerging research of ACT in the treatment of children is encouraging for the utility of this therapeutic approach for clinicians working with young people. To consolidate and build upon this preliminary evidence, larger methodologically rigorous trials are required across a broader spectrum of presenting problems and particularly among younger children. As difficulties in childhood can result in substantial impairment across various life domains, it is important that appropriate, evidence-based, treatment is available. It is hoped that the results of this review will support the conduct of future research in this area with increased methodological rigour, to provide additional data on the utility of ACT as a viable intervention available to clinicians in the treatment of problems among children.

Appendix A. Reasons for exclusion

See Appendix Table A1.

Table A1

Study	Reasons for exclusion
Asmundson and Hadjistavropolous (2006)	Commentary article
Bass et al. (2014)	Commentary article
Coyne, McHugh, and Martinez (2011)	Review article
Gundy, Woidneck, Pratt, Christian, and Twohig (2011)	Review article
Hadlandsmyth et al. (2013)	Theoretical paper
Hannan and Tolin (2005)	Theoretical book chapter
Kaiser (2012)	Theoretical paper
Murrell and Scherbarth (2006)	Review article
Robinson, Gregg, Dahl, and Lundgren (2005)	No psychometrics measures employed
Rowland (2011)	Theoretical paper
Ruiz (2010)	Review article
Ruiz (2012)	Review article
Zehnder, Meuli, and Landolt (2010)	Not an ACT intervention

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TRIALS

Acceptance and Commitment Therapy for anxious children and adolescents: study protocol for a randomized controlled trial

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Abstract

Background: Anxiety disorders affect approximately 10% to 20% of young people, can be enduring if left untreated, and have been associated with psychopathology in later life. Despite this, there is a paucity of empirical research to assist clinicians in determining appropriate treatment options. We describe a protocol for a randomized controlled trial in which we will examine the effectiveness of a group-based Acceptance and Commitment Therapy program for children and adolescents with a primary diagnosis of anxiety disorder. For the adolescent participants we will also evaluate the elements of the intervention that act as mechanisms for change.

Methods/design: We will recruit 150 young people (90 children and 60 adolescents) diagnosed with an anxiety disorder and their parent or caregiver. After completion of baseline assessment, participants will be randomized to one of three conditions (Acceptance and Commitment Therapy, Cognitive Behavior Therapy or waitlist control). Those in the Acceptance and Commitment Therapy and Cognitive Behavior Therapy groups will receive 10 × 1.5 hour weekly group-therapy sessions using a manualized treatment program, in accordance with the relevant therapy, to be delivered by psychologists. Controls will receive the Cognitive Behavior Therapy program after 10 weeks waitlisted. Repeated measures will be taken immediately post-therapy and at three months after therapy cessation.

Discussion: To the best of our knowledge, this study will be the largest trial of Acceptance and Commitment Therapy in the treatment of children and young people to date. It will provide comprehensive data on the use of Acceptance and Commitment Therapy for anxiety disorders and will offer evidence for mechanisms involved in the process of change. Furthermore, additional data will be obtained for the use of Cognitive Behavior Therapy in this population and this research will illustrate the comparative effectiveness of these two interventions, which are currently implemented widely in contemporary clinical practice. Anticipated difficulties for the trial are the recruitment and retention of participants, particularly adolescents. To avert these concerns and maximize recruitment, several strategies will be adopted to optimize referral rates as well as reduce participant drop-outs.

Trial registration: This trial is registered with the Australian and New Zealand Clinical Trials Registry, registration number: ACTRN12611001280998

Keywords: Acceptance and Commitment Therapy (ACT), Anxiety, Anxiety disorders, Adolescents, Children, Cognitive Behavior Therapy (CBT), Randomized Controlled Trial (RCT)

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Background

With a prevalence rate of 10% to 20%, anxiety disorders are the most common mental health concern affecting children and adolescents [1,2]. Young people with anxiety are typically underrepresented in clinical research, and anxiety in children is often minimized by health professionals, potentially due to a common perception that in this population anxiety is developmental, transient and innocuous [3,4]. Despite this, anxiety in childhood increases the likelihood of academic and social skills difficulties as well as substance abuse, and is often enduring if untreated [2]. Furthermore, a childhood history of anxiety is a common precursor to depression, and has been found to predict anxiety and depression in later life [5-7].

In a recent review of the best available evidence for the treatment of psychological disorders, Cognitive Behavior Therapy (CBT) was found to be the first-line evidence-based psychosocial intervention for anxiety among adults and is currently the most empirically supported therapeutic approach for children and adolescents [8]. In part, this is a consequence of insufficient evidence for alternative interventions [8], rather than findings indicating other treatments are unsuitable. Indeed, the dearth of population-specific research in this area is highlighted by the aforementioned review, which found a complete absence of studies assessing the efficacy of CBT in the treatment of panic disorder among children and variable levels of evidence for its use in other anxiety disorders in this population [8]. Furthermore, others have found that one in four children do not benefit from CBT [9]. As such, it is important that other interventions are developed and evaluated to address this shortcoming.

Acceptance and Commitment Therapy (ACT) has sparked increased interest among clinicians and researchers in the last decade [10]. ACT considers the fundamental cause of psychopathology and human suffering to be the interrelationships of cognition, language and life circumstances that lead to decreased capacity to modify or continue exhibiting behaviors that are in the service of personal values [11]. ACT aims to increase psychological flexibility; 'the process of contacting the present moment fully as a conscious human being and persisting or changing behaviour in the service of chosen values' [12]. Whereas other therapies focus on altering the content, frequency and form of private experience (thoughts, feelings and sensations), ACT works to modify the function of internal experience - such as supporting individuals to recognize thoughts for what they are, simply thoughts and not necessarily the truth - and thus reduce their bearing on behavior [13]. ACT focuses on assisting clients to live valued meaningful lives [11]. To do this, six core therapeutic processes organized in a 'hexaflex' model are employed, including 'acceptance,' 'defusion,' 'values,' 'committed action,' 'the present moment' and 'self-as-context' [14]. These processes are interrelated and support each other in increasing psychological flexibility.

ACT has a growing empirical base demonstrating its efficacy for an array of problems, including the treatment of anxiety concerns among adults such as social phobia [15,16], generalized anxiety disorder [17] and mathematics anxiety [18]. Indeed, in the first known review of published ACT controlled trials up to 2005, the authors found ACT to be superior to control conditions, waitlists and treatment as usual at both post-intervention and at follow-up across a myriad of different problems from psychosis to work stress [12]. Whilst evidence for the use of ACT in adult populations with anxiety has grown, there is currently a paucity of research examining the efficacy of ACT in children and adolescents with anxiety. A literature search produced only one published study, that being a case study [19]. However, preliminary research evidence supports the use of ACT among young people with other problems including depression [20], anorexia [21], chronic pain [22] and high risk sexual behavior [23].

Research evidence has supported the use of mindfulness, one of the ACT core processes, in the treatment of young people. Four studies have assessed the impact of mindfulness-based stress reduction among children and/or adolescents with anxiety and found it to be effective in reducing anxious symptoms [24-27]. A review of these studies has previously been conducted [28]. Although these studies show some early support for the use of ACT for the treatment of childhood problems including anxiety, they are subject to several methodological issues - small samples, a lack of either control group or random assignment, few objective measures, potential biases from recruited volunteers, reliance on self or non-blind parent or teacher reports and employment of non-clinical samples, and/or the inclusion of only one component of the ACT model (that is, mindfulness) - that limit their validity. More rigorous research is required to solidify the effectiveness of mindfulness in the treatment of child anxiety disorders and to extend the research into other ACT core processes.

Clinical research has typically focused on assessing the efficacy of interventions. However, this approach does not assist in the identification of the specific techniques that are empirically effective or, conversely, those that are harmful [14]. Identification of the mechanisms of action within a specific treatment could support clinical practice and enable interventions to be tailored to meet individual client needs. It has been proposed that ACT works by supporting increased acceptance of internal experience and reducing fusion with negative thoughts to

enable valued living, referred to in ACT as increasing psychological flexibility [12]. ACT studies have typically focused on evaluation of the core processes of the model, as described above, to examine the validity and impact of each [12]. These studies have found support for the roles of defusion [29] and acceptance [17,30], and some support for the role of values and/or committed action [17] in reducing psychopathology. Ultimately, this emerging research has led to the genesis of three ACT mediational hypotheses, that psychological inflexibility precedes suffering among clinical and non-clinical populations; ACT increases psychological flexibility; and psychological flexibility leads to enhanced well-being, decreased clinical symptoms and increased value-based activities [14]. However, these studies are preliminary and subject to several methodological limitations including measures that lack psychometric evaluation, the use of purely self-report measures and the use of measures that concentrate on a small number of core processes, leaving other parts of the ACT model untested [31]. Thus, to build upon the current empirical literature in this area, this randomized controlled trial design includes the investigation of mechanisms of change in adolescents with anxiety.

In summary, preliminary investigations of ACT in the treatment of adult anxiety have produced promising results. Other studies have also supported the use of mindfulness - one of the six ACT core processes - in the treatment of childhood anxiety, which suggest that approaches employed within ACT appear to be suitable for child populations. To the best of our knowledge, this will be the first randomized controlled trial to examine the effectiveness of ACT in young people with a diagnosed anxiety disorder. Given the popularity and use of ACT in clinical practice [10], it is imperative that this form of intervention be empirically evaluated for its efficacy. Thus, the aim of this research is to examine the effectiveness of a manualized ACT group-therapy program in the treatment of anxiety disorders among children and adolescents. It is hypothesized that ACT will be at least as effective in the treatment of anxiety disorders in these populations relative to a manualized CBT group-therapy program, and that ACT will be more effective in the treatment of anxiety disorders in this population relative to the control condition at both immediate post-treatment and at three-month follow-up on outcome measures. The secondary aim of the trial concerns the adolescent participants and is to identify the mechanisms of change surrounding the intervention that are critical to changes in outcome measures. It is hypothesized that these will include decreased experiential avoidance and cognitive fusion, as well as increased emotional awareness, acceptance and valued living.

Methods
Study design
This is a prospective randomized controlled trial. It is a three (group: two intervention and one control) by three (time: pre-, immediate post- and three-month post-treatment) repeated measures factorial design. The overall study design is illustrated in Figure 1.

Participants
Participants will be approximately 150 children (90 younger and 60 older children) aged 7 to 17 years with a primary diagnosis of a Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) anxiety disorder. The participants will be age-classified as 'children', aged 7 to 11 years, and 'adolescents', aged 12 to 17 years. Twelve years of age was determined as the cut-off point to be consistent with other research involving ACT as a treatment for problems among adolescents [20].

Participants will be recruited via referrals to the Department of Psychological Medicine, The Children's Hospital at Westmead (CHW), Sydney, NSW, Australia. Referrals will be accepted from anyone, including health professionals (general practitioners, psychologists, pediatricians), educational providers, and self-referrals. Written informed consent will be obtained from the parent or caregiver of the children and from the child/adolescent. Ethical approval was obtained for this study from the Human Research Ethics Committee at CHW and at The University of Newcastle.

The researchers predict that the majority of referrals will come from school counselors, followed by word of mouth, then via parents' referral through the CHW intake phone line. In terms of proportions, it is expected that 60% to 70% of referrals will come from school counselors. On the basis of recruitment efforts to date and requests to intake phone line, the researchers consider that the anticipated sample will be achieved.

Inclusion criteria

1. Aged between 7 and 17 years
2. Criteria met for a primary diagnosis of a DSM-IV anxiety disorder (including panic disorder and/or agoraphobia, obsessive compulsive disorder, specific phobia, social anxiety disorder or generalized anxiety disorder)
3. Available and able to attend CHW for pre-treatment, immediate post-treatment and three-month post-treatment assessments as well as attending a minimum of 80% of therapy sessions
4. Have a parent or caregiver who is willing to attend and participate in the assessment as well as a minimum of 80% of therapy sessions.

Figure 1 Study design.
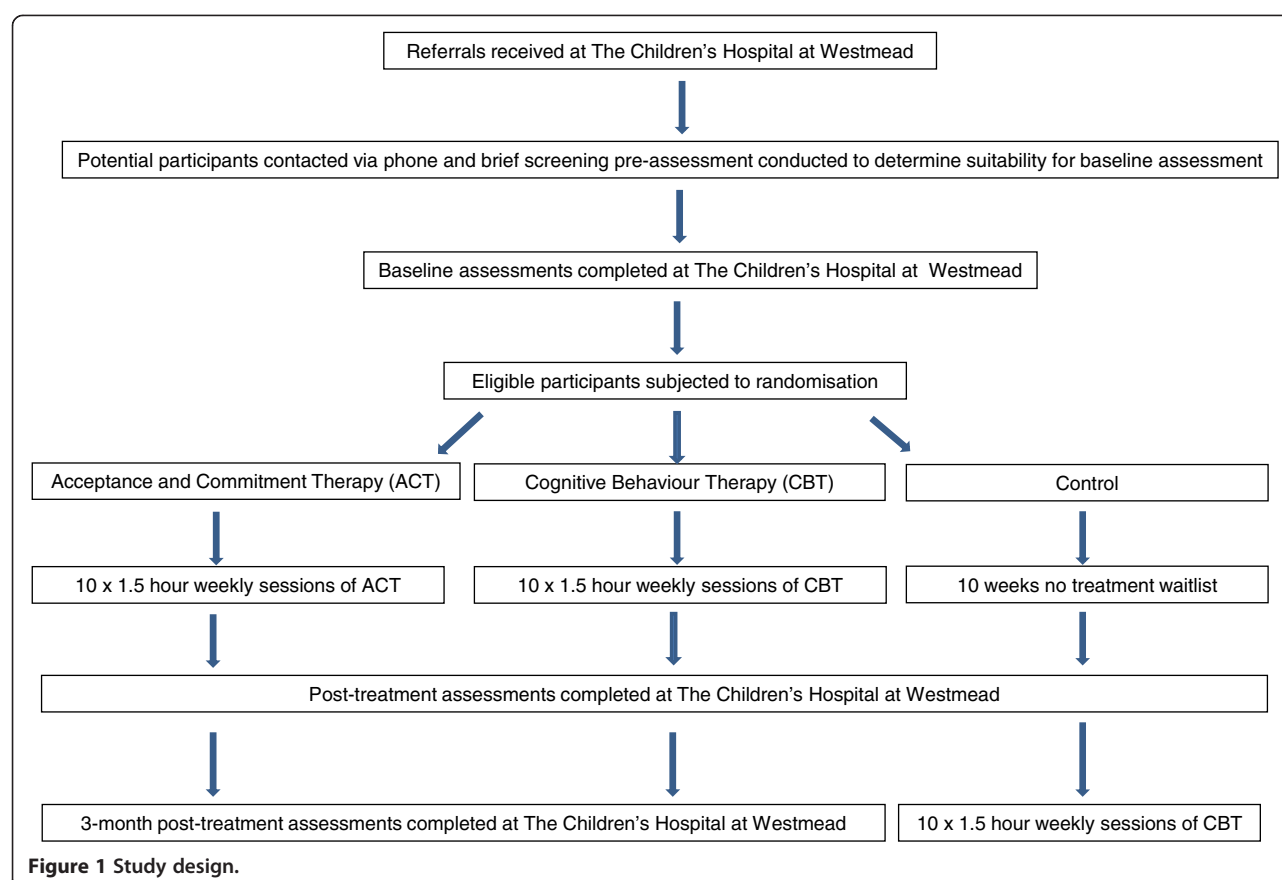
Exclusion criteria

1. Developmental or language delay, as reported by the parent or caregiver
2. Non-English speaker
3. Complex mental health problems such as psychosis, conduct disorder or active suicidality
4. Complex medical conditions with a high degree of medical dependence that would prevent them from being able to attend at least 80% of sessions
5. Attention deficit disorder with hyperactivity (ADHD) that is not well controlled. In addition to initial screening via parent and teacher reports as well as by a physician, as appropriate, ADHD will be assessed by clinicians according to DSM-IV criteria during the initial assessment. It was determined that, unless ADHD is sufficiently controlled, the group-based 1.5 hour program is an unsuitable structure for both the child with this identified concern as well as other group members
6. Medicated with an anxiolytic or antidepressant for less than two months. However, in the instance of a participant experiencing a marked increase in symptom severity across treatment, there may be a need to consider pharmacotherapy. Participants will

have weekly contact with the researchers across the course of the program and changes in functioning or status will be monitored in an ongoing way. Where a participant's progress appears to be worsening, a case-by-case consideration of the need for a medical assessment for potential commencement of pharmacotherapy will be undertaken. In addition to this, the uptake of medication external to that identified across the trial will also be assessed at follow-up assessment. If a participant does utilize medication of this kind throughout the course of the study, they will be excluded from data analysis.

7. Post-traumatic stress disorder (due to the potential distress caused to other participants in the group and the specialized treatment required for this disorder)
8. Completed <70% of sessions or dropped out of treatment - those who become lost to follow-up will be placed in the intention-to-treat category.

Procedure

Initial assessment

Following referral, the caregivers of potential child and adolescent participants will be briefly screened over the

phone to determine suitability for baseline assessment using a checklist developed for this study. Information collected as part of this assessment will include psychiatric diagnoses and psychiatric symptoms - to identify anxiety as the primary presenting problem and consider differential diagnoses - as well as current and previous treatment including medication (type, dosage, period of pharmacological treatment) in accordance with the aforementioned inclusion and exclusion criteria. If deemed suitable at this point, they will be sent an information pack about the study including consent forms, and a battery of questionnaires to be completed by both the child/adolescent and caregiver as part of the baseline assessment. All assessment tools employed have demonstrated reliability and validity (described in detail below). To complete the baseline assessment the child/adolescent and parent will attend CHW to undertake a face-to-face diagnostic interview to determine the presence of an anxiety disorder using the Anxiety Disorders Interview Schedule for DSM-IV [ADIS-IV] (Silverman & Albano, 1996). ADIS-IV interviews of both parent/caregiver and child/adolescent which will be conducted separately by psychologists trained in the administration of the instrument. All interviews will be recorded for reliability purposes. The researchers conducting baseline assessments will be blinded to the treatment type to reduce potential.

Randomization

Following baseline assessment, eligible participants and their caregivers will be randomized to one of three conditions - ACT, CBT or a waitlist control group - for a period of 10 weeks (described in detail below). Each group will comprise up to eight children/adolescents as well as their caregivers. The researchers involved in this study are six registered psychologists, all trained in ACT and CBT. This will be a block randomized controlled trial, with the participant serving as the unit of randomization. Randomization will be undertaken via a publically available random assignment software application, 'Graphpad' [www.graphpad.com/quickcalcs/].

Follow-up assessment

Follow-up repeated measures assessment will be completed immediately post-treatment - or after 10 weeks for the control group - and three months post-treatment for both intervention groups. Following completion of the 10-week post assessment, the control group will complete a program of 10 × 1.5 hour sessions of CBT. Although it will not be possible to ensure the researchers conducting post-intervention and follow-up assessments will be blinded to the treatment type, to reduce potential bias these interviews will be recorded for reliability purposes and reviewed and re-rated by an independent assessor - a psychologist within the Department of Psychological Medicine with training in the use of the ADIS-IV - blind to the diagnosis obtained. Participants will also be assessed on the uptake of pharmacotherapy throughout the course of the trial at follow-up.

Outcome measures
Primary outcome measures
Anxiety Disorders Interview Schedule (ADIS-IV) [32]. The ADIS-IV is a structured diagnostic interview that assesses for a range of DSM-IV disorders typically first diagnosed in childhood or adolescence [33] from the perspective of both child (ADIS-C) and parent (ADIS-P) [34]. The ADIS-C and ADIS-P demonstrate good-to-excellent clinician inter-rater agreement, diagnostic reliability and test-retest reliability [35,36].

Multidimensional Anxiety Scale for Children (MASC) [37]. The MASC is a 39-item self-report inventory of anxiety symptoms. It assesses four factors of anxiety including physiological symptoms, avoidance, social and separation anxiety [34,38]. Research has shown the MASC exhibits acceptable convergent and divergent validity, moderate-to-strong internal reliability, and adequate test-retest and discriminate validity [34,39,40].

Child Behavior Checklist - Parent Form (CBCL) [41]. The CBCL is a widely utilized standardized measure of children's and adolescents' (aged 5 to 18 years) emotional and behavioral functioning as well as social competence [42]. The social competence scales examine the child's adaptive functioning including their activities, and social and school performance [42]. Behavioral and emotional functioning is assessed by 118 items, which describe an array of problems that children might experience [42,43]. Validity and reliability data were obtained in a sample of over 5,000 children and were found to be moderate-to-high and high, respectively [44].

For the primary aim of the trial, relating to efficacy of the intervention, the primary outcome measures will be whether the participant meets criteria for one or more DSM-IV anxiety disorders and/or clinically significant changes in severity scores on the ADIS-IV, CBCL or MASC assessments. Clinically significant change will be defined as a change in score that places the participant within a different severity range on the relevant assessment. For the ADIS-IV, this will be a shift in interference ratings between 'Very severe' (8), 'Severe' (6 to 7), 'Moderate' (4 to 5), 'Mild' (1 to 3) or 'Absent' (0) ranges [45]. For the CBCL, this will be represented by a change in t-scores among the 'Clinical' (≥69); 'Borderline clinical' (56 to 69) and 'Normal' (≤55) ranges [41]. For the MASC, in accordance with March [37], this will be a shift in t-score between the 'Severe' (≥70); 'Moderate' (56 to 69) and 'Non-clinical' (≤55) ranges. Secondary outcome measures will include anxiety symptoms;

(depression symptoms; and quality of life and self-efficacy (Table 1).

Secondary measures

Child Depression Inventory (CDI) [46]. The CDI is one of the most widely utilized and cited diagnostic instruments for depression in children [47,48]. It is a 27-item self-report assessment, adapted from the Beck Depression Inventory [48]. Research has found the CDI test-retest reliability to be moderate range for clinical samples and adequate internal consistency, concurrent validity [47] and discriminant validity have been established [46].

Children's Anxiety Life Interference Scale - Child Form (CALIS-C) [49] - *Adolescents only.* The CALIS-C is a 10-item self-report questionnaire about the impact of fears and worries on an adolescent's quality of life, self-efficacy and well-being [49]. Reliability estimates were found to be adequate; moderate-to-strong convergent validity and discriminant validity have been observed [49]. The CALIS-C also demonstrates sensitivity to change [49].

McMaster Family Assessment Device (FAD) [50]. The FAD is a 53-item inventory completed by caregivers on the structure, organization and patterns of transactions within families [50]. Six dimensions of family functioning are identified in the model including Problem Solving, Communication, Roles, Affective Responsiveness, Affective Involvement and Behavioral Control [50]. Moderate-to-strong reliabilities have been obtained for the FAD [50]. It also has established discriminant [50] and concurrent validity [51].

Process measures – Adolescents only

Avoidance & Fusion Questionnaire - Youth (AFQ-Y) [52]. The AFQ-Y is a 17-item self-report measure of cognitive fusion and experiential avoidance for children and adolescents [52]. Confirmatory factor analysis has supported the hypothesized one-factor model of the AFQ-Y and internal consistency reliability was also found to be strong [52].

Child and Adolescent Mindfulness Measure (CAMM-20) [53]. The CAMM-20 is a 20-item self-report questionnaire that focuses on internal and external awareness as well as mindfulness [53]. Exploratory factor analysis found support for a CAMM-20 two-factor model of 'Observing', noticing and attending to stimuli including internal and external phenomena, and 'Acting with Awareness (AWA)' including items that involve absolute focus and engagement with activity in the present moment [53]. The internal consistency of both scales was in the moderate range [53].

Positive and Negative Affect Schedule (PANAS-X) [54]. The PANAS-X is a 20-item measure of emotional experience across two scales, Positive Affect (PA) and Negative Affect (NA) [55]. Respondents rate the extent to which they have experienced an emotion over a prescribed time [55]. Internal consistency reliabilities were found to be in the moderate-to-high range across both scales, and low correlations between the NA and PA scales indicate good discriminant validity [54], with similar results obtained in a sample of adolescents [53]. The PANAS-X demonstrates adequate construct validity and high internal consistency [54].

Toronto Alexithymia Scale (TAS-20) [56]. The TAS-20 is a 20-item self-report inventory of the construct of alexithymia and produces scores in three related domains: difficulty identifying feelings, difficulty describing feelings and externally-orientated thinking [57]. The TAS-20 has been found to demonstrate adequate convergent, discriminant and concurrent validity [58].

Valued Living Questionnaire (VLQ) [59]. The VLQ measures valued living or the degree to which an individual accesses their chosen values in everyday life [59]. The VLQ is comprised of two 10-item scales, where participants rate the importance of different domains of life - family, intimate relationships, parenting, friendship, work, education, recreation, spirituality, citizenship and physical self-care - and subsequently rate the consistency with which they have acted in accordance with their values in the past week [59]. Wilson *et al.* [59] found the VLQ to demonstrate adequate-to-good internal consistency across domains.

For the secondary aim of the trial, relating to the mechanisms for change, process outcome measures have been developed for adolescents only and have been selected in accordance with the domains hypothesized to be associated with treatment efficacy in line with results of previous research (described above). As such, primary process outcome measures include experiential avoidance, cognitive fusion, acceptance and valued living (Table 2).

Table 1 Primary and secondary outcome measures as they relate to the efficacy aim

Intervention efficacy outcome measures	Assessment tool/measured factor
Primary measures	
DSM-IV Anxiety disorder	ADIS-IV
Clinically significant change in anxiety severity	ADIS-IV, MASC, CBCL
Secondary measures	
Depression symptoms	CDI, CBCL
Quality of life and self-efficacy	CALIS-C
Demographic factors	FAD, age, sex

ADIS-IV, Anxiety Disorders Interview Schedule; CALIS-C, Children's Anxiety Life Interference Scale - Child Form; CBCL, Child Behavior Checklist - Parent Form; CDI, Child Depression Inventory; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders; FAD, Family Assessment Device; MASC, Multidimensional Anxiety Scale for Children.

Table 2 Primary outcome measures as they relate to the mechanism of change aim

Mechanisms of change outcome measures	Assessment tool/measured factor
Experiential avoidance	AFQ-Y, PANAS-X, TAS-20
Cognitive fusion	AFQ-Y
Acceptance	CAMM-20
Valued living	VLQ

AFQ-Y, Avoidance and Fusion Questionnaire - Youth; CAMM-20, Child and Adolescent Mindfulness Measure; PANAS-X, Positive and Negative Affect Schedule; TAS-20, Toronto Alexithymia Scale; VLQ, Valued Living Questionnaire.

Intervention

Participants allocated to ACT or CBT groups will complete a group-based therapy program of 10 × 1.5 hour sessions of the applicable treatment at CHW, which will be provided at no cost. Up to eight children or adolescents will be involved in each group program. Treatment will be conducted by between two and four psychologists, dependent upon final group numbers. All psychologists involved in the delivery of the intervention have been equally trained in both ACT and CBT, with the exception of one who has advanced training in CBT and intermediate training in ACT.

Caregivers will be involved concurrently in a "parent-as-coach" manner. Across both programs, the treatment will incorporate aspects that involve the participants and caregivers working independently of one another, as well as aspects that require working together. Both programs will also require regular completion of between-session practice tasks by both caregiver and the participant that will be reviewed at the subsequent session.

Both ACT [60-62] and CBT [63-65] programs will be based upon treatment manuals, tailored to the needs of participants. Manuals have been developed for children, adolescents, caregivers and therapists. Each program incorporates a series of psychological techniques consistent with the therapeutic modality employed. However, there are some commonalities across both interventions including psychoeducation, skills training and exposure. Although exposure to feared situations is a prominent technique employed across both ACT and CBT, the approach differs across therapies. In CBT, the focus is on challenging maladaptive thinking to enable performance of the exposure behavior, whereas in ACT, children or adolescents are encouraged to attempt to alter the relationship they have with their anxiety by distancing themselves from it and increasing their willingness to experience it.

CBT program - Cool Kids (ages 7 to 11 years) and Chilled® (ages 12 to 17 years)

The CBT program will comprise the Cool Kids and Chilled® Programs developed at the Centre for Emotional Health, Macquarie University [66]. The effectiveness of Cool Kids and Chilled® in treating anxiety has been empirically demonstrated [66]. Cool Kids and Chilled® assist children and adolescents, respectively, to learn skills to recognize their emotions and combat anxiety, encouraging brave behavior and gradual engagement with feared situations. Because CBT is currently the most empirically supported therapeutic approach for children and adolescents [8], it was determined to be the most stringent comparison condition to employ within this trial. The 'worry wave' section of the Cool Kids and Chilled® Programs will be omitted for the purposes of this research as it was considered to have mindfulness components more consistent with an ACT approach. This is a small component of the overall program.

ACT program - Cool Mind (ages 7 to 11 years) and Mindchill (ages 12 to 17 years)

The Cool Mind for Kids and Mindchill programs have been developed at CHW. They are both adaptations of the Cool Kids and Chilled® programs and were designed to conform to the overarching structure of these programs for comparison purposes. Cool Mind for Kids and Mindchill were developed on the basis of ACT-consistent protocols adapted from the Mindfulness-Based Cognitive Therapy for Children protocol [2]; Acceptance and Commitment Therapy Adapted for Children protocol [67], MiCBT protocol [68], and ACT Mindfully Workshops [69]. These programs incorporate all six ACT core therapeutic processes that target psychopathology including Acceptance, Being Present/Mindfulness, Valued directions, Committed Action, Self-as-context and Cognitive defusion. Children will learn skills to manage the distress associated with anxious thoughts and feelings. For example, whereas CBT attempts to dispute and modify unrealistic thoughts, ACT supports children to identify their values and behave in a value-consistent way. At the same time acceptance of anxious thoughts and feelings that may arise in the process of doing so is encouraged, as is learning to defuse these thoughts and feelings. While the content is similar for Cool Mind for Kids and Mindchill programs, the language is simplified for the child program and there is a greater focus on values for the adolescent program. Table 3 provides a session-by-session outline of the programs.

Controls

The control group in the study will be a waitlist group, also diagnosed with an anxiety disorder. Participants allocated to this group will complete baseline assessments and will receive CBT following a waiting list period of 10 weeks. This period was selected as it corresponds with the 10 week program, allowing for comparative post

Table 3 Session-by-session overview of the Acceptance and Commitment Therapy programs, Cool Mind and Mindchill

Session	Mindchill program (adolescents)	Cool Mind for Kids program (children)
1	Introductions, group expectations and an emphasis on the importance of practice tasks; psychoeducation on anxiety, values and feelings; introduction to acceptance and mindfulness as alternatives to 'getting rid' of unpleasant thoughts and feelings. Practice tasks: Mindful smiling	Introductions, group rules, psychoeducation on anxiety, learning about feelings, Feeling/worry scale, pink elephant and Chinese finger trap exercises to introduce the futility of control and acceptance as an alternative; introduction to mindfulness. Practice tasks: What I think and feel, mindful smiling/breathing whilst waking up
2	Barriers to mindfulness practice, mindfulness of the breath, mindful eating, choosing to live a valued life regardless of fear, mindful movement, rewards, Practice tasks: Additional mindfulness practice	Mindfulness of the breath, mindful eating, thoughts/feelings and control; anxiety and my body, psychoeducation on acceptance; mindful movement. Practice tasks: Mindfulness of the breath, mindfulness while lying down, mindfulness in everyday activities, 'Me and My Body' physiological aspects of anxiety
3	Mindful breathing; 'milk, milk, milk' exercise as introduction to defusion; mindful thinking; acceptance versus tolerance of anxiety. Practice tasks: Defusion and mindfulness exercises	Mindful breathing; 'milk, milk, milk' exercise as an introduction to defusion; introduction to and practice of defusion strategies; mindful thinking; introduction to rewards. Practice tasks: Defusion exercise, mindfulness of the breath, mindfulness in everyday activities
4	Body scanning; creating a fears and worries list; mindful thinking practice; introduction to stepladders (exposure) and first attempt to create own exposure hierarchy. Practice tasks: Body scanning, mindful thinking and working on personal stepladder	Body scanning; mindful thinking practice; creating a fears and worries list; introduction to stepladders (exposure) and first attempt to create own exposure hierarchy. Practice tasks: Daily body scanning, mindful thinking worksheets, create first stepladder
5	Imaginal exposure using stepladders; experiential avoidance and taking our worries with us through life; mindful thinking additional practice; revising stepladders. Practice tasks: Mindfulness practice and stepladders	Imaginal exposure using stepladders; experiential avoidance and taking our worries with us through life; mindful thinking for big worries; stepladders for big worries. Practice tasks: Body scanning, mindful thinking and exposure
6	Mindfulness practice, leaves on a stream exercise; judging versus describing, 'unhooking' from thoughts; letting go of negative self-judgements, acceptance. Practice tasks: Stepladders	Mindfulness practice, leaves on a stream exercise; judging versus describing, acceptance; working on stepladders for big worries. Practice tasks: Mindfulness meditation, imaginal exposure practice about the worst that can happen if he or she confronts the difficult situation and work on stepladders
7	Body scanning additional practice; dealing with set-backs or getting stuck; coping strategies; problem-solving skills building. Practice tasks: Body scanning and imaginal exposure on stepladders	Body scanning additional practice; mindful touch; problem-solving skills building; mindful thinking. Practice tasks: Mindfulness body scanning, exposure (both imaginary and real life)
8	Mindfulness practice; assertive communication; in-session exposure related to stepladders or fears and worries list; problem-solving any set-backs. Practice tasks: Mindful thinking worksheets with stepladders, seeking feedback for areas of self-doubt	Mindfulness practice; assertive communication; in-session exposure related to stepladders or fears and worries list; problem-solving any set-backs. Practice tasks: Mindfulness thinking, exposure in real life, practicing problem-solving
9	Mindful breathing additional practice; coping with teasing and bullying; external strategies to manage worries; review of progress towards goals; additional in-session exposure. Practice tasks: Act on one goal not yet achieved, family discussion of managing anxiety and stress in everyday life	Mindful breathing additional practice; outsmarting bullies; review of progress towards goals; additional in-session exposure. Practice tasks: Practicing describing thoughts rather than judging, practicing assertiveness, mindfulness activities, 10 minutes/day
10	Loving kindness meditation; reviewing goals; planning for the future; dealing with set-backs and celebrating success	Friendly wishes meditation; reviewing goals; focus on values guiding action; planning for the future; dealing with set-backs and celebrating success

measure. It was considered unethical to withhold treatment for longer than 10 weeks.

Treatment fidelity

Across the group treatment period, all psychologists will receive weekly group supervision. As the psychologists involved in the delivery of the treatment are involved in the delivery of both the ACT and CBT treatments, treatment fidelity is an important consideration that will be addressed via video-recording a subset of each 10 week program. Video-recording will be conducted with the consent of all participants and will be reviewed and analyzed by an independent assessor, for fidelity with the identified treatment (ACT or CBT) in accordance with a checklist designed for this study. The independent

assessor will be a psychologist, with training in the use of both ACT and CBT, within the Department of Psychological Medicine who is not involved in the treatment groups. Two independent assessors will be employed to ensure reliability of treatment fidelity ratings. Feedback on the outcome of these reviews will be provided back to the research team and subsequently explored within weekly supervision. In line with the protocol of Forman *et al.* [70], therapist allegiance towards treatment will be assessed by having each psychologist respond to the question 'Which treatment do you think leads to better outcomes, ACT or CBT?'. Therapist allegiance will be examined as a variable of interest in terms of any possible association with study outcomes.

Sample size calculation

A power analysis was conducted to determine the approximate sample size required to achieve an examination of the effectiveness of a manualized ACT group-therapy program, the most sensitive aim. At a power level of 0.8, with an effect size (ES) of 0.6 to 0.7, it is estimated that a minimum 30 participants in each group is required to detect a significant difference between each of the three groups. The employment of analysis of covariance and mixed model statistical tests for pre versus post comparisons will also offer increased power to detect significant differences. The estimated ES of 0.6 to 0.7 is based on the results of three previous meta-analyses of ACT. In terms of primary outcome measures, Hayes *et al.* [31] observed that, compared to structured interventions, ACT was superior after treatment (d = 0.48) and at follow-up (d = 0.63). Ost [71] found that ACT was superior to established treatments achieving a mean ES of 0.68. In contrast, Powers *et al.* [72] found that, on primary outcome measures, ACT achieved ES in the range g = 0.42 to 0.68 when ACT was compared with control or waitlist conditions and g = 0.18 compared to established treatments. The ES for the current study is estimated in line with the higher-end ES results achieved across the aforementioned meta-analyses. The rationale for this is that these meta-analyses have incorporated studies for a range of low-prevalence disorders - disorders that are typically considered to be treatment resistant - whereas the current study focuses only on anxiety, high prevalent disorders, widely acknowledged to be more responsive to treatment.

Statistical analysis

Data coding and analysis will be conducted using the IBM SPSS Statistics v.21 software program. Primary outcome measures will be examined both with intention-to-treat analyses and analyses conducted on treatment completers. For the efficacy hypotheses, paired t-tests and linear mixed models will be used to investigate changes in pre versus post primary and secondary outcome measures. Statistical significance will be considered as P <0.05. The mixed model approach has been selected as it allows for inter-participant and intra-participant variance as well as the inclusion of participants with missing data, whilst maintaining power.

In accordance with the protocol of Forman *et al.* [70], mechanism of change hypotheses will be examined using correlation and independent t-tests to determine which variables to include in a multivariate analysis of variance. Post-hoc multiple comparisons (for example, Bonferroni correction) will be performed to determine where significant differences lie. Multivariate regression examining factors related to treatment success will also be employed and will include examining any demographic (such as age, gender, family functioning) and clinical (such as pre-scores, psychological flexibility) factors that might be related to outcomes. Mediational analysis, a regression-based approach, will be used to test hypotheses about the mechanisms behind outcome, as this is a powerful way of determining mechanisms by which an effect operates rather than the existence of an effect [73]. It allows for more than one mediator and adjusts all paths for the potential influence of covariates not proposed to be mediators in the model. Receiver operating curve plots of the true positive and false positive rate for different possible cut-points of the regression test will be conducted because receiver operating curves convey information relating to the trade-off between sensitivity and specificity, and maximize predictive value. The coordinates of the receiver operating curve will be used to determine the optimal cut-point for the test. The full information maximum likelihood method will be used to deal with missing data.

Discussion

Whilst research has found that ACT is supportive in the treatment of anxiety in adult populations and has been found to be effective in the treatment of children with other concerns, there is a paucity of research examining the effectiveness of ACT among children with anxiety. To the best of the researchers knowledge, this study will be the first randomized controlled trial examining the effectiveness of ACT in young people with a diagnosed anxiety disorder. Conducted in a clinical practice context, this research will assess psychological interventions suitable for implementation in broader psychological settings. If found to be effective, this trial will support the development of ACT treatment protocols that could be made available to clinicians for use in both public and private contexts. It will offer the potential to provide an evidence base to support alternative treatment for anxiety in young people, particularly for those who do not benefit from standard treatments. This will allow for greater flexibility in the tools clinicians can use, and tailor treatment according to individual needs.

In terms of anticipated difficulties for the research, recruitment and retention of participants (particularly adolescents) has been identified as a potential caveat. A number of factors have been identified may contribute to this including the stringent inclusion and exclusion criteria, requiring a primary diagnosis of anxiety disorder and an absence of complex presentations such as suicidality; availability and interest of adolescents and caregivers to commit to attendance of at least 80% of sessions; and other issues specific to the population to be studied, such as School Certificate and Higher School Certificate examinations. To avert this anticipated concern, a proactive approach will be adopted to attempt to

increase appropriate referrals to the Department of Psychological Medicine, CHW, and will include contacting current and potential referrers - pediatricians, general practitioners, psychiatrists, health professionals within child and adolescent mental health, and private practitioners – to inform them about the study. Direct referral to community members will be encouraged among completers of the programs; school newsletter publications and CHW's Bandaged Bear Bulletin (distributed to all hospital staff and affiliates) will be employed to detail parents on the study; and physical advertisements will be placed in waiting rooms within CHW.

Other approaches will focus on school counselors, who often see adolescents with problems of anxiety, as previous research has found that schools were beneficial avenues for recruitment drives [74]. Methods of increasing referral rates will also include presentations of the research and inclusion criteria and peer networking undertaken by the researchers at various professional development courses as previous research with adolescents found that informing key decision makers and community sources in the early stages of the research were associated with better recruitment outcomes [74]. Another approach being considered is conducting adolescent groups at some of the high schools that have expressed interest. This will, however, require parents to attend in school time along with the students. Finally, other approaches will include cold calling and emailing to referrer mailing lists.

Although some studies have found monetary incentives facilitated increased recruitment and retention in research with adolescents [74], this has not been observed universally [75,76] and will not be feasible in the current study. Instead, engagement in the research will be supported by the provision of the treatment by registered psychologists experienced in the delivery of these programs at no cost and ensuring expectations of participants is communicated with clarity and consistency, particularly in the early stages of recruitment. Retention issues will also be addressed by enabling participants in the intervention groups to complete a 'catch-up' session the following week if they are unable to attend a session with one of the treating psychologists and encouragement of in-group socialization within the therapy to establish group cohesiveness. It is anticipated that these approaches will be somewhat supportive in addressing recruitment and retention issues in the current trial.

The researchers will publish outcomes of this trial in peer-reviewed clinical journals. Findings will also be disseminated at relevant conferences that would be attended by practicing clinicians. Findings will also be presented at CHW in-service days as well as for various community organizations in the Area Health Service, and school counselors can inform parents,

increase community awareness and refer clinicians to the program.

Trial status
Recruiting.

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Acceptance and Commitment Therapy versus Cognitive Behavior Therapy for

children with anxiety: Outcomes of a randomized controlled trial

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Abstract

Acceptance and Commitment Therapy (ACT) has a growing empirical base in the treatment of anxiety among adults and children with other concerns. This study reports on the clinical and quality of life (QOL) outcomes of a randomized controlled trial of ACT and CBT in children with a DSM-IV anxiety disorder. Participants were 193 children block-randomized to a 10-week group-based program of ACT or CBT or a 10-week waitlist control (WLC). Completers included 157 children (ACT=54; CBT=57; WLC=46; mean age 11 years). Pre-treatment, post-treatment, and 3 months post-treatment assessments included clinical (clinician/self/parent-reported measures of anxiety, depression, and child behavior), QOL (anxiety interference, psychosocial and physical health-related QOL, and global self-worth) and acceptance/defusion outcomes. Completer and intention-to-treat (ITT) analyses revealed ACT and CBT were both superior to WLC across outcomes, reflecting statistically and clinically significant differences, with gains maintained at 3MFU. While WLC improved significantly on some outcomes at post-treatment, improvements were not clinically significant. Both completer and ITT analyses found ACT and CBT to produce similar outcomes. However, at follow-up, ITT results (but not completer) found CBT evidenced significantly lower scores on clinician-rated, but not self/parent-reported outcomes. We conclude that ACT and CBT are both feasible treatments for improving clinical and QOL outcomes among children with anxiety.

1 Introduction

1.1 Cognitive behavioral therapy in children with anxiety

Cognitive Behavioral Therapy (CBT) is considered the evidence-based gold standard in the treatment of anxiety disorders (Otte, 2011). CBT has an established empirical base attesting to its effectiveness in improving clinical outcomes among children with anxiety in several randomized controlled trials (RCTs) and in naturalistic settings (Beck, 2005; Butler, Chapman, Forman, & Beck, 2006; Compton et al., 2004; James, James, Cowdrey, Soler, & Choke, 2013; Seligman & Ollendick, 2011). A recent review of 41 RCTs of CBT – delivered in individual or group format – for anxious children and adolescents found CBT was superior to no treatment, but not active control conditions, in improving clinical outcomes (James et al., 2013). These outcomes are not only specific to anxiety. Depression is a frequent co-morbid problem with anxiety in youth, particularly those with high anxiety severity, and symptoms have been found to improve following CBT treatment (Kendall et al., 2010; Suveg et al., 2009). Externalising disorders also co-occur and respond to CBT (Barrett, Duffy, Dadds, & Rapee, 2001; Kendall, Safford, Flannery-Schroeder, & Webb, 2004). However, as noted by Creswell, Waite, and Cooper (2014) in their review, one should not necessarily conclude that CBT is the most effective form of treatment for young people with anxiety, but the only one with an adequate evidence base to support its use. Despite the best evidence-base, the lack of control conditions in these studies limits the extent to which results can be attributed to treatment. Furthermore, whilst approximately 66% of children who receive CBT achieve diagnostic remission (Seligman & Ollendick, 2011), a significant proportion exhibit residual symptomatology at treatment cessation (Hudson, 2005). Thus there is room for improvement and there is a need for more rigorous research into alternative treatments.

1.2 Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) is considered to be part of the "third wave" of behavioral and cognitive therapies, incorporating elements of CBT with processes of mindfulness and acceptance (Fletcher & Hayes, 2005). ACT and CBT share commonalities. Both treatments regard thoughts as observable and separate from the self, facilitate heightened identification of personal experience and encompass behavioral approaches such as activation and exposure (Gaudiano, 2011). However, core differences include underpinning theories of psychopathology, putative mechanisms of change, therapeutic techniques, and emphasized outcomes (Gaudiano, 2011). CBT is not characterized by a unified theory, but rather is a broad term that encompasses an array of theoretical standpoints, some of which include common elements while maintaining unique features – such as the learning theories of classical vs operant conditioning – and the salience of particular approaches in terms of optimal treatment is the subject of greater professional conjecture (Herbert, Gaudiano, & Forman, 2013). The cognitive model of CBT posits psychopathology is a consequence of faulty information processing which is ameliorated via systematic techniques aimed at reducing clinical symptoms (Beck, 2005). These distortions and beliefs are subsequently considered to interact with the environment, producing feelings and behavior. In ACT, psychopathology results from becoming entangled in the content of thoughts (fusion), and the avoidance of internal experiences (e.g. thoughts, feelings, bodily sensations), leading to a rigid, psychologically inflexible, non-valued way of living (S. C. Hayes, Levin, Plumb-Vilardaga, Villatte, & Pistorello, 2013; S. C. Hayes, Villatte, Levin, & Hildebrandt, 2011; Luoma, Hayes, & Walser, 2007). Rather than a

focus on changing faulty beliefs, ACT turns toward attentional and metacognitive approaches to change a person's relationship to such beliefs (S. C. Hayes, 2004).

1.3 Emphasised psychotherapeutic outcomes: Clinical and quality of life considerations

The effectiveness of CBT in the treatment of children with anxiety has almost exclusively emphasised clinical outcomes such as diagnostic remission and symptom severity (Greco, Blackledge, Coyne, & Ehrenreich, 2005). However, this may be a narrow focus, in that it does not account for the gamut of health outcomes impacted by psychological concerns and subsequent intervention efforts (Gladis, Gosch, Dishuk, & Crits-Christoph, 1999; Jacobson, Roberts, Berns, & McGlinchey, 1999). Quality of life (QOL) indices allow for the examination of symptom-derived impairment on functioning and well-being (Mendlowicz & Stein, 2000) and arguably reflect the clinical significance of changes (Gladis et al., 1999; Kazdin, 1977; Safren, Heimberg, Brown, & Holle, 1996). Anxiety disorders in childhood have been associated with impaired overall QOL outcomes (Varni, Limbers, & Burwinkle, 2007), psychosocial health (Ginsburg, La Greca, & Silverman, 1998; Weitkamp, Daniels, Romer, & Wiegand-Grefe, 2013), physical health-related QOL (Clark & Kirisci, 1996; Varni et al., 2007) and anxiety life interference (Last, Hansen, & Franco, 1997), among others. This suggests the importance of establishing the effectiveness of therapy in improving QOL outcomes among this population. There is a dearth of research on the impact of CBT on these QOL indices among children (Greco et al., 2005; Safren et al., 1996), and among available studies, mixed evidence has been obtained.

Where traditional CBT places emphasis on clinical outcomes, with the assumption that symptom amelioration is a necessary precursor to living a better life,

ACT takes a radically different stance that emphasises QOL as a primary outcome. ACT assumes that (a) QOL is primarily dependent upon mindful, values-guided action, and; (b) this is possible regardless of the presence, or number, of symptoms – provided that symptoms are responded to with mindfulness (Harris, 2006). Despite the emphasis on QOL outcomes, a recent review of ACT in the treatment of children with a spectrum of presenting difficulties identified just four studies – on sickle cell disease, PTSD, stress, and pain – that examined specific QOL outcomes, with all obtaining improvements over time (Swain, Hancock, Dixon, & Bowman, 2014). Despite the emphasis on QOL outcomes, a growing evidence base supports the effectiveness of ACT in improving clinical outcomes, with several reviews and meta-analyses demonstrating improvements across a range of problems relative to control conditions (S. C. Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Ost, 2008; Powers, Zum Vörde Sive Vörding, & Emmelkamp, 2009; Smout, Hayes, Atkins, Klausen, & Duguid, 2012), and specifically in the treatment of anxiety disorders among adults (Bluett, Homan, Morrison, Levin, & Twohig, 2014; Swain, Hancock, Hainsworth, & Bowman, 2013). Given the impact of anxiety disorders on QOL, and the relative paucity of empirical evidence examining the impact of ACT and CBT on QOL among child populations, more research is required to extend emphasised outcomes to both clinical and QOL measures.

1.4 ACT for children with anxiety

A recent review found ACT to be effective in the treatment of anxiety disorders among adults (Swain, Hancock, Hainsworth, et al., 2013). While there is a dearth of published research attesting to the effectiveness of ACT in the treatment of children with anxiety, it has been argued that the employment of metaphors and experiential approaches in ACT may be particularly suited to children, as they think less literally

than adults and may readily grasp abstract concepts through experience (O'Brien, Larson, & Murrell, 2008). ACT processes have been found to operate in a similar way among children and adults (for a review see Coyne, McHugh, & Martinez, 2011), feasibility studies support the use of mindfulness-based approaches (such as ACT) with child populations (Burke, 2010) and others have shown such approaches are effective in the reduction of anxious symptomology among children (Biegel, Brown, Shapiro, & Schubert, 2009; Lee, Semple, Rosa, & Miller, 2008; Semple, Lee, Rosa, & Miller, 2010; Semple, Reid, & Miller, 2005). Despite this, the empirical base is subject to several limitations. The published literature is confined to two studies involving a total of four participants (Armstrong, Morrison, & Twohig, 2013; Brown & Hooper, 2009), which are subject to caveats including non-random treatment assignment, an absence of control or alternative treatment comparisons and questionable external validity. However, a recent review of 21 studies of ACT, involving a total of 707 children and adolescents with a range of other presenting problems, demonstrated emerging evidence for ACT in the treatment of children as young as 6 years (Swain, Hancock, Dixon, et al., 2014).

1.5 ACT versus CBT in the treatment of anxiety

Evidence on the comparative effectiveness of CBT and ACT in the treatment of anxiety is emerging. A recent systematic review and meta-analysis for a spectrum of psychological concerns found ACT outperformed CBT in 68% of included studies at post-treatment, with superior outcomes for ACT observed for all but one anxiety-specific study (Ruiz, 2012). Whilst, to the authors' knowledge, a comparison of ACT and CBT among children has not previously been empirically undertaken, two randomized clinical trials of over 100 adults with anxiety observed large improvements

in clinical outcomes for both ACT and CBT over time, with no significant differences between the two treatments (Arch et al., 2012; Forman et al., 2012).

There are currently no published studies on the impact of ACT for QOL outcomes among children with anxiety. However, emerging evidence suggests ACT produces positive outcomes on QOL indices (e.g. overall QOL/functioning and life interference) among children with chronic pain (Wicksell, Dahl, Magnusson, & Olsson, 2005; Wicksell, Melin, Lekander, & Olsson, 2009), sickle cell disease (Masuda, Cohen, Wicksell, Kemani, & Johnson, 2011) and depression (L. Hayes, Boyd, & Sewell, 2011). ACT has also been found to improve QOL outcomes among adults with social anxiety disorder (Dalrymple & Herbert, 2007) and generalised anxiety disorder (S. A. Hayes, Orsillo, & Roemer, 2010), among others.

1.6 Study aims

The current investigation aimed to evaluate the effectiveness of group-based ACT and CBT for mixed anxiety disorders in children through an examination of both clinical and QOL outcomes. It was hypothesized that both treatments would produce statistically and clinically significant change on clinician, parent and child self-reported clinical – anxiety disorder diagnosis, clinical severity, symptom severity for anxiety and depression, and child behaviors – and QOL outcomes – anxiety life interference, physical and psychosocial health-related QOL, and global self-worth – for children with anxiety disorders at post-treatment (post) and 3-month follow-up (3MFU). It was predicted that both ACT and CBT would be more effective than WLC post, and that differences between the two treatments would be non-significant. In line with the overarching aim of both treatments – reduction or remission of clinical symptoms / diagnostic status in CBT, and QOL in ACT – it was hypothesized that CBT would

produce greater effect sizes on clinical measures and that QOL measures would evidence greater effect sizes for ACT. Finally, in line with its theoretical underpinnings, it was hypothesized that greater changes in avoidance/fusion would be observed for ACT, relative to CBT and WLC.

2 Methods

Full details of the methodology have been previously reported (Swain, Hancock, Dixon, et al., 2013). A brief description follows.

2.1 Participants

Participants were 193 children who met criteria for one or more anxiety disorders using the *Anxiety Disorders Interview Schedule for Children for DSM-IV* (ADIS-IV; Albano & Silverman, 1996). Of those, 105 (54%) were children (7-11 years) and 88 (46%) were adolescents (12-17 years). They were randomized to ACT (n=68), CBT (n=63) or WLC (n=62) conditions. Figure 1 shows the patient flow diagram. Twenty-one participants (ACT=14; CBT=6) discontinued (i.e. completed less than seven sessions); thus were considered drop-outs. An additional CBT participant was excluded after concurrent individual treatment was commenced. There were no significant differences between completers and non-completers on sociodemographic variables (see Table 1) or ADIS-IV Clinical Severity Ratings (CSRs). In total, 157 participants completed treatment (ACT=54; CBT=57; WLC=46). The study was undertaken at the Department of Psychological Medicine, at the Children's Hospital at Westmead, (CHW) Sydney, Australia. Participants were recruited via referrals from school counsellors, parents, word of mouth, and health professionals. Exclusion criteria were non-English speaker; complex mental health problems (e.g. psychotic symptoms, major depression primary disorder) or medical conditions, as the program was not

designed for such complexities; attention deficit disorder with hyperactivity that was not well controlled; taking psychotropic medication for less than two months; posttraumatic stress disorder (due to specialized treatment required); or academically more than one grade behind peers. The majority of participants were medication free; with 8% stabilized on antidepressants for at least two months. No participants changed or commenced psychotropic medication during the course of the study. Participants received a movie voucher on completion of the 3MFU. The study was approved by the CHW Human Research Ethics Committee and The University of Newcastle Human Research Ethics Committee. Informed consent was obtained from all participants.

2.2 Design

Participants were assessed at pre- and post-treatment, or after 10 weeks waitlisted for the WLC. The treatment groups were also assessed at the 3MFU. Participants were block randomized to one of three groups, stratified by age (7-11 or 12-17 years). Blocks (5 to 9 per block) were generated by using a permuted block design with a computer random number generator using 'Graphpad' [www.graphpad.com/quickcalcs/]. Participant's enrolment into the study was conducted by an intake officer. They were subsequently assessed by researchers blinded to the treatment condition with both parties informed of the group allocation after assessment.

2.3 Treatments

2.3.1 Therapists

Therapists were three clinical psychologists, two registered psychologists and a clinical doctoral student (also a registered psychologist). All were involved in the delivery of the intervention, received weekly supervision, and were trained and experienced in delivering ACT and CBT (1-3 years for ACT, 2- 10+ years for CBT). Clinical doctoral psychology students on placement also co-facilitated groups under supervision (10 in

total over 3 years). This entailed receiving weekly supervision, where sessions were planned and reviewed. The majority of students played mostly an observer role. However, a minority with experience in these therapies co-facilitated some activities under the guidance of their supervisor. To counter therapist effect confounds, all therapists conducted both ACT and CBT groups. Reliability checks (see below for details) were conducted via audiotapes.

2.3.2 Intervention

Participants allocated to ACT or CBT completed a group-based therapy program of 10 x 1.5 hour sessions at no cost. A parent group ran concurrent to the child/adolescent group. This group involved providing the parents with psychoeducation and the same treatment skills as the children with the aim of fostering a "parent-as-coach" approach in order to facilitate generalization of skills. However, each session also incorporated time for children and parents to work together in pairs on skills within one large group. Treatment was conducted by between two and four psychologists, dependent upon group numbers (5-9 children per group). Although both programs incorporated psychoeducation, exposure and skills training (e.g. problem solving, social skills), the delivery of these three components differed by treatment groups (as described below).

The CBT program was the Cool kids/Chilled® programs for younger children (7-11 years) and adolescents (Rapee et al., 2006). This program involves anxiety management techniques of cognitive restructuring, graded exposure, problem solving and social skills training [for more details see Rapee et al. (2006)].

The ACT program was developed at CHW and used all ACT processes that comprise the "hexaflex" model - cognitive defusion, acceptance, mindfulness, self-as-context, committed action and values. Formal mindfulness exercises – including

mindful breathing, body scanning, mindful eating, meditation, and imaginal exposure as well as mindfulness in everyday activities – were undertaken at the beginning of each session. Psychoeducation (session 1 and 2) focused on a child-appropriate explanation of the ACT model through metaphor and experiential learning approaches such as the Chinese Finger Trap and Pink Elephant metaphors (S. C. Hayes, Stroshal, & Wilson, 1999). Psychoeducation differed to the CBT program in its emphasis on the components of the ACT model rather than CBT aspects (e.g. Fighting fear, and thoughts and feelings causing behaviors). The concept of living a valued life was conveyed through values cards (session 2). Cognitive defusion was employed as an alternative to cognitive restructuring (session 3 onwards) with metaphors such as "Hands as Thoughts" (Harris, 2009) and the "Milk, Milk, Milk" exercise (S. C. Hayes et al., 1999) as an introduction to the concept, followed by a "Mindful Thinking" worksheet that incorporated defusion and values. Similar to the Arch et al. (2012) study, the current study included traditional exposure exercises as the use of such behavioral methods are an intrinsic part of the ACT model and treatment protocols (S. C. Hayes, Strosahl, & Wilson, 2012). However, the ACT approach used graded exposure to support mindful observation and acceptance of anxiety while faced with fear in order to foster committed action in line with self-identified values (from session 4 onwards). Thus it differed in its focus on willingness whereas CBT focuses on fear ratings as an indicator of step graduation. Cognitive coping strategies focused on use of cognitive defusion, mindfulness, acceptance and reminders of values. Finally, problem solving and social skills were incorporated to facilitate valued action (covered in sessions 8 and 9). Further details on both the treatments and their differences can be found in Swain, Hancock, Dixon, et al. (2013). Contact the authors for a program copy.

2.4 Outcome Measures

All measures have well-established validity and reliability [see Swain, Hancock, Dixon, et al. (2013)]. Measures are presented in subgroups of clinical and QOL outcomes and process measures.

2.4.1 Clinical outcome measures

2.4.1.1 Anxiety disorder diagnosis and clinical severity

The ADIS-IV (Albano & Silverman, 1996), a structured diagnostic interview that assesses for a range of DSM-IV disorders typically first diagnosed in childhood or adolescence (Grills & Ollendick, 2003), was completed by participants and a parent. It produces a clinical severity rating (CSR) between 0-8. Scores greater than 4 are indicative of clinical disorders, with higher scores reflecting increasing disorder severity (5-6=severe, 7-8=very severe). All ADIS-IV interviews were audio-recorded. Inter-rater reliabilities of diagnoses at pre-and post-assessment were conducted on 33% of recordings by a clinician blinded to both the original interviewer's diagnosis and the treatment conditions. The K agreement for an overall diagnosis of anxiety disorder was 1, with a range of 0.87 to 0.97 across the major anxiety disorders. The overall CSR severity reliability rating was K=0.76. The sample had 2% with overall CSR ratings with a difference of 2 points between the raters, 11% with a difference of 1 point, and 86% identical.

2.4.1.2 Anxiety symptoms

2.4.1.2.1 The Multidimensional Anxiety Scale for Children (MASC)

The MASC is a self (MASC-C) and parent-report (MASC-P) inventory of anxiety symptoms including physiological symptoms, avoidance, social and separation anxiety

(March, Sullivan, & Parker, 1999; Rynn et al., 2006). In the present sample the average internal consistency across the MASC subscales was between α = .83 - .86, depending upon the assessment time point.

2.4.1.2.2 Depression: The Children's Depression Inventory (CDI)

The CDI is a self-report measure of depression for children and adolescents aged 8-16 years. It comprises 27 items assessing cognitive, affective and behavioral signs of depression (Carey, Faulstich, Gresham, Ruggiero, & Enyart, 1987; Saylor, Finch, Spirito, & Bennett, 1984). In the current sample the CDI produced internal consistency of α = .68.

2.4.1.2.3 Total problems and anxious/depressed behaviors: Child Behavior Checklist - Parent Form (CBCL)

The CBCL is a widely utilized, standardized measure of children's and adolescents' (aged 5 to 18 years) emotional and behavioral functioning as well as social competence (Achenbach, 1991; Siddons & Lancaster, 2004). This study focused on the Total Problems and Anxious/Depressed scores. In the present sample the internal consistency ranged from α = .60 - .89 for CBCL- AD.

2.4.2 QOL outcome measures

2.4.2.1 Anxiety life interference: Children's Anxiety Life Interference Scale (CALIS)

The CALIS is a self-report measure that assesses life interference across school, family, peers/friendships, and physical health. Items are rated on a five-point Likert scale from "not at all" to "all the time". There is a child (CALIS-C) and parent form, the latter having two subscales of child (CALIS-P) and family (CALIS-F) interference (Lyneham

et al., 2013). Test-retest reliability has been established as moderate (r = 0.66 - 0.87) and intra-class correlations (r = 0.38 - 0.74) acceptable (Lyneham et al., 2013). Reliability estimates were found to be good at 0.80 and convergent validity has been established (Lyneham et al., 2013). The CALIS-C was found to demonstrate moderate internal consistency (α = .54 - .88) in the current sample, dependent upon the assessment time point, and high for CALIS-F (α = .89) and CALIS-P (α = .93).

2.4.2.2 Physical and psychosocial health-related QOL: The Child Health Questionnaire (CHQ)

The CHQ is a generic, rather than disease specific, measure of health-related QOL. This study used the 50 –item parent version which measures 11 areas of health that can be summarized into physical (6) and psychological health-related QOL domains (4 areas), and one on limitations in family activities. Summary scores for psychosocial and physical health-related QOL can be derived. The scale has been found to have high validity and reliability (Landgraf, Abetz, & Ware, 1999). The scale has undergone extensive validation, been found to have strong validity and reliability, reliability ranging from 0.70-0.94, and confidence intervals for validity between +-6 to +-17 (Landgraf et al., 1999). Psychosocial internal consistency was high in the current sample (α = .94) and moderate for physical (α =0.57)

2.4.2.3 Global self-worth: The Self-Perception Profile for Children (SPPC)

The SPCC is a 12-item self-report magnitude estimation scale that measures a child's sense of general self-worth and self-competence in the domain of academic skills (Harter, 1982, 1985). This measure taps specific domains of self-concept as well as

global self-worth (Harter, 1985). For this study the global self-worth subscale is the outcome of interest. The scale has well established validity and reliability, with internal reliability estimates of 0.8 (Harter, 1982, 1985). The SPPC was found to demonstrate good internal consistency of α = .87 in the current sample.

2.4.3 Process measure

2.4.3.1 The Avoidance & Fusion Questionnaire - Youth (AFQ-Y)

The AFQ-Y is a 17-item self-report measure of cognitive fusion ("fusion") and experiential avoidance (EA; the antithesis of acceptance and defusion of/from anxious thoughts) for youth, developed among children aged 8-14 years and validated in a sample with an average age of 12.43 years (Greco, Lambert, & Baer, 2008). Confirmatory factor analysis has supported the hypothesized one-factor model of the AFQ-Y and internal consistency reliability was also strong at 0.90 (Silverman, Saavedra, & Pina, 2001). The AFQ-Y was found to demonstrate good internal consistency of α = .87 –.95 in the current sample depending upon the assessment time point.

2.4.4 Treatment fidelity and competence

A therapist adherence scale (available from the authors) was developed based on a similar scale used by Norton (2012). A therapist not involved in the treatment evaluated on a session-by-session basis the extent to which several therapy components described in the treatment manual were implemented effectively. The checklists closely followed the treatment manuals, including the structure of the session, activities, and the information to be presented and discussed. Ratings were performed on 20 randomly

selected video recording sessions, made on a 1 to 5 scale, ranging from 1 (ineffective) to 5 (extremely effective), with ratings of 4 (reasonably effective) or 5 considered "within protocol". Overall, raters judged the therapists to be consistent with both the treatment protocols, achieving an average adherence rating of 4.37, (SD=0.34) for ACT and 4.50 (SD=0.50) for CBT, with no significant group differences (t_{18}=-0.18, p=ns). For each CBT session, the checklist asked for a yes/no response to whether the therapist was CBT/ACT consistent throughout, depending on which treatment was being implemented. Therapist competence scale scores were measured using a validated sub-scale of an ACT/CBT adherence and competence tool (McGrath, Forman, & Herbert, 2013). This scale investigated factors such as "knowledge of treatment,", "skill in delivering treatment", "relationship with client" and "overall performance". At the end of each recording, therapist competence was rated and the mean of the scale items represented the therapist competence for that session, as per Arch et al. (2012). Results indicated very good therapist skills in both ACT (M=4.32, SD=0.40), and CBT (M=4.36, SD=0.60) with no significant group differences (t_{18}=-0.66, p=ns). There were no student video samples available for treatment adherence/competence ratings as most were of students observing, and as participants moved between rooms (parent and child groups) and while doing exposure, it was not always possible to follow every therapist. Student co-led components of the sessions comprised a very small percentage of the overall therapy time for this study.

2.4.5 Treatment credibility

Treatment credibility and parent expectancies for therapy were assessed on a sub-sample of 33% in the total group (ACT n=17, CBT n=19), using a modified version of the Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000). One

item assessed parents' perceptions of the credibility of treatment ("How much sense does the therapy offered to you seem to make?"). Another assessed parent expectancies for treatment ("By the end of therapy, how much improvement in your child's behavior do you think will have occurred?"). Previous psychometric evaluation of the CEQ revealed adequate reliability and construct validity in adult clinical samples (Devilly & Borkovec, 2000). The scale was administered during the first therapeutic contact. Credibility scores (maximum 5) suggested no significant group differences in perceptions for ACT (*M*= 4.24 *SD*=0.69) versus CBT (*M*=4.58, *SD*=0.81) (t_{34}=-1.92, *p*=ns), or expectancy (M= 3.88 for ACT, 3.89 for CBTt_{34}=-.05, *p*=ns). Whilst gathering both child and parent perceptions would have been ideal, we attempted wherever possible to minimise burden on the children, so such measures were limited to parents for this study.

2.4.6 Therapist allegiance

Upon commencement of the study, therapists were asked to rate therapeutic allegiance by answering the question at the commencement of the study "Which treatment do you think leads to better outcomes?" Three stated they believed both treatments would be equally effective, two ACT, and one CBT. Thus allegiance was dispersed. All therapists performed both treatments.

2.4.7 Data analysis

Data were analysed using SPSS 19 (IBM, USA) by a statistician who was blinded to group status (the data set was decoded for treatment group). Intention-to-treat (ITT) and completer analyses were conducted. The only differences were for the primary outcome – ADIS-IV – so both results are reported for this variable. ITT analyses included all

participants who were allocated to a condition. Missing data were handled using the last-observation-carried-forward (LOCF) method. Although there are limitations to the LOCF method due its underlying assumption that patients who receive interventions improve, the main outcomes of this study demonstrate that this assumption is not violated in the current sample. Thus, the LOCF method is a conservative approach to handling missing data. Data from all three conditions were available only at pre- and post-points as, for ethical reasons, the WLC participants were offered group treatment after the end of the waiting period. Thus, the three groups were compared on continuous measures at pre, post and 3MFU using mixed-model analyses (as it handles missing data at the 3 month time point for the WLC group).

The primary endpoint was the ADIS-IV (measured by CSR and number of diagnoses). Other outcomes included the MASC, CDI and CBCL (Total Problems and Anxious/Depressed scales). Linear mixed model analyses were used to determine differences between groups on continuous measures (pre, post and 3MFU). An unstructured covariance structure which provided the best fit was used. Post-hoc comparisons between groups were undertaken using Least Significance Differences. Corrections for Type 1 error were not used in this study due to it being an exploratory study, not a confirmatory one (Bender & Lange, 2001).

3 Results

3.1 Pre-treatment comparisons

Chi-square (χ^2) tests for categorical variables and one-way analyses of variance (ANOVAs) for continuous variables were employed to examine the three treatment groups (henceforth known as 'group'), differences on sociodemographic variables and pre-treatment outcome measures. There were no significant differences across groups

for any sociodemographic variable (*ps*>.13) or anxiety measure (*ps*>0.07). Exploratory data analyses ensured assumptions were met for mixed model ANOVA. When there were pre-treatment clinically significant differences between groups, analysis of covariance (ANCOVA) was used. This was only the case for CALIS-C. The only variable where age was significantly different comparing children versus adolescents was for the ADIS-IV. Due to the wide participant age range (7-17 years), preliminary analyses were performed with age as a co-variate. All effects for age were non-significant, with the exception of the ADIS-IV CSR. These results are presented with age as a co-variate, separately for younger children and adolescents.

3.2 Analyses of Drop-out Data

A total of 36 participants (18.65%) attended fewer than seven group treatment sessions, did not complete the waitlist period or had to be excluded from final analysis because they sought concurrent treatment. These consisted of 14 (20.6%) ACT, 6 (9.5 %) CBT, and 16 (25.8%) WLC participants. Although there were differences in drop-out rates across groups, reasons given were pragmatic rather than treatment related (e.g. moved house, illness, surgery) or motivationally based. Figure 1 lists the reasons for attrition.

Between-group differences were non-significant. All participants who completed treatment returned post data and only one was lost at the 3MFU. Drop-out participants were compared with completers on demographic and treatment outcome measures used in this study. Analysis of drop-outs versus completers demonstrated no significances on any pre-treatment measure.

3.3 Clinical outcomes

Means and standard deviations for outcome measures are presented in Table 2. Effect sizes for within-group and between-group change from pre- to post are listed by group in Table 2 (Cohen's *d* for within group, and Glass's Delta Δ for between group). Effect sizes for Cohen's *d* for within group differences were calculated using the mean differences of pre- and post-scores for within groups divided by the baseline standard deviation (SD; Becker, 2000). This measure can be used only when the SDs of two populations represented by the two groups are the same, and the population distributions are close to normal. The advantage is that it allows a comparison of effect sizes to known benchmarks. Effect sizes for comparison between the treatment groups were performed using Cohens *d* but using the pooled standard deviations of the two groups. Cohen's criteria for effect sizes was used for this study, with 0.2=small, 0.5=medium, and 0.8=large. Effect sizes for treatment versus WLC means using Glass's Delta Δ were calculated using the mean differences of post scores for the treatment group versus the WLC group divided by the post SD of the WLC (Dunlop, Cortina, Vaslow, & Burke, 1996). The rationale is that the SD of the control group is unaffected by the effects of the treatment and will therefore more closely reflect the population SD (Hedges, 1981).

3.3.1 ADIS-IV Anxiety disorder diagnosis and clinical severity (CSR)

Figure 2 shows the changes over time in CSR means. There were significant main effects for both groups and time for CSR based on both completer ($F_{2,145.29}$=20.91, p<0.001-group; $F_{2,128.86}$= 128.51, p<0.001- time) and the ITT samples ($F_{2,178.35}$=20.14, p<0.001-group; $F_{2,152.77}$= 106.38, p<0.001-time). A significant group x time interaction was also found across both analyses ($F_{3,195.19}$=9.67, p<0.001 for completers; $F_{3,242.87}$=11.44, p<0.001 for ITT). There were no significant ACT versus CBT differences for completer analysis across time (p=0.20) however both treatments had

significantly lower post CSR scores than the WLC ($p<0.001$ for both completer and ITT samples, $\Delta =1.32$ for ACT vs. WLC for CSR, $\Delta =1.60$ for CBT vs. WLC for completer; $\Delta =1.04$ for ACT vs. WLC for CSR, $\Delta =1.53$ for CBT vs. WLC for ITT). Thus Δ was similar for both ACT and CBT, being very large (see Table 3). Post- scores were significantly lower than pre-treatment scores for both treatment groups across completer and ITT samples ($p<0.001$, $d=3.39$ for ACT, $d=3.31$ for CBT for CSR for completers; $d=2.59$ for ACT for CSR, $d=3.09$ for CBT for ITT.) The d's were very large for both ACT and CBT. The d at post comparing ACT vs. CBT was very small (see Table 3). While the WLC group also had significant reductions in mean ADIS-IV CSR scores ($p<0.01$, $d=1.08$ for completers $d=0.77$ for ITT), this is a non-significant clinical finding, with a mean group reduction of one point still remaining within the severe CSR category. Improvements were maintained for the treatment groups at 3MFU using completer samples, with no significant differences between or within the two treatment groups ($p=0.13$). However, in the ITT sample, CBT had significantly lower CSR scores than ACT ($p<0.05$) at 3MFU.

3.3.1.2 CSR by age

When analysed by age, there was a significant age main effect ($F_{1,188.31}=14.52$, $p<0.01$). Adolescent mean CSRs were significantly higher than the younger children ($M= 5.42$ vs. 4.92 $p<0.01$). For younger children, there were significant main effects for treatment groups ($F_{2,97.41}=5.79$, $p<0.01$) across time ($F_{2,85.57}=71.63$, $p<0.001$) and a significant interaction ($F_{3,133.26}=6.37$, $p<0.001$). ACT and CBT scores were not significantly different ($p=0.17$); however, they both had significantly lower CSR scores than the WLC ($p<0.001$), which remained unchanged over time. Post- and 3MFU scores were significantly lower than pre-treatment scores for ACT and CBT ($p<0.001$), with no

significant time effect for the WLC ($p=0.74$). For adolescents, there was a significant main effect for groups ($F_{2,60.23}=20.38$, $p<0.001$; $F_{2,79.59}=170.52$, $p<0.001$), time ($F_{2,51.09}=43.41$, $p<0.001$; $F_{2,66.01}=37.02$, $p<0.001$), and interaction ($F_{3,80.79}=4.76$, $p<0.01$; $F_{3,105.28}=5.62$, $p<0.01$). Post-hoc LSD comparisons showed the same significance pattern as the younger children ($p<0.001$), but overall mean scores were higher.

3.3.1.3 Number of anxiety diagnoses

There was a significant group ($F_{2,181.77}=8.55$, $p<0.001$) and time main effect ($F_{2,159.79}=85.65$, $p<0.001$) and interaction ($F_{3,220.05}=7.59$, $p<0.001$). There were significantly fewer diagnoses over time for both treatment groups ($p<0.001$; $d=1.43$ for ACT $d=0.93$ for CBT; $\Delta=0.64$ for ACT vs. WLC, $\Delta=0.94$ for CBT vs. WLC, $d=0.32$ for ACT. Vs. CBT). The d was very large for ACT and large for CBT, and low for ACT vs. CBT (see Table 3).

3.3.2 Symptom severity & behavior problems

3.3.2.1 Anxiety (MASC P/C)

For the MASC-P there was no significant main effect for groups ($F_{2,181.37}=1.52$, $p=0.22$), but significance for time ($F_{2,159.78}=42.27$, p<0.001), and interaction ($F_{3,241.72}=7.47$, $p<0.001$). There were no significant comparisons for ACT versus CBT at post ($p=0.17$) or 3MFU ($p=0.19$); however, post CBT scores were significantly lower than WLC scores, ($p<0.01$), with a large $\Delta=1.01$, and borderline significance for ACT versus WLC ($p=0.06$). Post scores were significantly lower than pre scores for ACT and CBT ($p<0.001$ for both CBT and ACT, $d=0.72$ for CBT, $d=0.53$ for ACT), reflecting moderate d for ACT and moderate- to- large for CBT, and very small for ACT versus CBT. The WLC group had no significant change over time ($p=0.74$).

MASC-C results showed a significant main effect for groups ($F_{2,185.09}=5.76$, $p<0.01$), time ($F_{2,169.99}=44.19$, p<0.001), and interaction ($F_{3,215.56}=8.82$, $p<0.001$). There were significant differences between the three groups at post ($p<0.05$ for CBT versus ACT post, $\Delta=0.43$; and $p<0.001$ for CBT versus WLC; $\Delta=1.17$ and ACT versus WLC), revealing a large Δ for CBT and moderate for ACT. Post- scores were significantly lower than pre-treatment scores for ACT and CBT ($p<0.01$ for both ACT and CBT; $d=0.53$ for ACT, $d=0.85$ for CBT), with a large d for CBT and moderate for ACT, with the WLC group having no significant change over time (p=0.88). Although CBT scores were significantly lower than ACT at post with a small to moderate d ($p<0.05$, $d=0.37$), both were within the normal range. At the 3MFU treatment groups were not significantly different ($p=0.18$).

3.3.2.2 Depression (CDI)

The CDI showed a significant main effect for groups ($F_{,2,183.92}=8.41$, $p=0.001$), time ($F_{2,164.50}=40.63$, $p<0.001$) and interaction ($F_{3,211.63}=2.86$, $p<0.05$). Overall the WLC had significantly higher CDI scores than ACT and CBT, with a significant reduction in CDI scores over time for ACT and CBT ($p<0.05$, $d=0.46$ for ACT and 0.55 for CBT), but not WLC ($p=0.08$). A comparison of ACT vs. CBT revealed moderate d's for both ACT and CBT (see Table 3). ACT and CBT were not significantly different post ($p=0.70$) or 3MFU ($p=0.55$). Mean scores were within the normal range over time for all groups.

3.3.2.3 Child behavior (Total problems and anxious/depressed; CBCL)

There was no significant group main effect for CBCL total problems (TP) ($F_{2,154.36}=0.59$ $p<0.94$) or Anxious/Depressed (A/D) scores ($F_{2,154.34}=0.62$, $p=0.54$), but significance for time ($F_{2,131.49}=74.23$ $p<0.001$ for TP; $F_{2,136.06}=65.19$ $p<0.001$ for A/D)

and a significant groups by time interaction ($F_{3,209.21}$=3.42, p<0.05 for TP; $F_{3,212.57}$=3.06 , p<0.05 for A/D). Post scores were significantly lower than pre-treatment scores for both the ACT and CBT groups (p<0.001, d=0.72 for ACT and d=0.79 for CBT for TP: d=0.75 for ACT and d=0.68 for CBT for A/D), demonstrating moderate to large d's for both ACT and CBT, but small for WLC (d=0.27). There was also significance for pre versus 3MFU (p<0.001 for ACT, p<0.05 for CBT). The WLC group also improved, but the effect size was small, thus explaining the significant group by time interaction (p<0.05, d=0.24 for TP, d= 0.04 for A/D). There were no significant between group differences at post (p>0.09) or 3MFU (p>0.72).

3.4 Quality of life outcomes

3.4.1 Anxiety life interference (CALIS-C/P/F)

The CALIS-C showed a significant group main effect ($F_{2,153.73}$=29.90, p<0.001), and time ($F_{2,169.30}$=12.71, p<0.001), and a significant interaction ($F_{3,136.10}$=8.51, p<0.001), as did the CALIS-P ($F_{2,153.73}$=7.79, p<0.001; $F_{2,158.75}$=8.14, p<0.001 for groups; $F_{2,177.83}$=43.23, $F_{3,136.72}$=3.65, p<0.01; $F_{3,141.82}$=3.18, p<0.05 for interaction). For the CALIS-F, there was a significant time effect ($F_{2,175.96}$=13.43, p<0.001), but not group ($F_{2,158.84}$=2.47, p=0.08) or interaction ($F_{3,141.27}$=2.06, p=0.11) . For the CALIS-C, both the WLC and ACT groups had significantly higher life interference than the CBT group pre-treatment (p<0.01); the CBT group did not change over time (p=0.31, d=0.18), but the ACT group had significant improvements over time (p<0.001, d=0.83). This reflects a large d for ACT and small for CBT. The WLC had significantly higher scores from pre-treatment to post, indicating greater life interference (p<0.05, d=0.30). However, this was not a clinically significant difference. Due to pre-treatment group differences in CALIS-C scores, ANCOVA was performed between the three groups, with pre-

treatment CALIS-C entered as a covariate. After accounting for CALIS-C baseline scores, ACT and CBT scores were not significantly different at post (p=0.11) or 3MFU (p=0.15). For the CALIS-P perception of child, the ACT group reported significantly less interference than the CBT group at post (p<0.05,) and 3MFU (p<0.05), with a moderate effect size at post (d=0.42). Both ACT and CBT had significantly lower CALIS-P scores than the WLC condition post (p<0.001, d=2.12 and 1.83 respectively), indicating very large effect sizes for ACT and CBT.

3.4.2 Physical and psychosocial health-related QOL (CHQ)

For the CHQ (Psychosocial) there was a significant groups main effect ($F_{2,99.09}$=3.47, p<0.05), time ($F_{2,72.23}$=16.75, p<0.001; $F_{2,92.06}$=17.75, p<0.0001), and interaction ($F_{3,100.53}$=4.99, p<0.01; $F_{3,113.38}$=4.80, p<0.01). The treatment groups were not significantly different at post(p=0.79, d=0.08), indicating very small d's; however, ACT and CBT scores were significantly lower post than WLC, with large d's for both (p<0.001, d=0.88 for ACT, d=0.95 for CBT). Post scores were significantly higher than pre-treatment for ACT and CBT (p<0.001, Δ =0.71 for ACT, Δ =0.56 for CBT) indicating improved psychosocial health. This reflects a moderate to high Δ for ACT and moderate for CBT, which was maintained at follow-up, with no significant change over time for WLC. For the CHQ (Physical) there was no significant groups main effect ($F_{2,97.34}$=1.24, p=0.29), time ($F_{2,89.45}$=0.26, p=.97) or interaction ($F_{3,106.46}$=0.76, p=0.52).

3.4.3 Self-worth

The SPPC global self-worth scores were significantly different over time ($F_{2,91.95}$=23.23, p<0.0001), but between groups ($F_{2,102.27}$=1.36, p=0.27) and the interaction

($F_{3,130.92}$=0.26, p=0.85) were non-significant. Post- scores were significantly higher than pre-treatment scores, which were maintained at 3MFU ($p<0.01$). Effect sizes for most comparisons were very small (see Table 3), with a small d=0.28 for ACT vs. CBT.

3.4.3 Process measure

3.4.3.1 Acceptance and defusion (AFQ-Y)

For the AFQ-Y, there was a significant groups main effect ($F_{2,181.15}$=5.31, $p<0.01$), time ($F_{2,172.37}$=42.69), and interaction ($F_{3,220.54}$=6.59, $p<0.001$). Post-hoc analyses showed the treatment groups were not significantly different (p=0.23); however, ACT and CBT scores were significantly lower post compared with WLC means ($p<0.001$, d=0.61 for ACT, d=0.80 for CBT). This demonstrates moderate to large $d's$ for ACT and large for CBT. Post scores showed significantly less avoidance and fusion than pre-treatment scores for both treatment groups ($p<0.001$, Δ =0.50 for ACT, Δ =0.79 for CBT), with no significant change for the WLC group (p=0.52).

3.4.5 Clinical significance

Clinical significance was computed on the basis of the Jacobson and Truax (1991) model which requires both a reliable change index (a minimum decrease from pre-treatment to post) and that mean scores cross a cut-off point that approximates a shift from clinical to nonclinical status. It is commonly accepted to report clinical significance for those who completed the study (Forman, Herbert, Moitra, Yeomans, & Geller, 2007); thus analysis of recovery rates was based on completers. Due to the large amount of variables in this study, clinical significance is presented for the ADIS-IV outcome only. Groups were analysed according to those who scored less than 4 on the

CSR. The percentage of children who no longer met criteria for an anxiety disorder at post were 31.5% ACT, 42.1% CBT and 8% for WLC groups At 3MFU, 37% ACT and 54.4% of the CBT groups were diagnosis free. Chi-square analyses indicated there were no significant differences between ACT and CBT in the frequency of children without an anxiety diagnosis across time.

4 Discussion

4.1 Summary

On the basis of completer analyses, both ACT and CBT produced significant reductions in CSR in contrast to the WLC group. Gains in both ACT and CBT were maintained at the 3MFU, with a mean CSR score for both groups falling within the non-diagnostic category for anxiety overall. Means were neither statistically or clinically different over time overall when comparing ACT and CBT, with small effect sizes. Effect sizes were large when comparing pre to post CSR ratings for ACT and CBT, and also when comparing post treatment scores with the WLC. The mean number of anxiety diagnoses was reduced from three to one- a large effect size for ACT and CBT. Recovery rates also indicated superior outcomes for the treatment groups relative to WLC.

Younger children evidenced lower CSRs than adolescents on a statistical level, but this difference was not clinically meaningful. Furthermore, age was not significantly related to treatment outcomes, with the same pattern of results observed for younger children and adolescents.

As expected, anxiety and depression outcomes (MASC and CDI) showed significant improvements for both treatment groups over time and in comparison to the WLC group. Although MASC-C at post suggested superior outcomes for CBT relative

to ACT, this difference is not clinically meaningful, as both groups evidenced scores in the normal range.

The total problems / anxious depressed behavior data indicated that statistically all three groups improved from pre-treatment to post. In terms of QOL outcomes, after controlling for pre-treatment differences, both ACT and CBT evidenced significantly less anxiety life interference in accordance with the child-report, in line with hypotheses. There were significant improvements in child ratings of anxiety life interference among ACT (reflecting a movement from the high to the below-average range) participants, with a large effect size. This finding was further underscored by the parent-report, indicating that while both treatment groups evidenced superior outcomes to WLC, ACT participants had significantly less anxiety life interference than CBT at post and 3 MFU. The degree of interference of the child's anxiety on the family improved at post for both treatment groups, whereas no changes were observed for WLC; this remained at follow-up.

In line with our hypothesis, both treatment groups evidenced significant change over time and in comparison to WLC on QOL in terms of psychosocial health. This is consistent with the findings of other studies (e.g., Metzler, Biglan, Noell, Ary, & Ochs, 2000; Segool & Carlson, 2008). Results did not support the hypothesis that treatment would be associated with improvements in physical health-related QOL. However, mean pre-treatment scores were within the average range, so it would not be expected that scores would significantly improve.

Both treatment groups were avoiding and fusing less with anxious thoughts at post and in comparison to WLC, and most had high-end functioning. Post means for both treatment groups reflect average scores for a non-anxious population, but higher for the WLC. The clinical outcome of global self-worth scores revealed significant

change at post, but there were no differences between groups and they were not maintained at follow-up.

A secondary hypothesis was that CBT would obtain superior effect sizes on clinical outcomes relative to ACT. Using Cohen's criteria (small, medium, large), when comparing ACT with CBT, MASC-C outcomes revealed large effect sizes for CBT compared with moderate effect sizes for ACT. Thus there was limited support for this hypothesis. However, the effect size for number of diagnoses was larger for ACT than CBT, which was not expected, although both fell within the large ES range. For all other clinical outcomes, effect sizes were similar. Quality of life effect sizes were similar for all outcomes excepting the CALIS Child and Family versions, with larger effect sizes for ACT compared with CBT. Again, there was some support for our hypothesis, but outcomes were largely similar for both treatment groups.

4.2 Implications

Given that the pre-treatment mean CSR scores for all three groups were in the severe end of the spectrum of anxiety disorders, a movement in average scores from the severe range to non-diagnostic levels for both treatment groups is a highly positive outcome. It is also encouraging that around a third of participants in both treatment groups no longer met criteria for an anxiety disorder, and this was maintained and further improved at 3MFU.

Whilst there was a statistically significant improvement in WLC mean CSR at post, an improvement of 0.74 does not represent a clinically meaningful change, remaining within the severe range of anxiety. A discrepancy was also found between completer and ITT analyses at the 3MFU. While both treatment groups outperformed the WLC, CBT had significantly lower scores than ACT on ITT, but not completer

analyses. This difference in mean score was also less than one point and does not reflect a clinically meaningful distinction. The implications of these findings are that caution should be used in interpreting the ITT results. Significantly fewer CBT participants dropped out relative to the ACT group. Although it is not possible to know whether some of the reasons given were in fact motivationally based, the reasons appear to be extraneous variables (e.g. illness) and the use of LOCF for ITT results in a bias towards the null hypothesis. While the literature indicates mixed findings in terms of differences in therapeutic outcome by age, these findings are in line with a recent review that found no clinical or demographic factors moderated or predicted treatment outcome among children and adolescents (Nilsen, Eisemann, & Kvernmo, 2013). Findings also support other researchers' observations that children as young as 7 years can grasp ACT concepts due their ability to think abstractly, and that ACT processes operate similarly in children and adults (for reviews see Coyne et al., 2011; O'Brien et al., 2008), as well as studies supporting the utility of mindfulness-based approaches (such as ACT) with child populations. A weakness in existing child anxiety research is that there are few studies in adolescents over 14 years. This study included participants up to 17 years and the older children had similarly efficacious outcomes to younger children. These findings question common clinical perceptions that adolescent engagement challenges impair treatment success (see overview in Wuthrich et al., 2012)

A qualification to the statistical improvement in CDI scores over time is that depression scores for all three groups were within the normal range both prior to and following treatment. Thus, clinical improvements over time would not be expected. Only 18% of the sample met criteria for depressive mood pre-treatment, reflecting prevalence commonly reported for children with a primary anxiety disorder (Garber & Weersing, 2010), so a larger sample size is likely needed to determine whether

treatment impacts depressive symptoms. Similarly, self-worth results are qualified by pre-treatment scores that were within the normal range across groups, with little room to move. Thus it is difficult to make generalizations regarding the CDI and self-worth scores.

Clinically significant improvement was observed for internalising/externalising and behavioral problems, evidenced by a movement from the borderline clinical to the normal range for both ACT and CBT, whereas it remained in the borderline clinical range for WLCs. Thus, treatment appeared to improve behavioral problems as well as anxiety symptoms. This is consistent with previous research finding a reduction in externalizing symptoms following CBT anxiety treatment (Barrett et al., 2001; Kendall et al., 2004).

The finding that both treatment groups had increased psychosocial QOL is in line with the findings of other studies (e.g., Metzler et al., 2000; Segool & Carlson, 2008). Results did not support the hypothesis that treatment would be associated with improvements in physical health-related QOL. However, as mean pre-treatment scores were within the average range, it would not be expected that scores would significantly improve. The lack of change for physical QOL is in contrast to the results of studies of ACT for children with medical conditions, though only a few exist (Masuda et al., 2011; Wicksell et al., 2009). This suggests that health-related QOL has a greater impact among populations with physical problems than psychological with physiological sequelae, potentially as physical symptoms are more likely to be a more salient focus of treatment in the former.

Whilst the finding that both treatments evidenced favourable outcomes relative to WLC on avoidance and fusion was in line with hypotheses, it was also predicted that ACT would be superior to CBT in this outcome. Avoidance and fusion have been

theorized to be associated with treatment outcome among ACT participants, but a rationale for changes in these constructs produced by CBT is less well understood. Avoidance is a key in the maintenance of anxiety disorders and CBT encourages exposure and brave behavior in relation to fears, which necessitates changes in experiential avoidance. Defusion, on the other hand, is employed in ACT as an alternative to the CBT approach of cognitive restructuring, and as such changes in this measure are unexpected and may suggest these two differential approaches operate via similar mechanisms. In the current investigation, regardless of the methods of dealing with anxious thoughts, results suggest both strategies were effective in achieving clinical change. This is in line with the findings of other researchers who compared ACT with CBT in adults (Arch et al., 2012; Forman et al., 2012). It is possible that cognitive disputation requires some form of defusion. It may also be that once a more realistic thought is obtained the client is able to gain more distance from their anxious thoughts. However, these hypotheses require further investigation. The authors have reported on mediation effects in the adolescent sub-group of the current study (Swain, Hancock, & Bowman, 2014). They found limited support for the ACT hexaflex, and its core component processes, as mediators for treatment-related change.

The role of exposure may also offer some explanation for the findings. The design of this study enables a comparison of cognitive restructuring with cognitive defusion, plus mindfulness and emphasis on willingness in the service of values for ACT, as well as using exposure and skills training in an ACT conceptual framework. Given that both the ACT and CBT protocols utilised behavioral components such as exposure (albeit employed with divergent emphasis), social skills training and problem solving, the extent to which the behavioral components alone contributed to outcomes is difficult to determine. However, it should be emphasised that ACT is a behavioral

therapy (S. C. Hayes, Pistorello, & Levin, 2012) and as such it typically includes behavioral methods as part of its model and protocols (Bluett et al., 2014). Exposure is done in the context of increasing the clients' willingness to experience anxiety based on the goal of living a valued life. Our design is in line with that of Arch et al. (2012) who compared CBT with ACT, with both protocols integrating graded exposure methods. This is an exploratory study and future research could refine the elements of the program that are essential.

4.3 Limitations

The use of only one clinical site has advantages and disadvantages. The employment of the same programs, assessment methods, therapists and a real-life tertiary care setting minimises potential confounds. However, the lack of variability limits generalizability. Furthermore, most participants were from lower socioeconomic areas in Western Sydney so it was not possible to determine the effect of this factor. Future studies using multiple sites are recommended to address these deficits. Also, as discussed above, the differential attrition rates may have affected results, with more ACT participants dropping out.

Generalizability of findings is also limited by the pre-treatment group differences in CALIS-C scores, the ACT group having greater life interference pre-treatment. Although the CALIS-C has been shown to be reliable and valid, more research and wider use is recommended to further establish its validity and reliability. Further validation is also recommended on the AFQ-Y in younger children, as it was developed using children 8 years and above.

To our knowledge this is the largest RCT to date evaluating ACT for children with anxiety. While the results demonstrate that ACT is superior to WLC, a larger

sample size would be needed to show that it is not inferior to CBT. Being an iterative process, research firstly needs to show that it is effective in an RCT before equivalence, noninferiority or superiority over other treatments can be demonstrated. On the basis of the mean CSR, between groups comparison of ACT versus CBT at post-treatment, an N of approximately 65 would be needed to obtain statistical power at 0.80 to detect a moderate effect size. However, sample size was adequate if comparing either of the treatment groups with the WLC, with an effect size of greater than 1 for both, and only around 11-17 needed per group. Similarly, pre to post mean differences within treatment groups effect sizes were also large for this sample, indicating that the sample size was adequate. Thus, depending on the comparison required, the sample size for adequate power varied. Larger sample sizes are also needed to adequately investigate whether treatment improves co-morbid problems such as depression and low self-worth.

4.4 Final conclusions

Notwithstanding the above limitations, this study is novel in its investigating of the effects of ACT therapy for anxiety in children. As far as we are aware, this is the first RCT to compare ACT with CBT and a wait list control group in children with anxiety disorders. Although this study does not suggest ACT should be adopted in place of CBT, it does provide evidence that ACT is effective in treating anxiety symptoms in children and adolescents, with similar outcomes achieved. Further research is required to determine whether ACT is an effective treatment for children without the behavioral methods as a component of protocols, while at the same time bearing in mind that these methods are typically part of the ACT model.

Table 1 Demographic and Clinical Characteristics of the Intention-to-Treat Sample

Characteristic	Total (N=193)	ACT (n=68)	CBT (n=63)	Control (n=62)
Gender				
Female	58% (111)	54% (37)	60% (38)	58% (36)
Reported ethnicity				
Caucasian	78% (150)	77% (52)	78% (49)	79% (49)
European	7% (14)	10% (7)	6% (4)	5% (3)
Middle Eastern	9% (17)	7% (5)	8% (5)	11% (7)
Indian/Sri Lankan/Pakistani	5% (10)	3% (2)	8% (5)	5% (3)
Asian	1.0% (2)	2.9% (2)	(0)	(0)
Age				
in years M (SD)	11.20 (2.76)	11.15(2.50)	10.81(2.92)	11.66 (2.84)
Adolescents (12-17 yrs)	46% (88)	46% (31)	40% (25)	52% (32)
Currently on psychotropic med	3.6% (7)	7% (5)	2% (1)	2% (1)
Primary diagnosis				
Generalized anxiety disorder	39% (76)	38% (26)	37% (23)	44% (27)
Social anxiety disorder	21% (41)	25% (17)	27% (17)	11% (7)
Separation anxiety disorder	10% (20)	9% (6)	18% (11)	5% (3)
Specific anxiety disorder	8% (15)	7% (5)	10% (6)	7% (4)
Obsessive Compulsive Disorder	6% (12)	7% (5)	3% (2)	8% (5)
Agoraphobia without Panic	1% (1)	2% (1)	(0)	(0)
Co-morbid anxiety disorder	94% (181)	93% (63)	91% (57)	97% (61)
Co-morbid depressive disorder	18% (35)	18% (12)	13% (8)	24% (15)

Co-morbid Axis 2 disorder ADHD	3% (6)	2% (1)	8% (5)	(0)
Co-morbid Axis 2 disorder Asp*	2% (3)	3% (2)	2% (1)	(0)
Principal disorder clinical severity rating at pre, M (SD)	6.68(.96)	6.56 (.87)	6.59(1.026)	6.92 (.963)
Received previous treatment	71% (136)	72% (49)	78% (49)	61% (38)

Note: ACT=acceptance and commitment therapy; CBT = cognitive behavioral therapy; Pre= pre=treatment. * Asp=Asperger Syndrome. Comorbidity was defined as a clinical severity rating of 4 or above on the Anxiety Disorders Interview Schedule-IV (ADIS-IV) for Children

Table 2. Means and standard deviations (SD) of outcome measures for the three groups using intention-to-treat.

Measure and condition	Pre-trt*	Post-trt	3-month follow-up
Clinical outcomes			
ADIS Clinical Severity Rating			
ACT	6.56 (.87)	4.31(2.52)	4.07 (2.43)
CBT	6.59 (1.03)	3.44 (2.86)	3.12 (2.71)
WLC	6.92 (.96)	6.18 (1.80)	
ADIS Number of Anxiety Diagnoses			
ACT	3.21 (1.43)	1.88 (1.65)	1.71(1.62)
CBT	3.03 (1.09)	1.43 (1.38)	1.16 (1.22)
WLC	3.26 (1.19)	2.85 (1.51)	
MASC-Child			
ACT	62.21 (14.35)	54.56 (13.33)	51.74 (14.00)
CBT	59.58 (11.84)	49.46 (11.56)	48.85 (10.60)
WLC	61.54 (11.60)	61.23 (11.67)	
MASC-Parent			
ACT	59.97 (12.10)	53.59 (11.65)	51.56 (12.22)
CBT	58.64 (10.99)	50.79 (11.01)	48.71 (11.86)
WLC	57.81 (10.77)	57.42 (11.67)	
CDI			

ACT	52.56 (11.40)	47.36 (9.06)	45.87 (9.16)
CBT	52.87 (11.85)	46.39 (10.15)	44.64 (8.51)
WLC	57.53 (13.39)	50.55 (13.33)	
CBCL-Total Problems			
ACT	64.09 (7.98)	58.34 (9.61)	55.02 (8.63)
CBT	63.70 (7.66)	57.66 (9.07)	55.35 (9.36)
WLC	62.44 (9.23)	60.29 (9.55)	
CBCL-Anxious/depressed			
ACT	71.23 (9.71)	63.99 (9.82)	60.43 (8.11)
CBT	71.31 (9.60)	64.80 (9.38)	63.42 (9.64)
WLC	70.51 (8.49)	67.10 (8.97)	
SPPC 7-11 yrs only			
ACT	3.07 (0.57)	3.37 (0.55)	3.48 (0.37)
CBT	3.03 (0.60)	3.22 (0.58)	3.37 (0.42)
WLC	3.18 (0.45)	3.40 (0.39)	
Quality of Life outcomes			
CALIS-Parent Interference			
ACT	16.45 (6.19)	11.15 (5.18)	10.78 (5.21)
CBT	17.08 (5.35)	13.23 (4.51)	13.01 (4.78)
WLC	17.78 (4.96)	16.00 (3.41)	
CALIS-Family Interference			
ACT	13.07 (7.11)	9.77 (5.40)	9.68 (5.51)
CBT	14.22 (7.41)	10.79 (5.88)	10.93 (5.89)

WLC	14.04 (6.74)	13.22 (3.76)	
CALIS- Child Interference			
ACT	14.77 (5.98)	9.80 (5.93)	9.70 (5.92)
CBT	11.98 (5.25)	11.05 (5.49)	10.91 (5.45)
WLC	16.78 (7.12)	18.93 (4.30)	
CHQ-Psychosocial			
ACT	37.86 (10.74)	45.45 (8.59)	46.92 (7.34)
CBT	40.58 (9.95)	46.18 (8.98)	47.13 (9.94)
WLC	37.37 (10.73)	35.55 (11.25)	
CHQ-Physical			
ACT	52.09 (8.49)	54.00 (8.46)	54.83 (8.86)
CBT	54.68 (6.85)	54.58 (8.41)	55.76 (4.39)
WLC	52.11 (9.56)	49.82 (15.18)	
Process Measure			
AFQ-Avoidance Fusion			
ACT	29.43 (14.26)	22.30 (11.96)	19.24 (13.49)
CBT	30.86 (14.19)	19.67 (12.02)	17.81 (10.96)
WLC	31.97 (10.96)	30.53 (13.50)	

Note: ADIS=Anxiety Disorders Interview Schedule for Children; MASC=Multidimensional Anxiety Scale for Children; CDI=Child Depression Inventory; CBCL=Child Behavior Checklist; CALIS= Child Anxiety Life Interference Scale; AFQ-Y=Avoidance and Fusion Questionnaire for Youth; SPPC- Self Perception Profile for Children. Pre=Pre-treatment; Post=Post-treatment; ACT=Acceptance and Commitment therapy; CBT=Cognitive behavioral therapy; WLC=Waitlist control

Table 3. Effect sizes (ES) of outcome measures for within and between groups for the three groups using intention-to-treat .

Measure and condition	ES pre-to post within (*d*)	ES post trt vs. WLC (Δ)	ES post ACT vs. CBT (*d*)
Clinical outcomes			
ADIS Clinical Severity Rating			
ACT	2.59	1.04	0.32
CBT	3.09	1.53	0.32
WLC	0.77		
ADIS Number of Anxiety Diagnoses			
ACT	0.93	0.64	0.29
CBT	1.47	0.94	0.29
WLC	0.31		
MASC-Child			
ACT	0.53	0.57	0.37
CBT	0.85	1.01	0.37
WLC	0.03		
MASC-Parent			
ACT	0.53	0.33	0.23

CBT	0.72	0.57	0.23
WLC	0.04		
CDI			
ACT	0.46	0.24	0.10
CBT	0.55	0.31	0.10
WLC	0.52		
CBCL-Total Problems			
ACT	0.72	0.20	0.07
CBT	0.79	0.28	0.07
WLC	0.23		
CBCL-Anxious/depressed			
ACT	0.75	0.35	0.08
CBT	0.36	0.26	0.08
WLC	0.40		
Quality of Life outcomes			
CALIS-Parent Interference			
ACT	0.85	2.12	0.42
CBT	0.72	1.83	0.42
WLC	0.36		
CALIS-Family Interference			
ACT	0.46	0.92	0.18
CBT	0.46	0.65	0.18
WLC	0.29		
CALIS- Child Interference			

ACT	0.83	1.42	0.22
CBT	0.18	0.81	0.22
WLC	0.30		
CHQ-Psychosocial			
ACT	0.71	0.88	0.08
CBT	0.56	0.95	0.08
WLC	0.17		
CHQ-Physical			
ACT	0.22	0.28	-0.36
CBT	0.01	0.31	-0.36
WLC	0.24		
SPPS (7-11 yrs)			
ACT	0.16	0.01	0.28
CBT	0.11	0.17	0.28
WLC	0.56		
Process Measure			
AFQ-Avoidance Fusion			
ACT	0.50	0.61	0.21
CBT	0.79	0.80	0.21
WLC	0.73		

Note: ADIS=Anxiety Disorders Interview Schedule for Children;

MASC=Multidimensional Anxiety Scale for Children; CDI=Child Depression

Inventory; CBCL=Child Behavior Checklist; CALIS= Child Anxiety Life Interference

Scale; AFQ-Y=Avoidance and Fusion Questionnaire for Youth; SPPC- Self Perception

Profile for Children. Pre=Pre-treatment; Post=Post-treatment; ACT=Acceptance and Commitment therapy; CBT=Cognitive behavioral therapy; WLC=Waitlist control

d=Cohen's d, Δ =Glass's delta, ES=Effect Size.

Figure 1 Consort diagram of participants in the study

Enrollment

Assessed for eligibility (n= 273)

Excluded (n= 80)
- Not meeting inclusion criteria (n=43)
- Declined to participate (n= 37)

Block Randomized (n=193)

Allocation

Allocated to ACT intervention (n=68)
- Received allocated intervention (n=68)

Allocated to CBT intervention (n=63)
- Received allocated intervention (n=63)

Allocated to control (n= 62)
- Did wait list(n=46)
- Did not complete wait list (n=16, sought treatment elsewhere)

Post and 3MFU

Lost to post follow –up
Discontinued intervention (n=14)
-Other commitment conflict (n=7),
-Lost motivation (n=2)
-Group member conflict, (n=1)
-Illness/surgery (n=3)
-Moved (1)
Lost to 3MFU (n=1)

Lost to post follow –up
Discontinued intervention (n=5)
-Moved (n=1)
-Other commitment conflict (n=2)
-Lost motivation (n=1)
-Reported anxiety improved so treatment no longer required (n=1)
Sought individual treatment concurrently   (n=1)
Lost to 3MFU (0)

Lost to post follow –up
Sought treatment elsewhere (n=16)

Analysis

Analysed (n=54)
- Completers=54, Excluded from completer analysis (n=15, non-completers)
ITT=68

Analysed (n=57)
- Excluded from analysis (n=6, 5=non-completers, 1=sought individual treatment concurrently)
ITT=63

Analysed (n= 46)
- Excluded from analysis (n= 16 sought treatment elsewhere)
ITT=62

Figure 2. A-B: Primary outcome in the completer (A) and intention-to-treat (B) across the three conditions over time.
A. Anxiety Disorders Interview Schedule (ADIS): Intention-to-treat
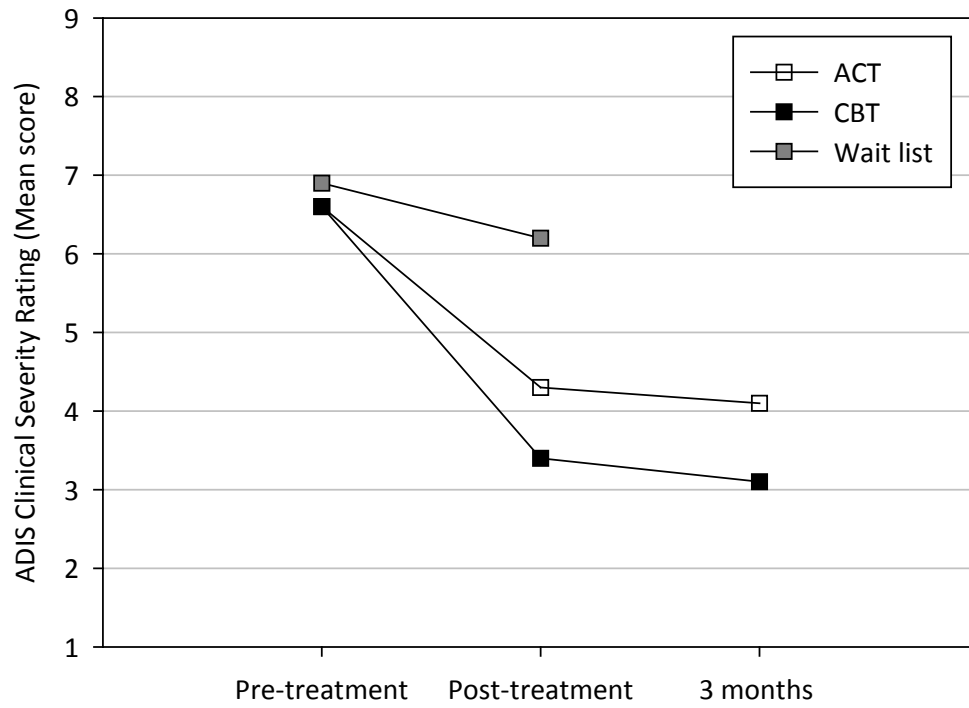
B. Anxiety Disorders Interview Schedule (ADIS): completers
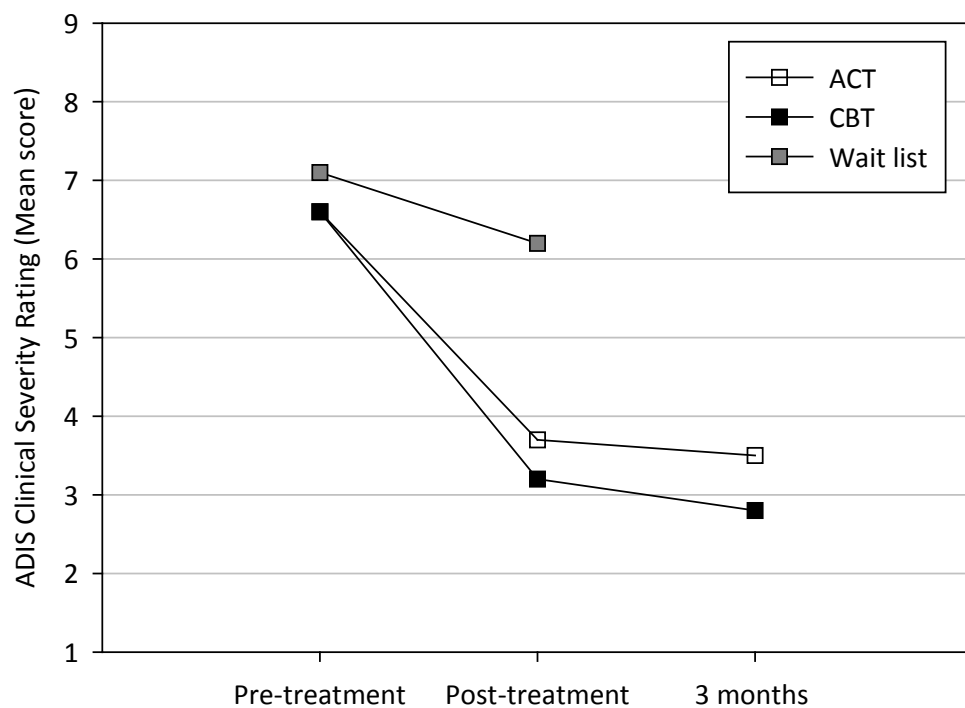
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Initial screening
Completed phone screening (n = )
Did not participate in intake interview (n = )
Did not qualify during phone screening (n = )
Invited to participate but chose not to (n = )
Participated in intake interview (n = )
```

```
Excluded (n = )
Did not meet inclusion criteria (n = )
Lost contact with study (n = )
Declined participation (n = )
o Reasons: schedule (n = ), uncomfortable
with being recorded (n = ), no reason given (n = )
Excluded from further analysis for diagnostic
reasons: principal PTSD (n = )
```

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Randomised to treatment (n=)
```

```
ACT (n = )
```

```
CBT (n = )
```

```
WLC (n = )
```

```
Fewer than 80% Rx sessions (n = )

Completed all 10 sessions (n = )

Average sessions attended =
```

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Fewer than 80% Rx sessions (n = )

Completed all 10 sessions (n = )

Average sessions attended =
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Lost to Post (n = )
Reason 1 n=?; etc etc
Lost to Follow-Up 1 (n = )
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Lost to Post (n = )
Reason 1 n=?; etc etc
Lost to Follow-Up 1 (n = )
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Lost to Post (n = )
Reason 1 n=?; etc etc
Lost to Follow-Up 1 (n = )
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Completed treatment (n=)
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Completed treatment (n=)
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Analysed (n=)
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Analysed (n=)
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Analysed (n=)
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Mechanisms of change: Exploratory outcomes from a randomised controlled trial of acceptance and commitment therapy for anxious adolescents

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1. Introduction

Evaluation of the efficacy of interventions has been the mainstay of clinical research for decades, generating an increasingly complex knowledge foundation of the utility of various psychotherapeutic approaches for disorder and population-specific intervention (Arch, Wolitzky-Taylor, Eifert, & Craske, 2012; Kazdin, 2007). Despite this, we are some way from establishing an empirical account for the basis of therapeutic effects – why and how even our most well-researched psychotherapies work, the processes through which interventions foster positive outcomes – typically termed "the mechanisms of change" (Ciarrochi, Bilich, & Godsell, 2010; Kazdin, 2007; Kraemer, Wilson, Fairburn, & Agras, 2002). Identification of treatment-specific mechanisms of change has been sought to support parsimonious clinical practice, optimising clinician–patient encounters to facilitate shorter term interventions delivered with improved sensitivity and specificity (Kazdin, 2007; Kraemer et al., 2002). While mediators of change, or variables that may statistically explain the relationship between therapy and outcome, are less specific than mechanisms of

change – in that they may not account for the exact process through which change occurs – understanding the factors that mediate outcomes is an important precursor to identifying mechanisms (Kazdin, 2007; Kraemer et al., 2002).

Acceptance and Commitment Therapy (ACT) is a behavioural and cognitive psychotherapy that aims to foster psychological flexibility; or the ability to respond to present moment experience of psychological phenomena, with increasing awareness, whilst engaging in value-directed behaviour (S. C. Hayes, Levin, Plumb-Vilardaga, Villatte, & Pistorello, 2013). Described as a "third wave" behavioural and cognitive therapy, ACT reflects a synthesis and reformulation of concepts underpinned by prior waves including traditional cognitive behaviour therapy (CBT). Both ACT and CBT focus on the relationship of unhelpful thoughts and beliefs to psychological distress, utilise experiential learning as well as behavioural techniques and are underpinned by behavioural theory which explains, in part, the presence of psychopathology (Forman & Herbert, 2009; S. C. Hayes, Luoma, Bond, Masuda, & Lillis, 2006). However, these therapies have been distinguished on theoretical foundations, change processes, treatment methods, and primary outcome goals (Gaudiano, 2011). CBT views psychopathology as a consequence of distorted thought patterns that are addressed in treatment through cognitive change processes of cognitive disputation and restructuring, the primary aim being symptom remission or reduction (Beck, 2005; Forman & Herbert, 2009).

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In ACT, psychopathology is construed as a consequence of psychological inflexibility that occurs due to entanglement or fusion with thoughts and subsequent maladaptive efforts to control internal experience ("experiential avoidance") that leads to a decreased capacity to modify or continue exhibiting behaviours that are in the service of personal values (S. C. Hayes et al., 2006; Luoma, Hayes, & Walser, 2007). Founded upon functional contextualism, ACT focuses on the historically and situationally-defined contexts in which psychological phenomena – thoughts, feelings and sensations – occur as the target of change interventions, in contrast to the first-order change of their form or frequency, exemplified by CBT (Blackledge, Ciarrochi, & Deane, 2009; Flaxman, Blackledge, & Bond, 2011; S. C. Hayes, 2004; S. C. Hayes, Villatte, Levin, & Hildebrandt, 2011; Ruiz, 2012). Rather than emphasising symptom remission, ACT aims to foster psychological flexibility via six interrelational core processes – mediators of change – that form a "hexaflex" model; acceptance, defusion, mindfulness, self-as-context, committed action and valued living (Luoma et al., 2007). These therapeutic techniques are adopted to support more flexible responding in relation to distressing thoughts, feelings or sensations, whilst simultaneously living one's values, thereby enhancing quality of life (QOL; Arch & Craske, 2008; Baer, 2003; Ciarrochi & Bailey, 2008; S. C. Hayes et al., 2006; O'Brien, Larson, & Murrell, 2008).

Anxiety disorders are among the most ubiquitous post-modern psychiatric afflictions. ACT has been found to be effective in the treatment of the range of anxiety disorders in a systematic review of 38 studies (Swain, Hancock, Hainsworth, & Bowman, 2013). A recent metaanalysis of nine ACT randomised controlled trials (RCTs) for the anxiety disorders also observed significant large effect sizes (ES) in favour of ACT relative to waitlist control and no significant ES difference relative to alternative manualised treatments (including traditional CBT) across outcome measures (Bluett, Homan, Morrison, Levin, & Twohig, 2014).

Despite the common misperception that ACT is too complex for children, it has been argued that the experiential and metaphorical delivery of ACT processes may be more suitable for children than traditional therapeutic methods such as cognitive disputation (Coyne, McHugh, & Martinez, 2011). Developmental adaptation of ACT processes has been undertaken. A systematic review of ACT in the treatment of problems among children found ACT to produce improvements in symptoms, QOL outcomes and/or psychological flexibility, with many studies demonstrating further gains at follow-up assessment (Swain, Hancock, Dixon, & Bowman, Submitted for publication). This was true for both adolescents and children as young as 6 years. This supports the conclusions of Coyne et al. (2011) – from an earlier review of the ACT literature for children – that ACT processes operate in a similar way among children and adults. Since the conduct of the most recent review, further evidence for the effectiveness of ACT in the treatment of anxiety among children has emerged. In a recent RCT of ACT versus CBT for mixed anxiety disorders, Hancock et al. (Submitted for publication) found ACT produced significant change of equivalent magnitude on clinician, parent and self-report anxiety outcome measures compared to CBT, as well as superior outcomes to waitlist control. However, relative to CBT there are comparatively fewer studies examining proposed mechanisms of change underpinning therapeutic effectiveness among anxious populations for ACT and, to date, none of the existing studies involve child populations. Despite this, one study found a significant relationship between acceptance and defusion and anxiety disorders among 111 inpatient adolescents (Venta, Sharp, & Hart, 2012). This is also in line with Coyne and colleagues' conclusion that child-focused studies generally support ACT's conceptual model in children, adolescents and parents, and that targeting processes such as acceptance and defusion are the indicated next step in research. In addition, given that children and adolescents are typically subsumed within a family system, the influence of specific factors such as family environment, parenting and emotion regulation that may impact these processes are also in need of investigation.

Laboratory-based component studies provide a controlled method of evaluating therapeutic processes of change. A recent metaanalysis of 66 studies was conducted of single-session ACT component conditions versus inactive and/or distinct alternative comparisons on a range of ACT theoretically specified outcomes (e.g. persistence/willingness to engage in a difficult task, belief in distressing cognitions and behavioural outcomes such as academic results) and other outcomes not theoretically postulated to change (Levin, Hildebrandt, Lillis, & Hayes, 2012). Results indicated some support for each of the core processes that make up the ACT hexaflex. The model as a whole was found to have a significantly greater impact on theoretically specified outcomes than inactive conditions, a finding of medium effect size. Whilst support was also identified for the hexaflex model in terms of impact on outcomes related to the intensity and frequency of negative thoughts/feelings, larger effect sizes were observed for theoretically postulated outcomes such as QOL (Levin et al., 2012).

Preliminary research in community settings offers mixed support for the ACT hexaflex model of psychological flexibility and its core component processes as mechanisms for change for the anxiety disorders (Ciarrochi et al., 2010; Forman, Herbert, Moitra, Yeomans, & Geller, 2007; S. C. Hayes et al., 2006). Bluett et al.'s (2014) meta-analysis of 63 studies examined the relationship between anxiety and measures of psychological flexibility. Results showed a significant medium correlation between psychological flexibility and anxiety disorder symptoms among both non-clinical and clinical samples (Bluett et al., 2014). The analysis found modest support for psychological flexibility as a mediator of change. However, mediation effects were treatment-common with no significant differences between ACT and other manualised programs (CBT) identified. For example, in one study defusion was found to be a treatment-common mediator of change in clinical worry, avoidance and QOL for ACT and CBT, but not post-treatment anxiety severity (as measured by the Anxiety Disorders Interview Schedule-IV-Revised) across treatment (Arch et al., 2012). Some evidence for treatment-specific mediation was obtained in the largest formal evaluation of mediation effects treated with ACT or cognitive therapy (CT), among 174 outpatients with anxiety/depression (Forman et al., 2012). Repeated measures of several putative mediator and outcome variables were taken with the Before Session Questionnaire (Forman et al., 2012) – a brief self-report measure that collects ratings on a Likert scale continuum with one pole reflective of CT and the other of ACT putative processes/outcomes – ahead of each therapy session. Results showed an emphasis on acceptance approaches in response to distressing psychological phenomena mediated change in symptom intensity ratings for ACT, but not CT participants (Forman et al., 2012). A movement from an emphasis on cognitive change approaches to that of acceptance across sessions was associated with reduced symptom intensity (Forman et al., 2012). Defusion and committed action were observed to be treatment-common change mediators in this study (Forman et al., 2012). Processes proposed to mediate change in CBT alone have also been found to be treatment-common to ACT such as anxiety sensitivity, dysfunctional thinking, as well as defusion in some studies (Arch et al., 2012; Forman et al., 2012). These findings highlight the need for further research examining an overarching mechanism of change across cognitive behavioural approaches for anxiety disorders.

The existing ACT mediation literature for anxiety is subject to several methodological limitations. Substantial heterogeneity has been observed in study design, sample, data collection schedule, outcomes and measurement tools, treatment protocol and statistical techniques; factors that impact the capacity to draw meaningful conclusions. Few studies have compared ACT to another active psychotherapy to determine whether proposed processes

are ACT-specific (Arch et al., 2012). It is also unclear whether particular elements of ACT are more critical in terms of therapeutic outcome or whether specific techniques are more effective for disorder- or population-specific samples (Ciarrochi et al., 2010). Furthermore, little is known about whether these processes are equivalently observable among child populations or whether therapy works to affect change differently in young people. To effectively assess mediation relationships, multiple measures completed at various time points are required. Thus, the challenge for researchers is to balance the need for a breadth of psychometrically reliable and valid outcome/process measures with considerations of the acceptability and possible participant burden created by multiple repeated assessment batteries (S. A. Hayes, Orsillo, & Roemer, 2010).

The current exploratory study aimed to examine the ACT hexaflex model as a mediator for therapeutic change among adolescents. The specific indirect effects of the core processes – acceptance and defusion, mindfulness/self-as-context and valued living/committed action (valued action) – collected at multiple time points, using measures with established psychometric reliability/validity, were also explored in terms of their actual and relative contribution to mediation effects. Finally, the specificity of observed mediation effects to ACT were identified through comparison to CBT. ACT has been purported to foster psychological flexibility, thereby enhancing QOL, via the aforementioned core processes. In line with this it was hypothesised that the ACT hexaflex, and its core component processes, would operate as mediators for change in across QOL, with mediation effects expected to be treatment-specific to ACT. While clinical outcomes such as symptom remission or amelioration are not the focus in ACT, research indicates that ACT also produces change in these outcomes. As such, it was hypothesised that both QOL and clinical outcomes (main outcomes) would also be mediated by the ACT hexaflex model and its core component processes for ACT, but not CBT or waitlist control (WLC) participants. To the researchers' knowledge, this study is the first of its kind to simultaneously examine all core processes as putative mediators and to extend the anxiety mediation research to a sample of young people.

2. Method

Data for the present investigation were collected as part of a larger RCT of ACT versus CBT in the treatment of anxiety disorders among children aged 7–17 years. As the full methodology of this study has been previously reported (Swain et al. 2013), methodological components of the trial relevant to the present investigation are presented below.

3. Participants

Participants were 49 adolescent outpatients (12–17 years) diagnosed with a *DSM-IV* anxiety disorder and their parent/caregivers (for more details see Hancock et al., Submitted for publication). Participants were randomised into ACT ($n=16$), CBT ($n=10$) or waitlist control (WLC; $n=23$). Inclusion criteria required participants to have completed a minimum of 70% of treatment sessions, as well as complete data for a minimum of one anxiety outcome measure and 75% of process measures (see Measures) to enable for an adequate examination of change processes. Data was collected for WLC participants at pre and after 10 weeks wait-listed, as such they are not included in 3 month follow-up (3MFU) analyses.

Participants were recruited via referral to The Department of Psychological Medicine at the Children's Hospital Westmead, Australia. The sample was 63.3% female, 67.3% Anglosaxon, 14.3% Middle Eastern, 8.2% European, 8.2% Indian/Sri-Lankan and 2% Asian

ethnicity. The average age was 13.8 years ($SD=1.4$). Diagnostic assessment was undertaken using the *Anxiety Disorders Interview Schedule for Children* (ADIS-IV; Albano & Silverman, 1996) by trained psychologists and doctoral students blind to treatment condition. Eligibility was determined by receipt of a principal diagnosis of anxiety disorder and not meeting exclusion criteria of complex mental health problems (e.g. psychosis, conduct disorder or active suicidality), medicated with an anxiolytic/antidepressant for less than 2 months or posttraumatic stress disorder. Principal diagnoses were 57.1% generalised anxiety disorder, 24.5% social anxiety disorder, 8.2% obsessive compulsive disorder, 4.1% separation anxiety disorder, 4.1% specific phobia and 2% agoraphobia without panic. Five (10.4%) were undergoing a pharmacological treatment regime that had commenced more than 2 months before study enrolment to ensure stabilisation. No participants altered their dosage whilst enroled in the study. Participants in each group did not differ on demographic variables or principal diagnosis ($p > .15$).

4. Measures

Measures included main and process outcome measures. Main outcome measures included clinical severity ratings for the principal diagnosis, anxious symptoms, total behavioural/emotional problems, depression, and QOL. Process outcome measures were incorporated on the basis of ACT putative mediator hypotheses (see Table 1). Assessment of all outcome measures were completed pre-therapy, with repeated measures undertaken immediately post (or after 10 weeks for WLC) and 3MFU for the intervention groups.

5. Main outcome measures

5.1. Anxiety disorder diagnosis clinical severity (primary outcome): Anxiety Disorders Interview Schedule (ADIS-IV; Albano & Silverman, 1996)

The ADIS-IV is a structured diagnostic interview that assesses a range of DSM-IV disorders among children aged 7–17 years, incorporating the perspectives of both child and parent (Albano & Silverman, 1996). Participants endorse symptoms as either present or absent and if symptom count is sufficient to meet diagnostic criteria, a clinical severity rating (CSR) from 0 to 8, where 0 indicates no impairment and 8 indicates significant impairment, is gathered (Silverman, Saavedra, & Pina, 2001). The

Table 1
Main and process outcomes by associated assessment tools.

Outcome	Measured construct	Assessment tool
Main outcomes	Clinical severity rating (CSR) of principal anxiety diagnosis	ADIS-IV
	Anxious symptoms	CBCL-AD MASC
	Behavioural/emotional problems	CBCL-TP
	Quality of life, self-efficacy, wellbeing	CALIS
	Depression	CDI
Process outcomes	Acceptance and defusion	AFQ-Y
	Mindfulness and self-as-context	CAMM-20 (OBS/AWA)
	Values and committed action (valued action)	VLQ

Key: ADIS-IV – Anxiety Disorders Interview Scale for DSM-IV; AFQ-Y – Avoidance and Fusion Questionnaire Youth; CALIS – Children's Anxiety Life Interference Scale Child Form; CAMM-20– Child and Adolescent Mindfulness; CBCL-AD – Child Behaviour Checklist Anxiety/Depression subscale; CBCL-TP – Child Behaviour Checklist Total Problems subscale; CDI – Child Depression Inventory; MASC – Multidimensional Anxiety Scale for Children; VLQ – Valued Living Questionnaire.

ADIS has established interrater, diagnostic, and test–retest reliability (Lyneham, Abbott, & Rapee, 2007; Silverman et al., 2001). For this study, the K agreement for an overall diagnosis of anxiety disorder was 1, with a range of .87–.97 across the major anxiety disorders. The overall CSR severity reliability rating was k=.76. This translated to 2% of the overall sample obtaining CSR ratings with an interrater difference of 2 points, 11% with a difference of 1 point, and 86% evidencing identical interrater reliability ratings.

5.2. Anxiety symptoms: Multidimensional Anxiety Scale for Children (MASC; March, 1997)

The MASC is a 39-item that measures four dimensions of anxiety – physiological symptoms, avoidance, social, and separation anxiety – in accordance with child (MASC-C) and parent reports (MASC-P; March, Sullivan, & Parker, 1999; Rynn et al. 2006). Clinical and community studies have cross-validated the factor structure of this inventory (Rynn et al., 2006). The MASC has moderate to strong internal reliability in the range .73–.89 and .70–.90 for child and parent reports, respectively (Baldwin & Dadds, 2007). Adequate test–retest reliability was established with the mean correlation coefficients .79 at 3 weeks and .93 at 3 months (March, Parker, Sullivan, Stallings, & Conners, 1997). In the present sample the average internal consistency across the MASC subscales was between α=.83–.86, depending upon the assessment time point.

5.3. Total problems and anxious/depressed behaviours: Child Behaviour Checklist (CBCL; Achenbach, Howell, Quay, & Conners, 1991)

The CBCL is a widely utilised standardised measure of emotional and behavioural functioning as well as social competence among children 5–18 years, completed by their primary caregiver (Siddons & Lancaster, 2004). Caregivers indicate how well each item fits their child's behaviour over the past 6-months on a three-point scale where 0=not true and 2=very/often true (Siddons & Lancaster, 2004). Validity and reliability data are moderate-to-high and high, respectively. Test–retest reliability was found to be strong across scales (mean r=.82) and concurrent validity was established via comparison to other widely implemented behaviour scales (Achenbach et al., 1991). In the present sample the internal consistency ranged from α=.60–.89 for CBCL–AD.

5.4. Depression: Child Depression Inventory (CDI; Kovacs, 1992)

The CDI is a 27-item self-report of depressive symptoms, adapted from the Beck Depression Inventory (Saylor, Finch, Spirito, & Bennett, 1984). It is one of the most widely utilised and cited diagnostic instruments for depression in children (Carey, Faulstich, Gresham, Ruggiero, & Enyart, 1987; Saylor et al., 1984). For each item the child responds by endorsing one of three statements that best describes them over the past 2 weeks (Miller, Epstein, Bishop, & Keitner, 1985; Saylor et al., 1984). Each item is scored between 0 and 2, with higher numbers representing increasing severity of a symptom (Miller et al., 1985). For clinical samples the CDI has test–retest reliability in the moderate range at .59–.87 (Saylor et al., 1984). Internal consistency calculations were found to be good (.80; Saylor et al., 1984). Adequate concurrent and discriminant validity have also been established (Kovacs, 1992). In the current sample the CDI produced internal consistency of α=.19–.68 dependent upon the assessment time point.

5.5. Quality of life (QOL): Children's Anxiety Life Interference Scale (CALIS; Lyneham et al., 2013)

The CALIS is a 10-item questionnaire completed as self (CALIS-C) and parent-report (CALIS-P) about the impact of the child's fears and worries on their QOL, self-efficacy and well-being. Respondents rate each question in terms of how much it relates to the child using a five-point scale where 0 is "not at all" and 4 is "a great deal" (Lyneham et al., 2013). Higher scores indicate increased interference of the anxiety on the child's life. Reliability estimates in terms of impact of anxiety on the child's life were found to be good at .80 (Lyneham et al. 2007). Test–retest reliability revealed acceptable (.84) stability, with convergent validity established with moderate to strong correlations obtained (Lyneham et al., 2007). The CALIS-C was found to demonstrate moderate internal consistency (α=.54–.88) in the current sample, dependent upon the assessment time point.

6. Process measures

The six core processes that make up the ACT hexaflex model of psychological flexibility are interrelated and overlap (Baer, 2010; S. C. Hayes et al., 2006). Arguably, mindful awareness of psychological phenomena is required to support acceptance and defusion. Values identification is indicated in order to determine what committed actions are required to live a meaningful life, and acceptance of distressing phenomena is a precursor to foster the willingness to exhibit them. Self-as-context is an extension of mindfulness, as it simultaneously emphasises the transient nature of private experience, whilst highlighting the self as a constant where these experiences take place (Coyne, Birtwell, McHugh, & Wilson, in press). Process measures can be grouped under two higher order factors: (1) mindfulness and acceptance processes and; (2) commitment and behaviour change processes (Baer, 2010; S. C. Hayes et al., 2006). Mindfulness and acceptance processes include acceptance, mindfulness, defusion, and self-as-context (S. C. Hayes et al., 2006). Commitment and behaviour change processes include mindfulness, self as context, values, and committed action. Mindfulness and self-as-context are present in both factors on the premise that psychological phenomena require contact with the present and an awareness of the context in which these phenomena occur (S. C. Hayes et al., 2006). The process measures included within the current study reflect the aforementioned interrelated nature of the processes underlying psychological flexibility.

6.1. Acceptance and cognitive defusion: Avoidance & Fusion Questionnaire (AFQ-Y; Greco, Lambert, & Baer, 2008)

The AFQ-Y is a 17-item self-report measure of cognitive defusion (defusion) and acceptance for children and adolescents. Respondents rate the degree to which items are true of them on a 5-point scale from 0 "not at all true" to 4 "very true". Lower scores are indicative of psychological flexibility (Grills & Ollendick, 2003). Factor analysis of the AFQ-Y revealed a one factor model – covering acceptance and defusion – to be the best fit for the data. In real terms this can be understood as reduced cognitive entanglement (defusion) resulting in more flexible responding to psychological phenomena, thereby supporting increased behavioural effectiveness (Greco et al., 2008). Evaluation of the psychometric properties of the AFQ-Y was undertaken among a school-based sample of 329 children, this revealed internal reliability of α=.9, item-total correlations of .47–.67 and confirmatory factor analysis supported the hypothesised AFQ-Y model (Greco et al., 2008). Support for the convergent and construct validity of the

AFQ-Y has also been obtained (Greco et al., 2008). The AFQ was found to demonstrate good internal consistency of $\alpha=.87$–.95 in the current sample depending upon the assessment time point.

6.2. Mindfulness/Self-as-context: Child and Adolescent Mindfulness Measure (CAMM-20; Ciarrochi, Kashdan, Leeson, Heaven, & Jordan, 2011)

The CAMM-20 is a 20-item self-report questionnaire of mindfulness. Exploratory factor analysis conducted among Australian adolescents found support for a CAMM-20 two-factor model of "observing" (CAMM-20-OBS), noticing and attending to stimuli including internal and external phenomena, and "acting with awareness" (CAMM-20-AWA) including items that involve absolute focus and engagement with activity in the present moment (Ciarrochi et al., 2011). The internal consistency coefficients were good, at .85 and .83, for the CAMM-20-OBS and CAMM-20-AWA, respectively (Ciarrochi et al., 2011). In the present sample the CAMM-20-OBS was found to have good internal consistency of $\alpha=.81$–.87 depending upon the assessment time point. Internal consistency was also good at $\alpha=.84$–.88 for the CAMM-20-AWA.

6.3. Valued living /Committed action (Valued action): Valued Living Questionnaire (VLQ; Wilson, Sandoz, Kitchens, & Roberts, 2010)

The VLQ is comprised of two 10-item scales (importance and consistency) that target both values identification and committed action. The importance scale measures the personal significance of different domains of life including family, boyfriend/girlfriend relationships, parenting, friendship, work, education, recreation, spirituality, citizenship and physical self-care. The consistency scale examines the degree to which the respondent considers they have acted in accordance with these values in the past week (Wilson et al., 2010). A valued living composite (VLC) is computed using the mean of the product of the importance and consistency scale scores (Wilson et al., 2010). Wilson et al. (2010) found the VLQ to demonstrate adequate-to-good internal consistency ($\alpha=.79$–.83 and $\alpha=.58$–.60) for the importance and consistency domains, respectively. Construct validity has also been established (Wilson et al., 2010). The VLQ has been adapted for adolescents (see Cook, 2008) as was the version of the VLQ included within the current study, and test–retest reliability ($r=.75$–.90) established among college students (Greco & Hayes, 2008). In the present sample the also evidenced good-to-acceptable internal consistency at $\alpha=.71$–.82 and $\alpha=.63$–.79.

7. Treatment

Participants assigned to ACT and CBT received 10×1.5 h weekly group therapy sessions using a manualised treatment programme, in accordance with the relevant therapy, delivered by psychologists. Psychologists were trained and experienced in delivering ACT and CBT (1–3 years for ACT, 2–10+ years for CBT) and provided both forms of therapy, with treatment adherence, credibility and therapist competency also assessed. Treatment fidelity was examined via analysis of videorecorded therapy sessions in accordance with a therapist adherence scale developed by the authors based on a similar scale used by Norton (2012). Therapist competence scale scores were measured using a validated subscale of an ACT/CBT adherence and competence tool (McGrath, Forman, & Herbert, Submitted for publication). Treatment credibility and parent expectancies for therapy were assessed using a modified version of the Credibility/Expectancy Questionnaire (CEQ; Devilly & Borkovec, 2000). Evaluators were experienced with both therapeutic modalities and the aforementioned

methods employed to assess these outcomes (for additional information see Hancock et al., Submitted for publication). Following 10 weeks waitlisted the WLC group received the CBT programme. Both treatments encompassed psychoeducation, exposure and skills training (e.g. problem solving and social skills). However, the delivery of these components differed by therapy (for further detail see Hancock et al., Submitted for publication).

CBT involved the empirically supported Chilled® program developed at Macquarie University, Australia (Rapee & Lyndham, 2006). Chilled® was designed to assist adolescents to learn skills to recognise their emotions and combat anxiety, encouraging brave behaviour and gradual engagement with feared situations.

ACT involved the "ProACTive" program developed at The Children's Hospital at Westmead. ProACTive was developed on the basis of ACT-consistent protocol incorporating all six ACT core therapeutic processes. Formal mindfulness practice was incorporated on commencement of each session. Psychoeducation (sessions 1 and 2) included an adolescent-adapted explanation of the ACT model via metaphor and experiential learning approaches. Values cards supported understanding of the concept of living a valued life (session 2). Defusion was taught via metaphors and experiential exercises (session 3 onwards). Graded exposure was undertaken using the ACT model whereby the act of confronting the fear was an exercise designed to enhance psychological flexibility, while the therapeutic procedure is what was performed in the presence of the feared situation. Specifically, emphasis was placed on supporting mindful observation and acceptance of anxiety while faced with fear in order to foster committed action in line with self-identified values (from session 4 onwards). Finally, problem solving and social skills were incorporated to facilitate committed action [covered in sessions 8 and 9; see Swain, Hancock, Dixon, et al. (2013) for a session-by-session outline of the ACT protocol. Contact the authors for a programme copy].

8. Data analysis

Data coding and analysis was conducted using the IBM SPSS Statistics v.21 software program. Preliminary linear mixed model analyses were undertaken with the Least Significance Differences method to examine group-related change in main outcome and process measures across time (pre-, post- and 3MFU). Ordinary Least Squares (OLS) regression with bootstrapping was employed to conduct exploratory mediation analyses. Residualised change scores were utilised in order to control for measurement error and account for change over time. OLS regression is a multiple mediation approach that examines the direct, indirect effects and total indirect effects of several putative mediators (Preacher & Hayes, 2008). This approach is preferable to several simple mediation analyses as it explains the degree of mediation for each putative mediator, while minimising bias (Preacher & Hayes, 2008). Mediation is investigated by exploring (1) the total indirect effect of all mediators and; (2) specific indirect effect of each mediator controlling for all other mediators (Preacher & Hayes, 2008). Bootstrapping is a nonparametric resampling approach that yields percentile-based confidence intervals for both the aforementioned total and specific indirect effects (for a discussion see A. F. Hayes, 2009). This approach was used rather than Hierarchical Linear Modelling (HLM), as it is advocated as a supplement to regression analyses in mediation studies with small samples as it makes no assumptions about the normality of the distribution (Preacher & Hayes, 2008). The bias-corrected bootstrap – 95% confidence interval – was utilised in the current investigation as extensive comparisons have found it to be superior to several alternative approaches in terms of the accuracy of confidence limits and power, whilst minimising Type I error (MacKinnon,

Lockwood, & Williams, 2004). In line with the recommendations of A. F. Hayes (2009), 5000 bootstrap samples were employed and an effect was deemed to be significant at the 95th percentile if the obtained confidence interval lower limit (LL) and upper limit (UL) did not contain zero, at $p < .05$ (A. F. Hayes, 2009). As the independent variable in the present investigation "group" was multicategorical (ACT, CBT and WLC) at the first two time points two dummy variables were created and the analyses for each dependent variable run twice with one dummy variable entered as the independent and the other, the covariate.

Missing outcome data was handled using the Last Outcome Carried Forward (LOCF) method. Whilst the LOCF method has been widely criticised due to an underlying assumption that patients who receive interventions improve, main outcomes of the RCT demonstrate that this assumption is not violated in the current sample (Hancock et al., Submitted for publication). Thus, the LOCF method reflects a conservative approach to handling missing data. For mediation data, as there were instances where data was available at later time points (e.g. pre-data was missing, but post was present) it was not possible to utilise LOCF. Instead, mean substitution using the group mean was applied to missing values. This approach has been found to be effective when the proportion of missing data is less than 5% (Rubin, Witkiewitz, St. Andre, & Reilly, 2007), as satisfied in this sample.

9. Results

A comparison of pre-treatment differences between groups revealed no significant differences for any sociodemographic or anxiety outcome measure ($p > .15$) with the exception of ADIS-IV clinical severity ratings (CSR; $p < .05$). The WLC obtained a CSR that was .7 higher than the treatment groups. While this result was statistically significant it was not a clinically meaningful difference as all groups evidenced ADIS-IV pre-treatment scores in the severe range (for full details see Hancock et al., Submitted for publication). For the process measures, pretreatment comparisons revealed no significant differences across groups on process measures with the exception of mindfulness/self-as-context, as measured by CAMM-20-OBS. On this measure while there were no differences between the treatment groups, WLC exhibited significantly greater scores than CBT ($p < .01$).

10. Changes in main outcomes across time and group

Mixed model analyses for main outcome measures were conducted among the full sample of children involved in the RCT, with age entered as a covariate. The only significant effects for age were for the ADIS-IV CSR. However, the differences were not clinically meaningful. Both treatment groups were found to produce equivalently statistically significant change for pre-post measures and in comparison to WLC of large-to-very large effect size for most measures (Hancock et al., Submitted for publication). Similar results were found at 3MFU for the completer analysis, but intention-to-treat (ITT) results showed that the CBT group had significantly lower CSR scores than the ACT group. However, the difference was not clinically meaningful. Overall, main outcomes demonstrated the improvements at post were maintained at the 3MFU, with minimal changes. The percentage of children who no longer met criteria for an anxiety disorder at post (according to CSR scores) were 31.5% ACT, 42.1% CBT and 8% for WLC groups. Both treatments had statistically higher proportions with no diagnosis compared to the WLC, but were not statistically different from one another. Effect sizes were similar for all clinical outcome measures from pre- to post-

treatment, excepting the MASC, with large effect sizes for CBT compared with moderate effect sizes for ACT. Again, however, the difference was not clinically significant. QOL effect sizes were similar for all outcomes excepting self-reported anxiety interference (CALIS-C), with larger effect sizes for ACT compared with CBT. In summary, both outcomes were largely similar for both treatment groups. Table 2 shows a summary of the means and effect sizes for the outcome measures over time.

11. Changes in process variables across time and group

11.1. Acceptance and cognitive defusion

Mixed model ANOVAs for the AFQ found significant main effects for group ($F\ 2181.15 = 5.31$, $p < .01$), time ($F\ 2172.37 = 42.69$), and the interaction ($F\ 3220.54 = 6.59$, $p < .001$). While there were no significant differences between ACT and CBT, both treatments produced improvements in acceptance and defusion compared with WLC ($p < .001$, $d = .61$ for ACT, $d = .80$ for CBT). ACT and CBT both resulted in significantly more acceptance and defusion at post ($p < .001$, $\Delta = .50$ for ACT, $\Delta = .79$ for CBT), with no significant change for the WLC. Improvements were maintained at the 3MFU for ACT and CBT. Though ACT and CBT means were not significantly different at 3MFU, there were continued improvements for ACT from post to 3MFU ($p < .01$), but not for CBT.

11.2. Mindfulness and self-as-context

On the CAMM-20-OBS significant main effects for time ($F\ 234.11 = 3.53$, $p < .05$) and group ($F\ 243.61 = 9.22$, $p < .001$) were obtained. The time × group interaction was not significant. At post, while within-group differences were non-significant, ACT evidenced significantly greater observing scores than CBT, as did the WLC. However, at 3MFU lower scores were obtained on observing relative to pretreatment for ACT participants ($p < .01$). In terms of the CAMM-20-AWA there was no main effect for time or the interaction, but significant effects for group ($F\ 2,42.67 = 3.79$, $p < .05$). At post there were no significant differences between the treatment groups. However, WLC exhibited significantly greater mindfulness in terms of acting with awareness than CBT. No significant differences at 3MFU were observed within or between groups.

11.3. Valued action

No significant within or between group differences were obtained for the VLQ at post or 3MFU.

12. Summary

ACT and CBT both evidenced increased acceptance and defusion (AFQ-Y) at post, with ACT evidencing further significant within-group improvements post to 3MFU. Within group changes on mindfulness/self-as-context (CAMM-20-OBS/AWA) at post-treatment were non-significant across groups, but ACT and WLC evidenced higher scores than CBT at this time point on mindful observing (CAMM-20-OBS). No significant changes were observed for valued action (VLQ).

13. Process measures as mediators of treatment outcome

Results of the OLS regression with 95% bias-corrected bootstrap confidence intervals (CI) are presented in Table 3. For the primary

Table 2
Means, standard deviations (SD) and effect sizes of outcome measures for the three groups using intention-to-treat.

Measure and condition	Pre-trt*	Post-trt	3MFU	Effect size (d)	Effect size (Δ)
Anxiety disorder CSR (ADIS-IV)					
ACT	6.56 (.87)	4.31(2.52)	4.07 (2.43)	2.59	1.04
CBT	6.59 (1.03)	3.44 (2.86)	3.12 (2.71)	3.09	1.53
WLC	6.92 (.96)	6.18 (1.80)		.77	
Anxiety symptoms – child (MASC-C)					
ACT	62.21 (14.35)	54.56 (13.33)	51.74 (14.00)	.53	.57
CBT	59.58 (11.84)	49.46 (11.56)	48.85 (10.60)	.85	1.01
WLC	61.54 (11.60)	61.23 (11.67)		.03	
Anxiety symptoms – parent (MASC-P)					
ACT	59.97 (12.10)	53.59 (11.65)	51.56 (12.22)	.53	.33
CBT	58.64 (10.99)	50.79 (11.01)	48.71 (11.86)	.72	.57
WLC	57.81 (10.77)	57.42 (11.67)		.04	
Total problems (CBCL – TP)					
ACT	64.09 (7.98)	58.34 (9.61)	55.02 (8.63)	.72	.20
CBT	63.70 (7.66)	57.66 (9.07)	55.35 (9.36)	.79	.28
WLC	62.44 (9.23)	60.29 (9.55)		.23	
Anxious/depressed behaviours (CBCL – AD)					
ACT	71.23 (9.71)	63.99 (9.82)	60.43 (8.11)	.75	.35
CBT	71.31 (9.60)	64.80 (9.38)	63.42 (9.64)	.36	.26
WLC	70.51 (8.49)	67.10 (8.97)		.40	
Depression (CDI)					
ACT	52.56 (11.40)	47.36 (9.06)	45.87 (9.16)	.46	.24
CBT	52.87 (11.85)	46.39 (10.15)	44.64 (8.51)	.55	.31
WLC	57.53 (13.39)	50.55 (13.33)		.52	
QOL – child (CALIS-C)					
ACT	14.77 (5.98)	9.80 (5.93)	9.70 (5.92)	.83	1.42
CBT	11.98 (5.25)	11.05 (5.49)	10.91 (5.45)	.18	.81
WLC	16.78 (7.12)	18.93 (4.30)		.30	
QOL – parent (CALIS-P)					
ACT	16.45 (6.19)	11.15 (5.18)	10.78 (5.21)	.85	2.12
CBT	17.08 (5.35)	13.23 (4.51)	13.01 (4.78)	.72	1.83
WLC	17.78 (4.96)	16.00 (3.41)		.36	

Note: ADIS-IV=Anxiety Disorders Interview Schedule for Children; MASC=Multidimensional Anxiety Scale for Children; CDI=Child Depression Inventory; CBCL=Child Behaviour Checklist (AD – Anxiety/Depression; TP – Total Problems); CALIS=Child Anxiety Life Interference Scale (P – Parent; C – Child); AFQ-Y=Avoidance and Fusion Questionnaire for Youth; Pre=Pre-treatment; Post=Post-treatment; ACT=Acceptance and Commitment Therapy; CBT=Cognitive Behavioural Therapy; WLC=Waitlist Control; d=Cohen's d; Δ=Glass's delta.

outcome, anxiety disorder diagnosis and clinical severity as measured by the ADIS-IV CSR, the total indirect effect of all process variables varied across treatment groups. The hexaflex model mediated the relationship between treatment and CSR for ACT [point estimate $(PE) = -.54$; lower limit $(LL) = -1.14$; upper limit $(UL) = -.16$], but not CBT. A significant indirect effect for acceptance and defusion (as measured by the AFQ-Y) was observed for ACT $[PE = -.48; LL = -1.14; UL = -.15]$. For CBT, the same pattern of results was observed $[PE = -.56; LL = -1.15; UL = -.21]$ indicating that increases in acceptance and defusion mediated reductions in anxiety CSR at post for both ACT and CBT. No significant effects were obtained for any other process measures across treatment for CSR.

For self-report anxiety symptoms (MASC-C) a significant total indirect effect was observed for ACT $[PE = -.55; LL = -1.09; UL = -.11]$ and CBT $[PE = -.78; UL = -1.31; LL = -.34]$. The hexaflex model mediated the relationship between treatment and improvements in child-reported anxious symptoms at post, across treatment. For specific indirect effects the same pattern of results was observed. Acceptance and defusion (AFQ-Y) revealed significant effects for ACT $[PE = -.46; LL = -.95; UL = -.15]$ and CBT $[PE = -.53; UL = -1.31; LL = -.34]$. Acceptance and defusion mediated change across treatment. Specific indirect effects were

nonsignificant for all other putative mediators for child and parent-reported anxious symptom outcomes (MASC-P), across treatment.

In terms of total problems and anxious/depressed behaviour (CBCL) outcomes, both the total indirect effect and all specific indirect effects were nonsignificant across group. The hexaflex model and its component processes did not mediate total problems or anxiety/depression outcomes for either CBT or ACT.

For depression (CDI) a significant total indirect effect was observed for both ACT $[PE = -.53; UL = -1.22; LL = -.06]$ and CBT $[PE = -.81; UL = -1.44; LL = -.26]$. The hexaflex model mediated the relationship between treatment and improvements in depression symptoms at post across treatment. Investigation of specific indirect effects revealed significant effects for acceptance and defusion (AFQ-Y) for both ACT $[PE = -.43; UL = -1.13; LL = -.09]$ and CBT $[PE = -.50; UL = -1.15; LL = -.13]$. Increases in acceptance and defusion were specific mediators of improved depression across treatment. No specific indirect effects were obtained for any of the other process measures.

For both self and parent-report QOL measures non-significant findings were observed for both the hexaflex model and all specific indirect effects in mediation of treatment-related change across group.

Table 3
Mediation analyses by main outcome and treatment group.

	ACT			CBT		
	Point estimate	BC 95% CI		Point estimate	BC 95% CI	
		Lower	Upper		Lower	Upper
Anxiety disorder diagnosis clinical severity (ADIS-IV CSR)						
Hexaflex (total)	−.54*	−1.14	−.16	−.48	−1.13	.02
Acceptance & defusion (AFQ)	−.48*	−1.14	−.15	−.56*	−1.15	−.21
Mindfulness/self-as-context (CAMM-OBS)	.00	−.12	.28	.2	−.19	.71
Mindfulness/self-as-context (CAMM-AWA)	−.07	−.43	.05	−.12	−.19	.71
Valued action (VLQ)	.00	−.12	.17	.00	−.17	.16
Anxiety symptoms – child (MASC-C)						
Hexaflex (total)	−.55*	−1.09	−.11	−.78*	−1.31	−.34
Acceptance & defusion (AFQ)	−.46*	−.95	−.15	−.53*	−1.07	−.24
Mindfulness/self-as-context (CAMM-OBS)	−.00	−.15	.07	−.11	−.39	.13
Mindfulness/self-as-context (CAMM-AWA)	−.07	−.27	.03	−.12	−.36	.01
Valued action (VLQ)	.02	−.15	.03	−.03	−.24	.05
Anxiety symptoms – parent (MASC-P)						
Hexaflex (total)	−.25	−.95	.15	−.35	−1.22	.22
Acceptance & defusion (AFQ)	.08	−.57	.20	−.09	−.62	.27
Mindfulness/self-as-context (CAMM-OBS)	−.00	−.09	.15	.02	−.34	.37
Mindfulness/self-as-context (CAMM-AWA)	−.14	−.55	.04	−.24	−.74	.03
Valued action (VLQ)	−.04	−.30	.03	−.04	−.48	.05
Total problems (CBCL – TP)						
Hexaflex (total)	−.22	−.80	.15	−.19	−.80	.31
Acceptance & defusion (AFQ)	−.03	−.55	.27	−.03	−.54	.39
Mindfulness/self-as-context (CAMM-OBS)	.01	−.11	.25	.15	−.18	.58
Mindfulness/Self-as-context (CAMM-AWA)	−.14	−.67	.04	−.25	−.90	.03
Valued action (VLQ)	−.05	−.34	.02	−.06	−.42	.06
Anxious/depressed behaviours (CBCL – AD)						
Hexaflex (total)	.04	−.38	.39	−.12	−.63	.39
Acceptance & defusion (AFQ)	.18	−.13	.61	.20	−.16	.71
Mindfulness/self-as-context (CAMM-OBS)	−.00	−.19	.11	−.10	−.53	.24
Mindfulness/self-as-context (CAMM-AWA)	−.12	−.51	.04	−.20	−.77	.04
Valued action (VLQ)	−.02	−.13	.61	−.02	−.31	.09
Depression (CDI)						
Hexaflex (total)	−.53*	−1.22	−.06	−.81*	−1.44	−.26
Acceptance & defusion (AFQ)	−.43*	−1.13	−.09	−.50*	−1.15	−.13
Mindfulness/self-as-context (CAMM-OBS)	−.01	−.21	.11	−.17	−.53	.08
Mindfulness/self-as-context (CAMM-AWA)	−.06	−.36	.02	−.11	−.40	.01
Valued action (VLQ)	.03	−.28	.05	−.04	−.49	.06
QOL – Child (CALIS-C)						
Hexaflex (total)	−.16	−.51	.28	−.35	−.96	.13
Acceptance & defusion (AFQ)	.01	−.28	.42	.02	−.33	.45
Mindfulness/self-as-context (CAMM-OBS)	−.00	−.20	.12	−.13	−.60	.21
Mindfulness/self-as-context (CAMM-AWA)	−.10	−.52	.03	−.17	−.66	.03
Valued action (VLQ)	−.07	−.20	.12	−.07	−.52	.06
QOL – Parent (CALIS-P)						
Hexaflex (total)	−.12	−.49	.22	−.12	−.65	.41
Acceptance & defusion (AFQ)	.02	−.28	.28	.02	−.34	.31
Mindfulness/self-as-context (CAMM-OBS)	.00	−.09	.26	.10	−.27	.53
Mindfulness/self-as-context (CAMM-AWA)	−.12	−.59	.05	−.21	−.93	.02
Valued action (VLQ)	−.02	−.27	.04	−.20	−.31	.07

Key: *=significant at $p < .05$; AFQ – avoidance and fusion questionnaire youth; CAMM-OBS – child and adolescent mindfulness measure, observing; CAMM-AWA – child and adolescent mindfulness measure, acting with awareness; VLQ – valued living questionnaire.

In summary, the hexaflex model mediated the relationship between treatment and CSR for ACT, but not CBT. It also mediated the relationship between depression (CDI) and treatment for both groups and this was also the case for self-reported anxiety symptoms (MASC-C). The hexaflex model and its component processes did not mediate parent-rated total problems and anxiety/depression symptoms (CBCL and MASC-P) or QOL outcomes.

While the overall model was identified to mediate these aforementioned outcomes, it would appear that the significance of these findings is better explained by the specific indirect effects of acceptance and defusion (AFQ) bolstering results. This assertion is supported by the lack of significant within-group changes observed for the mindfulness/self-as-context and valued action measures across treatment. Acceptance and defusion mediated the

relationship between treatment and CSR, as well as self-reported depression (CDI) and anxiety symptoms (MASC-C) for both groups. The AFQ did not mediate parent-rated total problems, anxiety/depression or QOL. Main outcomes were predominantly constant post to 3MFU, and no significant mediation effects were observed across this time. Change in process measures at 3MFU for intervention participants ($n=26$) was limited to significant within-group improvements on acceptance and defusion (AFQ-Y) and reductions in mindful observing (CAMM-OBS). Mediation analyses revealed no significant effects for this period.

14. Discussion

The current study examined the ACT hexaflex model and its component core processes as putative mediators for treatment-related change in a sample of adolescents with anxiety disorders. Participants were drawn from a larger RCT of ACT versus CBT to allow assessment of the treatment-specificity of mediation effects. Both treatments produced significant changes across main outcome measures over time and in comparison to WLC (Hancock et al., Submitted for publication).

In terms of putative mediators, we first considered whether treatment produced changes in process measures. At post both ACT and CBT, and not the WLC, evidenced changes across acceptance and defusion (AFQ-Y). However, the mindfulness/self-as-context and valued action components of the ACT hexaflex model (CAMM-20 and VLQ) did not evidence significant within-group change at post. The lack of significant change on mindfulness/self-as-context and valued action is in contrast to predictions and, in the case of valued action, to a study of changes in proposed mechanisms of change among 43 adults with generalised anxiety disorder treated with ACT, where session-by-session change in both acceptance and valued action was observed (S. A. Hayes et al., 2010). Several factors may underscore these unexpected findings. With respect to values, these are inherently difficult to define and have not been uniformly described in psychological literature, which may indicate inconsistency in the values construct. While values are dynamic and ever evolving (Wilson et al., 2010), the preponderance of literature broadly operates under the assumption that young people have clearly formulated value systems where they may better be viewed as fluid and ill-formed in this developmental period (Cohen & Cohen, 1996). It may be that the VLQ is not an optimal measure of valued action in this age group or to examine change over time, as the VLQ was normed upon a sample of young people with an average age of 22 years and trends in this measure have been found to be relatively stable over short periods (Wilson et al., 2010). In contrast to this perspective, values have been found to be observed from middle childhood and to broadly emulate the trends observed in adult populations (Cohen & Cohen, 1996), which suggests the appropriateness of adult measures for this population. The notion that the duration of this investigation was insufficient to allow for changes in this measure cannot be ruled out. The literature suggests that values identification is impacted by a myriad of factors including social class, maternal education, peer/social relationships, and the young person's personality/temperament (Cohen & Cohen, 1996), factors which were broadly unexplored within the current investigation. It is also possible that adolescents are more constrained in their agency to engage in valued action as a consequence of their age and limited control over their environment. Whether these factors may have greater influence on valued action is an area in need of further research.

Mindfulness is increasingly employed in the treatment of adolescents and a review of feasibility studies offered preliminary support for this approach among children and adolescents (Burke, 2010). Mindfulness is multifaceted and has been described as involving six facets; observing, describing, participating, nonjudgmentally, one-mindfully, and effectively (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). It may be that this construct is not fully captured by the CAMM-20 (Ciarrochi et al., 2011). Alternatively, whilst evidence for the utility of mindfulness approaches among adolescents is growing, others have suggested the mechanisms through which change occurs may be better explained by a higher order factor such as acceptance (Ciarrochi et al., 2011), as observed in the current study. It may be that self-report measures, such as the VLQ and CAMM-20, are subject to biased responding as prior to treatment clients may lack awareness, insight or self-awareness, which may lead to insignificant changes in such measures (S. A. Hayes et al., 2010). Finally, the moderately low sample size may have played a role in limiting the significance of some of the statistical tests conducted. On the basis of the mean CSR, between groups comparison of ACT versus CBT at post-treatment an N of approximately 65 would be needed to obtain statistical power at .80 to detect a moderate effect size. However, sample size was adequate if comparing either of the treatment groups with the WLC, with an effect size of greater than 1 for both, and only around 11–17 needed per group. Similarly, pre to post-mean differences within treatment groups effect sizes were also large for this sample, indicating that the sample size was adequate. Thus, depending on the comparison required, the sample size for adequate power varied.

While measures of clinical outcomes are profuse in the literature, those designed to target processes of change are comparatively less well researched (Twohig, Field, Armstrong, & Dahl, 2010). While growing literature attests to the effectiveness of ACT, far fewer studies have examined the processes of change underpinning treatment success. The literature is in its infancy in terms of the current availability of valid, reliable measurement tools that tap each of the hexaflex core processes, with some processes more thoroughly examined than others. In this study, the measure with the greatest research evidence is the AFQ-Y, and this may explain significant changes in acceptance and defusion in the absence of changes in the other processes. Alternatively, it may be that the processes of acceptance and defusion are the more relevant components of the ACT model to outcomes among adolescents with anxiety disorders. It is also possible that the employment of a group therapy format supported increases in acceptance, as the group setting may have supported normalisation of anxious symptomology and interference. Further research is required to compare group and individual therapy formats, or group treatment versus group active control including group support and attention in order to examine this possibility.

Overall, main outcomes were typically maintained at 3MFU for both ACT and CBT, with limited further changes observed. Among process measures, changes at 3MFU were limited to ACT – with no changes for CBT – and included further increases in acceptance and defusion (AFQ-Y) from that observed at post as well as reductions in mindfulness/self-as-context scores (CAMM-20-OBS) relative to pretreatment. This latter finding of reduced mindful observing among ACT participants was unexpected. The CAMM-20-OBS scale involves an individual's notice, observation, and attendance to both psychological and extraneous phenomena (Ciarrochi et al., 2011). One explanation for this finding may be that mindful observation is linked with hypervigilance, as young people with anxiety tend to be hypervigilant to, and detect high levels of threat; experiences that can exacerbate anxious distress (Dalgleish, Morad, Taghav, Neshat-Doost, & Yule, 2001). While it is difficult to draw firm conclusions, given the current paucity of research in this area, reductions in average observing scores among ACT participants may in fact reflect a decline in hypervigilance. In support of this assertion, Baer et al. (2006) found that

increases in mindful observing were associated with more psychological symptoms and offered the conjecture that increased observation does not necessitate reduced critical judgement or evaluation. Furthermore, another (longitudinal) study of adolescent found that mindful observing, as measured by the CAMM-20-OBS, failed to predict change in emotional well-being (Ciarrochi et al., 2011).

Upon establishment of changes in process measures, multiple mediation analyses examined the relationship between process measures and main outcome measures. Support for the hexaflex model in its entirety as a mediator of the relationship between treatment and outcome was limited to reductions in self-reported child anxiety (MASC-C) and depression (CDI) for both treatment groups, and for ACT but not CBT for CSR (approached significance for CBT). This same pattern, emerged for the specific indirect effect of acceptance and defusion (AFQ-Y), though for CSR the effect was for both ACT and CBT. Indeed the aforementioned results for the hexaflex appeared to be more optimally explained via the mediational role of acceptance and defusion exerting its influence across the broader hexaflex model as within-group changes for mindfulness/self-as-context and valued action were non-significant. The finding that increased defusion mediated improvements in anxiety for both ACT and CBT are in line with research conducted among adults (Arch et al., 2012; Forman et al., 2012).

Several researchers have suggested that the processes that form the hexaflex model are not unique to ACT (e.g. Arch & Craske, 2008; Levin et al., 2012) and may be shared with CBT. To exemplify, it has been speculated that the CBT technique of cognitive restructuring and ACT approach of defusion may exert their influence on the same underlying mechanisms (Forman et al., 2012). Even though CBT does not explicitly discuss cognitive defusion, this study provides support for the conclusion reached by Arch et al. (2012) that the process of cognitive defusion does occur in CBT, and underlies change as it does in ACT. Defusion has been described diminishing the literal nature of cognitions with the outcome of defusion "usually a decrease in believability of, or attachment to, private events" (S. C. Hayes et al., 2006, p. 12). This evidences clear overlap with the aims of cognitive restructuring in CBT, undertaken to reduce the believability of cognitions. Furthermore, cognitive restructuring may necessitate the achievement of a degree of mindfulness and defusion in order to more objectively scrutinise thought processes. Likewise, in ACT, defusion allows thoughts to be viewed as private experiences and not necessarily the truth, which may produce changes in the believability of thoughts. Cognitive restructuring and acceptance have also been argued to share the requirement for stating and attending to previously suppressed or avoided psychological phenomena and that these processes, which involve focusing on, noticing and disputing negative psychological phenomena may reflect a form of exposure (Arch & Craske, 2008), which may be an overarching mediator variable in treatment-related change.

Our results do not support the finding that ACT processes mediated QOL outcomes for ACT or CBT as observed among some studies of adults (e.g. Arch et al., 2012; S. A. Hayes et al., 2010). This finding is unexpected in light of the ACT hexaflex model of psychological flexibility, which has an overarching aim of improving valued living and, as such, QOL (Luoma et al., 2007). Whilst there is substantial research on the mediational role of psychological flexibility in ACT on a broad level, adult samples identified only modest support for the anxiety disorders (S. C. Hayes et al., 2006), which may also explain the relative lack of significant findings among this population. It may be that the treatment duration and 3MFU was an insufficient time period to identify changes in QOL. In support of this, in a recent systematic review of the utility of ACT among child populations several studies (e.g. L. Hayes, Boyd, & Sewell, 2011; Metzler, Biglan, Noell, Ary, & Ochs,

2000; Wicksell, Melin, & Olsson, 2007) found treatment gains were either not fully evident at posttreatment (or initial follow-up) or that greater improvements for ACT were obtained some months after therapy cessation (Swain et al., Submitted for publication). Internal consistency of the CALIS in the current sample was only moderate, and as such null findings may be a reflection of poor psychometrics. Alternatively it may be that QOL mediation effects occur differently among adolescents, and alternative extraneous processes – such as acceptability of treatment, fidelity of the intervention and therapeutic engagement – may mediate these outcomes (Arch et al., 2012). Adolescents are typically subsumed within a family system, and thus QOL may be impacted by the willingness of parents to support and positively influence the change. More research in this area is required to establish the possible role of these factors. However, even among the adult literature mixed findings have been observed. For example one study of adults with generalised anxiety disorder observed that changes in valued action (as measured by the VLQ) and acceptance predicted clinical outcome above and beyond diminished worry. However, acceptance, and not valued action, was found to predict QOL outcomes at posttreatment in this study (S. A. Hayes et al., 2010). As eluded to above, it may also be that the elements of therapy shared by both ACT and CBT in the current investigation (though used in different ways), such as exposure or psychoeducation, are in fact mediator processes and further studies may test this empirically.

Acceptance and defusion (AFQ-Y) were the only predictors of outcome change. However, there was some evidence that mediation effects varied by rater group in that self-reported anxiety differed between parent and child report on the MASC. Furthermore, all mediation analyses for parent-rated measures were non-significant. A review of the literature found agreement between parent–child reports on anxiety and other psychopathology to be poor (Klein, 1991) and a more recent study on the MASC observed parent–child concordance to low in community samples (Baldwin & Dadds, 2007), which may offer some explanation for these findings. It may be that some changes in an adolescent's experience of anxiety may reflect internal processes not available for external/behavioural observation and therefore not be evident on parent-reported measures.

Studies among adults with anxiety have typically been restricted to the assessment of one or two mediators of interest. This offers limited information, as similar outcomes may be reached via divergent paths. The assessment of multiple putative mediators allows the relative contribution of each to the overall outcome to be examined (Kazdin, 2007). This is of particular relevance as ACT process measures are considered to be interrelated and overlapping (S. C. Hayes et al., 2013). For the present investigation, given the relative lack of evidence pertaining to child samples, multiple psychometrically reliable and valid outcome/process measures enabled breadth of understanding of how these processes operate among adolescents. This resulted in increased time for participants to complete assessment batteries and hence it was unfeasible to undertake session-by-session repeated measures as it would be overly taxing to young participants. Instead, reassessment was limited to three time points (pre, post and 3MFU). Thus, evidence for observed mediation effects are tempered by the fact that process measures were obtained in concert with main outcome measures, precluding a formal examination of causal mediation. With few outcome changes observed in the present investigation it follows that there would be few process changes from post to 3MFU. However, the precise nature of the relationship between process and outcome variables is difficult to delineate. Future multiple mediation researchers should implement repeated multiple process and outcome measures at midtreatment, rather than follow-up, to mitigate this concern. A further limitation is that the interrelating

nature of ACT processes of change may produce resultant discriminative validity concerns in measurement tools, an area for future research. As this study was designed to measure ACT putative mediators for change, and required completion of a large battery of assessments to provide coverage for the ACT hexaflex, we did not examine whether CBT putative mediators (e.g. catastrophising, etc.) would also be treatment common. This is another area for further research.

Whilst several putative mediators in the ACT literature among adults have been identified, the literature is bereft of empirical evidence for child populations. Notwithstanding the aforementioned limitations, in the first preliminary exploration study of the gamut of these measures among anxious young people, our findings offered limited support for the ACT hexaflex, and its core component processes, as mediators for treatment-related change. Significant findings were restricted to the mediational role of the acceptance and defusion in clinical outcomes of clinician-rated anxiety clinical severity as well as self-reported anxiety and depression symptoms. Whilst support for the overall hexaflex model was also observed for these aforementioned outcomes, the lack of significant changes in these measures at posttreatment suggests that these findings are better explained via the specific indirect effects of acceptance and defusion. In line with a previous study of adults with mixed anxiety disorders (Arch et al., 2012), the current investigation did not support the assertion that ACT and CBT exert their influences through distinct processes, suggesting they may operate through similar mechanisms. These findings add weight to the emergent idea that investigation into overarching mediators for the behavioural and cognitive therapies may be warranted. This reflects an important finding in terms of furthering our understanding of the underlining mechanisms of change for ACT and CBT. It sets the foundation for future research focusing on mechanisms of change in children with anxiety.

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