MIXED REALITY TECHNOLOGIES TO DELIVER PSYCHOLOGICAL INTERVENTIONS FOR THE TREATMENT OF SYMPTOMS OF ANXIETY AMONG ADOLESCENTS WITH ASTHMA

by

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Abbreviations

ACQ: Asthma Control Questionnaire

ACT: Acceptance Commitment Therapy

ANZCTR: Australia and New Zealand Clinical Trials Registry

AR: Augmented reality

A/Prof: Associate Professor

ATS: American Thoracic Society

AT: Assertiveness Training

BT: Behavioural Therapy

BYI: Beck's Youth Inventory

CBCL: Child Behaviour Checklist

CBT: Cognitive and behavioural therapies

eCBT: Digital CBT

ED: Emergency Department

EIB: Exercise-Induced Bronchoconstriction

EPR3: Expert Panel Report-3

F: Female

FAMSS: Family Asthma Management System Scale

FeNo: Fractional Exhaled Nitric Oxide

FEV: Forced Expiratory Voluma

GINA: Global Initiative for Asthma

HREC: Human Research Ethics Committee

ICS: Inhaled corticosteroids

IgE: Immunoglobulin E

IM: Intervention Mapping

ITGV: Intrathoracic Gas Volume

M: Male

MEF50: Maximal Expiratory Flow at 50% of the Forced Vital Capacity

NHLBI: National Heart, Lung, and Blood Institute

NHMRC: National Health and Medical Research Council

PA: Physical Activity

PAQLQ: Paediatric Asthma Quality of Life Questionnaire

PEF: Peak Expiratory Flow

PEFR: Peak Expiratory Flow Rate

PROMIS: Patient-Reported Outcomes Measurement Information System

QoL: Quality of Life

RCT: randomized controlled trial

REBT: Rational Emotive Behaviour Therapy

RT: Relaxation Training

RV: Residual Volume

SAHMRI: South Australian Health and Medical Research Institute

SD: Standard Deviation

TDF: Theoretical Domains Framework

TFA: Theoretical Framework of Acceptability

TGV: Thoracic Gas Volume

TRIP: Translating Research into Practice

UK: United Kingdom

UniSA: University of South Australia

USA: United States of America

VR: Virtual reality

WCH: Women's and Children's Hospital

YAAS: Youth Asthma-related Anxiety Scale

Summary

Asthma is a chronic health condition currently affecting 1 in 10 Australian children (Health and Welfare, 2022), and a large proportion of these children experience high levels of psychological distress; both in relation to their condition, and otherwise (AIHW, 2019, Blanchard et al., 2014). Psychological interventions may provide individuals with tools and strategies to better manage symptoms of both conditions; potentially preventing exacerbations before they begin. However, uptake and quality of mental health services by young people varies widely, and recent data reflects that young people experiencing psychological distress opt for unhealth coping mechanisms such as “alcohol and drugs” or “nothing” before they reach out to a professional (Greenland and Hall, 2021). Given the burden of disease caused by these conditions, improving access to and uptake of evidence-based resources for young people with asthma and psychological distress is a key priority in this population.

The manuscripts within this thesis explore the use of psychological interventions to manage symptoms of anxiety and/or depression in adolescents with asthma, the modifiable biopsychosocial needs of adolescents with asthma, as well as mixed reality technologies as a delivery mechanism for these psychological interventions in young people experiencing symptoms of psychological distress.

Study 1 consists of a Cochrane systematic review, evaluating the effectiveness of psychological interventions as a treatment method for children and adolescents with asthma. Existing evidence was limited in quality and reflected mixed results, however for primary outcomes such as symptoms of anxiety and/or depression, as well as health outcomes such as asthma symptoms, most studies found a positive effect.

Study 2 provides an overview of the literature exploring the modifiable drivers of psychological distress in young people with asthma through a biopsychosocial needs assessment. A narrative review identifies potential avenues for intervention.

Based on data obtained through Studies 1 and 2, Study 3 evaluates the acceptability of mixed reality technologies to deliver psychological interventions among young people with asthma and symptoms of heightened psychological distress through qualitative interviews with three groups of stakeholders. These technologies were generally well-accepted by all groups, though concerns about ethicality were raised. The results indicate that mixed reality technologies could be a useful adjunct to existing treatment options.

Results from these studies provide important information towards the development of effective psychological interventions for use by young people with asthma and symptoms of heightened psychological distress. It also identifies large gaps in the literature which other researchers may use to direct future research priorities.

Declaration

This thesis presents work carried out by myself and does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; to the best of my knowledge it does not contain any materials previously published or written by another person except where due reference is made in the text; and all substantive contributions by others to the work presented, including jointly authored publications, are clearly acknowledged.

Kelsey Sharrad



10/05/2023

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Dissemination of research findings

Peer-reviewed publications

1. **Sharrad, KJ**., Kopsaftis, Z., Tai, A., Spurrier, N., Smith, R., Esterman, A., Gwilt, I., Sandford, D., & Carson-Chahhoud, K. Acceptability of mixed reality technology as a delivery mechanism for psychological intervention in adolescents with asthma: a qualitative study using the Theoretical Framework of Acceptability. JMIR mHealth and uHealth (*Accepted, copyediting Mar 2023)*

2. **Sharrad KJ**, Sanwo O, Carson-Chahhoud KV, Pike KC. Psychological interventions for asthma in children and adolescents. Cochrane Database of Systematic Reviews *(Accepted, copyediting Mar 2023)*

3. **Sharrad KJ**, Martini C, Kopsaftis ZK, Tai A, Spurrier N, Smith R, Esterman A, Gwilt I, Sandford D, Carson-Chahhoud KV. Augmented reality technology as a delivery mechanism for psychological intervention in adolescents with asthma: a randomised controlled feasibility trial protocol. BMC Pilot & Feasibility Studies. *(Undergoing peer/editorial review, Mar 2023)*

4. **Sharrad KJ**, Kopsaftis Z, Carson-Chahhoud KV, Stallman H. The modifiable biopsychosocial drivers of psychological distress for adolescents with asthma: implications for clinical care. Paediatric Respiratory Reviews 2021, Aug. DOI: https://doi.org/10.1016/j.prrv.2021.07.005

5. **Sharrad, K**., Kopsaftis, Z., Tai, A., Spurrier, N., Smith, R., Esterman, A., Gwilt, I., Stallman, H., & Carson-Chahhoud, K. (2021). Mixed Reality Technology as a Delivery Mechanism for Psychological Intervention in Adolescents with Asthma: A Qualitative Protocol. International Journal of Qualitative Methods. https://doi.org/10.1177/16094069211008333

6. **Sharrad KJ**, Sanwo O, Carson-Chahhoud KV, Pike KC. Protocol: Psychological interventions for asthma in children and adolescents. Cochrane Database of Systematic Reviews 2019, Issue 9. Art. No.: CD013420. DOI: 10.1002/14651858.CD013420.

Presentations

1. ***Oral presentation:*** TSANZ New Investigator Award (Finalist) - 'Augmented reality for psychological intervention in young people with asthma'. Adelaide 2022

2. ***Oral presentation:*** Kelsey Sharrad, Caitlin Martini, Dr Zoe Kopsaftis, Dr Andrew Tai, Assoc. Prof Nicola Spurrier, Assoc. Prof Ross Smith, Prof. Adrian Esterman, Prof Ian Gwilt, Dr Debra Sandford, Assoc. Prof Kristin Carson-Chahhoud. AR as a delivery mechanism for psychological intervention. Thoracic Society of Australia and New Zealand, Annual Scientific Meeting, Adelaide 2022.

3. ***Oral presentation:*** Kelsey Sharrad, Olatokunbo Sanwo, Sofia Cuevas-Asturias, Kristin V Carson-Chahhoud, Katharine C Pike. Psychological interventions for asthma in children and adolescents. Thoracic Society of Australia and New Zealand, Annual Scientific Meeting, Adelaide 2022.

4. ***Oral presentation:*** 'Augmented reality technology to deliver psychological interventions for the treatment of heightened psychological distress among children and adolescents with asthma'. Thoracic Grand Round, Royal Adelaide Hospital, 1st August 2019.

Media engagement

- Health Partners article 'Could it be asthma?' for Health Partners newsletter, June 2020.

- Channel 7 News, interviewed by Elise Baker during the evening news (22/05/2020) for the study 'Mixed reality and holographic technology (iHealth) to deliver cognitive and behavioural therapy for the treatment of symptoms of anxiety among teenagers with asthma'. https://www.facebook.com/7NEWSAdelaide/videos/732139817560254/

- National Radio News, interviewed by Peter Freestone (25/05/2020) for the study 'Mixed reality and holographic technology (iHealth) to deliver cognitive and behavioural therapy for the treatment of symptoms of anxiety among teenagers with asthma'.

1 Chapter 1 - Introduction

1.1 Background

1.1.1 Asthma burden and heightened psychological distress in young people

Australia has one of the highest asthma prevalence rates in the world (Asher and Ellwood, 2014), with this chronic and debilitating condition affecting one in ten people (AIHW, 2018). Asthma is the leading cause of disease burden among young Australians aged 5 to 14 years (AIHW, 2018), and the health and mental wellbeing of young people with asthma is worse than not only their peers without asthma, but also worse than that of people with asthma at other ages (Akinbami et al., 2009, Akinbami and Schoendorf, 2002). A 2014 survey of Australian adolescents aged 12 to 25 years found that half of young people with asthma experienced symptoms of heightened psychological distress (the experience of symptoms of anxiety and depression at sub-clinical levels (Drapeau et al., 2012)). This is double the rate of the wider community (Blanchard et al., 2014); a figure that has been significantly increasing (Mission Australia, 2017).

A range of challenges faced by children and adolescents with asthma may contribute to their increased experience of psychological distress, including: social isolation, restricted life choices, limitations on personal potential, embarrassment and shame about their condition and/or treatment, self-consciousness, potential mortality threat, and fear of disease exacerbation (Blanchard et al., 2014). These complex, interconnected issues compound the social, psychological and developmental challenges experienced by people during this life stage (Cohen et al., 2003, de Benedictis and Bush, 2007). This combined symptom profile contributes to higher levels of functional impairment (Akinbami and Schoendorf, 2002), lower quality of life (Goldney et al., 2003), and higher rates of preventable hospitalisation and mortality compared to people without asthma (Calmes et al., 1998).

1.1.2 Psychological interventions for asthma in children and adolescents

It is likely that a bidirectional relationship exists between asthma and symptoms of psychological distress (Baiardini et al., 2015). Psychological factors and negative life events have been shown to exacerbate inflammation and symptoms of asthma (French and Alexander, 1943, Van Lieshout and Macqueen, 2008, Sandberg et al., 2000); via

exacerbation of the immune response to external stimuli through increased activation of endocrine pathways (Chen and Miller, 2007). Psychological distress may also impact negatively upon self-efficacy and symptom perception and, in turn, upon medication adherence and other health behaviours, including frequency of healthcare utilisation (Baiardini et al., 2015). Positive cognitive experiences regarding asthma, specifically self-efficacy, outcome expectations, and perceptions of barriers, are associated with better asthma control and adherence to medication in young people (Rhee et al., 2018). Conversely, asthma in young people is associated with increased psychological distress and clinical diagnoses of psychological disorders (Katon et al., 2007, Pinquart and Shen, 2010, Dudeney et al., 2017). Asthma may negatively affect psychological and mental health outcomes, as individuals with asthma may experience heightened psychological distress due to the persistent fear of asthma attacks (GINA, 2018).

Psychological interventions may provide young people with techniques and strategies to manage psychological distress and therefore symptoms of asthma as they arise, in order to avoid exacerbations (Duff, 2001). For example, cognitive and behavioural therapy (CBT) is a psychological intervention which can be used in the treatment of anxiety disorders in young people (Andrews et al., 2018). It is a broad term that encompasses a variety of strategies, but simplistically, CBT aims to help patients recognise and modify dysfunctional thoughts and behaviours (Andrews et al., 2018). CBT is typically conducted in stages of increasing complexity, and involves education, arousal management, graded exposure, inhibitory control (learning to exert self-control to inhibit habitual behavioural responses), and cognitive strategies (The Australian Psychological Society, 2018, Andrews et al., 2018). A 2018 systematic review of five studies found that CBT was beneficial for reducing anxiety in adults, particularly when combined with asthma-related education. In children and adolescents with asthma, only two studies were eligible for inclusion, and results were mixed (Pateraki and Morris, 2018). CBT could be beneficial in treating symptoms of anxiety in patients with asthma, however, evidence suggests that uptake of mental health services is low in this population.

1.1.3 Current uptake of mental health services by young people

Psychological distress can be reduced with healthy coping strategies ranging from independent to dependent: self-soothing, relaxing or distracting activities, social support, and then professional support and psychological intervention when other strategies aren’t effective (Stallman, 2017). Findings from the national youth mental health survey

identified that the internet is a leading source of information for youth (Mission Australia, 2017), with a preference for self-help and self-reliance over seeking professional help or help from family and friends (Burns et al., 2016). However the effectiveness of unguided self-help varies greatly due to the wide range and quality of sources available (Andrews et al., 2018). Further, reports estimate that four out of five young people who could potentially benefit from psychological intervention are reportedly not accessing it (Bekker et al., 2017). In a 2016 Australian survey, 48% of parents of young people aged 12-17 years reported that their child refused help, 39% of parents were not sure where to get help, 33% could not afford help, whilst 29% reported that they could not get an appointment (AIHW, 2016). Even when services are accessed, a recent study conducted in 21 countries found that only 9.8% of individuals with an anxiety disorder received possibly-adequate treatment based on evidence-based guidelines (Alonso et al., 2018). To address these issues, government organisations are calling for technology-based solutions that can engage youth and address the current barriers to service uptake for both mental health outcomes (Blanchard et al., 2014, Mission Australia, 2017) and asthma management (Blanchard et al., 2014, Levy and Winter, 2015).

1.1.4 Utilising technology to deliver health interventions

Technology-delivered psychological interventions (also known as e-psychology, e-health or e-mental health) refer to psychological interventions delivered via technologies such as smartphone apps, wearable monitoring devices, online resources, and social media (RANZCP, 2019). These interventions are recognised by the Royal Australian and New Zealand College of Psychiatrists as a potentially effective option for psychiatric care and support, which may increase access to, and improve quality of care (RANZCP, 2019). Technology-delivered interventions have been identified as a key policy/practice initiative as *"…evidence-based programs can be delivered en masse at low cost without the need for teacher and clinician training."* (Mission Australia, 2017). Additional benefits of a technological interface include preserved anonymity and an alternative healthcare delivery option for rural and remote patients (Boydell et al., 2014). Furthermore, the cost of administering interventions such as CBT is high, and research demonstrates that technology-delivered mental health interventions can be cost-effective for both patients and providers (Solomon et al., 2015).

Recent evidence in children and adolescents is limited, although a 2016 meta-analysis found that children and adolescents receiving digital CBT (eCBT) experienced less anxiety

than participants in the control condition. Individuals receiving eCBT and minimal therapist care reported lower levels of anxiety than 99% of participants in the control condition, and individuals receiving eCBT with significant therapist care reported lower levels of anxiety than 62% of participants in the control group. No significant difference in efficacy between eCBT and face-to-face CBT was identified (Podina et al., 2016). Further research and program development is needed in order to ensure that online programs and interventions are evidence-based and easily accessible to maximise uptake (Mission Australia, 2017). To speed successful translation of evidence-based treatment into practice, a new approach is required. Innovative interactive health technology such as augmented reality (AR), may provide a novel, minimal-cost solution.

1.1.5 Augmented reality as a delivery mechanism for health interventions

Using a smartphone as a viewing device, AR superimposes digital information so that content seems to coexist within the real world (Bacca et al., 2014a). By delivering information through videos, graphics and animation, AR can: address poor health literacy (Bacca et al., 2014b, Kim and Xie, 2017); be tailored for population characteristics; increase engagement in content (Akcayir and Akcayir, 2017); improve geographic reach and accessibility of information (Porter and Heppelmann, 2015); and allow for real-time content updates. AR is cheap to produce due to low-cost development tools and the availability of premade 3D assets that can be purchased and are easily customisable. Available studies (Riva et al., 2016, Martín-Gutiérrez et al., 2017, Garzón et al., 2019) report AR technology to be an increasingly popular education tool given the ability for personalisation, and increase motivation to learn as viewers are placed at the centre of the knowledge process. A recent pilot study using AR to show videos of correct asthma inhaler technique identified qualitatively that iHealth technology was consistently believed to be helpful for inhaler technique, which was confirmed using 10-point Likert scales by patients, health professionals and key-community stakeholders (King et al., 2017).

For the delivery of psychological interventions, previous research in AR technology is lacking, however virtual reality (VR) – a completely immersive technology that uses a headset to view content – has been shown to be a promising education tool. A 2018 meta-review including 25 meta-analyses and systematic and narrative reviews, including five studies which used VR to deliver CBT specifically, found that VR and/or AR were effective for delivering behavioural treatment for anxiety disorders, eating and weight disorders, and pain management (Riva et al., 2018). A more recent pilot study also found

CBT delivered via VR to be useful in the treatment of symptoms of anxiety in adults with diagnosed generalised social anxiety disorder, with mean scores on the Social Interaction Anxiety Scale of 59.9 at baseline decreasing to 47.8 at project completion, and 43.1 at follow-up (Geraets et al., 2019). Limitations of these studies included high drop-out rates, and small sample sizes (Valmaggia et al., 2016).

Improving access to and uptake of evidence-based treatments for heightened psychological distress in young people with asthma can work to reduce the burden of this highly prevalent disease. This thesis will explore the use of AR as a delivery mechanism for CBT in the treatment of heightened psychological distress among young people with asthma.

1.2 Overview of aims and hypotheses

1.2.1 Aims

To address the barriers to service uptake in young people, this thesis aims to further understand the needs of young people with asthma and symptoms of psychological distress, understand potential avenues for treatment and their effectiveness, and to understand the appropriateness of technology-based resources to manage symptoms of psychological distress in young people with asthma. This will be done via:

- A systematic review (Study 1) aiming to fill a gap in the literature by evaluating the effectiveness of psychological interventions as a treatment method for children and adolescents with asthma.
- A needs assessment (Study 2) seeking to understand the modifiable drivers of psychological distress in young people – thus elucidating potential avenues for intervention. This will be achieved through a narrative review of the literature.
- To address the calls for evidence described in the introduction, AR technology will be evaluated as a delivery mechanism for psychological intervention among young people with asthma and heightened psychological distress (Study 3).

These studies form part of a larger body of work which follows the six-step intervention mapping process (Eldredge et al., 2016) to iteratively co-design intervention resources (Safourin, 1996). This process utilises information gained through qualitative research (i.e. Study 3) to put the end-user at the centre of both product and visual design processes. This

co-design process allows gradual product improvement until a final version of the tools is produced.

2 Chapter 2 - Methods

2.1 Overview of Research

Table 2: Summary of studies for proposed research project

	Study 1	Study 2	Study 3
Aim	To determine the efficacy of psychological interventions to reduce symptoms of psychological distress in children and adolescents with asthma	To understand the needs of young people with asthma and identify modifiable drivers of psychological distress	To evaluate mixed reality technologies as a delivery mechanism for CBT tools
Study Design	Systematic review	Needs assessment – narrative review	Qualitative research project

2.1 Systematic review: Psychological interventions for asthma in children and adolescents (Study 1)

These methods have been published as a protocol paper in the Cochrane Library (DOI: 10.1002/14651858.CD013420). A copy of this publication is attached in the Appendix (Chapter 7, section 3.1).

2.1.1 Method

This systematic review is being conducted with the Cochrane Airways Group, and will therefore follow the procedures outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011). Review activities that will be undertaken by the candidate as lead author are reported in Table 2.1 below.

Table 2.1: candidate's responsibilities as lead author of the review team.

Review Task
Initiation and coordination of review
Production of protocol manuscript
Responding to editorial and peer review comments and amending manuscript as required
Literature searching
Screening of search results
Organising retrieval of papers
Screening papers against eligibility criteria
Appraising quality of papers
Extracting data from papers

Data management
Entering data into RevMan software
Interpretation of data
Production of first draft of the manuscript
Responding to editorial and peer review comments and amending manuscript as required

Studies will be included that meet the following Participant, Intervention, Comparison, Outcome, and Study Design (PICOS) criteria:

Participants: both male and female children and adolescents aged between 5 and 18 years with asthma diagnosed by a physician or as per international and national guidelines will be included. Participants from both inpatient and outpatient settings will be included.

Intervention: trials which assess any psychological intervention (theoretically informed psychological strategies underpinned by clinical formulation) will be included. Studies with co-interventions (e.g. prescribed medications) will be included, provided they are not part of the randomised treatment. Treatments may include:

- Behavioural therapies
- Cognitive therapy
- Cognitive and behavioural therapy (CBT)
- Relaxation techniques
- Psychodynamic psychotherapy
- Counselling
- Group therapy
- Family therapy

Comparison: trials comparing psychological interventions with usual care, active control (e.g. self-help) or waitlist control groups will be included.

Outcome: primary outcomes include medical contacts, as measured by presentation to hospital, emergency room visits and/or GP visits; rate of asthma attack, as measured by number of children with asthma attacks (defined as an acute increase in asthma symptom severity requiring use of corticosteroids or hospital admission) during follow-up; and efficacy of intervention to reduce psychological distress, measured by change in anxiety and/or depression as per standard validated questionnaires. Secondary outcomes include self-reported asthma symptoms, medication use, self-reported quality of life as measured by validated questionnaires, and adverse events/side effects. Outcomes reported at different timepoints will be reported in the following way: less than 3 months from baseline, 3 to less than 6 months from baseline, 6 to less than 12 months from baseline, over 12 months from baseline.

Study Design: randomised controlled trials (RCTs), including cluster-randomised trials where the data has been or can be adjusted for clustering will be included. Studies will not be restricted by follow-up. Studies reported as full-text, abstract-only, and unpublished data will be included in the review.

2.1.2 Data sources

Trials will be identified from the Cochrane Airways Group's Specialised Register (CAGR), which is maintained by the Trials Search Co-ordinator for the Group. The Register contains trial reports identified through systematic searches of bibliographic databases including: CENTRAL, MEDLINE, Embase, PsycINFO, CINAHL EBSCO, AMED EBSCO, and hand-searches of the proceedings of major respiratory conferences. The US National Institutes of Health Ongoing Trials Register, and the World Health Organization International Clinical Trials Registry Platform will also be searched from inception to the present.

2.1.3 Study selection

A combination of two review authors will independently screen titles and abstracts for inclusion of all the potential studies identified as a result of the search, and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. Full-text study reports/publication of all potentially eligible studies will be retrieved, and two review authors will independently screen them for inclusion; identifying and recording reasons for exclusion of ineligible studies. Any disagreement will be resolved through discussion or, if required, consultation of a third person/review author. Duplicates will be identified and

excluded, and multiple reports of the same study will be collated so that each study, rather than report, is the unit of interest in the review. The selection process will be recorded in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table.

2.1.4 Risk of bias

A combination of two review authors will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011) according to the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other bias. Each potential source of bias will be graded as high, low or unclear, and a quote from the study report together with a justification will be provided in a 'Risk of bias' table.

2.1.5 Data extraction

A standardised data collection form will be used for study characteristics and outcome data – which has been piloted on at least one study – in the review. A combination of two review authors will extract study characteristics from included studies. The following study characteristics will be extracted: methods (study design, study location, clustering adjustments and effect, methods of analysis), participants (number, withdrawals, mean age, age range, gender, inclusion criteria and exclusion criteria, socioeconomic data, severity of condition, diagnostic criteria, symptomatology at baseline, smoking history), interventions (study setting, intervention description, comparison, concomitant pharmacotherapy, duration of intervention), outcomes (primary and secondary outcomes specified and collected, and time points reported), notes (funding for studies and notable conflicts of interest of trial authors).

2.1.6 Data analysis

Dichotomous data will be analysed as odds ratios (OR) and continuous data as the mean difference (MD) or standardised mean difference (SMD). For dichotomous outcomes, participants, rather than events, will be used as the unit of analysis (i.e. number of children admitted to hospital, rather than number of admissions per child). However, if rate ratios

are reported in a study, they will be analysed on this basis. Data presented as a scale will be entered with a consistent direction of effect.

Meta-analyses will be undertaken only where this is meaningful; that is, if the treatments, participants, and underlying clinical question are similar enough for pooling to make sense. A random-effect model will be used, and sensitivity analyses will be performed with a fixed model: excluding trials with a high risk of bias for randomisation or allocation concealment, or both; excluding unpublished/non-peer reviewed studies; excluding small trials (fewer than 20 participants in each arm); excluding trials in which the intervention is supportive rather than providing targeted psychotherapeutic input. If more than 10 studies are able to be pooled, a funnel plot will be created and examined to explore possible small study and publication biases.

Wherever multiple trial arms are reported in a single study, only the relevant arms will be included. If adjusted analyses are available (ANOVA or ANCOVA) these will be used as a preference in the meta-analyses. If both change-from-baseline and endpoint scores are available for continuous data, change-from-baseline will be used unless there is a low correlation between measurements in individuals. If a study reports outcomes at multiple timepoints, the latest recorded time point will be used. Intention-to-treat (ITT) or 'full analysis set' analyses will be used where they are reported (i.e. those where data have been imputed for participants who were randomly assigned but did not complete the study).

The I^2 statistic will be used to measure heterogeneity among the studies in each analysis. If substantial heterogeneity is identified (50% - 90%, as defined by the Cochrane handbook), this will be reported and explored by prespecified subgroup analysis.

The following subgroup analyses will be carried out: type of psychological intervention, individual vs group interventions, face-to-face vs online interventions, school age (primary (ages 5-12) vs secondary (ages 13-18)). The outcomes medical presentation, asthma attacks, and symptoms of anxiety and/or depression will be used in these analyses.

2.1.7 Assessment of quality of available evidence

A 'summary of findings' table will be created using the following outcomes at longest follow up point: medical contacts, rate of asthma attack, symptoms of anxiety and depression, asthma symptoms, medication use, and quality of life.

The five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness and publication bias) will be used to assess the quality of a body of evidence as it relates to the studies that contribute data to the meta-analyses for the prespecified outcomes. Methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins and Green, 2011) will be used, using GRADEpro software. All decisions to down- or up-grade the quality of studies using footnotes will be justified, and comments will be made to aid the reader's understanding of the review where necessary.

2.2 Needs assessment: Biopsychosocial needs of adolescents with asthma (Study 2)

2.2.1 Method

The biopsychosocial drivers of psychological distress for adolescents with asthma will be explored within the domains of the Biopsychosocial Model of Health and Wellbeing.

Authors will search databases such as Google Scholar and PubMed for literature pertaining to asthma in adolescents for each domain of the Biopsychosocial Model of Health and Wellbeing. This model provides an overview of the biological, social, and psychological domains and components that are associated with health and wellbeing; healthy environments, developmental competencies, sense of belonging, health behaviours, coping, resilience, and treatment of illness (Stallman, 2017, Stallman, 2020b). The Biopsychosocial Model of Health and Wellbeing provides a useful framework to examine the asthma-specific drivers of psychological in adolescents, facilitating understanding of which factors may be modifiable to allow for intervention and to help inform clinical care.

Review activities that will be undertaken by the candidate as lead author are reported in Table 2.2 below.

Table 2.2: responsibilities of the candidate during Study 2.

Review Task
Initiation and coordination of review
Review planning
Literature searching
Production of manuscript
Coordinating review and comments by co-authors
Responding to comments and amending manuscript as required

Formatting manuscript to suit journal requirements
Submitting manuscript to journals
Responding to editorial and peer review comments and amending manuscript as required

2.3 Qualitative project: Augmented reality technology to deliver cognitive and behavioural therapy to teenagers with asthma and heightened psychological distress (Study 3)

These methods have been published as a protocol paper in the International Journal of Qualitative Methods (DOI: 10.1177/16094069211008333). A copy of this publication is attached in the Appendix (Chapter 7, section 2.1).

Please note: since publication of the methodology below, amendments were made to the study design. Of note, one-on-one interviews were conducted in place of focus groups, and the final sample size was reduced. Upon consultation with respiratory clinicians, and in light of the evolving COVID-19 situation, one-on-one interviews with research participants were considered a safer option than focus groups; reducing the possibility of transmission of COVID-19 and other viruses between participants within this vulnerable population (young people with asthma). While fewer than originally planned, the final sample size was considered appropriate for the project timeline based on other similar qualitative studies, and a summary of "Rules of Thumb" for theoretical saturation in qualitative research. This is discussed in greater detail in Chapters 5 and 6.

2.3.1 Method

Evaluation of perceived useability and appropriateness of 3 AR tools by youth (13 to 17 years), parents/guardians of young people, and health professionals, will be explored using a qualitative research design as described below.

Table 2.3: responsibilities of the candidate during Study 3.

Project Task
Completing ethics applications for UniSA and WCHN HREC, as well as site-specific assessments for FMC and WCH, including the development of questionnaires and moderator guides
Recruitment: calling potential participants who have expressed interest in learning more about the project

Recruitment: emailing/posting information sheets and consent forms to potential participants to obtain informed consent
Scheduling focus groups (with participants, health professionals, study staff, and hospital staff for use of meeting spaces)
Moderating focus groups
Developing verbatim transcripts post-group/interview to be sent back to participants for validation
Analysing qualitative data
Communicating results of focus groups to AR development team in order to re-design tools for next focus group
Developing manuscript for publication
Dissemination of results to stakeholders
Presentation of results at conferences and community events

2.3.1.1 Development of AR tools

A CBT intervention will be created by a trained Clinical Psychologist in the research team based on a needs assessment. From this intervention, 3 CBT AR tools will be developed through an external company. The CBT intervention and AR tool development (including needs assessment) is outside the scope of this Masters thesis, and fits into a larger project, as detailed above.

2.3.1.2 Evaluation of AR tools – Qualitative research

Study design: To determine facilitators and barriers for use of each AR tool as well as evaluating perceptions of usability and appropriateness to reach target audience, qualitative research will be carried out through focus groups and one-on-one interviews.

Setting: Interviews and focus groups will take place in meeting spaces in the respiratory department at Women's and Children's Hospital (WCH), and paediatric department at Flinders Medical Centre (FMC).

Participants: Thirty-six participants will be recruited for this study from WCH and FMC, including 24 young people with asthma, and 12 parents of young people with asthma. One-on-one interviews will also be conducted with ten healthcare professionals (2 general paediatricians, 2 psychologists, 2 psychiatrists, 2 nursing staff, and 2 paediatric respiratory specialists). While a priori determination of sample size is not without limitation, this sample size is based on a variety of 'rules of thumb' from previous research in the area (Sim et al., 2018), and are similar to sample sizes used in other qualitative feasibility studies in the area (Duncan et al., 2018, Anderson et al., 2016, Rhee et al., 2014, Arden-Close et al., 2013). Based on the extensive experience of the research team, this sample size is also anticipated to be appropriate for the project timeline.

Inclusion criteria for young people:

Young people will be eligible for inclusion in this study if they: are aged between 13 and 17 years; have been formally diagnosed with asthma by a health professional (inpatients or outpatients); have experienced or are currently experiencing heightened symptoms of anxiety determined by the K10 scale (Kessler et al., 2002) (appendix 2.2); have access to a smartphone with the owner's permission to use it; are English speaking/able to understand written English.

Inclusion criteria for caregivers/parents:

Participants will be eligible for inclusion in this study if they: are the caregiver/parent of a child with asthma (aged 13 to 17 years) who currently has/or has reported in the past heightened symptoms of psychological distress (does not need to be the parent/caregiver of a child actively participating in this study); have access to a smartphone and able to use smartphone technology (basic level); are English speaking/able to understand written English.

Inclusion criteria for health professionals:

Health professionals will be eligible for inclusion in this study if they: have been practicing in their respective fields for at least 12-months; have access to a smartphone and are able

to use smartphone technology (basic level); are English speaking/able to understand written English.

Exclusion criteria:

Participants with an intellectual disability or cognitive impairment that would inhibit their ability to provide informed consent and participate in the project will be ineligible to participate.

2.3.2 Procedure

Participants will be identified through Respiratory Department inpatient and outpatient lists at the Women's and Children's Hospital and the Paediatric Department Flinders Medical Centre, retrospective screening of patient databases, via flyers and radio/television news stories advertising the project. Hospital staff will provide potential participants with a copy of the participant information sheet and consent form for their review. Participants will only be approached by research staff once written consent has been provided to say that they are willing to discuss the project more with research staff, in order to undertake informed consenting procedures and complete the K10 scale (Kessler et al., 2002) to assess level of psychological distress.

During the sessions, AR tools will be demonstrated and participants allocated time to interact with the resources themselves. Semi-structured moderator guides will be used by the candidate to direct focus groups with young people, which will be conducted separately for age ranges 13-15 and 16-17 years (4 focus groups). Two focus groups will also be conducted with parents, producing a total of 6 focus groups with approximately 6 participants in each. One-on-one interviews will occur among health professionals including 2 general paediatricians, 2 psychologists, 2 psychiatrists, 2 nursing staff and 2 paediatric respiratory specialists. One-on-one interviews will run for approximately one hour, while focus groups will run for 2.5 to 3 hours.

Focus groups and interviews will be staggered to allow for the iterative co-design process (Safourin, 1996). Following participant feedback from the first two focus groups with young people and the first focus group with parents, tools will be improved before being shown to the next set of focus groups and interview participants.

Moderator guides (appendix 2.3) used to direct dialogue will be developed based on grounded theory (Khambete, 2010, Charmaz, 2006) and 18 categories of the theoretical

domains framework (TDF) (McCullough et al., 2015). These theories have been chosen to add methodological rigour to the analysis process, and to assist the translation of evidence to policy. Qualitative interviews will be supplemented with Likert scales in a questionnaire (appendix 2.4) based on the Enlight protocol – an evaluation tool for eHealth interventions (Baumel et al., 2017). Sessions will be audio-recorded with transcripts typed verbatim and sent back to the participant for validation post interview.

2.3.3 Outcome variables

Data obtained through analysis of interview transcripts, along with data obtained from participant questionnaires, will allow researchers to evaluate acceptability of AR tools within the target population, and appropriateness of the tools to meet the objectives of the project.

2.3.4 Analysis

Qualitative data will be coded twice, once under the TDF to aid knowledge translation potential (McCullough et al., 2015), and then using line-by-line grounded theory coding, as per recommendations set out by Charmaz (Charmaz, 2006) to inform AR design decisions. Transcripts will be coded by two independent researchers in NViVo software v.12. Missing information from quantitative scales and surveys will be accounted for through random imputation.

Qualitative data gained through this study will be placed into the IM matrix, guiding further development of the tools for evaluation in future studies.

2.3.5 Ethical considerations

This project has received ethical approval by the Human Research Ethics Committee for the Women's and Children's Health Network (HREC/18/WCHN/172), and the University of South Australia Ethics Committee (Application ID: 201967).

The discussion of symptoms of psychological distress or asthma may be upsetting for some participants. Participants will be encouraged to take breaks throughout the focus groups as needed, and if further support is required a Clinical Psychologist will be available to speak with participants. If support is required, this information will be sent back to the participant's treating physician for further follow-up.

2.3.6 Resources

This project has been funded for $75,000 over two years by the Channel 7 Children's Research Foundation, as well as discretionary funds supplied by the University to support A/Prof Carson-Chahhoud's fellowship.

3 Chapter 3 – Cochrane systematic review

University of South Australia

Statement of Authorship

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This chapter is undergoing copyediting for publication in the Cochrane Library of Systematic Reviews. Additional information relevant to this chapter is attached in the Appendix (Chapter 7, section 3).

3.1 Abstract

3.1.1 Background

Rates of asthma are high in children and adolescents, and young people with asthma generally report poorer health outcomes than those without asthma. Young people with asthma experience a range of challenges which may contribute to psychological distress. This is compounded by the social, psychological and developmental challenges experienced by all people during this life stage. Psychological interventions (such as behavioural therapies, or cognitive therapies) have the potential to reduce psychological distress, which might improve behavioural outcomes such as self-efficacy and medication adherence. In turn, this may reduce medical contacts and asthma attacks.

3.1.2 Objectives

To determine the efficacy of psychological interventions in modifying health and behavioural outcomes in children with asthma, compared with usual treatment. Primary outcomes included the efficacy of the intervention to reduce psychological distress, medical contacts, and asthma attacks. Secondary outcomes included self-reported asthma symptoms, medication use, quality of life, and adverse events.

3.1.3 Search methods

The Cochrane Airways Group Specialised Register (including CENTRAL, CRS, MEDLINE, Embase, PsycINFO, CINAHL EBSCO, AMED EBSCO), proceedings of major respiratory conferences, reference lists of included studies, and online clinical databases were searched. The most recent search was conducted in August 2022.

3.1.4 Selection criteria

We have included randomised controlled trials (RCTs) comparing psychological interventions of any duration with a control in male and female children and adolescents with asthma, aged between 5 and 18 years.

3.1.5 Data collection and analysis

Following standard Cochrane methodology, a pair of review authors independently screened titles and abstracts for inclusion of all studies identified as a result of the search. We retrieved the full-text study reports/publications for all potentially eligible studies and two review authors independently screened these for inclusion, identifying and recording reasons for excluding ineligible studies. Disagreements were resolved through discussion and consensus. A pair of review authors independently extracted outcome data from included studies. We used a data collection form for study characteristics and outcome data. One review author extracted study characteristics from included studies, which was spot-checked by another author for accuracy. A pair of review authors independently assessed risk of bias for each study. We resolved disagreements by discussion and consensus.

3.1.6 Main results

This review includes 24 studies (n = 1639) published between 1978 and 2021. Eleven studies were set in the USA, five in China, two in Sweden, three in Iran, and one each in the Netherlands, UK, and Germany. Participants all had a diagnosis of asthma ranging from mild to severe. Three studies included primary-school aged participants (5 to 12 years), two were secondary-school aged (13 to 18 years), and 18 included both age groups, while one study was unclear on age ranges. Interventions ranged from three days to eight months, with only one study being conducted online as opposed to face-to-face. No studies were at low risk of bias across all domains; all were judged to be at high risk of bias in at least one domain and many judgements were unclear due to insufficient reporting.

Meta-analysis was not possible due to clinical heterogeneity in the interventions, populations, outcome tools and definitions and length of follow-up. Results were tabulated and summarized narratively with reference to direction, magnitude and certainty of effects. Evidence quality was very low for all outcomes meaning the findings are very uncertain. A lack of information about scale metrics and minimal clinically important differences for the anxiety, depression, asthma symptoms, medication use and quality of life scales used make it difficult to judge clinical significance.

Within the primary outcomes, four studies reported positive or mixed effects of psychological interventions vs controls for symptoms of anxiety (n = 327), and one found little to no difference between groups (n=152). Two studies reporting symptoms of

depression both found benefits of psychological interventions vs controls. A reduction in medical contacts was seen in three small studies (n = 92) but two larger ones found little to no difference between groups (n = 544). Two out of three studies (n = 107) reporting asthma attacks found important benefits of the intervention vs control (i.e. reduction in asthma attacks) and one small study (n = 22) found little to no difference.

Among the secondary outcomes, 11 studies (n = 720) reported asthma symptoms and most reported a positive effect of the intervention vs control on at least one measure, although some reported mixed findings (n = 257) and two found little to no difference between groups (n = 132). Eight studies (n = 670) reported a variety of medication use measures, most of which found a positive effect of the intervention vs control (n = 670) and two found little to no difference between groups (n = 131). Across six studies reporting measures of quality of life (n = 653), the largest studies found little to no difference between groups (n = 522) and where findings were positive or mixed there was evidence of selective reporting (n = 131). No studies reported data related to adverse effects.

3.1.7 Authors' conclusions

Most studies reporting symptoms of anxiety, depression, asthma attacks, asthma symptoms and medication use found a positive effect of psychological intervention vs control on at least one measure. However, some findings were mixed, it was difficult to judge clinical significance, and the evidence for all outcomes is very uncertain due to clinical heterogeneity, small sample sizes, incomplete reporting and risk of bias. There is limited evidence that psychological interventions reduce the need for medical contacts or improve quality of life, and no studies report adverse events.

It was not possible to identify components of effective interventions and distinguish these from interventions showing no evidence of an effect due to substantial heterogeneity. Future research examining evidence-based psychological techniques should consider standardising outcomes to support cross-comparison to build upon studies showing positive effects, and to meet patient and policymaker needs.

3.2 Plain language summary

Psychological interventions to help children and adolescents with asthma

3.2.1 Background

Children and adolescents with asthma are more likely to experience symptoms of psychological distress (symptoms of anxiety and/or depression) than those without asthma. Treatments involving a psychological intervention might help reduce psychological distress, and therefore improve how children and adolescents are able to manage their asthma and might improve asthma outcomes in these individuals.

3.2.2 Review question

This review aimed to determine whether psychological interventions might benefit children and adolescents with asthma.

3.2.3 Study characteristics

We included randomised controlled trials (RCTs) comparing psychological interventions (such as behavioural therapies, cognitive therapies, or counselling interventions) to control groups (e.g. standard asthma care, or no intervention) in male and female children and adolescents (aged 5 to 18 years) with asthma.

3.2.4 Key results

From the database searches, we found 24 studies meeting our inclusion criteria, involving 1639 young people. The results of these studies suggest that psychological interventions could be beneficial for children and adolescents with asthma, particularly to reduce symptoms of anxiety and/or depression, reduce asthma attacks, reduce asthma symptoms and improve medication use. However, findings for some outcomes were mixed and for most studies it was difficult to judge how important the benefits were because the assessment scales used were not well described. There is limited evidence that psychological interventions reduce the need for medical contact (such as going to hospital or visiting an urgent care centre) or improve quality of life (being an individual's perception of their position in life), and no studies report adverse events (unintended negative effects from the intervention). The evidence for all outcomes is very uncertain and difficult to interpret because the studies used different theories to develop their

interventions, different tools to measure results, different follow-up periods, and different definitions for the outcomes (for example, one study measured daytime symptoms while another measured total asthma symptoms) — this meant we were unable to make comparisons between the studies. Most studies didn't include many people and not all studies reported their results comprehensively, this made them unreliable or difficult to interpret.

3.2.5 Certainty of the evidence

We classified the evidence to be of very low quality for all outcomes. This is due to the substantial differences between studies, as well as small sample sizes, and the overall high risk of bias in the included studies.

3.2.6 Bottom line

We found mixed results for nearly all outcomes in this review — whilst many interventions demonstrated benefits, some showed no evidence of effect. More high-quality research is needed to strengthen the evidence base for using psychological interventions with children and adolescents with asthma, and to determine which types of psychological interventions might be most helpful.

Table 3.2: Summary of findings

Psychological interventions compared to control for adolescents with asthma				
Patient or population: adolescents with asthma **Setting:** Hospital, school, asthma clinic, camp, children's medical centre **Intervention:** psychological interventions **Comparison:** control				
Outcomes	**Summary of intervention effects**	**№ of participants**	**Certainty of the evidence**	**Conclusion**

		(studies)	**(GRADE)**	
Symptoms of anxiety assessed with: Validated Questionnaire follow up: range 1 to 12 months	Three studies (n = 279) report a benefit of the psychological intervention vs control, one without supporting data, one reports mixed findings (n = 48) and one found little to no difference between groups (n = 104).	431 (5 RCTs)	⨁⊖⊖⊖ VERY LOW 1 2 3	The evidence is very uncertain. Most studies report positive or mixed findings, but scales vary and have unknown MCIDs, so the magnitude and clinical significance of potentials benefits are unclear.
Symptoms of depression assessed with: Validated Questionnaire follow up: range 1 to 4 months	Both studies report a benefit of the psychological intervention vs control.	166 (2 RCTs)	⨁⊖⊖⊖ VERY LOW 1 2 3	The evidence is very uncertain. Studies report benefits on different scales with unknown MCIDs, so the magnitude and clinical significance of potentials benefits are unclear.
Medical contacts assessed as hospital admissions, ED presentations or asthma- related urgent care visits follow up: range 2.6	Three small studies (n = 92) report benefits of the psychological intervention vs control across a mixture of contact types. Two larger studies report mixed findings or little to no difference between groups (n = 544).	636 (5 RCTs)	⨁⊖⊖⊖ VERY LOW 1 2	The evidence is very uncertain. Small studies report benefits that are likely to be clinically significant and larger studies report mixed findings or no difference between groups.

months to 3.5 years				
Asthma attacks follow up: range 1 to 6 months	Two studies (n = 107) report a benefit of the psychological intervention vs control, and one (n = 22) found little to no difference between groups.	129 (3 RCTs)	⨁⊖⊖⊖ VERY LOW 1 2 3	The evidence is very uncertain. Studies report mixed findings using different definitions and measures, but positive findings are likely to be clinically significant.
Asthma symptoms assessed with: Self- report follow up: range 1 to 12 months	Four studies (n = 332) report benefits of the psychological intervention vs control, five report mixed or unclear findings (n = 257), and two report little to no difference between groups (n = 131).	720 (11 RCTs)	⨁⊖⊖⊖ VERY LOW 1 2 3	The evidence is very uncertain. Most studies report positive findings on at least one measure but on a variety of scales with unknown MCIDs meaning their clinical significance is unclear.
Medication use follow-up: range 1 month to 3.5 years	Six studies (n = 670) report benefits of the psychological intervention vs control, one without supporting data. Two studies report little to no difference between groups (n = 152).	822 (8 RCTs)	⨁⊖⊖⊖ VERY LOW 1 2 3	The evidence is very uncertain. Most findings are positive but on a variety of scales with unknown MCIDs, so the magnitude and clinical significance of potentials benefits are unclear. Some report adherence as a positive outcome and others report prescriptions or reliever use as proxy for poor control.
Quality of life	One study (n = 48) reports a benefit of the intervention vs control with limited supporting data. Two	653 (6 RCTs)	⨁⊖⊖⊖ VERY	The evidence is very uncertain. The largest studies found little to no difference between groups, and where findings were mixed there

assessed with: Validated Questionnaire follow up: range 2.6 to 7 months	studies report mixed findings (n = 83) and three studies report little to no difference between groups (n = 522).		LOW 1 2 4	was evidence of selective reporting. A variety of scales were used with unknown MCIDs, so the magnitude and clinical significance of benefits where reported are unclear.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **ED**: emergency department; **MCID**: minimal clinically important difference; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

1 Significant heterogeneity was observed across all psychological interventions, from theoretical foundations to intensity and duration of treatment, mode of delivery, setting, and intended objective. Significant heterogeneity was also observed for the outcome, with different validated tools used between studies. Some heterogeneity also existed across the populations, including asthma severity (from mild to severe) and age (downgraded for inconsistency).

2 Due to the nature of psychological interventions, they could not be blinded to participants. Outcomes are subjective, therefore subjective to bias. Inadequate reporting was observed for several of the other risk of bias outcomes, resulting in an assessment of "unclear" (downgraded for risk of bias).

3 Studies reporting this outcome had relatively small sample sizes (downgraded for imprecision).

4 Multiple tools used to assess the outcome with substantial variability, resulting in heterogeneity (downgraded for inconsistency).

3.3 Background

3.3.1 Description of the condition

Asthma is a complex and phenotypically diverse disease, characterised by chronic inflammation of the airways (GINA 2021). Though a universally-accepted definition of asthma is lacking, asthma is generally defined as “a history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time” (GINA 2021).

Asthma contributes substantially to the global burden of ill health. It is currently estimated that 262 million people worldwide experience symptoms of asthma (Lancet 2020). Countries with the highest prevalence rates include Brazil, the Netherlands, UK, Sweden, and Australia (To 2012).

Individuals with asthma may experience exacerbations of asthma symptoms or 'attacks'; these attacks can be life-threatening and, therefore, impose significant psychological burdens on patients and their communities (GINA 2021). Poor day-to-day control of asthma symptoms can also contribute to the psychological burden of having asthma (Goodwin 2013). Psychological distress can itself trigger or exacerbate symptoms of asthma (Van Lieshout 2008).

Rates of asthma are high in children and adolescents. Global prevalence rates indicate that 10.2% of children aged 6 to 7 years, and 11.3% of children aged 13 to 14 experience symptoms of asthma (ISAAC 1998b). The highest rates of asthma in these age groups were observed in the UK, Australia, New Zealand, and Republic of Ireland (ISAAC 1998a). Young people with asthma generally report poorer health outcomes than those without asthma (Blanchard 2014). A 2014 survey of Australians aged 12 to 25 years found that half of young people with asthma experienced symptoms of heightened psychological distress (the experience of symptoms of anxiety and depression at sub-clinical levels (Drapeau 2012)). This is double the rate of the wider community (Blanchard 2014); and a figure that has been increasing (Mission Australia 2017). Both poor asthma outcomes and poor mental

health outcomes disproportionately affect those from less wealthy backgrounds (AIHW 2020 Evans 2012 GINA 2021).

Children and adolescents with asthma face a range of challenges which may contribute to their increased experience of psychological distress. These may include social isolation, restricted life choices, limitations on personal potential, embarrassment and shame about their condition or treatment (or both), self-consciousness, concerns about disease exacerbation, and fear of life- threatening attacks (Blanchard 2014). These complex, interconnected issues compound the social, psychological and developmental challenges experienced during childhood and adolescence (Cohen 2003; de Benedictis 2007) and likely contributes to higher levels of functional impairment (Akinbami 2002), lower quality of life (Goldney 2003), and higher rates of preventable hospitalisation and mortality compared to people without asthma (Calmes 1998).

3.3.2 Description of the intervention

It is likely that the relationship between asthma and symptoms of psychological distress is bidirectional (Baiardini 2015). First, psychological factors and negative life events can exacerbate inflammation and symptoms of asthma (French 1943; Sandberg 2000; Van Lieshout 2008). It has been suggested that psychological distress may exacerbate the immune response to external stimuli via increased activation of endocrine pathways — the sympathetic and adrenomedullary (SAM) system and the hypothalamic-pituitary-adrenocortical (HPA) axis (Chen 2007). Long periods of exposure to stress hormones can lead to down- regulation of receptors to these molecules and dysregulation of inflammatory responses to asthma triggers. Production of Th2 cytokines and recruitment of eosinophils can be exaggerated under these conditions, promoting output of neurotransmitters which can increase inflammation (Wright 1998; Wright 2005). Second, asthma in young people is associated with increased psychological distress and clinical diagnoses of psychological disorders (Dudeney 2017; Katon 2007; Pinquart 2010). Anxiety in people with asthma can develop into chronic and excessive psychological distress (Thomas 2011). Asthma may negatively affect psychological and mental health outcomes, as individuals with asthma may experience heightened psychological distress due to the persistent fear of asthma attacks (GINA 2018).

Psychological interventions refer to theoretically informed psychological strategies underpinned by clinical formulation. Various types of interventions exist, underpinned by distinct theoretical frameworks. This review will explore the following types of

intervention: behavioural, cognitive, cognitive behavioural, relaxation, psychodynamic psychotherapy, counselling, group therapy, and family therapy. Behavioural therapies focus on identifying and changing learned behaviours, cognitive therapies identify and manage thoughts and perceptions, while cognitive behavioural therapy (CBT) incorporates aspects of both of these models.

Relaxation techniques are designed to control psychological distress, in people with asthma may improve perception of respiratory symptoms. Psychodynamic therapy, counselling, group therapy and family therapy all involve the discussion of issues with a licensed professional in group or individual formats. The current evidence assessing the efficacy of individual versus group therapy formats is generally mixed, and may differ based on which symptoms of psychological distress are experienced (Craigie 2009; Flannery-Schroeder 2000; Manassis 2002; Wierzbicki 1987). All interventions can be delivered in person, via printed self-help materials, or via the Internet. Online or technology-delivered psychological interventions (also known as e-psychology, e-health or e- mental health) have been shown to be an effective option for psychiatric care and support, which may increase access to and improve quality of care (RANZCP 2019), and can be a cost-effective treatment option for both patients and providers (Solomon 2015).

3.3.3 How the intervention might work

Children and adolescents with psychological distress might not manage their condition as well as those not experiencing psychological distress. Psychological distress may impact negatively upon self-efficacy and symptom perception and, in turn, upon medication adherence and other health behaviours, including frequency of health service utilisation. In general, individuals experiencing symptoms of anxiety or depression may over- or underused medications — both of which can result in poor asthma outcomes (Rietveld 2003). Psychological interventions may provide young people with techniques and strategies to reduce the negative impact of psychological distress upon asthma self-management and avoidance of asthma attacks (Duff 2001). These interventions might include, for example, behaviour therapy to increase adherence to treatment, cognitive therapy to address emotional reactions, relaxation techniques such as progressive muscle relaxation to reduce psychological distress, or family therapy to question and discuss familial concerns and allow for increased understanding and support by family members (Duff 2001).

Positive cognitive experiences regarding asthma — specifically self-efficacy, outcome expectations, and perceptions of barriers — are associated with better asthma control and adherence to medication in young people (Rhee 2018). Psychological interventions may also be effective in reducing asthma symptoms using some interventions described above (Kew 2016; Knapp 1978; Moore 1965).

We hypothesise that psychological interventions may be of value to children and adolescents with asthma. Psychological interventions may reduce asthma-related anxiety in turn, this may reduce psychological distress, which may improve behavioural outcomes such as self-efficacy and medication adherence, reduce inflammation, and, ultimately, reduce medical contacts and asthma attacks in children and adolescents.

3.3.4 Why it is important to do this review

Despite evidence that psychological interventions are beneficial in the treatment of psychological distress and psychological disorders, reports indicate that four out of five young people who could potentially benefit from psychological intervention are reportedly not accessing it (Bekker 2017). This systematic review aims to evaluate the effectiveness of psychological interventions as a treatment method for children and adolescents with asthma. It is intended that evidence gained from this review can address these issues and be used to inform best practice guidelines and recommendations for health professionals treating patients with asthma, and aid in efforts to increase uptake of psychological interventions in this age group.

The current review builds on a previous systematic review investigating psychological interventions for children with asthma (Yorke 2005). The main objectives of these reviews are similar; however this review will use current Cochrane methodology and included a full range of psychological interventions, including family therapy. The primary and secondary outcomes have also been amended to align with current clinical practice. This update adds a number of new studies published in the 14 years since the original review was conducted, and provides a comprehensive overview of the evidence base using methods for synthesis without meta-analysis.

3.4 Objectives

3.4.1 Main objectives

To determine the efficacy of psychological interventions in modifying health and behavioural outcomes in children with asthma, compared with usual treatment.

3.4.2 Secondary objectives

To compare efficacy of different types of psychological interventions for children with asthma.

To assess the comparative efficacy of individual and group formats of psychological therapy for children with asthma.

3.5 Methods

3.5.1 Criteria for considering studies for this review

Types of studies

We have included randomised controlled trials (RCTs), including cluster-randomised trials where the data has been or can be adjusted for clustering. We have included studies reported as full text, abstract only, and unpublished data. We did not restrict studies by duration of follow-up.

Types of participants

We have included studies involving male and female children and adolescents aged between 5 and 18 years with asthma diagnosed by a physician or according to international or national guidelines, irrespective of psychological symptoms at baseline, from both inpatient and outpatient settings.

Types of interventions

We have included trials which assess all psychological interventions of any duration compared with a control. Psychological interventions must have been created or delivered by a qualified professional, and may include in-person or online formats. We have included studies with co-interventions (e.g. prescribed medications), provided they are not part of the randomised treatment. Treatments may include the following.

1. Behavioural therapies: concerned with identifying the processes by which behaviour has been learned via association, reward or observation and modifying behaviour using methods such as systematic desensitisation, selective reinforcement and positive modelling. The behaviour itself, rather than the underlying motivations, is the focus of behavioural interventions.

2. Cognitive therapy: identification and constructive management of damaging thoughts, such as perceptions of helplessness or disproportionate fear of asthma attack that can trigger respiratory symptoms and/or asthma symptoms.

3. Cognitive behavioural therapy (CBT): incorporating the key elements of both behavioural and cognitive models.

4. Relaxation techniques: designed to control stress and anxiety which, in asthma, may improve breathing and respiratory function. The following approaches are used:

    a. Progressive relaxation: systematically creating tension and release in different parts of the body and/or via guided imagery.

    b. Autogenic training: focuses on attending to bodily feelings and mentally controlling them.

    c. Hypnosis: deep relaxation that may be induced using mental imagery, often accompanied by autosuggestion to create positive thoughts and feelings.

    d. Biofeedback: feedback of biological indicators which the subject must control via relaxation. May also be considered a behavioural intervention since the feedback can act as a reinforcer.

5. Psychodynamic psychotherapy: including psychoanalysis, psychosomatic therapy, and hypnosis.

6. Counselling: involves talking over problems with a health professional. In supportive counselling, the counsellor aims to be a good listener and

provide emotional support, rather than offering a more targeted psychotherapeutic intervention.

7. Group therapy: psychotherapeutic interventions conducted in groups (e.g. group psychosomatic therapy).

8. Family therapy: works to change the relationships within families to help them better deal with a wide range of problems.

We have included trials comparing psychological interventions with usual care, active control (e.g. self-help) or wait-list control groups.

We have excluded treatments involving educational approaches, and breathing re-training techniques. These treatments have been independently reviewed previously (Haby 2001; Wolf 2003).

Types of outcome measures

The main objective will be explored through the following primary and secondary outcomes. Had meta-analysis been possible, we would have explored the secondary objective(s) through subgroup analysis.

Primary outcomes

1. Primary efficacy of intervention to reduce psychological distress: change in anxiety or depression (or both), as measured by standard validated questionnaires (e.g. the State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Kessler Psychological Distress Scale (K10)).

2. Medical contacts, as measured by hospital admission, emergency room or GP presentation, singly or in combination.

3. Asthma attacks, as measured by number of children with one or more asthma attack (defined as an acute increase in asthma symptom severity requiring use of corticosteroids or hospital admission) during follow-up, or rate of asthma attacks.

Secondary outcomes

1. Self-reported asthma symptoms (e.g. asthma symptom scale such as Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ)).
2. Medication use (e.g. frequency of use, dosage). Use of preventer inhalers. Use of reliever inhalers.
3. Self-reported quality of life as measured by validated questionnaires (e.g. Paediatric Asthma Quality of Life Questionnaire (PAQLQ)).
4. Adverse events/side effects.

We would have grouped outcomes reported at different time points in the following way: less than 3 months from baseline; 3 months to less than 6 months from baseline; 6 months to less than 12 months from baseline; and 12 months and over from baseline.

Reporting one or more of the outcomes listed here in the study was not an inclusion criterion for the review.

3.5.2 Search methods for identification of studies

Electronic searches

We identified trials from from searches of the following databases and trial registries:

1. Cochrane Airways Trials Register (Cochrane Airways 2019), via the Cochrane Register of Studies, all years to August 2022;
2. Cochrane Central Register of Controlled Trials (CENTRAL), Issue 1 of 12 2021, via the Cochrane Register of Studies, all years to August 2022;
3. MEDLINE Ovid SP (ALL) 1946 to August 2022;
4. Embase Ovid SP 1974 to August 2022;
5. PsycINFO Ovid SP from 1967 to August 2022;
6. US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov) all years to August 2022;
7. World Health Organisation International Clinical Trials Registry Platform (apps.who.int/trialsearch) all years to August 2022.

Search strategies for each source are detailed in Appendix 3.1. The search strategies were developed and conducted by the Cochrane Airways Information Specialist in collaboration with the authors.

We searched all sources all databases and trials registries from their inception to August 2022 with no restriction on language or type of publication. Hand-searched conference abstracts and grey literature were identified through the Cochrane Airways Trials Register and the CENTRAL database.

Searching other resources

We checked reference lists of all included studies and review articles for additional references, and conducted a search of the World Health Organisation International Clinical Trials Registry Platform and the US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov).

We searched for errata or retractions from included studies published in full text on PubMed, to August 2022.

3.5.3 Data collection and analysis

Selection of studies

We used Cochrane's 'Screen4Me' workflow to help assess the results of our search for RCTs. Screen4Me comprises three components: known assessments — a service that matches records in the search results to records that have already been screened in Cochrane Crowd and have been labelled as 'RCT' or as 'Not an RCT'; the RCT classifier — a machine-learning model that distinguishes RCTs from non-RCTs (Marshall 2018); and if appropriate, Cochrane Crowd — Cochrane's citizen science platform where 'the crowd' help to identify and describe health evidence (Noel-Storr 2020).

Following use of the Screen4Me workflow, a pair of review authors independently screened titles and abstracts for inclusion of all the potential studies identified as a result of the search. These were coded as 'Yes' (eligible or potentially eligible/unclear) or 'No' using Covidence software (Covidence 2021). We retrieved the full-text study reports/publication of all potentially eligible studies and two review authors independently screened them for inclusion, identifying and recording reasons for exclusion of ineligible studies. Disagreements were resolved through discussion and consensus. Duplicates were identified through Covidence, and we collated multiple reports of the same study so that

each study, rather than report, is the unit of interest in the review. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table (Moher 2009).

Data extraction and management

We used a data collection form for study characteristics and outcome data — which has been piloted on at least one study. One review author (KJS) extracted study characteristics from included studies, which was spot-checked by another author (OS, SC-A, KVCC, KK or KP), for accuracy. We extracted the following study characteristics.

1. Methods: study design, study location, clustering adjustments and effect, methods of analysis.
2. Participants: number, withdrawals, mean age, age range, gender, inclusion criteria and exclusion criteria, socioeconomic data, severity of condition, diagnostic criteria, psychological symptomatology at baseline, smoking history.
3. Interventions: study setting, intervention description, comparison, concomitant pharmacotherapy, duration of intervention.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: funding for studies and notable conflicts of interest of trial authors.

A pair of review authors independently extracted outcome data from included studies. We have noted in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We resolved disagreements by discussion and consensus. One review author (KJS) transferred data into the Review Manager 5 file (Review Manager 2014). We double-checked that data were entered correctly by comparing the data presented in the systematic review with the study reports.

Assessment of risk of bias in included studies

A pair of review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved disagreements by discussion. We assessed the risk of bias according to the following domains.

1. Random sequence generation
2. Allocation concealment
3. Blinding of participants and personnel
4. Blinding of outcome assessment
5. Incomplete outcome data
6. Selective outcome reporting
7. Other bias

We graded each potential source of bias as high, low or unclear and provided a quote from the study report together with a justification for the judgement in the 'Risk of bias' table. We have summarised the risk of bias judgements across different studies for each of the domains listed. Where information on risk of bias relates to unpublished data or correspondence with a trialist, this is noted in the 'Risk of bias' table.

When considering treatment effects, we have taken into account the risk of bias for the studies that contribute to that outcome.

Assessment of bias in conducting the systematic review

We have conducted the review according to the published protocol (Sharrad 2019) and have reported any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We planned to analyse dichotomous data as odds ratios (OR) and continuous data as the mean difference (MD). Where appropriate, we planned to use standardised mean difference (SMD) to pool results from various assessment scales. We planned to

enter data presented as a scale with a consistent direction of effect.

However, we were unable to undertake meta-analysis, as treatments, participants and underlying clinical questions were not similar enough for pooling to make sense.

We have narratively described skewed data reported as medians and interquartile ranges.

Where multiple trial arms were reported in a single study, we have included only the relevant arms. If two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) are combined in the same meta-analysis, we planned to either combine the active arms, or halve the control group to avoid double-counting.

If adjusted analyses are available (ANOVA or ANCOVA) these would have been used as a preference in the meta-analyses. Where both change-from-baseline and endpoint scores were available for continuous data, we planned to use change-from-baseline unless there was low correlation between measurements in individuals. If a study reports outcomes at multiple time points, we planned to use the latest recorded time point.

Intention-to-treat (ITT) or 'full analysis set' analyses has been extracted where they are reported (i.e. those where data have been imputed for participants who were randomly assigned but did not complete the study) instead of completer or per protocol analyses.

Unit of analysis issues

For dichotomous outcomes we planned to use participants, rather than events, as the unit of analysis (i.e. number of children admitted to hospital, rather than number of admissions per child). However, if rate ratios were reported in a study, we planned to analyse them on this basis.

Dealing with missing data

We have contacted investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). If we had undertaken meta-analysis, and if the missing data were thought to introduce serious bias, we would have explored the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Assessment of heterogeneity

We planned to use the I^2 statistic to measure heterogeneity among the studies in each analysis. If substantial heterogeneity was identified, this would have been reported and possible causes have been explored through prespecified subgroup analysis.

Furthermore, to aid interpretation of the pooled estimates, a summary table has been included, which outlines the key features of the included studies to allow easy comparison

between trials contributing data to the review. We have explored possible clinical heterogeneity narratively in the discussion.

Assessment of reporting biases

We were unable to assess reporting bias, as we were not able to pool 10 or more studies. Had there been 10 or more studies, we would have created and examined a funnel plot to explore possible small-study and publication biases.

Data synthesis

We planned to use a random-effects model.

Subgroup analysis and investigation of heterogeneity

No subgroup analyses were conducted due to meta-analysis not being possible. Had we been able to pool the results, we would have conducted the following subgroup analyses:

1. Type of psychological interventions (e.g. behavioural intervention, cognitive behavioural therapy, psychodynamic therapy, etc.).
2. Individual vs group interventions.
3. Face-to-face vs online interventions.
4. School age (primary (ages 5 to 12) vs secondary (ages 13 to 18)).

The following outcomes would have been used in subgroup analyses.

1. Primary efficacy of intervention to reduce psychological distress: change in anxiety and/or depression, as measured by standard validated questionnaires (e.g. the State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Kessler Psychological Distress Scale (K10)).
2. Medical contacts, as measured by presentation to hospital, emergency room visits, GP visits, alone or in combination.
3. Asthma attacks, as measured by number of children with one or more asthma attack (defined as an acute increase in asthma symptom severity requiring use of corticosteroids or hospital admission) during follow-up, or rate of asthma attacks.

We would have used the formal test for subgroup interactions in Review Manager 5 (Review Manager 2014).

Sensitivity analysis

No sensitivity analyses were conducted. Had we been able to pool the results, we planned to conduct the following sensitivity analyses:

1. Exclusion of trials with high risk of bias for randomisation, or allocation concealment, or both.
2. Exclusion of unpublished data/non-peer reviewed studies.
3. Investigation of the potential influence of study size on effect size, by removing small trials (those with fewer than 20 participants in each arm) in a sensitivity analysis (Fisher 2018).
4. Exclusion of trials in which the intervention is supportive rather than providing targeted psychotherapeutic input.

The results from a fixed-effect model would have been compared with the random-effects model.

Summary of findings and assessment of the certainty of the evidence

We created a 'Summary of findings' table (Table 3.2) using the following outcomes at longest follow-up point (maximum 1-year post-treatment): medical contacts, rate of asthma attack, symptoms of anxiety and depression, asthma symptoms, medication use, and quality of life. We have used the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of a body of evidence as it relates to the studies that contribute data to the meta-analyses for the prespecified outcomes. We used methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) using GRADEpro software (GRADEpro GDT). We justified all decisions to down- or up-grade the quality of studies using footnotes, and we made comments to aid the reader's understanding of the review where necessary.

3.6 Results

3.6.1 Description of studies

See Characteristics of included studies (Appendix 3.3) and Characteristics of excluded studies (Appendix 3.4)

3.6.2 Results of the search

From the database searches in 2019, 2020, 2021 and 2022, we identified a total of 9732 records after duplicates were removed. One additional reference was identified through other sources. We used Cochrane's Screen4Me workflow to help identify potential reports of randomised trials: 277 records were excluded by Cochrane Crowd Known Assessments, 2363 records were excluded by the Cochrane RCT Classifier, leaving 7092 records for manual screening. Of these, 308 additional duplicates were identified and 6574 records were excluded based on titles and abstracts. Full texts for 211 relevant references were assessed for further inclusion. We included 34 references, regarding 24 studies. We also identified three ongoing studies (ACTRN12621001282875, NCT01445015 2011, NTR6540 2017), and one study is listed as awaiting confirmation because we could not verify the age of the population (Higgins 2022). One was a conference abstract (Khoshnavay Fomani 2013). See Figure 1 for additional study flow details.

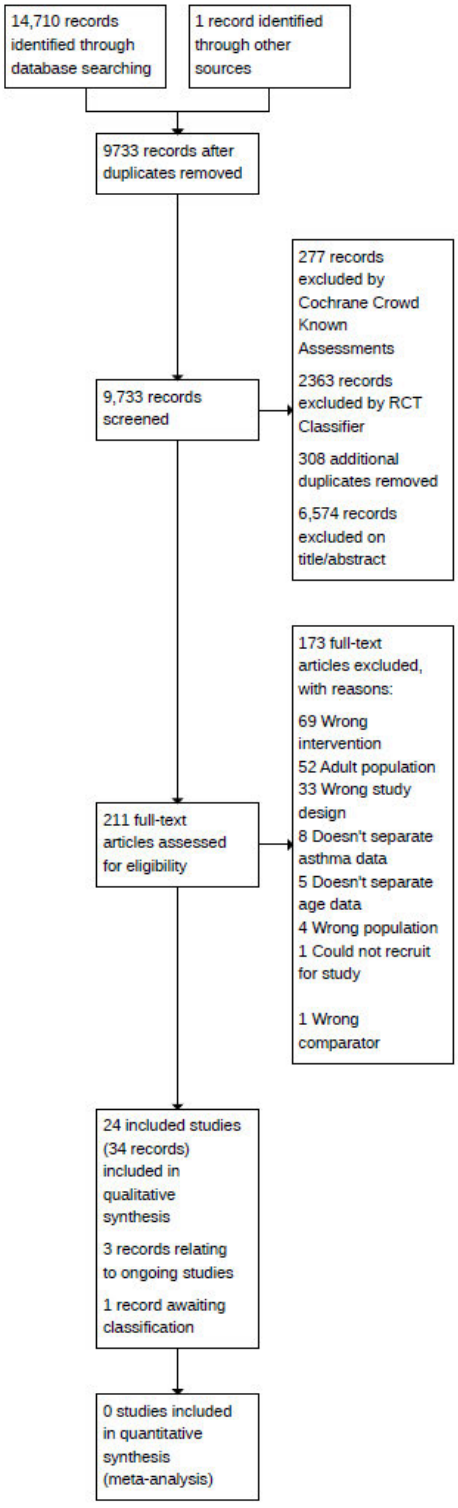


Figure 1: study flow diagram

We report information about ongoing studies in the Characteristics of ongoing studies table, and we list reasons for the exclusion of studies in the Characteristics of excluded studies table (Appendix section 3).

3.6.2.1 Included studies

Details of the 24 included and completed studies are reported in the Characteristics of included studies tables (Appendix section 3).

Study design and settings

All included studies were published between 1978 and 2021. Eleven studies were set in the USA (Alexander 1972, Beebe 2010, Bruzzese 2008, Bruzzese 2020, Halterman 2021, Hock 1978, Kohen 1996, Marsland 2019, Naar 2018, Pulgaron 2010, Warner 2006), five in China (Chiang 2009, Tong 2002, Tseng 2020, Wang 2012, Yang 2004), two in Sweden (Dahl 1990, Gustafsson 1986), three in Iran (Barikani 2021, Khoshnavay Fomani 2013, Taheri 2019), and one each in the Netherlands (Colland 1993), UK (Lask 1979), and Germany (Loew 1996). Participants were recruited from hospitals (n=10), schools (n=6), asthma clinics (n=5), children's medical centre (n=1), camp (n=1). The remaining study setting was unclear.

Participant characteristics

There was a total of n=1,639 participants included in the analyses across the 24 studies. We included only studies with participants aged 5-18 years; in the included studies, three included primary-school aged participants (5-12 years) (Colland 1993, Khoshnavay Fomani 2013, Kohen 1996), two were secondary-school aged (13-18 years) (Bruzzese 2020, Halterman 2021), and 18 included participants across both age groups (Alexander 1972, Barikani 2021, Beebe 2010, Bruzzese 2008, Chiang 2009, Gustafsson 1986, Hock 1978, Lask 1979, Loew 1996, Marsland 2019, Naar 2018, Pulgaron 2010, Taheri 2019, Tong 2002, Tseng 2020, Wang 2012, Warner 2006, Yang 2004). One study did not provide clear data on age range (Dahl 1990). All studies with data on gender included both male and female participants, except Hock 1978 who included only males. The majority of studies included more males than females, though Bruzzese 2020 and Warner 2006 included more female participants. Asthma diagnoses of included participants ranged from mild to severe.

Intervention characteristics

Intervention lengths ranged in length from three days to eight months, with only one study (Bruzzese 2020) being conducted online as opposed to face-to-face. One study (Khoshnavay Fomani 2013) did not provide clear data on intervention format. Seven

studies (Alexander 1972, Chiang 2009, Hock 1978, Kohen 1996, Loew 1996, Tong 2002, Yang 2004) utilised a relaxation intervention, three (Bruzzese 2008, Gustafsson 1986, Lask 1979) involved family therapy, three (Colland 1993, Dahl 1990, Khoshnavay Fomani 2013) involved a type of behavioural therapy, two (Bruzzese 2020, Naar 2018) utilised multi-component interventions, three utilised motivational interviewing (Barikani 2021 Halterman 2021, Taheri 2019), and one study each utilised art therapy (Beebe 2010), counselling (Wang 2012), a problem-solving intervention (Pulgaron 2010), a self-management intervention based on psychological theory (Tseng 2020), a stress-management intervention (Marsland 2019), and written disclosure (Warner 2006).

3.6.2.2 Excluded studies

We excluded 173 records from the updated reference list following full-text assessment against eligibility criteria (see Characteristics of excluded studies table). The most common reason for study exclusion was wrong intervention (n = 69 studies), followed by adult population (n = 52), wrong study design (n = 33), doesn't separate asthma data (from other conditions) (n = 8), and doesn't separate age data (from ineligible age groups) (n = 5).

3.6.2.3 Risk of bias in included studies

Of the 24 included studies, we judged none to be at low risk of bias across all domains, and all to be at high risk of bias in at least one domain. Many studies did not provide sufficient information to assess the risk of bias, resulting in many “unclear” judgements across domains. 'Risk of bias' judgements are summarised in Figure 2 and Figure 3 below. Full details of our 'Risk of bias' judgements can be found in the Characteristics of included studies table (Appendix 3.3). Risk of bias was judged by two independent review authors, and consensus was reached for all assessments.

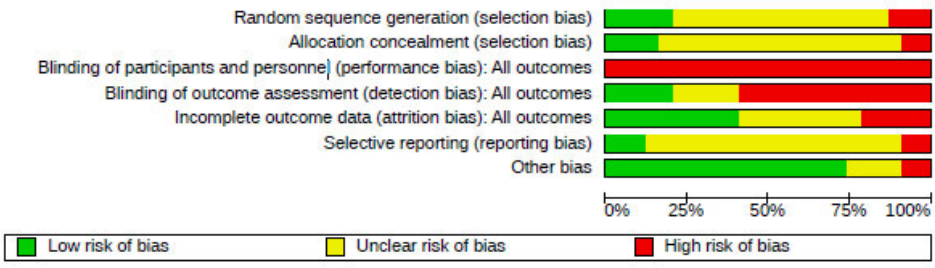


Figure 2: risk of bias graph.

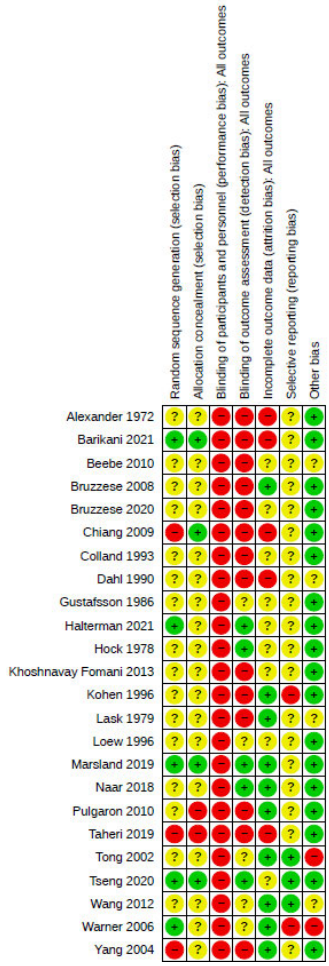


Figure 3: risk of bias summary

Allocation

We assessed three studies (Chiang 2009, Taheri 2019, Yang 2004) as high risk for inadequate random sequence generation, five studies as low risk (Barikani 2021, Halterman 2021, Marsland 2019, Tseng 2020, Warner 2006), and the remaining unclear (Alexander 1972, Beebe 2010, Bruzzese 2008, Bruzzese 2020, Colland 1993, Dahl 1990, Gustafsson 1986, Hock 1978, Khoshnavay Fomani 2013, Kohen 1996, Lask 1979, Loew 1996, Naar 2018, Pulgaron 2010, Tong 2002, Wang 2012).

Similarly, two studies (Pulgaron 2010, Taheri 2019) were determined to be at high risk of bias for inadequate allocation concealment, four studies (Barikani 2021, Chiang 2009, Marsland 2019, Tseng 2020) as low risk, and 17 studies (Alexander 1972, Beebe 2010, Bruzzese 2008, Bruzzese 2020, Colland 1993, Dahl 1990, Gustafsson 1986, Halterman 2021, Hock 1978, Khoshnavay Fomani 2013, Kohen 1996, Lask 1979, Loew 1996, Naar 2018, Tong 2002, Wang 2012, Warner 2006, Yang 2004) were determined to be unclear risk.

Blinding

Study authors made the decision to assess all studies with insufficient information about blinding of participants (performance bias) as high risk of bias. As such, all 24 studies were determined to be at high risk of bias for this domain.

Fourteen studies (Alexander 1972, Barikani 2021, Beebe 2010, Bruzzese 2008, Bruzzese 2020, Chiang 2009, Colland 1993, Dahl 1990, Khoshnavay Fomani 2013, Kohen 1996, Lask 1979, Pulgaron 2010, Taheri 2019, Yang 2004) were deemed to be at high risk of detection bias, five (Halterman 2021, Hock 1978, Marsland 2019, Naar 2018, Tseng 2020) were determined to be low risk, and five were unclear (Gustafsson 1986, Loew 1996, Tong 2002, Wang 2012, Warner 2006).

Incomplete outcome data

Five studies (Alexander 1972, Barikani 2021, Chiang 2009, Dahl 1990, Taheri 2019) were determined to be at high risk of attrition bias. Ten studies (Bruzzese 2008, Kohen 1996, Lask 1979, Marsland 2019, Naar 2018, Pulgaron 2010, Tong 2002, Wang 2012, Warner 2006, Yang 2004) were assessed as low risk of bias, and the remaining nine studies (Beebe 2010, Bruzzese 2020, Colland 1993, Gustafsson 1986, Halterman 2021, Hock 1978, Khoshnavay Fomani 2013, Loew 1996, Tseng 2020) were assessed to be unclear.

Selective reporting

We assessed two studies (Kohen 1996, Warner 2006) to be at high risk of reporting bias, three studies (Tong 2002, Tseng 2020, Wang 2012) to be at low risk of bias, and the remaining 19 studies (Alexander 1972, Barikani 2021, Beebe 2010, Bruzzese 2008, Bruzzese 2020, Chiang 2009, Colland 1993, Dahl 1990, Gustafsson 1986, Halterman 2021, Hock 1978, Khoshnavay Fomani 2013, Lask 1979, Loew 1996, Marsland 2019, Naar 2018, Pulgaron 2010, Taheri 2019, Yang 2004) to be at unclear risk of bias.

Other potential sources of bias

Eighteen studies (Alexander 1972, Barikani 2021 Bruzzese 2008, Bruzzese 2020, Chiang 2009, Colland 1993, Gustafsson 1986, Halterman 2021, Hock 1978, Khoshnavay Fomani 2013, Kohen 1996, Loew 1996, Marsland 2019, Naar 2018, Pulgaron 2010, Taheri 2019, Tseng 2020, Yang 2004) were determined to be at low risk, as no other potential sources of biases were identified by review authors. Two studies (Tong 2002, Warner 2006) were considered to be at high risk of bias, while four studies (Beebe 2010, Dahl 1990, Lask

1979,, Wang 2012) were determined to be at unclear risk of bias, due to reasons such as baseline demographics and differences not being reported, baseline differences in outcome variables which may or may not have been considered in the analysis, and small case numbers.

3.6.3 Effects of interventions

See: Summary of findings (Table 3.2) and Summary of direction of effect of included studies (Appendix 3.5).

3.6.3.1 Primary outcomes

Meta-analysis for all primary and secondary outcomes was not possible due to clinical heterogeneity in the interventions, populations, outcome tools and definitions and length of follow-up.

Anxiety as measured by standard validated questionnaire

Five studies including 431 participants (Beebe 2010, Chiang 2009, Colland 1993, Marsland 2019, Yang 2004) used validated tools to measure symptoms of anxiety (Beck's Youth Inventory (BYI), Chinese Children's Manifest Anxiety Scale (CCMAS), Screen for Child Anxiety-Related Emotion Disorder, State-Trait Anxiety Inventory for Children), one of which also used a tool focussed on symptoms of stress (Perceived Stress Scale; Marsland 2019). Numerical data for individual studies along with follow-up duration, scale metrics (where known) and a brief narrative interpretation are summarised in Analysis 1.1 and are described below.

Three studies (n = 279) report a benefit of the psychological intervention vs control (Beebe 2010; Colland 1993; Yang 2004), one without supporting data (Colland 1993), and one other reports mixed findings (Chiang 2009); one study (n = 104) found little to no difference between groups (Marsland 2019). No data could be identified for the minimal clinically important difference for the scales used, so the magnitude and clinical significance of potentials benefits are unclear. These results should be interpreted with caution, as the wide confidence intervals, large standard deviations, and small standard errors (where reported) suggest uncertainty in the reported findings. Overall, the evidence was downgraded to very low for inconsistency, risk of bias and imprecision and is therefore considered very low quality.

Beebe 2010 found a statistically significant difference in favour of the art therapy intervention, with lower anxiety scores on the BYI for this group (mean -14, SD 14.304) compared with control (mean 0.545, SD 19.387) at 6 months follow-up (p = 0.030). Chiang 2009 identified that total anxiety and general tendency to anxiety changed more in the relaxation group than in the control group over time (β= 9.21, SE = 4.05, p=0.027, CI: 1.11, 17.32) using the CCMAS (β = 5.96, SE = 2.51, p=0.012, CI: 1.34, 10.59) (mean change in score -5.62 compared to 2.25 and -3.97 compared to 1.03, respectively), but non-statistically significant results were selectively reported. Colland 1993 collected data at three time points. At the first follow-up immediately following the behavioural self-management intervention, they identified a statistically significant reduction in trait-anxiety, and a statistically significant reduction in asthma-specific anxiety. At the second follow-up, 6 months later, trait anxiety levels no longer differed significantly between the intervention and control groups, however asthma-specific anxiety was significantly reduced in the intervention group, only for extremely anxious children. At the final follow-up, 1 year later, participants in the intervention group reported clinically significant reductions in anxiety during an asthma attack, compared with controls. No statistically significant difference was identified in Marsland 2019 for scores on the Perceived Stress Scale (1.24 points lower for intervention participants, p=0.43, SE=1.55), and no difference in state or trait anxiety scores was observed between groups. Finally, Yang 2004 identified a statistically significant difference between the intervention and control groups, with anxiety scores (mean=18.27, SD=6.95 vs mean=23.21, SD=7.26) significantly decreasing after receiving relaxation therapy.

However, this data could not be meta-analysed. For the three included studies with numerical data on anxiety (Beebe 2010, Chiang 2009, Yang 2004), all used different tools. Although all tools were in the same direction, one used change scores, while two used absolute values. We have not pooled results because data is skewed for Chiang (i.e. SD > half the mean), and we cannot pool the remaining two studies as follow-ups are too varied (6 months vs 4 weeks).

Depression as measured by standard validated questionnaire

Two studies including 166 participants (Marsland 2019, Yang 2004) used a validated tool to measure symptoms of depression (Child Depression Index, Depression Self-Rating Scale for Children). Both report a benefit in favour of the psychological intervention vs control. However, no data could be identified for the minimal clinically important

difference for the scales used, so the magnitude and clinical significance of potentials benefits are unclear. Numerical data for individual studies along with follow-up duration, scale metrics (where known) and a brief narrative interpretation are summarised in Analysis 1.2 and are described below.

In Marsland 2019, a statistically significant difference in symptoms of depression was observed in participants receiving the stress management intervention when compared with control (scoring 2.68 points lower than control, p=0.02, SE=1.29). Yang 2004 also identified a statistically significant difference between the intervention and control groups, with scores depression scores (mean=8.62, SD=3.95 vs mean=12.97, SD=4.69) significantly decreasing after receiving relaxation therapy.

Medical contacts, as measured by hospital admissions, emergency room or GP presentations, singly or in combination

Five studies involving 636 participants reported outcomes of medical contacts, including hospital admissions, or presentation to emergency room and General Practitioner. Results were mixed in the two studies, Naar 2018 (hospitalisations were statistically significantly different, while ED visits were not) and Halterman 2021 (no significant differences), making up the majority of this outcome's population with n=544 participants. The remaining three studies range in size from n=13 to n=61 participants. Whilst four of the five studies identified improvements within the intervention arms to reduce hospitalisation or emergency room visits, when compared to control, the evidence was very uncertain. No studies reported outcomes for General Practitioner visits. Numerical data for individual studies along with follow-up duration, outcome definitions used within the studies, and a brief narrative interpretation are summarised in Analysis 1.3 and are described below. It was not possible to conduct meta-analysis because of heterogeneity of interventions and outcomes and the evidence is considered very low quality due to inconsistency, risk of bias and imprecision.

In the Bruzzese 2020 study, a 69% lower risk of having at least one asthma-related urgent care visit within the past three-months was observed in the Controlling Asthma Program for Adolescents (CAMP Air) e-health intervention when compared to control. A statistically significant difference between groups was also observed at one-month follow-up with 12% of the CAMP Air population requiring an asthma-related urgent care visit compared with 41% in the control arm (adjusted mean difference 0.31; 95%CI 0.10 to 0.99; p=0.04). An evaluation of hospitalisation data 12-months post intervention in the

Naar 2018 study identified that the Multisystemic Therapy - Health Care group had a lower frequency of hospitalisations compared with the in-home family support comparison group (β=-0.882; p=0.04; incidence rate ratio=0.414; 95% CI 0.175 to 0.978). After adjusting for pre-baseline differences and covariates, the mean number of hospitalisations of 0.87 at baseline dropped to 0.24 by 12-months in the Multisystemic Therapy

— Health Care group, with smaller declines observed in the control group with 0.66 at baseline and 0.34 post-baseline. No significant differences was observed between groups for emergency department visits (β=-0.153; p=0.63). The Gustafsson 1986 study, which followed up n=18 children over three and a half years, found a reduction in emergency hospitalisation days per year from 2.67 to 0.17 days per year, after family therapy relative to before therapy (p=0.06). No improvement was observed in the control arm. In the three arm study by Halterman 2021, (total n=377) no differences between any of the groups were observed for emergency visits or hospitalisations. By seven-month follow-up the number of participants with more than or equal to one emergency department presentation, urgent care visit or hospitalisation was n=17 (12%) in the SB-ACT group, n=22 (16%) in the DOT group and n=15 (11%) in the asthma education (control) group (p=0.672). The four-arm Kohen 1996 study (n=28) identified fewer emergency room visits in the experimental relaxation/mental imagery self-hypnosis group compared to traditional control group (Chi-squared of 3.90; p<0.05). Other groups, including the walking suggestion group and attention-placebo control group showed no significant difference in emergency room visits when compared to traditional (no attention) control. However, due to the small number of participants in this study, the positive results observed need to be interpreted with caution.

Asthma attacks

Three studies reported asthma attacks/exacerbations (Beebe 2010, Hock 1978, Yang 2004), including a total of 129 participants. Data on asthma attacks were collected via medical charts/nursing records, parental report, or follow-up phone call from doctors. Two studies (Hock 1978; Yang 2004) report benefit in favour of the intervention compared with control and one small study (Beebe 2010) found little to no difference between groups. Numerical data for individual studies along with follow-up duration, outcome definitions used within the studies, and a brief narrative interpretation are summarised in Analysis 1.4, and are described below.

Overall the evidence was again considered very low quality due to inconsistency, risk of bias and imprecision, and heterogeneity of interventions and outcome periods prevented meta-analysis.

In Beebe 2010, three children in the art therapy group (3/22) and four in the control group (4/22) experienced asthma attacks requiring medical contact during the six months prior to participating in the study. In the six months following the study, two children in each group experienced an asthma attack. Hock 1978 found that Relaxation Training (RT) significantly reduced rate of asthma attack when compared with control. Additionally, when combined with Assertiveness Training (AT), the combined treatment significantly reduced asthma attacks compared to all other groups (RT alone or control). Yang 2004 also reported a reduced rate of asthma attack in relaxation intervention participants compared with control. 61.3% of intervention participants reported more than one asthma attack at follow-up, compared with 90.9% of control participants.

3.6.3.2 Secondary outcomes

Self-reported asthma symptoms

Eleven studies reported asthma symptoms, including 720 participants. The evidence is very uncertain about an effects on of psychological interventions on self reported asthma symptoms. Meta-analysis was not possible since the definition of asthma symptoms used varied between studies (i.e. day symptoms, night symptoms, wheeze, total symptoms), along with the tools used to measure asthma symptoms, and the recall period (i.e. symptoms in last two weeks vs last week vs daily symptom diary). Five studies used a type of self-report or asthma symptom diary, four used validated tests (Asthma Sum Scale, Asthma Control Test, Children's Health Survey for Asthma, Asthma Control Questionnaire), one used a “standard measure of asthma symptom severity” which was not described, and one used an asthma symptoms checklist.

Four of the studies (n = 332) report consistent benefits of the psychological intervention vs control, five report mixed or unclear findings (n = 257), and two report little to no difference between groups (n = 131). Most studies reported statistically significant differences between intervention and control groups for at least one measure (for example, a statistically significant difference for night symptoms, but not day symptoms), but on a variety of scales with unknown MCIDs meaning their clinical significance is unclear. Numerical data for individual studies along with follow-up duration, scale metrics (where

known) and a brief narrative interpretation are summarised in Analysis 1.5, and results are described below.

Bruzzese 2008 found that intervention participants reported a 67% reduction in the number of nights awakened by asthma symptoms in the past two weeks (from mean 2.0 (SD 1.3) nights to mean 0.7 (SD 1.8) nights), compared with a 19% increase in the control group (from mean 1.75 (SD 2.8) nights to mean 2.1 (SD 4.1) nights) at two months post-intervention. No significant effect was observed for daytime symptoms. Similarly, Bruzzese 2020 found that intervention participants had significantly lowered incidence of night waking in the prior two weeks compared with control (adjusted MD 0.36, 95%CI 0.22 to 0.61, p=0.0002), while no significant effect was observed for daytime symptoms (adjusted MD 0.86, 95%CI 0.64 to 1.14, p=0.29). Chiang 2009 reported that asthma symptoms were reduced from 9.46 to 6.93 in the experimental group and 10.44 to 7.24 in the control group. While an improvement was observed in both groups over time, there was no significant between-group difference over time (β=-0.70, SE=0.77, p=0.369, CI: -2.24, 0.84). In Dahl 1990, daily charts kept by both children and parents reported a 50% reduction in subjective asthma symptoms in the intervention group. Diary cards utilised by Lask 1979 demonstrated a statistically significant improvement in asthma symptom score in favour of the intervention group (mean 7, SD 8 vs mean 21, SD 11, P < 0.01). Marsland 2019 utilised two intervention groups which both reported significantly fewer symptoms over the past two weeks on the Children's Health Survey for Asthma (mean 30.84, SD 3.91), compared with controls (mean 27.52, SD 4.99). However, twice daily asthma symptom diaries did not identify any significant differences between the groups — as reported by both children and their parents. A significantly greater reduction in asthma symptoms was observed for intervention participants in Naar 2018 (from mean 2.75 to 1.43 vs mean 2.67 to 2.58, β=-0.601, p=0.03, CI:-1.127, -0.074), and similarly, the mean score of asthma control for intervention participants in Taheri 2019 was significantly less than the control group at 3 months follow-up (MD -5.22, SD 4.02 vs MD -0.08, SD 1.27, p < 0.001). However, no significant difference was observed in Asthma Control Test scores between groups in Tseng 2020.

In Warner 2006, baseline symptoms predicted follow-up symptoms positively and strongly. Among those with high baseline asthma symptoms (above the median), disclosure writing led to a larger drop in symptoms (mean−6.93, SD = 6.58, 67% improved) than did control writing (mean −2.40, SD = 4.27, 40% improved),but this group effect was absent among those with low baseline asthma symptoms (disclosure change,

mean +1.92, SD = 5.38, 15% improved; control change, mean +0.33, SD = 3.45, 17% improved) (mean=10.25, SD=4.77) (mean=11.05, SD=6.66). In Yang 2004, weekly follow-up visits or calls reported statistically significant differences in both daytime (mean=0.98, SD=0.29 vs mean=1.8, SD=0.41, p<0.01) and nighttime symptom scores (mean=1.15, SD=0.42 vs mean=2.11, SD=0.58, p<0.01) between intervention and control groups.

Medication use

Eight studies reported data on medication use, with a total of 822 participants. The evidence about an effect of psychological interventions on medication use for asthma is very uncertain. Meta-analysis was not possible because the outcome was reported in several ways across the studies, including as medication use, prescriptions, change in medication type, and as part of validated assessment tools, including the Asthma Medication Score, Family Asthma Management System Scale (FAMSS) and Daily Phone Diary (DPD). Most scales or measures do not have established MCIDs, meaning the magnitude and clinical significance of benefits are difficult to judge. Some studies were interested in adherence as a positive outcome and others looked for increased prescriptions or reliever use as proxy for poor control. Overall, six studies (n = 670) report benefits of the psychological intervention vs control, one without supporting data (Gustafsson 1986) and two studies found little to no difference between groups (n = 152).

Numerical data for individual studies along with follow-up duration, scale metrics (where known) and a brief narrative interpretation are summarised in Analysis 1.6, and results are described below. Again, the evidence is considered very low quality due to heterogeneity, imprecision and risk of bias.

Barikani 2021 used the Medication Adherence Scale (MARS) and found that children in the motivational interviewing group showed more improvement at follow-up than those receiving usual care (mean (SD) improved from 3.77 (0.80) to 4.62 (0.50) in the intervention group and from 4.08 (0.56) to 4.15 (0.52) in the control group; p-value adjusted for baseline = 0.000). The Asthma Medication Score was used to assess medication use in the Chiang 2009 study, identifying that less medication was used over time in the experimental group (mean score 5.10, SD:3.34 to 2.75 SD:2.84) and comparison group (4.17 SD:2.68 to 1.94 SD:2.18).

However, results from the mixed model analysis showed that group x time interaction was not statistically significant (β=0.13; 95%CI -1.90 to 2.15; p=0.90). Results from the Dahl 1990 study identified a statistically significant reduction in the use of beta-2- agonist doses in the behavioural intervention arm compared to control. No correlation was observed between number of beta-2- agonist doses and objectively measured air flow obstruction. Though it is important to note that the same size was small (n=19 children). Medication use in the Gustafsson 1986 study was reduced in the family therapy group, with the total number of Beta-2- agonist doses significantly reduced (p<0.01), as was use of inhaled beta-2-agonists at night (p < 0.05). However, no evidence of effect was observed in the control arm over time. In the intervention group, n=4 participants reported improvements in required doses of beta-2-agonist, while n=0 reported the same in the control group. Steroid medication was also reduced in the family therapy group relative to control, though results were not statistically significant. Meanwhile, the Hock 1978 study reported on changes in prescribed medications, with fewer changes made in the relaxation training group (n=3 out of n=9 participants) compared with the combined relaxation and assertive training group (n=6 out of n=10 participants), however, the results were not statistically significant. Similarly, no evidence of effect was observed for changes made in the assertive training group (n=6 out of n=9 participants) and the medical control group (n=5 out of n=6 participants). However, it is unclear if this outcome is considered by authors to be a positive or negative outcome. The study by Halterman 2021 identified significantly lower preventative medication prescription use among teens in the asthma education (control) group compared to those in the School-Based Asthma Care for Teens (SB-ACT) program at three-, five- and seven-month follow-ups (p<0.001). However, around the time that many of the teens discontinued involvement in the interventions, adherence reverted to similar levels at baseline assessment. Preventive medical prescriptions among the SB-ACT group were: 22% at baseline, 69% at three-months and 70% at five-months. At the seven-month assessment adherence was between 30-40% across all three groups (including the asthma education control group). Statistically significant time by treatment interactions were observed in medication adherence scores in the Naar 2018 study based on a sub-scale of the FAMSS tool (β=0.485; p=0.03) and the DPD assessment tool (β=0.193; p=0.004). From baseline to 12-month follow-up, FAMSS adherence scores improved from 4.19 to 5.24 in the Multisystemic Therapy — Health Care group compared with 4.61 to 4.72 in the control group. When using the DPD, adherence scores improved from a mean of 0.33 at baseline to 0.69 in the Multisystemic Therapy — Health Care group compared

with 0.43 to 0.46 in the control group. Finally, lower reported use of beta- agonist inhalers was observed in the 'I Can Cope' arm of the Marsland 2019 study, however, results were not statistically significant (p=0.15). Authors report that these analyses are underpowered and therefore should be considered as preliminary.

Self-reported quality of life as measured by validated questionnaires

Quality of life was reported in six studies with a total of 653 participants. The evidence for an effect of psychological interventions on self-reported quality of life in children and young people with asthma is very uncertain. Meta-analysis was not possible due to heterogeneity of intervention type, follow up duration and assessment tool. Two studies used the Paediatric Asthma Quality-of-Life Questionnaire (PAQLQ), while the remaining four studies used different validated questionnaires or subscales. A variety of scales were used with unknown MCIDs, so the magnitude and clinical significance of benefits where reported are unclear.

One study (n = 48) reported a benefit of the intervention vs control but provided limited supporting data (Khoshnavay Fomani 2013), two studies reported mixed findings across subscales (n = 83; Beebe 2010; Bruzzese 2008) and the three largest studies found little to no difference between groups (n = 522; Halterman 2021; Marsland 2019; Pulgaron 2010). Numerical data for individual studies along with follow-up duration, scale metrics (where known) and a brief narrative interpretation are summarised in Analysis 1.7, and results are described below. Again, the evidence is considered very low quality due to heterogeneity and imprecision.

The Beebe 2010 study reported quality of life using the Paediatric Quality of life asthma module (PedsQL), identifying an immediate change in scores after art therapy for both parent-reported (p=0.0144) and child-reported (p=0.0142) worry scores from the PedsQL questionnaire, which was sustained within the intervention group by six-month post therapy completion for both parents (p=0.024) and children (p=0.0279). However, overall (total) quality of life scores were not statistically significantly improved by six-month follow-up (p=0.177). The Bruzzese 2020 study reported a statistically significant improvement in the PAQLQ for the symptom domain, with mean scores of 5.21, SD=1.00 in the CAMP Air arm compared to 4.74, SD=1.30 in the control arm (adjusted mean difference 0.42; 95%CI 0.01 to 0.82; p=0.04). The other two domains, emotions and physical activity interference were not reported, which may suggest selective reporting. No differences between groups were observed in quality of life for the Halterman 2021 study,

based on the PAQLQ and the Paediatric Asthma Caregiver's Quality of Life Questionnaire. Mean change from baseline to seven-month follow-up in the paediatric quality of life questionnaire was 0.82, SD=1.3 for SB-ACT, 0.80, SD=1.1 for DOT and 0.83, SD=1.3 for asthma education (p-value 0.662). Meanwhile, the Khoshnavay Fomani 2013 study identified a statistically significant improvement in quality of life scores using the OXFORD Mini Asthma Quality of Life questionnaire in the rational emotive behaviour therapy arm compared to control (p=0.03), in n=48 elementary school students with asthma. Emotional and social dimensions of the tool were also found to have statistically significant improvements in the intervention arm compared to control, with p=0.01 for both. Total scores were not provided. The Children's Health Survey for Asthma identified that both interventions ("I Can Cope" and "Open airways") in the Marsland 2019 study were associated with improved physical health-related quality of life (p=0.07 and p=0.05 respectively) compared to the no treatment control group. However, no significant difference was observed between the two groups and there were no improvements identified in the emotional or activity-related quality of life domains.

Finally, quality of life was measured through the Miami Paediatric Quality of Life Questionnaire in the Pulgaron 2010 study, with separate child and parent scores reported for self-competence and social competence subscales; mean differences did not suggest a difference between groups on any of the subscales (see Analysis 1.7).

Adverse events/side effects

No studies reported on adverse events.

3.7 Discussion

3.7.1 Summary of main results

This review contains data from 24 studies; however, this review is limited by heterogeneity and low quality evidence. Meta-analysis was not possible for any outcome, due to lack of quantitative data, heterogeneity of populations, scales, tools used, and periods of follow-up, skew, and the combination of raw and change scores. Many studies observed effects in favour of the intervention for the outcomes of interest, but findings overall were mixed and the evidence of very low quality.

There were mixed findings for the primary outcomes of symptoms of anxiety and depression, with most studies reporting the outcomes showing benefits on at least one

measure in favour of the intervention at the initial follow-up post-intervention, and one showing sustained reductions in anxiety at final follow-up. However, small sample sizes, a mix of scales without established MCIDs and wide confidence intervals suggest limited certainty in these results. For the primary outcome of medical contacts, three small studies showed benefits in favour of the intervention for hospital admissions or emergency room visits, but the two larger ones reporting similar outcomes found little to no difference between groups. The final primary outcome, asthma attacks, was defined and reported differently across studies. Two of the included studies reported a statistically significant benefit in favour of the intervention, with no evidence of effect observed in the remaining small study. Measures of effect size and certainty were not reported by study authors, so caution should be used when interpreting these results.

Nine of the 11 studies reporting on asthma symptoms described a benefit of the intervention versus the control group in at least one reported area (e.g. daytime symptoms), but five of these and the remaining two studies also reported less positive findings.

However, a limitation of this data is the heterogeneity in tools used by studies, with no two studies utilising the same standardised tool. There was also heterogeneity in the definition of asthma symptoms reported, with day symptoms, night symptoms, wheeze, and total symptoms being reported across the studies. Measures of effect size and certainty suggest that the intervention likely does reduce asthma symptoms. Medication use was reported variably as either adherence (a positive outcome) or medication need (a negative outcome), but overall most studies reported a positive effect of psychological interventions versus the control groups, although the clinical significance across scales is unclear. For self-reported quality of life, only one study of six reporting either total quality of life or sub-scales of a quality of life tool reported a statistically significant improvement, and the largest studies found little to no difference between groups. Once again, this data is limited by the heterogeneity of tools used to measure this outcome. While two studies did use the same validated tool (PAQLQ), the remaining four used different questionnaires.

Adverse events were not reported in any of the included studies.

3.7.2 Overall completeness and applicability of evidence

The included studies recruited participants with asthma over a range of severities from a variety of clinical and community settings. Males and females were represented, as were both primary and secondary school-age participants. A number of different interventions

were included but apart from interventions based upon relaxation, family therapy or behavioural interventions, many interventions were represented by two or fewer studies. Variation within inclusion criteria and outcome measures meant it was not possible to perform subgroup analysis or sensitivity analyses. Insufficient data for subgroup analyses prevented us from reaching conclusions about the relative efficacy of different types of psychological interventions for children with asthma or to assess the comparative efficacy of individual and group formats of psychological therapy for children with asthma.

The included studies supported a narrative description of the primary outcomes anxiety or depression, medical contacts and asthma attacks, although medical contacts was restricted to hospital or emergency room visits since there was no data on primary care (general practitioner) contacts. A narrative analysis was possible for secondary outcomes; asthma symptoms, medication use and quality of life. No study presented data on adverse effects.

3.7.3 Quality of the evidence

GRADE assessment determined all outcomes to be of very low certainty, meaning that we have very little confidence in the effect estimate. This is due to the significant heterogeneity observed across all psychological interventions (from theoretical foundations to intensity and duration of treatment, mode of delivery, setting, and intended objective), outcomes (different validated tools used between studies), outcome measures, and populations (age, asthma severity). Other factors impacting certainty of the evidence include inability to blind, subjective outcome reporting, inadequate reporting for risk of bias, and small sample sizes.

Due to these limitations it was not possible to conduct meta-analysis within these areas. These limitations were compounded by gaps in reporting for some studies and problems with protocol adherence among clinicians in other studies. Overall, these factors weaken the quality of evidence provided.

3.7.4 Potential biases in the review process

There are several potential biases identified in this review. Types of interventions eligible for inclusion needed to be either created or delivered by a qualified professional, meaning any intervention that was developed and delivered without input from clinical psychologists or an individual with similar expertise, was excluded. Although this slightly limits the pool of available studies, it does ensure that rigour of intervention design and delivery is heightened. Only randomised controlled trials were included, meaning studies

that used other research methodology such as controlled clinical trials without randomisation, interrupted time series studies, pseudo-randomised controlled trials and other comparative studies will have been excluded. Again, although this limits the available evidence base and therefore generalisability of findings, this strict criteria does strengthen review quality.

Potentially relevant research findings that could add value to this evidence base may have been inadvertently missed from this review, due to presentation in forms other than peer reviewed publications or online clinical trial registries. However, we believe the search strategy undertaken was comprehensive and broad enough to capture identification of the vast majority of relevant studies. To minimise potential biases in the review process, criterion for potential bias assessment during screening, data extraction and analyses of included studies, strictly comply with the *Cochrane Handbook of Systematic Reviews* (Higgins 2011). Both selection of studies for inclusion and risk of bias assessment was undertaken by a combination of two independent review authors. Where disagreements arose, these were resolved through discussion and consensus. Similarly, assessment using the GRADE methodology as reported in the summary of findings table was undertaken by two researchers (KS and KC). Disagreements in quality assessment for each of the outcomes was resolved through discussion and consensus. None of the review authors have contributed as an author on any of the publications identified as Included studies, Excluded studies, Studies awaiting classification or Ongoing studies for this review.

3.7.5 Agreements and disagreements with other studies or reviews

In-keeping with the previous review, this review has shown that while individual studies suggest psychological interventions may be beneficial in the management of children and young people with asthma, the overall findings are inconclusive. Despite a number of studies evaluating a specific intervention, such as relaxation training in the previous review (Yorke 2005), or outcome measure, such as depression and anxiety in this review, the data cannot be meta-analysed. Previously, this was due to the use of a variety of interventions and outcome measures, small sample sizes, insufficient data and poor study quality, highlighting the need for robust randomised trials. While there are a higher number of studies available for this review, meta-analysis could not be carried out due to a wide variety of interventions and outcome measures, skew, and a lack of quantitative data. As well as highlighting the need for high quality data, this review also demonstrates the vast range of interventions and outcomes used in this area of research. As stated in the previous

review, this could be addressed by the introduction of a research programme using specified outcome measures and manualised interventions to evaluate psychological interventions for children/young people with asthma.

3.8 Authors' conclusions

3.8.1 Implications for practice

Most studies reporting symptoms of anxiety, depression, asthma attacks, asthma symptoms and medication use found a positive effect of psychological interventions vs controls on at least one measure. However, findings were mixed for all outcomes, it was difficult to judge the magnitude of effects, and the evidence for all outcomes is very uncertain due to clinical heterogeneity, small sample sizes, incomplete reporting and risk of bias. Further, most scales or measures do not have established MCIDs, meaning the clinical significance of potentials benefits are unclear. There is little evidence that psychological interventions reduce the need for medical contacts or improve quality of life, and no studies report adverse events.

It was not possible to identify components of effective interventions and distinguish these from interventions showing no evidence of an effect due to substantial heterogeneity in intervention design, tools used to examine the outcomes and population characteristics. There is some limited evidence to support the use of psychological interventions to reduce hospital admissions, emergency room visits and asthma symptoms. Though no overall evidence of effect was observed for changes in quality of life with mixed results related to medication use. These results should be interpreted with great caution, due to the substantial heterogeneity across different aspects of the psychological interventions themselves, the characteristics of participants evaluated, including asthma severity, age, socio-economic status and control, as well as the tools used to measure the outcomes.

3.8.2 Implications for research

Psychological interventions are continuing to evolve and develop in response to research evidence and strategic directions of organisations and governments to support this research. However, the safety and efficacy of psychological interventions for asthma in children and young people remains unknown, largely due to the variability between studies of these interventions. GRADE assessment determined all outcomes to be of very low certainty. This is due to the significant heterogeneity observed across psychological

interventions, outcomes, and populations, as well as risk of bias and small sample sizes. Varied approaches to meet the objectives and needs of the target audience should not be stifled.

However, future research programs that examine the latest evidence based psychological techniques should consider standardising outcome assessment tools to support cross-comparison and meta-analysis. Consideration should also be given to the extended range of outcomes to inform the array of clinical care delivery needs, patient objectives and policy requirements. In particular, future studies may consider identifying outcomes of interest that are of importance to patients, directly from patients and their caregivers. Of 24 studies identified in this review, only five reported validated questionnaires assessing symptoms of anxiety and depression. No studies reported on adverse events, despite the seriousness of psychological distress and potential for complications due to ineffective treatment delivery. Similarly, few studies reported on asthma attacks, medication use and quality of life. Additional methodologically rigorous studies (i.e. with care taken to reduce potential risks of bias) with larger sample sizes and using standardised, validated outcome assessment tools are required to determine if psychological interventions can be effective in reducing psychological distress among children and adolescents with asthma.

3.9 Data and analyses

Table 3.9.1: Analysis 1.1 – Change in anxiety

Change in anxiety							
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Scale metrics**	**Numerical data**	**Narrative interpretation**
Beebe 2010	22	6	7 weeks art therapy *vs* no intervention *(*wait list)	Beck Anxiety Inventory for Youth (BAI-Y)	Range 0-60; MCID not known; lower=better	***Intervention vs control*** *mean change (SD)*: -14 (14.3) *vs* 0.55 (19.4) Difference between groups p = 0.03	**Bnefit of intervention** with unknown clinical significance
Chiang 2009	48	3	12 weeks relaxation *vs* active control *(*asthma self-management)	1) Chinese Children's Manifest Anxiety	Ranges and MCID not known; lower=better	***Intervention vs control*** *mean change and between group difference*:	**Mixed findings/selective reporting**. Benefits of intervention on 2/3 scales with unknown clinical significance.

				2) CCMAS: General Anxiety Scale for Chinese Children 3) CCMAS: Total anxiety		1) Not reported ('not significantly different') 2) -3.97 vs 1.03 (β = 5.96, SE = 2.51, p=0.012, 95% CI: 1.34, 10.59) 3) -5.62 vs 2.25 (β= 9.21, SE = 4.05, p=0.027, 95% CI: 1.11, 17.32)	
Colland 1993	195	2.3, 6 and 12	10 weeks behavioural self-management *vs* active control *(*information session) or no intervention	1) Screen for Child Anxiety Related Emotion Disorder (SCARED): Trait anxiety	Subscale ranges and MCID not known; lower=better	Not reported	**Claims of intervention benefit** post-treatment without supporting raw data and unknown clinical significance. Mixed findings after 6 months.

				2) Screen for Child Anxiety Related Emotion Disorder (SCARED): Asthma-specific anxiety			
Marsland 2019	104	2-4	2-4 months stress management (SM) intervention *vs* active control (asthma management (AM)) or no intervention (NI)	1) 3-item Perceived Stress Scale 2) State Trait Anxiety Inventory	1) Range and MCID unknown 2) Range 20-80; MCID not known	1) **SM** 1.24 points better than **NI** (p = 0.43, SE = 1.55) 2) *Post-treatment means (SD):* **SM**: state 28.5 (5.3); trait 34.6 (7.7) **AM**: state 28.8 (5.5); trait 33.7 (8.4) **NI**: state 28.5	**Little to no difference between groups**

						(5.32); trait 34.1 (7.0)	
Yang 2004	62	1	4 weeks relaxation *vs* no intervention	Screen for Child Anxiety Related Emotion Disorder (SCARED)	41 items rated 0-2; MCID not known; lower=better	***Intervention vs control*** *post-treatment mean (SD)*: 18.27 (6.95) vs 23.21 (7.26)	**Benefit of intervention** with unknown clinical significance

Table 3.9.2: Analysis 1.2 – Change in depression

Change in depression							
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Scale metrics**	**Numerical data**	**Narrative interpretation**
Marsland 2019	104	2-4	2-4 months stress management intervention *vs* asthma management or no intervention	Child Depression Index	Range and MCID not known; lower=better	**Intervention** 2.68 points better than **control** (p=0.02, SE=1.29)	**Benefit of intervention** with unknown clinical significance

Yang 2004	62	1	4 weeks relaxation *vs* no intervention	Depression Self-Rating Scale for Children	0-36; MCID not known; lower=better	***Intervention vs control*** *post-treatment mean (SD)*: 8.62 (3.95) *vs* 12.97 (4.69)	**Benefit of intervention** with unknown clinical significance

Table 3.9.3: Analysis 1.3 – Change in medical contacts

Medical contacts						
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Numerical data**	**Narrative interpretation**
Bruzzese 2020	61	1.6 (post-treatment) and 1 month later	7 weeks multi-prong intervention *vs* active control (educational materials)	Asthma-related urgent care visit (at least one in past 3 months)	***Intervention vs control:*** *Post-treatment* 69% lower risk *1 month later* 12% vs 41% (adjusted mean difference: 0.31; 95%CI 0.10 to 0.99; p=0.04)	**Benefit of intervention** with likely clinical signifcance

Gustafsson 1986	18	42	8 months family therapy *vs* usual care	Emergency hospitalisation days per year	*Within-group change*: **Intervention**: 2.67 to 0.17 days per year (p=0.06) **Control**: No improvement	**Possible benefit of intervention** with likely clinical significance
Halterman 2021	377	7	6 weeks motivational interviewing (MI) *vs* two active controls: (i) directly observed treatment (DOT) or ii) asthma education (AE)	ED visits, hospitalisations and urgent care visits	**MI**: 17 (12%) **DOT**: 22 (16%) **AE**: 15 (11%) p = 0.672	**Little to no difference between groups**
Kohen 1996	13	24	1 session relaxation *vs* active control (waking suggestion group), attention control (conversation/games) or no intervention	ER visits	χ^2 3.90; $p < 0.05$ *vs* no intervention	**Benefit of intervention***vs* no intervention and **little to no difference** *vs* other groups
Naar 2018	167	7	6 months multi-systemtic therapy *vs* active control (weekly, non-directive family support)	1) Hospitalisations (mean N per year) 2) ED visits	1) M*ean N per year baseline to follow-up and between-group difference:*	**Mixed findings**

					Intervention: 0.87 to 0.24 **Control**: 0.66 to 0.34 β=-0.882; p=0.04; incidence rate ratio=0.414; 95% CI 0.175 to 0.978 2) No significant differences between groups (β=-0.153; p=0.63)	

Table 3.9.4: Analysis 1.4 – Change in asthma attacks

Asthma attacks						
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Numerical data**	**Narrative description**
Beebe 2010	22	6	7 weeks art therapy *vs* no intervention *(*wait list)	Exacerbations requiring medical contact	6 months before study to 6 months after:	**Little to no difference between groups**

					Intervention: n = 3 to n = 2 **Control**: n = 4 to n = 2	
Hock 1978	43	3 (2 month intervention + 1 month follow-up)	8 weeks relaxation (R) or relaxation + assertiveness training (R+A) *vs* i) usual care (UC) or ii) active control (usual care + peer support)	Mean number of asthma attacks per patient per week	*Pre, post* **RT**: 0.43, 0.44 **RT+AT**: 0.52, 0.60 **UC**: 0.93, 2.57 **UC+PS**: 0.26, 0.13	**Benefit of both intervention groups vs usual care** with possible clinical significance
Yang 2004	64	1	4 weeks relaxation *vs* no intervention	Children with more than one asthma attack	**Intervention vs control:** 61.3% vs 90.9%	**Benefit of intervention** with possible clinical significance

Table 3.9.5: Analysis 1.5 – Change in asthma symptoms

Asthma symptoms							
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Scale metrics**	**Numerical data**	**Narrative interpretation**

Bruzzese 2008	23	2	6 weeks family therapy *vs* no intervention	In past 2 weeks: 1) Number of symptomatic days 2) Number of nighttime awakenings due to asthma	Range 0-14; MCID not known; lower=better	*Mean (SD) at baseline and after treatment (% change):* 1) **Intervention**: 4.8 (3.0) to 1.8 (2.2) **Control**: 4.1 (4.3) to 2.2 (2.9) -63% *vs* -46% 2) **Intervention**: 2.0 (1.3) to 0.7 (1.8) **Control**: 1.75 (2.8) to 2.1 (4.1) -67% vs +19%	**Mixed findings** and unknown clinical significance
Bruzzese 2020	61	1.6 (post-treatment) and 1 month later	7 weeks multi-prong intervention *vs* active control (educational materials)	In past 2 weeks: 1) Number of symptomatic days	Range 0-14; MCID not known; lower=better	***Intervention vs control*** *adjusted MD after treatment (95% CI):*	**Mixed findings** and unknown clinical significance

				2) Number of nighttime awakenings due to asthma		1) 0.86 (0.64 to 1.14), p=0.29 2) 0.36 (0.22 to 0.61), p=0.0002	
Chiang 2009	48	3	12 weeks relaxation *vs* active control (asthma self-management program)	Asthma symptom diary	Range and MCID not known; lower=better	*Means at baseline to after treatment with between-group difference*: **Intervention**: 9.46 to 6.93 **Control**: 10.44 to 7.24 β=-0.70, SE=0.77, p=0.369, CI: -2.24 to 0.84	**Little to no difference between groups**
Dahl 1990	19	1	4 weeks behaviour therapy *vs* usual care	Daily asthma charts (children and parents)	Range and MCID not known; lower=better	50% reduction in the intervention group	**Unclear** if reported benefit is a within-

							group effect of vs usual care
Lask 1979	39	12	4 months family therapy *vs* usual care/attention control (3-weekly contact with paediatrician)	Diary cards: Daytime wheeze and activity limitation	Range 0-3 (unclear how totals were calculated over 6-week observation period); MCID not known; lower=better	***Intervention vs control*** *mean (SD) after treatment and p-value for difference*: 7 (8) *vs* 21 (11); p < 0.01	**Benefit of intervention** with unknown clinical significance
Marsland 2019	104	2-4	2-4 months stress management intervention (SM) *vs* active control (asthma management (AM)) or no intervention (NI)	1) Children's Health Survey for Asthma (symptoms in last 2 weeks) - children and parents	1) Symptoms rated 0-5 and summed over 2 weeks; MCID not known; higher=better 2) 5 symptoms rated 0-4; MCID	***Intervention vs control*** *mean (SD) after treatment:* 1) Children 30.8 (3.9) *vs* 27.5 (5.0); Parents 30.7 (3.7) *vs* 29.9 (4.2) 2) 2.5 (5.7) *vs* 4.2 (8.5)	**Mixed findings,** skewed data and unknown clinical significance

				2) Twice daily asthma symptom diaries	not known; lower=better		
Naar 2018	167	7	6 months multi-systemtic therapy *vs* active control (weekly, non-directive family support)	Family Asthma Management System Scale	Range and MCID not known; lower=better	*Means at baseline to after treatment (difference, 95% CI and p-value):* **Intervention**: 2.75 to 1.43 **Control**: 2.67 to 2.58 β=-0.601, CI:-1.127, -0.074, p=0.03	**Benefit of intervention** with unknown clinical significance
Taheri 2019	64	3	5 weeks motivational interviewing *vs* no intervention	Asthma Control Questionnaire	Usual range 0-6 with MCID 0.5. Study reports with a range of 0-42 so	***Intervention vs control*** *mean change (SD) at*	**Clinically significant benefit of intervention**

					corresponding MCID = 3.5 (0.5*7); lower=better	*follow-up with p-value for difference*: -5.22 (4.02) *vs* -0.08 (1.27), p < 0.001	
Tseng 2020	83	1	4 weeks self-management *vs* unclear control	Asthma Control Test	Range 5-25; MCID 2 (for adolescents); higher=better	***Intervention vs control*** *median scores (min-max) at follow-up*: 23 (15-25) *vs* 23 (14-25)	**Little to no difference between groups**
Warner 2006	50	2	3 days written disclosure *vs* attention control (writing about behaviours)	Asthma Sum Scale, past 2 weeks	Range 0-36; MCID not known; lower=better	***Intervention vs control*** *mean change (SD) and % improvement:* *Overall*: -2.82 (NR) *vs* -0.9 (NR) 21.6% *vs* 7.5%	**Mixed findings**. Benefit of intervention dependent on baseline severity and with unknown clinical significance.

						High baseline severity: −6.93 (6.58) *vs* −2.40 (4.27) 67% *vs* 40% *Low baseline severity*: +1.92 (5.38) *vs* +0.33 (3.45) 15% *vs* 17%	
Yang 2004	62	1	4 weeks relaxation *vs* no intervention	1) Daytime symptoms 2) Nighttime symptoms	Range and MCID not known; lower=better	***Intervention vs control*** *mean (SD) and between group p-value*: 1) 0.98 (0.29) *vs* 1.8 (0.41), p < 0.01 2) 1.15 (0.42) *vs* 2.11 (0.58), p < 0.01	**Benefit of intervention** with unknown clinical significance

Table 3.9.6: Analysis 1.6 – Change in medication use

Medication use							
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Scale metrics**	**Numerical data**	**Narrative interpretation**
Barikani 2021	46	2	3 weeks motivational interviewing vs usual care	Medication Adherence Scale (MARS)	Range 1-5; MCID not known; higher=better (adherence)	*Mean (SD) at baseline and post-treatment with within-group p-value*: **Intervention**: 3.77 (0.80) to 4.62 (0.50); p = 0.000 **Control**: 4.08 (0.56) to 4.15 (0.52); p = 0.477 p = 0.000 group difference adjusted for baseline	**Benefit of intervention**

Chiang 2009	48	3	12 weeks relaxation *vs* active control (asthma self-management program)	Asthma Medication score	Range and MCID not known; lower=better	*Mean (SD) at baseline and post-treatment with group x time interaction*: **Intervention**: 5.10 (3.34) to 2.75 (2.84) **Control**: 4.17 (2.68) to 1.94 (2.18) β=0.13; 95% CI -1.90 to 2.15; p=0.90	**Little to no difference between groups**
Dahl 1990	19	1	4 weeks behaviour therapy *vs* usual care	% change in number of beta2-agonist 'sprays'	Not a validated scale; lower=better	***Intervention vs control*** *% estimated from figure*: -60% *vs* +10%	**Benefit of intervention**
Gustafsson 1986	18	42	8 months family therapy *vs* usual care	1) Total beta2-agonist doses 2) Beta2-agonist use at night	Not validated scales; lower=better	1) 'significantly reduced' with intervention (p<0.01) and not controls	**Claims of intervention benefit** without numerical data and

				3) Steroid use		2) 'significantly reduced' with intervention ($p < 0.05$) and not controls 3) 'reduced' with intervention relative to controls	unknown clinical significance
Halterman 2021	377	7	6 weeks motivational interviewing (MI) *vs* two active controls: (i) directly observed treatment (DOT) or ii) asthma education (AE)	1) % with a preventative medication prescriptions 2) % medication adherence daily in past 2 weeks	Not validated scales; higher=better (adherence)	*% (some estimated from graph) at baseline, 3m, 5m and 7m, with p-values for group differences*: 1) **MI**: 70%, 99%, 99%, 100% **DOT**: 70%, 99%, 98%, 97% **AE**: 70%, 71%, 70%, 68%	**Benefit of intervention** vs asthma education that may wane over time, and unknown clinical significance

						p-values: 0.88, <0.001 at 3, 5 and 7m 2) **MI**: 22%, 69%, 70%, 40% **DOT**: 29%, 71%, 63%, 39% **AE**: 30%, 37%, 43%, 32% p-values: 0.39, <0.001, 0.003, 0.49	
Hock 1978	43	2 (1 month intervention + 1 month follow-up)	8 weeks relaxation (R) or relaxation + assertiveness training (R+A) *vs* i) usual care (UC) or ii) active control (usual care + peer support)	Changes in prescribed medications	Not a validated scale; lower=better (assumed)	**R**: 3/9 (33%) **R+A**: 6/10 (60%) **UC**: 5/6 (83%)	**Possible benefit of intervention** with unknown clinical significance
Marsland 2019	104	2-4	2-4 months stress management intervention (SM) *vs* active control	Beta2-agonist use in past 2 weeks (total)	Not a validated scale; lower=better	*Mean (SD) before to after*:	**Little to no difference between groups**

			(asthma management (AM)) or no intervention (NI)			**Intervention**: 6.65 (9.37) to 3.23 (6.99) **Control**: 7.43 (10.23) to 5.86 (7.67) Adjusted difference -2.14, p = 0.15	
Naar 2018	167	7	6 months multi-systemtic therapy *vs* active control (weekly, non-directive family support)	1) Family Asthma Management System Scale - medication adherence subscale 2) Use of controller medication (combined from 2x24-hr daily phone diary assessments in past two weeks	1) Range 1-9; higher=better (adherence); MCID not known 2) Range 0-2; higher=better (adherence); MCID not known	Change in means from baseline to 12-months with time by treatment interaction: 1) **Intervention**: 4.19 to 5.24 (+1.05) **Control**: 4.61 to 4.72 (+0.11) β=0.485; p=0.03 2) **Intervention**: 0.33 to 0.69 (+0.36)	**Benefit of intervention** with unknown clinical significance

						Control: 0.43 to 0.46 (+0.03) β=0.193; p=0.004	

Table 3.9.7: Analysis 1.7 – Change in quality of life

Quality of life							
Study	**N**	**Follow-up (months)**	**Comparison**	**Measure(s)**	**Scale metrics**	**Numerical data**	**Narrative interpretation**
Beebe 2010	22	6	7 weeks art therapy *vs* no intervention (wait list)	Paediatric Quality of life asthma module (PedsQL)	28 questions rated 1-5; MCID not known; lower=better	***Intervention vs control*** *p-values for worry scale, post-treatment and 6-month follow-up*: Parent-reported p=0.0144, p=0.024 Child-reported p=0.0142, 0.0279	**Mixed findings/selective reporting**. Benefit of intervention in worry domain with unknown clinical significance.

						Overall scores 6-month follow-up p=0.177	
Bruzzese 2020	61	1.6 (post-treatment) and 1 month later	7 weeks multi-prong intervention *vs* active control (educational materials)	Paediatric Asthma Quality of Life Questionnaire (PAQLQ): Symptom domain only (emotions and physical activity not reported)	Range 1-7; MCID 0.42; higher=better	***Intervention vs contol*** *mean (SD):* 5.21 (1.00) vs 4.74 (1.30) *Adjusted mean difference*: 0.42, 95%CI 0.01 to 0.82; p=0.04	**Mixed findings/selective reporting**. Possible clinically significant benefit of intervention in symptom domain.
Halterman 2021	377	7	6 weeks motivational interviewing (MI) *vs* two active controls: (i) directly observed treatment (DOT) or ii) asthma education (AE)	PAQLQ - child and caregiver versions	Range 1-7; MCID for child version 0.42, MCID for adult version 0.5; higher=better	*Mean change (SD) (0 to 7m)*: **MI**: 0.82 (1.3) **DOT**: 0.80 (1.1) **AE**: 0.83 (1.3)	**Little to no difference between groups**

						p-value for between-group differences = 0.662	
Khoshnavay Fomani 2013	48	Not reported	10 sessions Rational Emotive Behaviour Therapy *vs* usual care	OXFORD Mini Asthma Quality of Life Questionnaire	Range 1-7; MCID for full version 0.5; higher=better	***Intervention vs control** p-values*: Total score $p \leq 0.03$; emotional and social dimensions $p \leq 0.01$	**Claims of intervention benefits**, reported insufficiently to judge clinical significance
Marsland 2019	104	2-4	2-4 months stress management intervention (SM) *vs* i) active control (asthma management (AM)) or ii) no intervention (NI)	Children's Health Survey for Asthma: 1) Physical health QoL 2) Activity QoL 3) Emotional health QoL	Ranges and MCIDs unknown; higher=better	***SM vs NI** mean (SD) before to after treatment with p-value for between-group adjusted difference*: 1) 76.8 (15.4) to 83.3 (16.9) vs 69.6 (21.2) to 73.3 (17.8); p=0.07	**Little to no difference between groups**. Possible intervention benefit in one domain with unclear clinical significance

						2) 80.1 (16.1) to 84.0 (15.0) vs 75.9 (18.4) to 76.8 (24.5); p=not reported 3) 78.0 (20.0) to 83.3 (17.0) vs 75.3 (18.6) to 82.4 (17.2); p=not reported	
Pulgaron 2010	41	4-5	4 sessions problem solving intervention *vs* attention control (standard cabin chat)	Miami Paediatric Quality of Life Questionnaire subscales: 1) Self-competence - child 2) Social competence - child 3) Self-competence - parent	Range, MCID and direction unknown	Mean (SD) baseline to final follow-up with difference between groups: 1) **Intervention**: 3.88 (0.55) to 3.88 (0.55) **Control**: 3.90 (0.50) to 3.69 (0.62) MD = -0.36, p = not sig	**Little to no difference between groups**

				4) Social competence - parent		2) **Intervention**: 3.80 (0.65) to 4.00 (0.65) **Control**: 3.95 (0.58) to 3.62 (0.62) MD = -0.62, p = 0.08 3) **Intervention**: 3.59 (0.67) to 3.68 (0.54) **Control**: 3.77 (0.74) to 3.61 (0.72) MD = -0.34, p = not sig 4) **Intervention**: 3.64 (0.82) to 3.52 (0.62) **Control**: 3.93 (0.84) to 3.62 (0.72)	

						MD = -0.29, p = not sig	

4 Chapter 4 – Needs Assessment

University of South Australia

Statement of Authorship

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Title: The modifiable biopsychosocial drivers of psychological distress for adolescents with asthma: Implications for Clinical Care

4.1 Abstract

Purpose: Overwhelming distress exceeds the capacity of healthy coping strategies to feel better using healthy coping strategies alone, resulting in the use of unhealthy coping strategies. Unhealthy coping strategies may exacerbate asthma symptoms and asthma can contribute to overwhelming distress. This study aimed to review the modifiable drivers of overwhelming distress in adolescents with asthma.

Methods: The biopsychosocial drivers of psychological distress for adolescents with asthma were explored within the domains of the modifiable biopsychosocial model of health and wellbeing.

Results: Asthma in adolescents is associated with problems in the domains of environment, developmental outcomes, sense of belonging, health behaviours, coping, and treatment of illness.

Conclusions: The relationship between asthma and psychological distress highlights the need for holistic treatment of asthma. Further research is needed to establish causation between variables and to investigate whether interventions that address either asthma symptoms or biopsychosocial drivers of distress can improve both factors.

Keywords: asthma, psychological distress, adolescent, child, mental health, psychological adaptation, health behaviour

Educational Aims

- To review the evidence of biopsychosocial drivers of psychological distress and asthma in adolescents.
- To examine the clinical implications of causes of psychological distress in asthma care in adolescents.

Future Research Directions

Future research is needed to evaluate interventions that target the biopsychosocial drivers of psychological distress in adolescents on asthma and wellbeing outcomes.

4.2 Introduction

Asthma is a significant health problem that contributes to the global burden of disease (Masoli et al., 2004). The prevalence of asthma is higher in children and adolescents than adults (ISAAC, 1998, Global Asthma Network, 2018), and the rate seems to increase over childhood (e.g., 10.2% in 6–7-year olds; 11.3% in 13–14%) (ISAAC, 1998). Adolescents with asthma have higher rates of psychological distress than adolescents who do not have asthma (AIHW, 2019, Blanchard et al., 2014). One Australian study, for example, found more than 50% of adolescents with asthma had high levels of psychological distress (Blanchard et al., 2014). Many of the causes of psychological distress are common across adolescents with and without asthma, for example, self-consciousness and body image problems (Blanchard et al., 2014). However, some stressors are illness-related (Blanchard et al., 2014). Psychological distress can impair cognitive functions needed for educational outcomes, including attention (Purcell et al., 1997), behavioural inhibition (Murphy et al., 1999) memory (Ilsley et al., 1995), planning (Beats et al., 1996) and flexible decision making (Murphy et al., 2001). Understanding the asthma-specific determinants of psychological distress is therefore critical for optimal outcomes for adolescents.

Biopsychosocial Model of Health and Wellbeing

While there are genetic, biological, social and psychological contributors to psychological distress, optimal clinical care requires an understanding of which factors are modifiable. The Biopsychosocial Model of Health and Wellbeing provides an overview of the biological, social, and psychological domains and components that are associated with health and wellbeing healthy environments, developmental competencies, sense of belonging, health behaviours, coping, resilience, and treatment of illness (Stallman, 2017, Stallman, 2020b). Problems in one or more of these areas is associated with overwhelming psychological distress. Overwhelming distress is unpleasant emotions that exceed the capacity of healthy coping strategies (i.e. self-soothing, relaxation/distraction, social support and professional support) to reduce the distress (Stallman et al., 2021). When distress exceeds the capacity of healthy coping strategies, people use unhealthy coping strategies to feel better (i.e. negative self-talk, harmful activities, social withdrawal, and suicidality) (Stallman, 2020a). Chronic psychological distress during childhood and adolescence is associated with lifelong relationship problems (Nguyen et al., 2017), employment problems (Allwood and Widom, 2013, Currie and Widom, 2010) and psychiatric illness in adulthood (Weich et al., 2009, Norman et al., 2012). Chronic use of

unhealthy coping strategies to reduce overwhelming distress can result in harm, including disorders developed from unhealthy coping harmful activities (e.g. eating disorders, substance use disorders), criminal charges (e.g., from aggression) and death by suicide. The Biopsychosocial Model of Health and Wellbeing therefore, provides a useful framework to examine the asthma-specific drivers of psychological in adolescents to inform clinical care.

4.3 Modifiable Asthma-Related Biopsychosocial Drivers of Psychological Distress

Healthy environments

Allergens, and irritants in the physical environment can exacerbate asthma symptoms. These include allergen-specific immunoglobulin E antibodies (Comberiati et al., 2017), airborne irritants, foods (e.g., eggs, cow's milk, and nuts), dust mites, mould, and pollen, animal dander (Foong et al., 2017, Vernon et al., 2012). Airborne irritants that exacerbate asthma include aerosols or chemical fumes, cigarette smoke. Viral infections can also trigger asthma symptoms (Vernon et al., 2012).

A healthy environment also includes a social environment that supports the health and wellbeing of the child or adolescent. A systematic review that included 25 studies of parents and caregivers of children with and without asthma found greater psychological distress in parents and caregivers of children with asthma (Easter et al., 2015). The reason for the increased distress in these parents is unknown. Parental psychological distress (in particular, maternal distress) adversely affects asthma severity, control, and medication adherence in children—the reasons are not well understood (Licari et al., 2019). In contrast, emotional support by parents is associated with increased perception of treatment control, reduced stress, and a reduced risk of emotional issues in children (Vazquez-Ortiz et al., 2020). A systematic review of 106 studies found that conflict in peer and family relationships (e.g. teasing, arguing, disagreements) is related to increased self-reported asthma symptoms (Vazquez-Ortiz et al., 2020). Professional support also impacts asthma outcomes. Empathetic relationships between patients and physicians that include clear communication, confidentiality, and shared decision-making also important to this population, and promotes honest disclosure of information by young people with chronic disease (Wilson, 2017).

The economic environment also affects psychological distress and asthma-care outcomes. Economic disadvantage can be particularly challenging for treating asthma as optimal

treatment requires regular preventative pharmacotherapy (Scal et al., 2008, Reddel et al., 2018) and is associated with poor treatment adherence (Vazquez-Ortiz et al., 2020, Apter, 2019). For parents, childhood asthma can also have indirect economic impacts such as work absences, lost productivity, and healthcare costs (Deloitte Access Economics et al., 2015). Prevalence of delayed or unmet needs for care due to financial barriers in the United States, for example, is estimated at 8%–26.6.% for adolescents (Scal et al., 2008). These threats to a healthy environment for adolescents with asthma can increase asthma symptoms and psychological distress.

Developmental competencies

Adolescence is a developmental period that includes widespread biological, physical, and psychological changes (Cohen et al., 2003, de Benedictis and Bush, 2007). Developmental competencies needed to be achieved during childhood for health and wellbeing are a stable sense of identity, emotional and behavioural regulation, interpersonal skills and problem-solving skills (Stallman, 2020b). Adolescents with asthma frequently have problems across all four developmental competencies—identity, emotional and behavioural regulation, interpersonal and problem-solving. An increasing desire for independence and rejection of parental modelling (Vazquez-Ortiz et al., 2020, Kaplan and Price, 2020); difficulty organising time, forgetfulness, conflict with parents and confusion over responsibility of medication-taking (Kaplan and Price, 2020), increased perception of barriers (Rhee et al., 2018); difficulty adequately expressing their health concerns or communicating their experience of symptoms (Szefler and Chipps, 2018), perceived social stigma (Vazquez-Ortiz et al., 2020); and lack of engagement in medication decision-making (Kaplan and Price, 2020) all contribute to issues in these domains. The importance of social feedback for identity formation during adolescence can lead to self-perceptions of being different from their peers and sickly (Bruzzese et al., 2004), which is related to greater morbidity (Bruzzese et al., 2004). A qualitative review of 5 studies found that people with asthma, like individuals with other chronic diseases thought their condition threatened their autonomy, and in turn their sense of identity (Eassey et al., 2019).

Sense of belonging

Feeling included and valued is a core component of health and wellbeing. A sense of belonging through peer support is associated with medication adherence (Vazquez-Ortiz et al., 2020). Supportive environments are associated with better self-management, asthma control, and improved quality of life (Vazquez-Ortiz et al., 2020). However, many children

and adolescents with asthma report feeling socially isolated because of their illness (Stewart et al., 2012, Vazquez-Ortiz et al., 2020). Qualitative studies report adolescents experiencing social isolation due to their diagnosis and a desire not to be seen as an "ill person" or to be treated differently (Kaplan and Price, 2020). One qualitative study found that adolescents struggled with the incongruity of being accepted socially, and managing their condition (Jonsson et al., 2017). Strategies used by some to feel a sense of belonging include ignoring symptoms and not taking medication in public (Kaplan and Price, 2020, Jonsson et al., 2017).

Health behaviours

Health behaviours—sleep, nutrition and physical activity—are key components of wellbeing and asthma management (Vazquez-Ortiz et al., 2020). Psychological distress has a bidirectional relationship with health behaviours, contributing to problems and problems causing distress. Distress and rumination can disrupt sleep onset and cause maintenance insomnia and inadequate sleep can contribute to mood dysregulation. Inadequate nutrition can disrupt mood regulation and eating can be used as a coping strategy to reduce distress. Inadequate physical activity affects mood and psychological distress can make it challenging to be active.

Inadequate sleep quality and quantity are more common in adolescents with asthma, as is distress before sleep onset and maintenance insomnia problems (Fidler et al., 2019, Meltzer et al., 2014). Poor quality sleep is related to increased asthma symptoms (Meltzer et al., 2020) and psychological distress (Willis and Gregory, 2015). A recent experimental study (Meltzer et al., 2020) found that when adolescents had 6.5 hours of sleep per night, they reported more asthma symptoms and quality of life than those who had 9.5 hours sleep

Nutrition plays a role in the management of asthma in adolescents (Papoutsakis et al., 2013, Alwarith et al., 2020). Consumption of adequate amounts of fruits and vegetables has been associated with a reduced risk of developing asthma, as well as increased asthma control, likely due to components such as antioxidants, fibre, polyunsaturated fatty acids, and vitamin D which may affect immune pathways. In contrast, dairy consumption has been associated with an increased risk of asthma exacerbation. A recent meta-review reported that Mediterranean and vegan diets which encourage consumption of fruits, vegetables, legumes, and whole grains, and reduce emphasis on animal products (namely

saturated animal fat and dairy products), may reduce the risk of asthma development and exacerbation (Alwarith et al., 2020).

Being overweight also increases the likelihood of having asthma (Azizpour et al., 2018, Mannino et al., 2006), more asthma symptoms (Black et al., 2012, Trasande et al., 2009), greater asthma-related healthcare utilisation (Taylor et al., 2008, Black et al., 2013), and less responsiveness to inhaled corticosteroids (Pradeepan et al., 2013, Forno et al., 2011)—all evidence of greater difficulty controlling asthma symptoms.

There is no evidence that adolescents with asthma are overall less physically active than adolescents without asthma (Cassim et al., 2016, Oudjedi and Said Aissa, 2020). In addition to the general health benefits, physical activity in adolescents is associated with better lung function scores, fewer asthma exacerbations, hospital admissions, school absenteeism, and asthma medication usage (Oudjedi and Said Aissa, 2020, Lochte et al., 2016, Teng et al., 2015, Dantas et al., 2014). In contrast, a meta-analytic review of 11 cross-sectional studies found that low physical activity was associated with new-onset asthma and increased asthma symptoms (Lochte et al., 2016). Physical activity, however, can trigger asthma symptoms of exercise-induced bronchoconstriction leading to the avoidance of physical activity to prevent symptoms (Oudjedi and Said Aissa, 2020). Additionally, uncontrolled asthma can make physical activity more difficult, which also results in avoidance. These unpleasant experiences are greater in adolescents with asthma who are also overweight or obese (Oudjedi and Said Aissa, 2020).

Coping

While the Health Theory of Coping suggests that all coping strategies are useful for the purpose of reducing distress (Stallman, 2020c), strategies can be considered healthy or unhealthy depending on their risk of adverse consequences. For example, healthy strategies include relaxing, distracting or self-soothing activities, social support, and professional support, while unhealthy strategies include harmful activities such as alcohol and drug use, as well as social withdrawal. A recent observational study (Stallman et al., 2021) found that participants at all levels of distress used healthy coping strategies, turning to unhealthy coping strategies when the healthy strategies failed to reduce their distress.

A systematic review of 24 studies found that as with people generally, children and adolescents use a range of healthy coping strategies, including changing position, decreasing activity, taking fluids, relaxing activities such as listening to music, distracting

activities such as watching TV, and social support. Interestingly, the review found that asthma patients tended to use different coping strategies than healthy participants and patients with other chronic illnesses. (Barton et al., 2003). Similarly, a study of 553 Dutch adolescents aged 12-16 with asthma found that the use of healthy coping strategies prevented a decline in QoL scores (Van De Ven et al., 2007). Strategies such as thinking more positively about their condition resulted in higher QoL scores, while strategies such as increased worrying and restricting their lifestyle resulted in lower QoL scores. Positive QoL scores were also seen for adolescents who actively sought information.

Compared with their peers, adolescents with asthma are likely to use more unhealthy coping strategies, such as alcohol, smoking (Lang and Tang, 2019, Dowdell et al., 2011, Vázquez-Nava et al., 2017), and suicidality (Barker et al., 2015), indicative of overwhelming distress. One study found adolescents with asthma are more likely to smoke than healthy adolescents and continue to smoke to cope with distress (Vázquez-Nava et al., 2017). Smoking is particularly problematic in this population as it increases the risk of asthma symptoms and exacerbations and causes a reduced response to asthma medication (Lang and Tang, 2019).

Resilience

Resilience is an innate capacity to bounce back after adversity. A perception of one's resilience is important for health and wellbeing. The belief that you can do something—self-efficacy—improves actions (Robert et al., 1979). There has been no research on the self-perception of resilience in adolescents with asthma directly. However, self-efficacy and outcome expectations for asthma treatment is associated with better treatment adherence in adolescents (Rhee et al., 2018).

Treatment of illness

Early and effective treatment for biopsychosocial drivers of distress and asthma management is critical to minimise the impact of distress and symptoms on health and wellbeing. It is estimated that many adolescents with asthma have not been formally diagnosed or received treatment (Yeatts et al., 2003). In addition to asthma-related morbidity, these adolescents are likely to be further disadvantaged through absenteeism from school, reduced activities and sleep disturbances (Yeatts et al., 2003). Of those who have been diagnosed and received treatment, treatment adherence varies considerably; estimates range from 49 to 71% (Desager et al., 2018, Kaplan and Price, 2020).

Nonadherence contributes to poor disease control and adverse asthma outcomes (Rhee et al., 2018). In addition to other economic and developmental competency barriers to treatment adherence, other factors associated with poor medication adherence in adolescents include treatment provision factors (lack of perceived need or effectiveness, not understanding how to use medication, forgetting to use medication, healthcare relationship), medication-related factors (e.g., difficulty using an inhaler, side-effects), and social factors (stigma) (Vazquez-Ortiz et al., 2020, Apter, 2019, Wilson, 2017).

There is a bidirectional relationship between psychological distress and asthma treatment adherence. Psychological distress can impair treatment adherence (Apter, 2019). Subsequently, asthma that is not adequately controlled can increase the risk of asthma exacerbations, increasing psychological distress (GINA, 2018, Goodwin et al., 2013). Psychological distress may also negatively impact self-efficacy and symptom perception and, in turn, upon medication adherence and other health behaviours, including frequency of healthcare utilisation (Baiardini et al., 2015). Treatment for psychological distress in people generally with asthma typically includes pharmacotherapy and/or psychotherapy for symptoms (Yorke et al., 2005, Sharrad et al., 2019)rather than underlying drivers of distress. There is little research on interventions in children and adolescents (Yorke et al., 2005, Sharrad et al., 2019).

Table 4. Modifiable biopsychosocial domains and components of health and wellbeing and asthma-related vulnerabilities

	Domain	Components	Asthma-related vulnerabilities
1	Healthy Environment	Physical, social, cultural economic	Allergens and irritants Parental distress Direct costs of medication/treatment; Indirect financial costs of asthma
2	Developmental competencies	Healthy identity, emotional and behavioural regulation, interpersonal skills, problem-solving skills	Effect of illness on identity formation Behavioural regulation problems with asthma management Parent-child conflict related to medication

			Problems with responsibility for medication
3	Sense of belonging	Feeling connected to community	Social isolation due to asthma – perceived social isolation and physical isolation
4	Health behaviours	Sleep, nutrition, exercise	Increased likelihood of poor sleep, nutrition Low physicial activity associated with onset of asthma and increased asthma symptoms
5	Coping	Healthy and unhealthy strategies	More likely to use unhealthy coping strategies – alcohol, smoking, suicidality Unhealthy coping strategies exacerbate symptoms
6	Resilience	Sense of innate resilience	
7	Treatment of illness	Early and effective treatments for physical and psychological problems	Asthma is underdiagnosed Treatment adherence

4.4 Implications for clinical care

This review of the biopsychosocial drivers of overwhelming distress that particularly relate to adolescents with asthma highlights its critical role in assessment and treatment—summarised in Table 4. This distress is not necessarily caused by asthma symptoms and asthma may not necessarily cause the distress. However, as adolescence is the time for the onset of most mental illnesses that can have lifelong adverse impacts across functioning, the results have implications for asthma healthcare provision. Holistic care is warranted that includes:

- A thorough biopsychosocial assessment for all children and adolescents presenting with asthma symptoms to understand holistic functioning of the adolescent and the context of the family. Ongoing monitoring is needed over time to monitor change.

- Including children, adolescents and their parents in assessment and treatment planning to ensure the plan is understood, accepted and works for the family. Encourage and support autonomy as appropriate.

- Coping assessment and planning with all adolescents to ensure they have a coping plan that works for them to cope when they are distressed (Stallman, 2020a).

- Referral to and communication between medical, psychological and social service providers as needed to ensure holistic care.

4.5 Conclusion

This paper provided a narrative review of the literature on modifiable biopsychosocial factors of health and wellbeing that have been shown to be associated with asthma in children and adolescents. Although primarily correlational research, the relationships between asthma with psychological distress and drivers of distress highlights the need for holistic assessment and treatment of asthma. Longitudinal research that measures the domains of wellbeing is needed to better understand the interrelationships between drivers of distress and asthma outcomes. Clinical trials are also needed to evaluate the extent to which ameliorating the drivers of distress indirectly impact asthma outcomes.

5 Chapter 5 - Qualitative research study

University of South Australia

Statement of Authorship

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This chapter has been accepted and is undergoing copyediting for publication in the JMIR Human Factors. Additional information relevant to this chapter is attached in the Appendix (Chapter 7, section 5).

Title: Acceptability of mixed reality technology as a delivery mechanism for psychological intervention in adolescents with asthma: a qualitative study using the Theoretical Framework of Acceptability.

5.1 Abstract

Background: Interactive, mixed-reality technologies such as augmented reality (AR), virtual reality (VR) and holographic technology may provide a novel solution to fast-track the translation of evidence into practice; and may help overcome barriers to both mental health and asthma management service uptake, such as cost, availability of appointments, fear of judgement, and quality of care.

Objectives: The aim of this study was to investigate if mixed reality technology is an acceptable mechanism for the delivery of a component of Cognitive and Behavioural Therapies (CBT) for the management of elevated psychological distress among young people with asthma.

Methods: To explore the perceived acceptability of these technologies, mixed reality tools were evaluated via qualitative, one-on-one interviews with young people with asthma and symptoms of psychological distress, parents/caregivers of young people with asthma and symptoms of psychological distress, and relevant health professionals. The Theoretical Framework of Acceptability (TFA) was used for deductive coding of recorded interview transcripts.

Results: Three young people with asthma and symptoms of psychological distress (2 female, mean age (years) = 14, SD= 1.73), four parents/caregivers of individuals with asthma (1 female, mean age (years) = 55, SD= 14.58) and six health professionals (4 females, mean age = 40.8, SD= 4.32) consented to participate. Four constructs – experienced affective attitude, experienced effectiveness, self-efficacy and intervention coherence – were coded in all participant transcripts. The most frequently coded constructs were experienced affective attitude and intervention coherence; both reported a total of 96 times, while the least frequently coded construct was anticipated opportunity cost; reported a total of 5 times. Participants were mostly positive about the mixed reality resources.

However, some concerns were raised regarding ethicality, particularly in relation to privacy, accessibility, and messaging. Participants noted the need for technology to be used in conjunction with face-to-face engagement with health professionals, and that some patients would respond to this type of delivery mechanism better than others.

Conclusions: These results suggest that mixed reality technology for the purposes of delivery of psychological intervention may be an acceptable addition to current healthcare practices for young people with asthma and symptoms of psychological distress.

Trial registration: The study was prospectively registered with the Australia and New Zealand Clinical Trials Registry (ANZCTR): ACTRN12620001109998.

Keywords: asthma; augmented reality; virtual reality; mixed reality; psychological distress; adolescent; cognitive behavioural therapies

5.2 Background

5.2.1 Asthma and psychological distress in adolescence

Australia has one of the highest asthma prevalence rates in the world (GINA, 2018), with 11% of people being affected, as per self-report (AIHW, 2020). Asthma is the leading cause of disease burden among young Australians aged 5 to 14 years, with 460,000 young people (10%) affected (AIHW, 2020). (GINA, 2020, Prapa et al., 2017, Desager et al., 2018, Kaplan and Price, 2020, Baiardini et al., 2015)

According to a 2018 report, people with asthma were more likely to experience psychological distress (the experience of symptoms of anxiety and depression at sub-clinical levels (Drapeau, 2012)) than individuals without asthma – 15% vs 8.7% for high levels, and 11% vs 3.4% for very high levels (AIHW, 2019). In adolescents, a 2014 survey of 533 Australians aged 12 to 25 years found that half of young people with asthma experienced symptoms of heightened psychological distress (Blanchard et al., 2014). The most common causes of distress were similar to those of adolescents without asthma, however, asthma-related problems also contributed to psychological distress in this sample. The study highlights that psychological distress is not uncommon and has both asthma and non-asthma-related triggers. (Tran, 2019, Prapa et al., 2017, Smith and Jones, 2015)

5.2.2 Psychological interventions for people with asthma

Due to the bidirectional relationship between asthma and symptoms of psychological distress (Baiardini et al., 2015), psychological interventions may offer techniques and strategies to manage both psychological distress and symptoms of asthma, thus reducing the risk of exacerbations (Duff, 2001). Research in this population is limited, with a 2005 systematic review (currently being updated (Sharrad et al., 2019)) unable to draw conclusions about the potential role of psychological interventions for children with asthma, due to heterogeneous data (Yorke et al., 2005). Cognitive and behavioural therapies (CBT) are a type of psychological intervention which helps patients recognise and modify thoughts and behaviours that may be detrimental to health and wellbeing (Andrews et al., 2018). CBT-based strategies could be useful in the treatment of symptoms of heightened psychological distress in people with asthma; however, evidence suggests that engagement with treatment is low in this population, with reports estimating that four out of five children and adolescents who could potentially benefit from psychological intervention are reportedly not accessing it (Bekker et al., 2017). In a 2016 Australian survey, 48% of parents of adolescents aged 12-17 years reported that their child refused help, 39% of parents were not sure where to get help, 33% could not afford help, whilst 29% reported that they could not get an appointment (AIHW, 2016). Even when services are accessed, a recent study conducted in 21 countries found that only 9.8% of individuals with an anxiety disorder received possibly-adequate treatment based on evidence-based guidelines (Alonso et al., 2018).

5.2.3 Technology for health interventions

A recent systematic review of 28 studies found that text-based internet searches were the most commonly-identified help-seeking approach among adolescents, along with other online communities (Pretorius et al., 2019). Reasons for this preference for online help-seeking include anonymity and privacy, immediacy, ease of use, inclusivity, connection with others, and an increased sense of control (Pretorius et al., 2019). However, the effectiveness and safety of unguided self-help varies significantly due to the wide range and quality of sources available (Andrews et al., 2018). Evidence-based psychological interventions delivered via technologies such as smartphone apps and online resources – also known as e-psychology, e-health, or e-mental health interventions - have potential to be an effective option for psychological wellbeing support, which in turn may increase access to, and quality of, care (RANZCP, 2019). A 2016 meta-analysis exploring the use

of digital CBT (eCBT) in children and adolescents reported reduced anxiety in the intervention group, compared with control. No statistically significant differences in efficacy were observed between digital and in-person treatment modalities (Podina et al., 2016).

5.2.4 Mixed reality for health interventions

Interactive technologies such as augmented reality (AR), virtual reality (VR) and holographic technology (also known as mixed reality technology), may provide a novel solution to aid in the timely translation of evidence-based treatment into practice. Using a smartphone as a viewing device, AR superimposes digital information into the real world, so that content seems to coexist with reality (Bacca et al., 2014a), VR uses a headset for viewing of content, allowing the viewer to feel completely immersed in the digital world, while holographic technology uses the projection of diffracted light to create images. Mixed reality technologies deliver treatment and healthcare information through videos, graphics and animation, which can: address low health literacy (Bacca et al., 2014a, Kim and Xie, 2017); allow for tailoring for individual population characteristics (e.g. age, language); increase engagement (Akcayir and Akcayir, 2017); increase accessibility of information (Porter and Heppelmann, 2015); and allow for real-time updates of content, thus reducing the evidence-to-practice gap. AR and VR have been studied in multiple healthcare contexts including cancer, autism, and chronic pain, with feasibility, acceptability and early efficacy data suggesting that these modes of intervention delivery may be beneficial for adolescents (Radovic and Badawy, 2020, Flujas-Contreras et al., 2020, Tennant et al., 2020).

In children and adolescents with asthma, a recent scoping review found that digital health interventions (including virtual reality and augmented reality interventions) were a promising option for asthma management and treatment delivery, and were perceived positively by healthcare professionals and by patients (Mosnaim et al., 2021). Methodologically rigorous research is needed to ensure evidence-based, easily accessible digital interventions are made available (Mission Australia, 2017, Mosnaim et al., 2021).

This research will examine acceptability of mixed reality technology as a CBT delivery mechanism to manage symptoms of elevated psychological distress among young people with asthma.

5.2.5 Aims

The aim of this study was to investigate if mixed reality technology is an acceptable mechanism for the delivery of a component of CBT for the management of symptoms of elevated psychological distress among young people with asthma.

5.3 Methods

This paper focusses on the acceptability of mixed reality technology as a delivery mechanism for a component of CBT for the management of symptoms of elevated psychological distress among young people with asthma. The mixed reality tools utilised for this qualitative study were pre-existing resources, including one bespoke AR resource (such as Figure 4), one VR resource and one holographic resource (Figure 5). For the AR resource, participants used the camera on a smartphone to make a digital image of a human body appear as though it was in the real space (e.g. Figure 4). The digital image provides information about asthma and the effect it can have on various body systems; demonstrating how psychoeducation (a technique used in CBT) could be offered using this technology. For the VR resource, participants wore a cardboard headset over their eyes, into which a smartphone was placed. The smartphone played a VR-specific video of calming nature landscapes while a meditative audio track played. The holographic resources involved a small plastic projector (Figure 5) being placed over a smartphone. When a specific video was played, images appeared in 3D within the plastic projector. The VR and holographic resources demonstrate the capacity for these technologies to deliver mindfulness strategies. Three different technologies were chosen for hypothesis-generating purposes to establish if one mechanism is more acceptable than others.

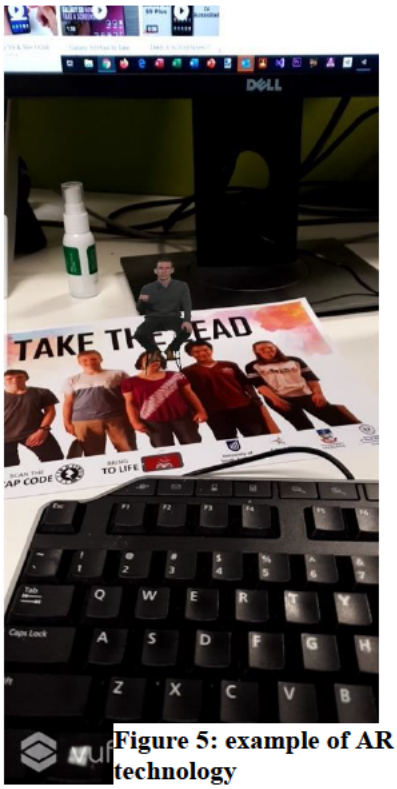


Figure 5: example of AR technology

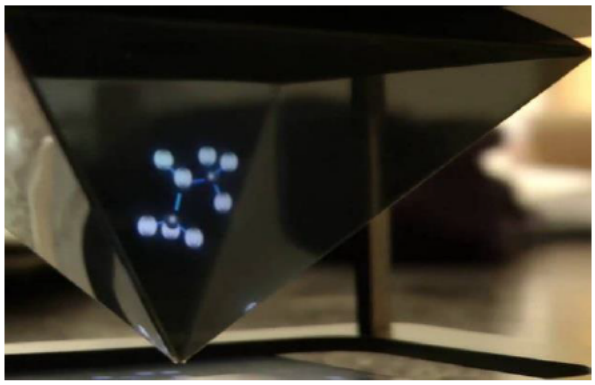


Figure 4: example of holographic technology

To evaluate perceptions of usability and appropriateness, one-on-one interviews were

carried out with the target audience. Semi-structured moderator guides (appendix 2.3) were developed to direct interviews with young people with asthma, parents of young people with asthma, and health professionals, including general paediatricians, psychologists, psychiatrists, nursing staff and paediatric respiratory specialists. Participants were not provided with access to the mixed reality resources before the interview. During the interviews, researchers provided a brief training session, and participants were provided with the mixed reality resources with which to interact in their own time. Interviews ran for approximately one hour; and took place in meeting spaces in the respiratory department at two large, teaching hospitals in metropolitan Adelaide, South Australia, or online via Zoom software. Sessions were audio-recorded, and verbatim transcripts were sent back to the participant for validation post interview. Participants also completed a simple questionnaire (appendix 2.4) requesting demographic information, as well as self-reported measures of asthma knowledge and technology useability that will be explored in subsequent manuscripts.

5.3.1 Sampling/Recruitment

Participants were all identified through a paediatric respiratory specialist at the Women's and Children's Hospital. Health professionals were recruited through word-of-mouth. Purposive sampling was utilised to ensure a good representation of participant characteristics to meet the requirements of the research question.

Hospital staff provided potential participants with a copy of the participant information sheet and consent form for their review. If participants were interested in learning more, consent to contact was obtained, and research staff were given contact details to follow-up for screening and consenting procedures.

Inclusion criteria for young people: Young people were eligible for inclusion in this study if they: were aged between 13 and 17 years; have been formally diagnosed with asthma by a health professional (inpatients or outpatients); have experienced or are currently experiencing symptoms of psychological distress determined by the K10+ scale (Kessler et al., 2002), have access to a smartphone with the owner's permission to use it during the interview; are English speaking/able to understand written English.

Inclusion criteria for caregivers/parents: Participants were eligible for inclusion in this study if they: are the caregiver/parent of a child with asthma (aged 13 to 17 years) where the child currently has/or has reported in the past elevated symptoms of psychological

distress (does not need to be the parent/caregiver of a child actively participating in this study); have access to a smartphone and able to use smartphone technology (basic level); are English speaking/able to understand written English.

Inclusion criteria for health professionals: Health professionals were eligible for inclusion in this study if they: have been practising in their respective fields for at least 12-months; have access to a smartphone and can use smartphone technology (basic level); are English speaking/able to understand written English.

Exclusion criteria for all participant groups: Participants with an intellectual disability or cognitive impairment that would inhibit their ability to provide informed consent and participate in the project were ineligible to participate. Young people with a history of epilepsy or other contraindication for the use of VR will also be ineligible to participate.

5.3.2 Qualitative Data Analysis

Qualitative data was coded using three pre-specified lenses to enable insight into different aspects of the mixed reality interventions – the Theoretical Domains Framework (TDF), the Theoretical Framework of Acceptability (TFA), and the Enlight protocol. This publication will focus solely on data obtained through the TFA, while the TDF and Enlight protocols will be featured in separate manuscripts. Deductive thematic coding was used with a framework analysis technique based on the TFA (Sekhon, Cartwright & Francis 2017). The TFA comprises seven constructs reflecting the multi-faceted nature of acceptability, incorporating both anticipated and experienced thoughts, beliefs and feelings regarding the intervention (Pavlova et al., 2020, Sekhon et al., 2017). The seven constructs are ethicality, self-efficacy, intervention coherence, affective attitude, burden, opportunity costs and perceived effectiveness, with the last four separated into ‘anticipated’ and ‘experienced’ subcategories. The TFA has been shown to be successful for exploration of acceptability in health promotion interventions (Murphy and Gardner, 2019). Previous research demonstrates more robust understandings of acceptability when a framework is applied, compared with no framework (Murphy and Gardner, 2019, Pavlova et al., 2020, Sekhon et al., 2017).

All transcripts were coded by two independent researchers (KS and CM), with discrepancies resolved through discussion and consensus, or discussion with a third party (KCC). During the coding process, quotes were determined to be generally positive,

negative, or neutral toward the mixed reality technology. A standardised, pilot-tested data extraction Microsoft Excel template was used for data management.

5.3.3 Ethics Approval

This project is conducted in accordance with the principles of the Declaration of Helsinki (2013) and has received ethical approval by the Human Research Ethics Committee for the Women's and Children's Health Network (HREC/18/WCHN/172), and the University of South Australia Ethics Committee (Application ID: 201967).

5.4 Results

5.4.1 Participants

A total of 19 participants were approached to take part in the study, with 13 completing interviews. Two young people and one parent withdrew from the project for psychological reasons, and another two young people and one parent were considered ineligible. Interviews were conducted by one of three researchers - KS, ZK and KCC.

The 13 participants included three young people with asthma, four parents of young people with asthma, and six health professionals (including two psychologists, one psychiatrist, one medical consultant, one respiratory nurse consultant, and one respiratory sleep nurse consultant). Average duration of experience among health professionals was 17.08 ± 5.87 years. As per the inclusion criteria, all young people reported to have experienced or were currently experiencing symptoms of psychological distress determined by the K10+ scale. The technology experience level of participants varied greatly. Full demographic details are presented in Table 5.1.

Table 5.1: Participant demographic data.

Participants	*Young people with asthma*	*Caregivers of young people with asthma*	*Health professionals*
Total	*3*	*4*	*6*
Age – mean years (SD)	*14 (1.73)*	*55 (14.58)*	*40.8 (4.32)*

Gender – n female	*2*	*1*	*4*
Ethnicity	*n=3 Australian*	*n=4 Australian*	*n=5 Australian, n = 1 Australian/UK*

Key: SD=standard deviation; all values are numbers (n-values) unless otherwise stated.

Qualitative analysis

Four constructs – experienced affective attitude, experienced effectiveness, self-efficacy and intervention coherence – were coded in all 13 participant transcripts. The most frequently coded constructs were experienced effective attitude and intervention coherence; both reported a total of 96 times, while the least frequently coded construct was anticipated opportunity cost; reported a total of 5 times. The remaining categories were coded between 11 and 85 times. Example quotes for each TFA construct are included in Appendix 5.1.

Participant groups were similar in their proportion of positive, negative, and neutral quotes across all constructs (as seen in Table 5.2).

Table 5.2: Positive, negative, and neutral quotes obtained from participant interviews, organised by participant group.

Participant group	*Positive*	*Neutral*	*Negative*
Health professionals	138 (56%)	78 (31.8%)	29 (11.8%)
Young people with asthma	48 (64%)	23 (30.6%)	4 (5.3%)
Parents of young people with asthma	79 (66.4%)	32 (26.9%)	8 (6.7%)

Affective attitude

Affective attitude is defined as "how an individual feels about taking part in an intervention" (Sekhon et al., 2017). Transcripts were coded with quotes prior to and following exposure to the intervention, in order to assess anticipated and experienced affective attitude. There were 25 quotes identified for anticipated affective attitude, with most being positive (n=13). Most quotes were identified in interviews with health professionals, with a common theme emerging of the potential for technology to be a useful tool when used in conjunction with face-to-face consultation with physicians

"*I think on its own, I would be worried, but if they're also seeing a therapist, counsellor, psychologist... or had a trusted adult and health professional to talk to, I think it could be very positive*".

Young people were also generally positive about the idea of technology:

"*Um, yeah, definitely. It would help. A lot because you know a lot of people spend most of their time on their phones nowadays, having an app like that. Well, you know, it would probably help a lot and you would be more, you know, you would probably use it more*."

Similarly, 96 quotes were identified for experienced affective attitude, with the majority being positive (n=73). "Calming", "cool", and "engaging" were terms often used by participants in all groups to describe their experience. However, not all experiences were positive. One health professional suggested that

"Uh, I probably couldn't be bothered doing it myself, I guess. Um, I think sometimes it's just about grabbing people's attention and to me I felt that had a sense that young people would say, yeah, yeah, whatever.".

The comment that the holographic technology did not meet expectations was commonly occurring among health professionals and parents of young people especially, along with disappointment about the size of the hologram.

"I think if you kept, like, if you kept it, that kind of size, I think you'd lose engagement. Cause it would just be too little. But if you could have that, so it was like a really big thing then that'd be cool." – Health professional

Perceived effectiveness

Effectiveness refers to "the extent to which the intervention is perceived as likely to achieve its purpose" (Sekhon et al., 2017). Once again, transcripts were coded to assess

both anticipated and experienced effectiveness. Twenty-three quotes were identified for anticipated effectiveness, with n=11 positive, n=2 negative, and n=9 neutral. When asked if this kind of technology could be useful for young people with asthma, young people tended to answer in the affirmative, with one participant explaining:

"Um, yeah, definitely. It would help. A lot because you know a lot of people spend most of their time on their phones nowadays, having an app like that. Well, you know, it would probably help a lot and you would be more, you know, you would probably use it more."

As with affective attitude, quotes coded for this domain in transcripts with health professionals focussed on the need for technology to be used in conjunction with face-to-face engagement with health professionals. Participants also noted that some participants would respond well to information delivered via technology, and others wouldn't:

"I think it's a really good adjunct because there are some people that that will be like perfect for them. And there are some people that it will be okay with and there'll be some people that won't engage with it or won't have the actual technology resources themselves, like the phone and the iPads... have access to do it. So I think it just adds another string to your bow, it's some other way that will work. And it's about figuring out that goodness of fit." – Health professional

Eighty-five quotes were coded for experienced effectiveness; n=56 positive, n=8 negative, and n=21 neutral. Participants felt that the technologies would be beneficial, particularly for the purpose of education, given the engaging visual nature of the information:

"So the goal is to understand as best you can, what's happening either inside your own body or inside your child's body? Okay. So that's, that's the aim. What is the best mechanism for doing that? Well, to see it really, isn't it. And so then to see it in the most representative and the most real and the most, um, sort of engaging way becomes I guess the goal." – Parent of young person with asthma.

Once again, participants in all groups suggested that some people would respond more positively than others –

"It would be very beneficial for them. At least. Um, or at least some people, depending on if they prefer it this way or that way. It would be very beneficial to the people who absolutely prefer something like this to learn, and to discover more about themselves." - *Young person with asthma.*

Participants also noted the ease of accessibility of the information:

"Yeah, definitely because that's something that they can access at home and it's something that they can access at any time. Um, it's creating that, um, autonomy to the, to the patient, to the family, um, re- reinforcing education that they might want, but in their own time and privacy of their own home." – Health professional.

Ethicality

Ethicality is "the extent to which the intervention has good fit with an individual's value system" (Sekhon et al., 2017). Fifteen quotes were coded for this construct, with the majority (n=8) being classified as neutral, n=2 as positive, and n=5 as negative. Twelve of these quotes were coded in interviews conducted with health professionals, and none were from interviews with young people. Issues identified included questions of accessibility – "*they might not have access to reliable internet, or they may not have the money or access to a device, then, you know, it's all very well having that, but they might not have the ability to use it*" – privacy – "*Um, I think I have concerns over privacy and access to data and so on, in particular as most, um, servers seem to be based overseas*" – accuracy of online messaging – "*as long as you… stick to your mainstream stuff and um, organisations that publish things*" - and importance of human interaction – "*I think that it's important that not everything is self-diagnosed and then self-referred to sort of technology treatments, I suppose. I think probably having an element of, um, human interaction is important*".

Opportunity costs

Opportunity costs refer to "the extent to which benefits, profits or values must be given up to engage in the intervention". Transcripts were coded to assess both anticipated and experienced effectiveness. Five quotes were coded for anticipated opportunity costs, all from interviews with health professionals. Health professionals were asked if they thought that learning to use this kind of technology would be a good use of their time; n=4 quotes were positive, and n=1 was negative. The positive comments were replying to the question in the affirmative - *"Yeah. Yes. Because then it would help me to keep up with the young people, and know what they're talking about."* – while the negative comment expressed that the technology would not be relevant to her work – *"Not for me. No."*. Eleven quotes were coded for experienced opportunity costs, with quotes identified from all three categories of participant – n=8 of these were positive, and n=1 were neutral. Health

professionals commented on whether or not learning to use and recommend the technology would be a good use of their time – "*Yeah, definitely because that's something that they can access at home and it's something that they can access at any time*" - well as the accessibility of the technology for the purpose of intervention delivery.

"Particularly if it's say if it's an app you download on your phone, if it's a card box that you can easily access, think what people are looking for is that con- convenience, just download the app. That's sort of a low cost, no cost apps or the little cardboard boxes. And that again in my sort of world in education. They're easy recommendations to make." – Health professional

Likewise, young people and parents of young people commented predominantly on the accessibility of the technology. One parent noted that the accessibility would depend on the skills and abilities of the user: *"Um, I would say that if it's on the phone, it's more accessible, probably quicker, but that would also depend on your knowledge. [inaudible] accessing it."*

Burden

This construct was also separated into anticipated and experienced sub-categories, and is defined as "the perceived amount of effort that is required to participate in the intervention". Fourteen quotes were identified for anticipated burden, with n=6 positive, n=1 negative, and n=7 neutral. The majority of comments regarding anticipated burden related to the age of the participants, with comments identified in interviews with all three groups of participants. When asked if they thought the technologies would be difficult to use, one health professional said *"For me? Yes. For a young person? No."*, and one parent of a young person agreed:

"Probably difficult for my age group. Um, because you know, we didn't grow up with them, but the kids it's just like, they don't find it difficult at all."

Young people with asthma also echoed that sentiment - *"Um, in some cases maybe".* While another parent of a young person with asthma disagreed:

"I think the awareness of technology these days of people my age as well as the younger generation is pretty reasonable. So most things you pick up on pretty quickly.".

Similarly, some health professionals expressed confidence in their ability to use the technology – "*Um, no. I think everyone's pretty up to date relatively with smart phones and that these days, so... no. not really difficult."* – while another expressed concerns:

"I've noticed that I'm getting to an age now where I might not be quite up to speed with all, all the technology. So, you know, that can be a barrier as well if the clinicians and the treating teams aren't up to speed.".

Forty-six quotes were coded for experienced burden, with the majority (n=30) being positive. Seven (n=7) comments were negative, and n=5 were neutral. Many participants used the words "*easy*" and "*simple"* to describe their experience using the technologies, with individuals expressing that it would be easy to use once familiar with the technologies (*"Um, I suppose anything like that is easy once you're using it for a while"* – Parent of young person with asthma), and once again citing age as a confounding factor (*"Um, probably easy for young people and it'd be harder for older people."* – Young person with asthma). Notably, participants expressed concerns about burden of the holographic technology more than the AR and VR tools.

"I think we'd have to say it was moderately difficult. Right? If I didn't have a skilled proponent of the technology that I would have seen nothing cause you, but you could imagine a little arrangement that has a black bit of cardboard at the back and then something that sort of positions that somehow, need a little bit of thoughts and kind of got to position it from above don't you, otherwise you interrupt one of your pictures." – Parent of young person with asthma

Self-efficacy

This construct refers to "the participant's confidence that they can perform the behaviour(s) required to participate in the intervention". Twenty-nine quotes were coded for this construct, with n=17 positive, n=5 negative, and n=6 neutral. Similarly to quotes identified for the Burden construct, participants often shared that they found the technology easy. Once again, a few of the adult participants commented that they might find the technology difficult, but that a younger person probably would not, with one health professional explaining; *"I'm not tech savvy"*. One parent shared that while some people of his age would adapt well to technology, he found it more difficult:

"Look, uh, certainly there would be a certain amount in my generation. I would think that, um, possibly, a little bit more, uh... You know, adaptable to computers and

things. There's some pretty smart people out there of my age that, you know, it's. Computers and that, and technology is natural for them. It's never been sort of part of what I've ever done if you know what I mean?"

Likewise, when the young people with asthma were asked if they would use the tools themselves, most answered in the affirmative – "*Yes of course I would. These like, really work, very informative and very, very calming."* – and most indicated that they were comfortable using the technology.

Intervention coherence

Intervention coherence is defined as "the extent to which the participant understands the intervention and how it works". There were 96 quotes coded for this construct. While some were unsure about the technology prior to experiencing the intervention (*"I have heard of it. I don't sort of understand it too much." – Parent of young person with asthma*), most demonstrated understanding afterwards. Researchers also considered that quotes regarding how the technology could be used outside of the current project demonstrated an understanding of the intervention and how it worked, and thus were appropriate to this construct. For example, one health professional said:

"Yeah. To be used as like a treatment tool for those kids? I guess it depends on what you're actually wanting to deliver, but I can definitely see potential that if you're giving, um, if you're giving education on how like lungs work and how the pathophysiology of it all and the effectiveness and how medications work like um, your bronchodilators or whatever, then that could be really good cause I can actually see what's happening inside of them. So I think that would then help them kind of put the picture together as opposed to just talking to them. From an anxiety and depression point of view. Um, yeah, I mean, I think that like a guided meditation type thing, like you did with the [VR] one that could, that could be useful in that kind of scenario."

5.5 Discussion

The findings of this study suggest that mixed reality technologies are generally acceptable to a group of young people with asthma, parents of young people with asthma, and health professionals. Participants across all three groups largely felt positively toward the mixed reality technology (as per Table 2), considered them to be potentially effective, and considered the technology easy to use. This is also seen in a recent study in hospitalised children and adolescents with chronic illnesses, which found that, when compared to face-

to-face CBT, a VR treatment involving education, breathwork, and mindfulness techniques received higher perceived efficacy scores (Flujas-Contreras et al., 2020). Similarly, a 2020 study exploring the feasibility and acceptability of a VR intervention for psychological wellbeing in children and adolescents with cancer found that the technology was viewed positive by health professionals, parents/caregivers, and patients (32). The largely positive affective attitude towards the mixed reality resources is promising, as affective attitude is an important determinant of behaviour (Fishbein and Ajzen, 2011), and has been demonstrated to be a predictor of engagement with health behaviours (Conner et al., 2014, Lawton et al., 2009, Conner and Norman, 2021, McEachan et al., 2016).Many participants – particularly health professionals – highlighted the need for technological interventions to be offered as an adjunct to existing resources, and stressed the importance of face-to-face communication with care providers – to ensure participant understanding of treatment instructions, and to ensure ongoing relationships between patients and healthcare professionals. This is supported in previous literature, with authors suggesting that technology-delivered healthcare may be suitable to provide support between face-to-face appointments (Mosnaim et al., 2021). It was also noted that patients respond differently to different modes of treatment delivery, and that some may prefer in-person communication while others may prefer online modes. Health professionals were also most likely to have concerns relating to the opportunity cost of the intervention (e.g. time taken to learn the technology and teach patients). This fits with recent literature, which states that health professionals are reported to be time-poor and overburdened (Miles et al., 2017).

Concerns were raised among all three groups of participants surrounding the ethicality (how well the intervention fit with the participants' values) of the intervention, but was mostly discussed by health professionals. Privacy and accuracy of messaging were identified as potential issues, as well as accessibility of a technological intervention for all socioeconomic groups. Issues surrounding privacy and mobile technologies in healthcare have already been identified in prior research, with some participants expressing concerns about the safety of medical data collected or transmitted via mobile devices (Atienza et al., 2015, Dang et al., 2021). Accessibility issues are also of legitimate concern, as while 9/10 Australians own a smartphone, rates of use are still low in some groups, including those with disabilities, and low household income (Economics). Additional research is warranted to explore the potential effects of this disparity.

Interestingly, multiple participants – most commonly health professionals and parents of young people with asthma – reported being disappointed with the holographic technology

due to high expectations based on the portrayal of holographic technology in movies and TV shows. These preconceived perceptions may have introduced bias for the assessment of this type of technology. Future research with a larger budget may consider upscaling this type of resource to meet preconceived perceptions. Participants also expressed concerns about the burden of using holographic technology moreso than VR or AR. The feedback comparing the mixed reality technology modalities led researchers to amend protocols for future studies limiting intervention content to AR.

5.5.1 Limitations

The sample of participants were all recruited from the one hospital in Adelaide, South Australia, limiting the generalisability of the results to the larger population. While fewer than originally planned, this sample size was considered appropriate for the project timeline. Sim et al (Sim et al., 2018) included such "Rules of Thumb" as "between 12 and 20 participants in interview studies", "2-10 participants in order to achieve 'redundancy or saturation'", and "at least five one-hour interviews for theoretical saturation in grounded theory studies". Furthermore, recent qualitative studies report similar sample sizes (Beauregard et al., 2017, Chew et al., 2018, Pateraki et al., 2018, Holmes et al., 2019, DeSouza, 2017).

5.5.2 Implications for practice

Findings from this study demonstrate that mixed reality resources may be an acceptable treatment/intervention delivery mechanism for young people with asthma. Participants reported feeling positive about the technology and the potential efficacy of this delivery mechanism, and the technology was largely considered easy to use. Healthcare services might consider the use of mixed reality technology in conjunction with existing resources to diversify treatment delivery, and to increase engagement.

5.6 Conclusion

Results from this study suggest that mixed reality resources may be an acceptable addition to current healthcare practices for the purposes of delivering psychological intervention to young people with asthma. Participants were mostly positive about the mixed reality resources, however some concerns were raised regarding the ethicality, particularly in relation to privacy, accessibility, and accuracy of messaging. Participants noted the need for technology to be used in conjunction with face-to-face engagement with health professionals, and that some patients would respond to this type of delivery mechanism

better than others. Further randomised trials are warranted to explore the effect of mixed reality resources on health and behaviour outcomes in this population.

5.7 Acknowledgements

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5.8 Conflict of Interest

The authors report no conflicts of interest to be declared.

6 Chapter 6 - Discussion

The manuscripts within this thesis explored the use of psychological interventions to manage symptoms of anxiety in adolescents with asthma, needs of adolescents with asthma, as well as mixed reality technologies as a delivery mechanism for these psychological interventions in young people experiencing symptoms of psychological distress. We aimed to understand the needs of young people with asthma and symptoms of psychological distress, understand potential avenues for treatment and their effectiveness, and to understand the appropriateness of technology-based resources to manage symptoms of psychological distress in young people with asthma. Study 1 sought to fill a gap in the literature by evaluating the effectiveness of psychological interventions as a treatment method for children and adolescents with asthma, via a Cochrane systematic review. We found existing evidence was limited, with mixed results for the use of psychological interventions in children and adolescents with asthma. However, for primary outcomes such as symptoms of anxiety and/or depression, as well as health outcomes such as asthma symptoms, most studies found a positive effect. Due to the heterogeneity of interventions, outcomes and outcome measures, small sample sizes, and risk of biases, the evidence for all outcomes is very uncertain. Study 2 aimed to understand the modifiable drivers of psychological distress in young people with asthma via a needs assessment. We explored the literature through narrative review, and identified potential avenues for intervention; of note, including children and adolescents in their treatment planning, coping assessment and planning with adolescents, and referral to and communication between healthcare service providers. Study 3 sought to evaluate mixed reality technologies as a potential delivery mechanism for psychological intervention among young people with asthma and symptoms of heightened psychological distress. In Study 3, we identified that mixed reality technologies were generally well-accepted as a delivery mechanism for psychological intervention in young people with asthma and symptoms of psychological distress. Concerns were raised regarding ethicality, particularly in relation to privacy and accessibility, and results highlighted the need for technology to be used as an adjunct to existing face-to-face engagement with healthcare professionals.

Results from these studies can be used to direct future research in this field, as well as help inform future guidelines for practice and policy. As described in greater detail in sections 6.1.4 and 6.3 below, the data obtained through these studies has been used to develop a

feasibility study, as well as a fully funded RCT exploring the efficacy of novel technology resources to deliver psychological intervention along with asthma self-management strategies to young people with asthma. This work has continued to strengthen the relationship of the research team with Asthma Australia; who have contracted the team to undertake systematic reviews and inform their research plan for policy and advocacy. Further, the team was previously commissioned by the Sax Institute to explore Potentially Preventable Asthma-Related Hospitalisations. These recommendations, including those for technology-based solutions, were provided to the NSW Government to inform future policy and guidelines. Ongoing engagement with these key stakeholders facilitates advocacy for greater investment in the technology agenda, and strengthens the evidence for novel technologies as an asthma service delivery pathway. The body of work contained in this thesis has built upon previous studies by the research team, exploring AR as a modality for asthma inhaler education to children with asthma (O'Connor et al., 2023b), which has been used to develop an AR-enabled asthma inhaler chart, which was taken up by the National Asthma Council and has been used in clinical practice. This demonstrates the potential for the evidence obtained through this body of work to indirectly and directly inform future guidelines along with policy and practice. The following sections will compare and contrast findings from this program of work with existing literature, summarise the limitations of the present studies, and provide recommendations for future research and clinical care based on our findings.

6.1 Findings from similar studies

6.1.1 Psychological interventions for asthma

While some asthma guidelines (GINA, 2020) acknowledge the need for psychological and social support in asthma management (Prapa et al., 2017), the focus of clinical asthma treatment is predominantly on the biological needs associated with asthma and diseases which are correlated with asthma. Recent research demonstrates that adherence to treatment plans is generally poor, with reported nonadherence rates ranging from 49 – 71% in children and adolescents (Desager et al., 2018, Kaplan and Price, 2020). Psychological distress may also impact negatively upon medication adherence and other health behaviours, including frequency of healthcare utilisation (Baiardini et al., 2015).

As presented in the introduction, psychological interventions may provide young people with techniques and strategies to manage symptoms of psychological distress and asthma,

potentially avoiding exacerbations. In turn, this can potentially improve behavioural outcomes such as self-efficacy and medication adherence, while reducing inflammation directly - overall reducing asthma symptoms in children and adolescents.

6.1.2 Acceptability of mixed reality technology for asthma

The acceptability of AR for use by asthmatic populations explored in Chapter 5 has also been identified in recent qualitative research investigating the use of AR for demonstrative inhaler technique education in adults (O'Connor et al., 2023a). Participants in this study strongly believed in the potential for AR to improve inhaler technique. However, similarly to our study, barriers identified included access and appropriateness for different populations.

In children and adolescents, as identified in Chapter 5, a recent scoping review found that digital health interventions (which included AR and VR) were a promising option for asthma management and treatment delivery, and were perceived positively by patients and their healthcare professionals (Mosnaim et al., 2021). Recent qualitative research (O'Connor et al., 2023b) has found AR to be an acceptable modality for delivery of asthma inhaler education to children with asthma, as identified through interviews with healthcare professionals, children with asthma, and caregivers of children with asthma. Furthermore, an information recall study on the MySpira project (an AR-based app providing education on inhaler use and triggers) found that the AR resources were received better than the traditional leaflet and video educational materials, particularly in terms of enjoyment rating by children aged 6-13 years (Al-Naimi et al., 2021).

6.1.3 Acceptability of mixed reality technology for use in other chronic conditions

For use in other healthcare contexts (such as cancer, autism, ADHD, and chronic pain), AR and VR have been found to be beneficial for adolescents (Radovic and Badawy, 2020, Flujas-Contreras et al., 2020, Tennant et al., 2020, Goharinejad et al., 2022, Bailey et al., 2022). As identified in Chapter 4, participants across all three stakeholder groups felt positively toward the mixed reality technology, considered them to be potentially effective, and considered the technology easy to use. Similarly, a 2020 study in hospitalized children and adolescents with chronic conditions found that a VR intervention (which included psychological components such as mindfulness and psychoeducation), rated more highly on perceived efficacy scales than face-to-face CBT (Flujas-Contreras et al., 2020). Likewise, children and adolescents with cancer reported positive affect for a VR-based

psychological intervention in a 2020 feasibility and acceptability study (Tennant et al., 2020).

For the delivery of psychological interventions in other health contexts, VR and AR have been reported as effective for delivering treatment for anxiety disorders and phobias, eating disorders, and for pain management (Riva et al., 2018, Geraets et al., 2019, Riva et al., 2016). A recent review of mixed reality games for psychological intervention in children with ADHD found that mixed reality environments could reduce or eliminate symptoms of ADHD, including inattention, distraction, and hyperactivity, while improving social skills and executive function (Doulou and Drigas, 2022). Notably, authors found that AR environments in particular can help children with ADHD develop traits such as adaptability and resilience – important facets of the Biopsychosocial Model of Health and Wellbeing which are as yet lacking in evidence within the context of asthma and children, as identified in Study 2 (Sharrad et al., 2022). One included study reports the design, implementation and case study for an AR-based CBT game for children with ADHD (Alqithami et al., 2019). The game utilized a common therapy tool; gamification for testing and extending attention span. Authors found that the patient followed along the anticipated improvement trajectory, and found AR to be an accessible medium for therapy.

6.1.4 Gaps

No research currently exists on the use of mixed reality technology for psychological interventions in young people with asthma. However, a feasibility study is currently underway by the author team (protocol at Appendix 6.2), using AR technology to deliver a psychological intervention to young people with asthma. An 80-page workbook has been developed based on best-practice asthma guidelines and through consultation with field experts in Psychology and Paediatric Respiratory Medicine. Content includes educational information about asthma and/or psychological distress, and strategies such as mindfulness activities. The AR tools have been developed using data obtained in Study 2 and Study 3.

6.2 Limitations

Reported in more detail in Chapter 1, outcomes of the systematic review were all determined to be of very low certainty via GRADE assessment, due to substantial heterogeneity observed for psychological interventions, outcomes, and populations. This also meant we were unable to perform sensitivity analyses or subgroup analyses. Risk of

bias was also high, which impacted the certainty of the evidence; including inability to blind, subjective outcome reporting measures utilized, and small sample sizes.

Bias in the review may have been introduced via the methodology – interventions were only eligible for inclusion if they had been created or delivered by a qualified professional, and only randomized controlled trials were eligible (excluding trials such as interrupted time series, comparative studies, and controlled clinical trials without randomization). Furthermore, only peer-reviewed publications or online clinical registries were included in the review. However, while these factors limit the data available for review, they do increase rigour and strengthen review quality. To minimize the risk of biases, the review process was conducted in compliance with the *Cochrane Handbook of Systematic Reviews* (Higgins and Green, 2011).

In Chapter 4, narrative review of the data presented primarily correlational research, however, this highlights the need for additional, longitudinal, methodologically rigorous research in this area.

As explored in more depth in Chapter 5, participants in Study 3 were all recruited from one hospital, which limits generalizability of the results. Another limitation was the use of existing tools for Study 3. Bespoke resources, delivering psychological interventions aimed at children or adolescents with asthma may yield different results. The limitations of the technology reported in Chapter 5 (ethicality, accessibility, privacy etc) have been, and should continue to be, taken into consideration when planning future research directions.

6.3 Recommendations for future research and clinical care

Health care services might consider the use of mixed reality technologies in conjunction with existing treatment options to diversify delivery of psychological interventions, or other asthma treatments, and increase engagement in this population.

Due to the substantial limitations of the evidence identified in Study 1, clinical significance of the observed benefits of psychological interventions for children and adolescents with asthma remains unclear. Future research studies, using rigorous methodology with larger sample sizes and validated outcome assessment tools, are essential. The use of standardized outcome assessment tools to support cross-comparison and meta-analysis should be considered, as well as the identification of outcomes of interest that are important to patients themselves, in order to inform clinical care needs, patient objectives, and policy requirements. Future studies may consider consulting with patients and

caregivers directly to identify outcomes of interest during the project planning phase. For example, as described in section 6.1.4, the authors are embarking on a feasibility study and a full scale RCT to explore the efficacy of AR tools for psychological intervention in young people with asthma. This RCT has been co-designed with a group of stakeholders including individuals with asthma themselves, to ensure patient objectives are considered. Assessment tools have been chosen which are validated for use in the target population, and have been used in other similar studies to allow for direct comparison. Furthermore, future studies should include reporting on adverse events, disease exacerbations, and quality of life, due to the seriousness of psychological distress in young people, and the potential for complications due to ineffective treatment delivery.

Study 2 identified that holistic treatment of asthma is warranted in this population, including a thorough biopsychosocial assessment for all children and adolescents presenting with asthma, including children and adolescents in their treatment planning, coping assessment and planning with adolescents, and referral to and communication between healthcare service providers. These findings have been used by the author team to develop research tools which aim to teach and promote healthy coping strategies specifically for young people with asthma. The tools will also link participants to resources addressing other domains of the Biopsychosocial Model of Wellbeing, promoting holistic consideration of asthma management (i.e. advise on the importance of healthy eating, medication adherence, and avoidance of unhealthy coping strategies such as smoking).

Further randomized trials are warranted to explore the effect of mixed reality resources on health and behaviour outcomes in this population. Based on feedback obtained in Study 3, resources using AR technology have already been developed; using a bespoke smartphone application to activate AR technology embedded within a custom 80-page workbook (Appendix 6.1), including mindfulness activities as well as psychoeducation delivered by respiratory and psychology specialists (see Appendix 6.2 for published protocol). This work has also formed the foundation of a successfully funded grant application to further explore the use of technology as a delivery mechanism for health education and intervention through a randomized controlled trial (see Appendix 6.3 for successful application).

7 Chapter 7 - Conclusions

This thesis explored the use of psychological interventions as a treatment option for children and adolescents with asthma, biopsychosocial needs of adolescents with asthma, and mixed reality technologies as a potential delivery mechanism for psychological interventions via a Cochrane systematic review, narrative literature review, and a qualitative study.

The systematic review found limited, though predominantly positive evidence for the effects of psychological interventions. However, clinical significance remains unclear, and the certainty of the evidence was very low due to research methodology and substantial heterogeneity. The needs assessment provided a summary of the literature on modifiable biopsychosocial factors of health and wellbeing that have been shown to be associated with asthma in children and adolescents. The clear relationship between asthma and psychological distress highlights the need for holistic assessment and treatment of asthma. The qualitative study demonstrated that mixed reality resources may be an acceptable intervention delivery mechanism for adolescents with asthma. Three groups of stakeholders reported feeling positively about the technology and the potential efficacy, and found the technology easy to use. More research is warranted in both of these areas to more thoroughly explore the effects of psychological intervention when delivered via mixed reality technology for children and adolescents with asthma.

Determining safe and effective treatment for psychological distress in children and adolescents with asthma is a key priority in Australia, as identified in Chapter 1. Recent data demonstrates that 1 in 10 Australian children have asthma (Health and Welfare, 2022), and nearly half are extremely or very concerned about their mental health (Greenland and Hall, 2021). However, a recent Australian youth survey found that young people in distress will opt to do “alcohol and drugs” or “nothing” before they reach out to a professional (Greenland and Hall, 2021). This thesis has demonstrated the potential for psychological interventions, delivered via mixed reality technology, to help manage symptoms of increased psychological distress in young people with asthma. This work forms a foundation of knowledge; taking steps towards addressing the barriers to treatment in this population to try and reduce the proportion of young people turning to unhealthy coping mechanisms in the face of their chronic condition.

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8 Appendices

Section 2

2.1 Qualitative study protocol (published)

Title page

Title: Mixed reality technology as a delivery mechanism for psychological intervention in adolescents with asthma: a qualitative protocol.

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Conflict of Interest: The authors report no conflicts of interest to be declared.

Abstract

Australia has one of the highest asthma prevalence rates in the world, with this chronic and debilitating condition affecting one in nine people. The health and mental wellbeing of young people with asthma are worse than not only their peers without asthma but also worse than that of people with asthma at other ages. Psychological interventions could be beneficial in treating symptoms of elevated psychological distress in patients with asthma. However, evidence suggests that engagement with mental health services is low in this population. Technology-based solutions that engage youth may overcome barriers to service uptake for both mental health and asthma management. To fast-track the successful translation of evidence-based treatment into practice, interactive, mixed-reality technologies such as augmented reality (AR), virtual reality (VR) and holographic technology may provide a novel, low-cost solution, yet to date, methodological rigour in the evaluation of mixed reality for this purpose is lacking. To evaluate the perceived useability and acceptability of these technologies, mixed reality tools will be developed by the author team to deliver a component of a psychological intervention for treatment of elevated psychological distress among young people with asthma. Qualitative research will be conducted through one-on-one interviews with young people with asthma, parents/caregivers of young people with asthma, and with health professionals, during which participants will have time to interact with the resources. Moderator guides will be used to direct interviews, and will be supplemented with a questionnaire, including Likert-type measures of usability and acceptability to facilitate triangulation of data.

Understanding and data obtained through this study will be used to develop version 2.0 mixed reality tools, which will be tested for feasibility in a RCT. Improving access to and uptake of evidence-based treatments for elevated psychological distress in young people with asthma may reduce the burden of this highly prevalent disease.

Keywords: asthma, augmented reality, virtual reality, holographic technology, mixed reality, cognitive and behavioural therapy, psychological distress, adolescents

Background/Study Justification

Asthma in adolescence

Australia has one of the highest asthma prevalence rates in the world (GINA, 2018). This chronic and debilitating condition affecting one in nine people (AIHW, 2020), and is the leading cause of disease burden among young Australians aged 5 to 14 years (AIHW,

2020). The health and mental wellbeing of young people with asthma are worse than not only their peers without asthma, but also worse than that of people with asthma at other ages (Akinbami, Moorman, Garbe, & Sondik, 2009; Akinbami & Schoendorf, 2002). A 2014 survey of Australian adolescents and young adults aged 12 to 25 years (mean age 21.5 years, 80.3% female, 19.7% male) found that 50% of these young people with asthma experienced symptoms of elevated psychological distress. This is double the rate of the general population (Blanchard et al., 2014); a figure that has significantly increased from 18.7% in 2012, to 22.8% in 2016 (Mission Australia, 2017).

Asthma and psychological distress in adolescence

A range of challenges faced by children and adolescents with asthma may contribute to their increased experience of psychological distress, including social isolation, restricted life choices, limitations on personal potential, embarrassment and shame about their condition and/or treatment, self-consciousness, potential mortality threat, and fear of disease exacerbation (Blanchard et al., 2014). These complex, interconnected issues compound the social, psychological and developmental challenges experienced by people during this life stage (Cohen, Franco, Motlow, Reznik, & Ozuah, 2003; de Benedictis & Bush, 2007). This combined symptom profile contributes to higher levels of functional impairment (Akinbami & Schoendorf, 2002), lower quality of life (Goldney, Ruffin, Fisher, & Wilson, 2003), and higher rates of preventable hospitalisation and mortality compared to people without asthma (Calmes, Leake, & Carlisle, 1998).

A bidirectional relationship likely exists between asthma and symptoms of psychological distress (Baiardini, Sicuro, Balbi, Canonica, & Braido, 2015). Psychological factors and adverse life events exacerbate inflammation and symptoms of asthma (French & Alexander, 1943; Sandberg et al., 2000; Van Lieshout & Macqueen, 2008). Psychological distress may also impact negatively upon self-efficacy and symptom perception and, in turn, upon medication adherence and other health behaviours, including frequency of healthcare utilisation (Baiardini et al., 2015). Therefore, psychological interventions may provide young people with techniques and strategies to manage psychological distress and symptoms of asthma as they arise, in order to avoid exacerbations (Duff, 2001). For example, cognitive and behavioural therapies (CBT) are psychological interventions that treat anxiety disorders (Andrews et al., 2018). These therapies help patients recognise and modify dysfunctional thoughts and behaviours (Andrews et al., 2018). CBT can involve psychoeducation, arousal management, graded exposure, inhibitory control (learning to exert self-control to inhibit habitual behavioural responses), and/or cognitive strategies

(Andrews et al., 2018; The Australian Psychological Society, 2018). A 2018 systematic review of five studies found that CBT was beneficial for reducing symptoms of anxiety (as measured by a range of non-diagnostic tools, including the Perceived Stress Scale, Beck Anxiety Inventory, and the State Trait Anxiety Inventory) in adults, particularly when combined with asthma-related education. In children and adolescents with asthma, only two studies were eligible for inclusion, and results were mixed (Pateraki & Morris, 2018). Components of CBT could be beneficial in treating symptoms of anxiety in patients with asthma by providing strategies to promote coping; however, evidence suggests that engagement with treatment is low in this population.

Technology for health interventions

Findings from the national youth mental health survey identified that the internet is a leading source of information for youth (Mission Australia, 2017), with a preference for self-help and self-reliance over seeking professional help or help from family and friends (Burns et al., 2016). However, the effectiveness of unguided self-help varies significantly due to the wide range and quality of sources available, as well as retention rates (Andrews et al., 2018). To address these issues, peak bodies are calling for technology-based solutions that can engage youth and address the current barriers to care uptake for both mental health outcomes (Blanchard et al., 2014; Mission Australia, 2017) and asthma management (Blanchard et al., 2014; Levy & Winter, 2015).

Technology-delivered psychological interventions (also known as e-psychology, e-health or e-mental health) refer to psychological interventions delivered via technologies such as smartphone apps, wearable monitoring devices, online resources, and social media (RANZCP, 2019). These technologies have potential to be an effective option for mental health support, which may increase access to, and quality of, care (RANZCP, 2019). Technology-delivered interventions have been identified as a key policy/practice initiative as *"...evidence-based programs can be delivered en masse at low cost without the need for teacher and clinician training."* (Mission Australia, 2017). Additional benefits of a technological interface include preserved anonymity and an alternative healthcare delivery option for rural and remote patients (Boydell et al., 2014). Furthermore, the cost of administering interventions such as CBT is high, and research demonstrates that technology-delivered mental health interventions can be cost-effective for both patients and providers (Solomon, Proudfoot, Clarke, & Christensen, 2015).

A 2016 meta-analysis found that children and adolescents receiving digital CBT (eCBT) experienced less anxiety than participants in the control condition. Individuals receiving eCBT and minimal therapist care reported lower levels of anxiety than participants in the control (waitlist) condition (g=1.410, p=0.008). No significant difference in efficacy between eCBT and face-to-face CBT was identified (Podina, Mogoase, David, Szentagotai, & Dobrean, 2016). Further research and program development are needed in order to ensure that online programs and interventions are evidence-based and easily accessible to maximise uptake (Mission Australia, 2017). To fast-track successful translation of evidence-based treatment into practice, a new approach is required. Innovative interactive health technology such as augmented reality (AR), virtual reality (VR) and holographic technology, commonly referred to as mixed reality technologies, may provide a novel solution.

Mixed reality for health interventions

Using a smartphone as a viewing device, AR superimposes digital information so that content seems to coexist within the real world (Bacca, Baldiris, Fabregat, & Graf, 2014). VR is an entirely immersive technology that uses a headset for viewing of content, whilst holographic technology diffracts light into an image that is then projected. These mixed reality technologies are a novel mechanism to deliver evidence-based CBT for young people with elevated psychological distress. By delivering information through videos, graphics and animation, mixed reality technologies can: address low health literacy (Bacca et al., 2014; Kim & Xie, 2017); be tailored for population characteristics; increase engagement in content (Akcayir & Akcayir, 2017); improve geographic reach and accessibility of information (Porter & Heppelmann, 2015); and allow for real-time content updates, thus reducing the evidence to practice gap. Mixed reality resources are cheap to produce due to low-cost development tools and the availability of premade 3D assets that can be purchased and are easily customisable. Available studies (Garzón, Pavón, & Baldiris, 2019; Martín-Gutiérrez, Mora, Añorbe-Díaz, González-Marrero, & Education, 2017; Riva, Baños, Botella, Mantovani, & Gaggioli, 2016) report mixed reality technology to be an increasingly popular education tool given the ability for personalisation, and increase motivation to learn as viewers are placed at the centre of the knowledge process. A recent pilot study identified qualitatively that mixed reality technology was consistently rated to be helpful for inhaler technique by patients, health professionals and key-community stakeholders (King, Carson, Van Agteren, Kopsaftis, & Smith, 2017).

The evidence-base underpinning mixed reality for the delivery of psychological interventions is lacking. A 2018 meta-review including 25 meta-analyses and systematic and narrative reviews, found that mixed reality tools were effective for delivering behavioural treatment to reduce symptoms of anxiety disorders, eating and weight disorders, and pain management (Riva, Wiederhold, & Mantovani, 2018). Authors suggest that this is due to the ability for VR technology – like the human brain – to create an embodied simulation of the body in the world; that is, for the user to experience sensory events, and determine the best course of action to deal with those events, creating neural pathways which are activated when the simulated event is experienced in the real world (Riva et al., 2018). A more recent pilot study also found CBT delivered via VR to be feasible for the treatment of symptoms of anxiety in adults with diagnosed generalised social anxiety disorder, with mean scores on the Social Interaction Anxiety Scale decreasing significantly from baseline to follow-up (mean (SD) at baseline=59.9 (8.1), follow-up=43.1(13.9), p=0.003) (Geraets et al., 2019). Limitations of these studies included high drop-out rates and small sample sizes (Valmaggia, Latif, Kempton, & Rus-Calafell, 2016).

To date, methodological rigour in the evaluation of mixed reality technologies is lacking (Bacca et al., 2014). To overcome previous limitations, this research will examine acceptability of mixed reality technologies as a CBT delivery mechanism to manage symptoms of elevated psychological distress among young people with asthma.

Aims

Explore the feasibility of mixed reality tools to aid the delivery of CBT to manage symptoms of elevated psychological distress among young people with asthma, aged 13 to 17 years. This will be achieved through two stages:

Develop mixed reality-enabled CBT resources

Explore the acceptability and usability of these CBT resources for use by youth (13-17 years), their guardians and health professionals

Explanation and Justification of Method

This project will utilise a qualitative action research framework, in which researchers and patients work collaboratively to explore and address healthcare topics which may be sensitive (C. Pope, 2006; Malterud, 2001).

Moderator guides will direct evaluation of the tools via qualitative research (interviews), developed based on 18 categories of the theoretical domains framework (TDF) (McCullough et al., 2015), the Theoretical Framework of Acceptability (TFA) (Sekhon, Cartwright, & Francis, 2017) and the Enlight protocol (Baumel, Faber, Mathur, Kane, & Muench, 2017). The TDF will help frame the data through a policy lens to allow for translation of evidence to policy and practice. The TFA comprises seven constructs reflecting the multi-faceted nature of acceptability, incorporating both anticipated and experienced thoughts, beliefs and feelings regarding the intervention (Pavlova, Teychenne, & Olander, 2020; Sekhon et al., 2017). Previous research demonstrates more robust understandings of acceptability when a framework is applied, compared with no framework (Murphy & Gardner, 2019; Pavlova et al., 2020; Sekhon et al., 2017). The Enlight protocol is an evaluation tool for eHealth interventions (Baumel et al., 2017). Qualitative interviews will be supplemented with a questionnaire, including self-reported measures of acceptability and usability to facilitate triangulation of data.

Methods

Aim 1: Development of mixed reality resources

Mixed reality tools will be developed by the experienced author team. These will be based on needs assessment of the biopsychosocial needs of adolescents with asthma, coupled with information gained through consultation with key stakeholders (health professionals, experts in design and technology). One AR resource, one VR resource, and one holographic resource will be evaluated. Three different technologies have been chosen for hypothesis-generating purposes to establish if one mechanism is superior to others, which can be a focus in future research.

Aim 2: Evaluation of mixed reality resources – Qualitative research

To determine facilitators and barriers for the use of each mixed reality tool as well as evaluating perceptions of usability and appropriateness to reach the target audience, qualitative research will be carried out through one-on-one interviews.

During the interviews, participants will be allocated time to interact with the mixed reality resources. Semi-structured moderator guides will be used to direct interviews with n=10 young people, n=10 parents, and n=10 health professionals, including general paediatricians, psychologists, psychiatrists, nursing staff and paediatric respiratory specialists. Interviews will run for approximately one hour, and will take place in meeting spaces in the respiratory department at two large, teaching hospitals in metropolitan Adelaide, South Australia, or online via Zoom software. Sessions will be audio-recorded, and verbatim transcripts will be sent back to the participant for validation post interview.

Sampling/Recruitment

Thirty participants will be recruited for this study from participating hospitals, including 10 young people with asthma, 10 parents of young people with asthma, and 10 health professionals. Participants will be identified through Respiratory Department inpatient and outpatient lists at the Women's and Children's Hospital and the Paediatric Department' Flinders Medical Centre, and via flyers and radio/television news stories advertising the project. Health professionals will be recruited through flyers advertising the project, as well as through presentations by project staff, facilitated by the Department Head. Purposive sampling will be utilised to ensure a good representation of participant characteristics to meet the requirements of the research question.

Hospital staff will provide potential participants with a copy of the participant information sheet and consent form for their review, and research staff will follow up with interested individuals for screening and consenting procedures.

Justification of the sample size: While previous studies often referred to "saturation" to justify sample size in qualitative research, this is a problematic approach, as saturation point may be different for any given research project (Sim, Saunders, Waterfield, & Kingstone, 2018). Another common approach is applying "Rules of thumb", based on methodological considerations and past experiences with similar studies. Sim et al (Sim et al., 2018) collated some of these recommendations, which included "a broad range of between a dozen and 60, with 30 being the mean" (Adler & Adler, 2012), "20-30 informants" (Creswell & Poth, 2016), "20-30 interviews (Marshall, Cardon, Poddar, & Fontenot, 2013), "at least five one-hour interviews for theoretical saturation" (Corbin & Strauss, 2014). Though a priori determination of sample size is an imperfect approach, these rules of thumb are similar to sample sizes used in other qualitative feasibility studies (Anderson, Burford, & Emmerton, 2016; Arden-Close et al., 2013; Duncan et al., 2018;

Rhee, Allen, Mammen, & Swift, 2014), based on the extensive experience of the research team, the sample size chosen is anticipated to be appropriate for the project timeline.

Inclusion criteria for young people: Young people will be eligible for inclusion in this study if they: are aged between 13 and 17 years; have been formally diagnosed with asthma by a health professional (inpatients or outpatients); have experienced or are currently experiencing elevated symptoms of psychological distress determined by the K10+ scale (Kessler et al., 2002), have access to a smartphone with the owner's permission to use it during the interview; are English speaking/able to understand written English.

Inclusion criteria for caregivers/parents: Participants will be eligible for inclusion in this study if they: are the caregiver/parent of a child with asthma (aged 13 to 17 years) where the child currently has/or has reported in the past elevated symptoms of psychological distress (does not need to be the parent/caregiver of a child actively participating in this study); have access to a smartphone and able to use smartphone technology (basic level); are English speaking/able to understand written English.

Inclusion criteria for health professionals: Health professionals will be eligible for inclusion in this study if they: have been practising in their respective fields for at least 12-months; have access to a smartphone and can use smartphone technology (basic level); are English speaking/able to understand written English.

Exclusion criteria: Participants with an intellectual disability or cognitive impairment that would inhibit their ability to provide informed consent and participate in the project will be ineligible to participate. Young people with a history of epilepsy or other contraindication for the use of VR will also be ineligible to participate.

Data Handling/Analysis

Qualitative data will be coded using three pre-specified lenses to enable insight into different aspects of the mixed reality interventions – the TDF, the TFA, and the Enlight protocol. Transcripts will be coded by two independent researchers, with discrepancies resolved through discussion and consensus. Analysis of the questionnaire data will be descriptive, with counts and percentages for categorical data, and means and standard deviations for continuous data. Missing information from quantitative scales and surveys will be accounted for through random imputation.

Based on qualitative feedback mixed reality resources will be improved (version 2.0) for use in future feasibility studies.

Upon completion of the project, data will be synthesised for use in publications and conferences. Reports will be provided to participants and relevant consumer stakeholders, as well as funding bodies as per requirements. All ethical reporting procedures will be followed.

Ethical and Legal Aspects

Confidentiality and security of data: All data will be de-identified. De-identified data will not be stored in the same place as identified data (e.g. names, contact numbers). Hard copies will be stored in a locked filing cabinet at the South Australian Health and Medical Research Institute (SAHMRI). Electronic files will be stored in a password-protected folder on the secure University of South Australia network. It will be stored for seven years in accordance with responsible research guidelines.

Anonymity: As sessions will be audio-recorded, participants will be able to choose a name to be used throughout the interview if they do not wish to use their real name.

Informed consent: Screening will be conducted by clinical staff who will provide potential participants with a copy of the participant information sheet and consent form for their review, not research personnel. Participants will only be approached by research staff once written consent has been provided to say that they are willing to discuss the project more with research staff, in order to undertake informed consenting procedures. Participants under the age of 18 will need to obtain consent from a parent or guardian. Participants who are unable to communicate effectively in English will be excluded from the study.

Protection of participants' safety, emotional and psychological security and wellbeing: All staff interacting with young people will obtain a Working with Children Check through the SA government. Participants will have access to a trained clinical psychologist and/or paediatrician if they require additional support. The study will be undertaken using a semi-structured moderator guide with questions formulated to reduce the risk of safety, emotional and psychological security concerns. A Clinical Psychologist will be available to participants on request and this will be made clear to participants at the beginning of the interviews. Moreover, participants will be made aware that they can stop participating at any time and will be able to talk with a health professional if needed during the interview.

Risks of technology: Dizziness and nausea are possible side-effects which can occur when using the VR headsets. Participants will be informed of this possibility before interacting with the devices and will be encouraged to take breaks as needed throughout the session.

Rigour

Dependability: Interviews will be audio-recorded, and verbatim transcripts will be sent back to the participant for validation post-interview.

Credibility: To facilitate data triangulation, interviews will be supplemented with Likert scales – both validated scales and those specific to the research project – within a questionnaire. Data from participants will be compared with the Likert scale responses, adding depth and support to the interpretation of qualitative responses during interviews (Catherine Pope & Nicholas Mays, 2006).

Furthermore, the moderator guides have been developed using headings aligned with the TDF, TFA, and Enlight protocols, and data will be coded using these frameworks. This includes once under the TDF to aid knowledge translation potential (McCullough et al., 2015), again under the TFA to evaluate acceptability of the mixed reality intervention as a method to deliver CBT to young people with asthma, and once using Enlight domains to evaluate quality and therapeutic potential for the intervention.

Finally, the project proposal has undergone independent peer review through the Channel 7 Children's Research Foundation grant submission process. The proposal passed the initial EOI (expression of interest) stage where peer review comments were obtained that allowed for tailoring of the full application. The full application was submitted and approved for funding by the Channel 7 Children's Research Foundation.

Transferability: By using three groups of participants (young people with asthma, parents/caregivers of young people with asthma, and health professionals), the relevance and credibility of results are more likely to reflect the broader asthma community.

Authors' Note

The study is registered with the Australia and New Zealand Clinical Trials Registry (ANZCTR): ACTRN12620001109998.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The authors report no declarations of interest.

Ethics Approval

This project is conducted in accordance with the principles of the Declaration of Helsinki (2013) and has received ethical approval by the Human Research Ethics Committee for the Women's and Children's Health Network (HREC/18/WCHN/172), and the University of South Australia Ethics Committee (Application ID: 201967).

Funding

This project has been funded by the Channel 7 Children's Research Foundation (peer-reviewed process), the UniSA Cancer Research Institute, A/Prof Carson-Chahhoud's NHMRC TRIP Fellowship, as well as discretionary funds supplied by the University to support A/Prof Carson-Chahhoud's fellowship.

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2.2 K10+ Kessler Psychological Distress scale

K-10+

Patient or Client Identifier: |__|__|__|__|__|__|__|__|__|__|

Surname:

Other names:

Date of Birth: __ __ / __ __ / __ __ __ __

Gender: Male ☐1 Female ☐2 Other ☐3

Address:

Date completed: _ _ / _ _ / _ _ _ _

Instructions

The following ten questions ask about how you have been feeling in the **last four weeks**. For each question, mark the circle under the option that best describes the amount of time you felt that way.

		None of the time	A little of the time	Some of the time	Most of the time	All of the time
1.	In the last four weeks, about how often did you feel tired out for no good reason?	O	O	O	O	O
2.	In the last four weeks, about how often did you feel nervous?	O	O	O	O	O
3.	In the last four weeks, about how often did you feel so nervous that nothing could calm you down?	O	O	O	O	O
4.	In the last four weeks, about how often did you feel hopeless?	O	O	O	O	O
5.	In the last four weeks, about how often did you feel restless or fidgety?	O	O	O	O	O
6.	In the last four weeks, about how often did you feel so restless you could not sit still?	O	O	O	O	O
7.	In the last four weeks, about how often did you feel depressed?	O	O	O	O	O
8.	In the last four weeks, about how often did you feel that everything was an effort?	O	O	O	O	O
9.	In the last four weeks, about how often did you feel so sad that nothing could cheer you up?	O	O	O	O	O
10.	In the last four weeks, about how often did you feel worthless?	O	O	O	O	O

2.3 Moderator guides used in interviews

Moderator guide for interviews with young people with asthma.

MODERATORS:

Kelsey Sharrad

Kristin Carson-Chahhoud / Zoe Kopsaftis

LOCATION:

TBA

WELCOME:

Welcome/who we are:

Welcome. My name in Kelsey Sharrad I am a researcher from The University of South Australia and this is [Kristin Carson-Chahhoud who is an Associate Professor and research fellow] [Zoe Kopsaftis who is a post-doctoral researcher], and we are studying mixed reality technology for the treatment of symptoms of anxiety and/or depression in young people with asthma.

Why you:

You have been invited to this session because you have identified that you experience or have experienced symptoms of depression or anxiety. Our team is trying to determine whether technology such as virtual reality, augmented reality and holographic technology might be useful in delivering cognitive and behavioural therapies to treat these symptoms. To get this information, we need to understand your experience with asthma and mental health, and need your honest opinions about the mixed reality tools and how they might be useful to you. We'll talk briefly about your experience with asthma and mental health, but mostly we will discuss your experience with and opinions of the mixed reality tools.

Honesty/audio taping:

It is very important that we get your honest opinions about the issues and topics during the interview. Remember, there are no wrong answers to what we'll be talking about. We are interested in your experience and opinions, but everything discussed here will remain

completely anonymous. We will be audio recording the session for transcription purposes, however only the direct research team will have access to these audiotapes. You will not be individually identified in any of our presentations or publications.

Housekeeping:

If you need to take a break at any stage for any reason, please feel free. Let's begin.

Some generic probes

You mentioned _____, tell me more about that.

You mentioned _____, what was that like for you?

You talked about _____, describe that experience in as much detail as possible.

What else happened?

What were your feelings about that?

It sounds as though you had a pretty strong reaction.

It sounds like you're saying…….

INTERVIEW QUESTIONS

The experience of asthma and mental health issues:

What is your understanding of the relationship between asthma and anxiety or depression?

What do you think is a good treatment option for anxiety and depression? Could you give me some examples?

Where do you and people your age look for information about mental health and/or asthma? (Why?)

What do you think are the barriers to treatment in people your age?

Cognitive and behavioural therapies:

Have you heard of cognitive and behavioural therapies, or CBT, prior to this study? If so, what do you think it is?

Do you think CBT is a good tool for treating anxiety and depression in young people? Why or why not?

Technology questions:

Do you use or have access to a smartphone?

Do you use any apps relating to health – including for asthma or mental health? Do you think they're useful?

Have you heard of augmented reality, virtual reality, or holographic technologies? What is your understanding of them?

Do you think that these technologies would be difficult to use?

Break to allow participant to use mixed reality tools

15 minutes

Augmented reality tools:

Was it what you expected?

What did you like and dislike about the AR tools?

What did you think of the design of the tools?

Did you find the tools easy to use, or more difficult?

How could we make the AR tools better or more engaging?

Virtual reality tools:

Was it what you expected? Why or why not?

What did you like and dislike about the VR tools?

What did you think of the design of the tools?

Did you find the tools easy or difficult to use? Why?

How could we make the VR tools better or more engaging?

Holographic tools:

Was it what you expected?

What did you like and dislike about the holographic tools?

What did you think of the design of the tools?

Did you find the tools easy or difficult to use?

How could we make the holographic tools better or more engaging?

Mixed reality tools in general:

What age group do you think these resources were aimed at? Why?

Do you think people in this age group would benefit from these tools? Why or why not?

Would you, personally use the mixed reality tools?

Are there any other technology-based tools that we should be considering?

Closing comments:

What else would you like to tell me about your experience with asthma and anxiety, CBT, or about the mixed reality tools? Please tell me about anything else you feel is important for us to know.

Thank you for your time.

Moderator guide for interviews with parents of young people with asthma.

MODERATORS:

Kelsey Sharrad

Kristin Carson-Chahhoud / Zoe Kopsaftis

LOCATION:

TBA

WELCOME:

Welcome/who we are:

Welcome. My name in Kelsey Sharrad I am a researcher from The University of South Australia and this is [Kristin Carson-Chahhoud who is an Associate Professor and research fellow] [Zoe Kopsaftis who is a post-doctoral researcher], and we are studying mixed reality technology for the treatment of symptoms of anxiety and/or depression in young people with asthma.

Why you:

You have been invited to this session because you have identified that your child experiences or has experienced symptoms of anxiety or depression. Our team is trying to determine whether technology such as virtual reality, augmented reality and holographic technology might be useful in delivering cognitive and behavioural therapies to treat these symptoms. To get this information, we need to understand your experience relating to asthma and mental health issues, and need your honest opinions about the mixed reality tools and how they might be useful to your child. We'll talk briefly about your child's experience with asthma and symptoms of anxiety and/or depression, but mostly we will discuss your experience with and opinions of the mixed reality tools.

Honesty/audio taping:

It is very important that we get your honest opinions about the issues and topics during the interview. Remember, there are no wrong answers to what we'll be talking about. We are interested in your experience and opinions, but everything discussed here will remain completely anonymous. We will be audio recording the session for transcription purposes,

however only the direct research team will have access to these audiotapes. You will not be individually identified in any of our presentations or publications.

Housekeeping:

If you need to take a break at any stage for any reason, please feel free. Let's begin.

Some generic probes

You mentioned _____, tell me more about that.

You mentioned _____, what was that like for you?

You talked about _____, describe that experience in as much detail as possible.

What else happened?

What were your feelings about that?

It sounds as though you had a pretty strong reaction.

It sounds like you're saying…….

INTERVIEW QUESTIONS

The experience of asthma and mental health issues:

What is your understanding of the relationship between asthma and anxiety or depression?

What do you think is a good treatment option for anxiety and depression? Could you give me some examples?

Where do you and people your age look for information about mental health and/or asthma? (Why?)

What do you think are the barriers to treatment in people your age?

Cognitive and behavioural therapies:

Have you heard of cognitive and behavioural therapies, or CBT, prior to this study? If so, what do you think it is?

Do you think CBT is a good tool for treating anxiety and depression in young people? Why or why not?

Broad technology questions:

Does your child use or have access to a smartphone?

Do you know if they use any apps relating to health – including for asthma or mental health? What do you think about those sorts of apps?

Have you heard of augmented reality, virtual reality, or holographic technologies? What is your understanding of them?

Do you think that these technologies would be difficult to use?

Break to allow participant to use mixed reality tools 15 minutes

Augmented reality tools:

Was it what you expected?

What did you like and dislike about the AR tools?

What did you think of the design of the tools?

Did you find the tools easy to use, or more difficult?

How could we make the AR tools better or more engaging?

Virtual reality tools:

Was it what you expected? Why or why not?

What did you like and dislike about the VR tools?

What did you think of the design of the tools?

Did you find the tools easy or difficult to use? Why?

How could we make the VR tools better or more engaging?

Holographic tools:

Was it what you expected?

What did you like and dislike about the holographic tools?

What did you think of the design of the tools?

Did you find the tools easy or difficult to use?

How could we make the holographic tools better or more engaging?

Mixed reality tools in general:

What age group do you think these resources were aimed at? Why?

Do you think people in this age group would benefit from these tools? Why or why not?

Would you, personally, use the mixed reality tools?

Are there any other technology-based tools that we should be considering?

Closing comments:

What else would you like to tell us about your experience with asthma and anxiety, CBT, or about the mixed reality tools? Please tell us about anything else you feel is important for us to know.

Thank you for your time.

Moderator guide for interviews with health professionals.

INTRODUCTION:

Welcome/what we are trying to achieve

Thank you for agreeing to do this interview. As you know, we are undertaking this research to investigate the potential for mixed reality technology to deliver cognitive and behavioural therapies (CBT) to young people with asthma, for the treatment of symptoms of anxiety and depression. We are conducting these interviews to determine facilitators and barriers of each tool as well as evaluate perceptions of usability, and appropriateness to reach the target audience. We will talk briefly about your experience treating asthma and mental health issues in young people, then you will have an opportunity to trial the tools for yourself, after which time we will discuss your opinions on the tools.

Honesty/audio taping

It is very important that we get your honest opinions and the issues and topics during the interview and remember that everything discussed in this interview and your specific opinions will remain completely anonymous. We will be audio recording the session for transcription purposes, however only the direct research team will have access to these audiotapes. You will not be individually identified in any of our presentations or publications.

Some generic probes

You mentioned _____, tell me more about that.

You mentioned _____, what was that like for you?

You talked about _____, describe that experience in as much detail as possible.

What else happened?

What were your feelings about that?

It sounds as though you had a pretty strong reaction.

It sounds like you're saying…….

INTERVIEW QUESTIONS

Asthma and mental health issues:

In your experience, how often do you treat a young person with co-morbid asthma and mental health issues?

What is your understanding of the relationship between asthma and anxiety or depression?

Do you feel that young people feel comfortable speaking with health professionals about mental health issues?

Do you feel that you received the necessary training and information to manage symptoms of anxiety and/or depression in young people with asthma?

Cognitive and behavioural therapies:

What do you recommend as a treatment option for a young person who has asthma with symptoms of anxiety and/or depression?

Healthcare system:

How do you feel about the way that mental health issues in youth are currently handled in the healthcare system?

How do you feel about the role that technology currently plays in healthcare?

How would you feel about technology delivering healthcare information and treatment? Could you see any issues arising from this?

Do you think that apps relating to health could be useful?

Novel technology:

What is your understanding of augmented reality, virtual reality, and holographic technologies?

Do you think that these technologies would be difficult to use?

Do you think that using this kind of technology to deliver CBT would be a good use of your time?

Break to allow participants to use mixed reality tools

15 minutes

Augmented reality tools:

Was it what you expected?

What did you like and dislike about the AR tools?

What did you think about the design of the tools?

Did you find the tools easy to use, or difficult?

How could we make the AR tools better or more engaging?

Virtual reality tools:

Was it what you expected?

What did you like and dislike about the VR tools?

What did you think about the design of the tools?

Did you find the tools easy to use, or difficult?

How could we make the VR tools better or more engaging?

Holographic tools:

Was it what you expected?

What did you like and dislike about the holographic tools?

What did you think about the design of the tools?

Did you find the tools easy to use, or difficult?

How could we make the holographic tools better or more engaging?

Smartphone systems:

What age group do you think these resources were aimed at? Why?

Do you think people in this age group would benefit from these tools? Why or why not?

Do you think learning to use and recommend these resources would be a good use of your time? Why or why not?

Do you think young people would respond well to treatment delivered via smartphone?

What did you think about the included content? Do you have any comments regarding accuracy and messaging?

Closing comments

Is there anything else you would like to tell us about asthma, mental health, technology, or the tools? Please tell us about anything else you feel is important for us to know.

Thank you for your time.

2.4 Questionnaires used in qualitative study

Questionnaire for young people with asthma.

BACKGROUND

1. Current school year level: _____ 2. Age: _____

3. Gender: Male____ / Female_____

4. What is your nationality? _____

5. What area do you live in? (e.g., Western suburbs of Adelaide) _____

6. How long have you lived in this location? _____

7. Could you please list any health problems:

Started	Health problems	Finished	On Medication
March 2014	e.g. Wheeze, dry cough, diabetes	Ongoing	Yes – Puffer

ASTHMA HISTORY

How old were you when you were first diagnosed with asthma?

_____

Do you take medications for your asthma? Y / N

If yes, which medication(/s) do you use?

_____

_____

_____

Have you ever been hospitalised due to your asthma?

_____

Do your parents or siblings have asthma?_____

Please tick what triggers your asthma (tick any that apply and/or add your own)

	Outdoor allergens (pollen, grass etc)		Indoor allergens (dust, pet hair etc)
	Exercise		Household cleaning products
	Stress		Foods
	Weather conditions (cold air, humidity)		Colds and flus
	Smoke (cigarettes, fires etc)		

ANXIETY HISTORY

1. Do you experience symptoms of anxiety? Y / N

2. If yes, what symptoms of anxiety have you experienced?

_____

3. Have you spoken with a health professional about your symptoms of anxiety, if so what type of health professional?

_____

4. What steps do you take when you are feeling anxious? (e.g. speak to friends/family, take deep breaths, exercise, etc.)

_____

_____

_____

5. What do you think triggers your symptoms of anxiety?_____

_____

_____

6. What treatments for anxiety have you heard of? Where did you hear about them?

_____

_____

_____

_____

_____

_____

DEPRESSION HISTORY

1. Do you experience symptoms of depression? Y / N

2. If yes, what symptoms of depression have you experienced?

_____

3. Have you spoken with a health professional about your symptoms of depression, if so what type of health professional?

_____

4. What steps do you take when you are feeling depressed? (e.g. speak to friends/family, take deep breaths, exercise, etc.)

_____

_____

_____

5. What do you think triggers your symptoms of depression?_____

_____

_____

5. What treatments for depression have you heard of? Where did you hear about them?_____

_____

_____

_____

_____

HEALTH SCALE QUESTIONNAIRE

Please read the following questions and circle the answer that best represents you.

	1 = strongly agree, 2 = agree, 3 = more or less agree, 4 = undecided, 5 = more or less disagree, 6 = disagree, 7 = strongly disagree
I know very little about anxiety and depression	(1) (2) (3) (4) (5) (6) (7)
I often experience physical issues (exacerbations) relating to my asthma	(1) (2) (3) (4) (5) (6) (7)
I prefer to find information about health online, rather than asking my doctor	(1) (2) (3) (4) (5) (6) (7)
I feel confident in managing my asthma	(1) (2) (3) (4) (5) (6) (7)
Cognitive and behavioural therapies (CBT) is a useful treatment for symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)
Symptoms of anxiety and/or depression are common in people my age	(1) (2) (3) (4) (5) (6) (7)
I am familiar with novel technologies such as	(1) (2) (3) (4) (5) (6) (7)

augmented reality, virtual reality, and holographic technology	
I often experience symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)
Technology, such as smartphone apps can be a good educational tool for people my age	(1) (2) (3) (4) (5) (6) (7)
Asthma contributes to my symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)

SOFTWARE REVIEW

Please read the following questions and circle the answer that best represents you.

How easy is it to navigate (move	Very poor	Poor	Fair	Good	Very good
How easy is it to learn how to use	Very poor	Poor	Fair	Good	Very good
How easy is it to use the tools and	Very poor	Poor	Fair	Good	Very good
How attractive is visual design	Not attractive at all	Not attractive	Fair	Attractive	Very attractive
Do the tools appear well	Very poor	Poor	Fair	Good	Very good
Are the sizes of the	Very poor	Poor	Fair	Good	Very good
Is the content presentation	Very poor	Poor	Fair	Good	Very good
What did you think about the	Very poor	Poor	Fair	Good	Very good
Are the tools irritating?	Very poor	Poor	Fair	Good	Very good
How easy is it to customise the	Very poor	Poor	Fair	Good	Very good
How interesting are the tools?	Very poor	Poor	Fair	Good	Very good
What are your thoughts about the	Very poor	Poor	Fair	Good	Very good
What do you think about the	Very poor	Poor	Fair	Good	Very good
How would you rate the sufficiency	Very poor	Poor	Fair	Good	Very good
Is the intended use and purpose of the	Very poor	Poor	Fair	Good	Very good

Scale adapted from Enlight protocol (Baumel 2017).

Questionnaire for parents of young people with asthma.

BACKGROUND

1. Relationship to child with asthma:

_____

2. Gender: Male / Female 3. Age: _____

4. Nationality?

_____

5. Highest level of formal education:_____

5. What area do you live in? (e.g., Western suburbs of Adelaide)

_____

6. How long have you lived in this location?

_____

7. Could you please list any health problems you have:

~~Started~~	~~Health problems~~	~~Finished~~	~~On Medication~~
March 2014	e.g. Wheeze, dry cough, diabetes	Ongoing	Yes – Puffer

ASTHMA HISTORY

How old was your child when they were first diagnosed with asthma?

_____

Does your child take medications for asthma? Y / N

If yes, which medication(/s) do they use?

_____

_____

_____

Has your child ever been hospitalised due to asthma?

_____

Does anyone in the child's immediate family have asthma, if so who?_____

Please tick what triggers the child's asthma (tick any that apply and/or add your own)

	Outdoor allergens (pollen, grass etc)		Indoor allergens (dust, pet hair etc)
	Exercise		Household cleaning products
	Stress		Foods
	Weather conditions (cold air, humidity)		Colds and flus
	Smoke (cigarettes, fires etc)		

ANXIETY HISTORY

1. Does the child experiences any symptoms of anxiety? Y / N

2. If yes, what symptoms of anxiety have they experienced?

_____

_____

_____

3. Have you or your child spoken with a health professional about their symptoms of anxiety, if so what type of health professional?

_____

4. What do you think triggers your child's symptoms of anxiety?_____

_____

_____

5. What treatments for anxiety have you heard of? Where did you hear about them?

_____

_____

_____

_____

_____

_____

DEPRESSION HISTORY

1. Does your child experiences any symptoms of depression? Y / N

2. If yes, what symptoms of depression have they experienced?

_____

_____

_____

3. Have you or your child spoken with a health professional about their symptoms of depression, if so what type of health professional?

_____

4. What do you think triggers your child's symptoms of depression?_____

_____

_____

5. What treatments for depression have you heard of? Where did you hear about them?

_____

_____

_____

_____

_____

_____

HEALTH SCALE QUESTIONNAIRE

Please read the following questions and circle the answer that best represents you.

	1 = strongly agree, 2 = agree, 3 = more or less agree, 4 = undecided, 5 = more or less disagree, 6 = disagree, 7 = strongly disagree
I know very little about anxiety and depression	(1) (2) (3) (4) (5) (6) (7)
I believe that young people find new technology easy to use	(1) (2) (3) (4) (5) (6) (7)
Young people prefer to find information about health online, rather than asking their doctor	(1) (2) (3) (4) (5) (6) (7)
I feel confident in my child's ability to manage their asthma	(1) (2) (3) (4) (5) (6) (7)
Cognitive and behavioural therapies (CBT) is a useful treatment for symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)
I think symptoms of anxiety and/or depression are common in young people	(1) (2) (3) (4) (5) (6) (7)

I am familiar with novel technologies such as augmented reality, virtual reality, and holographic technology	(1) (2) (3) (4) (5) (6) (7)
I believe my child would benefit from some form of treatment for their symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)
Technology, such as smartphone apps can be a good educational tool for young people	(1) (2) (3) (4) (5) (6) (7)
Asthma contributes to my child's symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)

SOFTWARE REVIEW

Please read the following questions and circle the answer that best represents you.

How easy is it to navigate (move	Very poor	Poor	Fair	Good	Very good
How easy is it to learn how to use	Very poor	Poor	Fair	Good	Very good
How easy is it to use the tools and	Very poor	Poor	Fair	Good	Very good
How attractive is visual design	Not attractive at all	Not attractive	Fair	Attractive	Very attractive
Do the tools appear well	Very poor	Poor	Fair	Good	Very good
Are the sizes of the	Very poor	Poor	Fair	Good	Very good
Is the content presentation	Very poor	Poor	Fair	Good	Very good
What did you think about the	Very poor	Poor	Fair	Good	Very good
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How easy is it to customise the	Very poor	Poor	Fair	Good	Very good
How interesting are the tools?	Very poor	Poor	Fair	Good	Very good
What are your thoughts about the	Very poor	Poor	Fair	Good	Very good
What do you think about the	Very poor	Poor	Fair	Good	Very good
How would you rate the sufficiency	Very poor	Poor	Fair	Good	Very good
Is the intended use and purpose of the	Very poor	Poor	Fair	Good	Very good

Scale adapted from Enlight protocol (Baumel 2017).

Questionnaire for health professionals.

BACKGROUND

1. Qualification:

_____

2. Nationality:

_____

3. Current occupation and employer:

_____

4. Years with current employer:

_____

5. Gender: Male / Female 6. Age: _____

7. How many years of experience do you have in this field?

_____

8. Do you have any personal experience with asthma?

_____

ASTHMA AND MENTAL HEALTH

Do you have experience treating young people with asthma? Y / N

What are some of the symptoms of anxiety ? 3. What are some of the symptoms of depression?

_____

_____

_____

Research suggests that half of young people with asthma also experience symptoms of anxiety and/or depression. Has this been your experience? Elaborate if possible.

_____

_____

_____

_____

_____

_____

What do you currently advise for young patients with asthma who present with symptoms of anxiety and/or depression?

_____

_____

_____

Do you find CBT to be an effective tool for treating symptoms of anxiety and/or depression in young people? Why/Why not?

_____

_____

_____

HEALTH SCALE QUESTIONNAIRE

Please read the following questions and circle the answer that best represents you.

	1 = strongly agree, 2 = agree, 3 = more or less agree, 4 = undecided, 5 = more or less disagree, 6 = disagree, 7 = strongly disagree

I am very confident that I could manage a patient with asthma and symptoms of anxiety/depression on my own	(1) (2) (3) (4) (5) (6) (7)
I have the knowledge and skills necessary to help a young person manage their symptoms of anxiety/depression	(1) (2) (3) (4) (5) (6) (7)
I believe symptoms of anxiety are managed poorly in current practice	(1) (2) (3) (4) (5) (6) (7)
I believe symptoms of anxiety and depression are easily recognised among young people with asthma	(1) (2) (3) (4) (5) (6) (7)
I believe symptoms of anxiety and depression are managed well by health professionals for young people with asthma	(1) (2) (3) (4) (5) (6) (7)
I feel that technology would be an effective medium to engage young people in education	(1) (2) (3) (4) (5) (6) (7)
I think CBT would be very effective if delivered via technology for young people with symptoms of anxiety and/or depression	(1) (2) (3) (4) (5) (6) (7)

Symptoms of anxiety and/or depression are common in young people with asthma	(1) (2) (3) (4) (5) (6) (7)
CBT delivered via technology to treat symptoms of anxiety and/or depression in young people with asthma would make my job easier	(1) (2) (3) (4) (5) (6) (7)
Young people do not tend to seek help from health professionals for symptoms of anxiety and depression	(1) (2) (3) (4) (5) (6) (7)

SOFTWARE REVIEW

Please read the following questions and circle the answer that best represents you.

How easy is it to navigate (move	Very poor	Poor	Fair	Good	Very good
How easy is it to learn how to use	Very poor	Poor	Fair	Good	Very good
How easy is it to use the tools and	Very poor	Poor	Fair	Good	Very good
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How interesting are the tools?	Very poor	Poor	Fair	Good	Very good
What are your thoughts about the	Very poor	Poor	Fair	Good	Very good
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Is the intended use and purpose of the	Very poor	Poor	Fair	Good	Very good

Scale adapted from Enlight protocol (Baumel 2017).

Section 3

3.1 Protocol (published)

[Intervention Protocol]

Psychological interventions for asthma in children and adolescents

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A B S T R A C T

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:
Main objectives
To determine the eCicacy of psychological interventions in modifying health and behavioural outcomes in children with asthma, compared with usual treatment.
Secondary objectives
To compare efficacy of different types of psychological interventions for children with asthma.

To assess the comparative efficacy of individual and group formats of psychological therapy for children with asthma.

B A C K G R O U N D

Description of the condition

Asthma is a complex and phenotypically diverse disease, characterised by chronic inflammation of the airways (GINA 2018). Though a universally-accepted definition of asthma is lacking, asthma is generally defined as "a history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time" (GINA 2018).

Asthma contributes substantially to the global burden of disease. It is currently estimated that 300 million people worldwide experience symptoms of asthma (Masoli 2004). Countries with the highest prevalence rates include Brazil, the Netherlands, UK, Sweden, and Australia (To 2012).

Individuals with asthma may experience exacerbations of asthma symptoms or 'attacks'; these attacks can be life-threatening, and therefore impose significant psychological burdens on patients and their communities (GINA 2018). Furthermore, asthma which is not under adequate control can increase this psychological burden (Goodwin 2013), and likewise psychological distress can trigger or exacerbate symptoms of asthma (Van Lieshout 2008).

Rates of asthma are high in children and adolescents. Current global prevalence rates indicate that 10.2% of children aged 6 to 7 years, and 11.3% of children aged 13 to 14 experience symptoms of asthma (ISAAC 1998b). The highest rates of asthma in these age groups were observed in the UK, Australia, New Zealand, and Republic of Ireland (ISAAC 1998a). Young people with asthma generally report poorer health outcomes than those without asthma (Blanchard 2014). A 2014 survey of Australians aged 12 to 25 years found that half of young people with asthma experienced symptoms of heightened psychological distress (the experience of symptoms of anxiety and depression at sub-clinical levels (Drapeau 2012)). This is double the rate of the wider community (Blanchard 2014); and a figure that has been significantly increasing (Mission Australia 2017). In addition, both poor asthma outcomes and poor mental health outcomes disproportionately aCect those from poorer backgrounds (AIHW 2016; Evans 2012 GINA 2019).

Contributing to their increased experience of psychological distress, a range of challenges faced by children and adolescents with asthma may include social isolation, restricted life choices, limitations on personal potential, embarrassment and shame about their condition

or treatment (or both), self- consciousness, potential mortality threat, and fear of disease exacerbation (Blanchard 2014). These complex, interconnected issues compound the social, psychological and developmental challenges experienced by people during this life stage (Cohen 2003; de Benedictis 2007). This combined symptom profile contributes to higher levels of functional impairment (Akinbami 2002), lower quality of life (Goldney 2003), and higher rates of preventable hospitalisation and mortality compared to people without asthma (Calmes 1998).

Description of the intervention

It is likely that a bidirectional relationship exists between asthma and symptoms of psychological distress (Baiardini 2015). Psychological factors and negative life events can exacerbate inflammation and symptoms of asthma (French 1943; Sandberg 2000; Van Lieshout 2008). It has been suggested that psychological

distress may exacerbate the immune response to external stimuli via increased activation of endocrine pathways — the sympathetic and adrenomedullary (SAM) system and the hypothalamic- pituitary-adrenocortical (HPA) axis (Chen 2007). Long periods of exposure to stress hormones can lead to down-regulation of receptors to these molecules and dysregulation of inflammatory responses to asthma triggers. Production of Th2 cytokines and recruitment of eosinophils can be exaggerated under these conditions, promoting output of neurotransmitters which can increase inflammation (Wright 1998; Wright 2005). Conversely, asthma in young people is associated with increased psychological distress and clinical diagnoses of psychological disorders (Dudeney 2017; Katon 2007; Pinquart 2010). Although some experience of anxiety in people with asthma is healthy, this can develop into chronic and excessive psychological distress (Thomas 2011). Asthma may negatively aCect psychological and mental health outcomes, as individuals with asthma may experience heightened psychological distress due to the persistent fear of asthma attacks (GINA 2018).

Psychological interventions refer to theoretically informed psychological strategies underpinned by clinical formulation. Various types of interventions exist, underpinned by distinct theoretical frameworks. This review will explore the following types of intervention: behavioural, cognitive, cognitive behavioural, relaxation, psychodynamic psychotherapy, counselling, group therapy, and family therapy. Behavioural therapies focus on identifying and changing learned behaviours, cognitive therapies identify and manage thoughts and perceptions, while cognitive behavioural therapy (CBT) incorporates aspects of both of these models. Relaxation techniques are designed to control psychological distress, though in this situation may also improve respiratory functioning. Psychodynamic therapy, counselling, group therapy and family therapy all involve the discussion of issues with a licensed professional in group or individual formats. The current evidence assessing the eCicacy of individual versus group therapy formats is generally mixed, and may diCer based on which symptoms of psychological distress are experienced (Craigie 2009; Flannery-Schroeder 2000; Manassis 2002; Wierzbicki 1987). All interventions can be delivered in person, via printed self- help materials, or via the internet. Online or technology-delivered psychological interventions (also known as e-psychology, e-health or e-mental health) have been shown to be an eCective option for psychiatric care and support, which may increase access to and improve quality of care (RANZCP 2019), and can be a cost-eCective treatment option for both patients and providers (Solomon 2015).

How the intervention might work

From a behavioural perspective, children and adolescents with psychological distress might not manage their condition as well as those not exposed to adverse life events or experiencing psychological distress. Psychological distress may impact negatively upon self-eCicacy and symptom perception and, in turn, upon medication adherence and other health behaviours, including frequency of health utilisation. In general, individuals experiencing symptoms of anxiety tend to overuse medications, while individuals experiencing symptoms of depression may over- or underuse medications — both of which can result in poor asthma outcomes (Rietveld 2003). Psychological interventions may provide young people with techniques and strategies to manage psychological distress and therefore symptoms of asthma as
they arise, in order to avoid exacerbations (DuC 2001). These interventions might include, for example, behaviour therapy to increase adherence to treatment, cognitive therapy to address emotional reactions, relaxation techniques such as progressive muscle relaxation to reduce psychological distress, or family therapy to question and discuss familial concerns and allow for increased understanding and support by family members (DuC 2001). Positive cognitive experiences regarding asthma — specifically self-eCicacy, outcome expectations, and perceptions of barriers — are associated with better asthma control and adherence to medication in young people (Rhee 2018). Psychological interventions may also be eCective in reducing asthma symptoms using some of the interventions described above (Kew 2016; Knapp 1978; Moore 1965).

Psychological interventions can reduce asthma-related anxiety and increase positive experiences regarding asthma. In turn, this can reduce psychological distress, which can improve behavioural outcomes such as self-eCicacy and medication adherence, while reducing inflammation, with the overall eCect of reducing medical contacts and asthma attacks in children and adolescents.

Why it is important to do this review

Despite evidence that psychological interventions are beneficial in the treatment of psychological distress and psychological disorders, reports indicate that four out of five young people who could potentially benefit from psychological intervention are reportedly not accessing it (Bekker 2017). This systematic review aims to fill a gap in the literature by evaluating the eCectiveness of psychological interventions as a treatment method for children and adolescents with asthma. It is intended that evidence gained from this review can address these issues and be used to inform best practice guidelines and recommendations for health professionals treating patients with asthma, and aid in eCorts to increase uptake of psychological interventions in this age group.

The current review builds on a previous systematic review investigating psychological interventions for children with asthma (Yorke 2005). The main objectives of these reviews are similar; however this review will use the latest Cochrane methodology and focus on diCerent types of psychological interventions. The primary and secondary outcomes have also been amended to align with current clinical practice. Additionally, meta-analyses on primary outcomes were not possible due to limitations in number and quality of studies included in the previous review; we now plan to undertake these meta-analyses with the addition of new studies published in the 14 years since the original review.

O B J E C T I V E S

Main objectives

To determine the eCicacy of psychological interventions in modifying health and behavioural outcomes in children with asthma, compared with usual treatment.

Secondary objectives

To compare eCicacy of diCerent types of psychological interventions for children with asthma.

To assess the comparative eCicacy of individual and group formats of psychological therapy for children with asthma.

M E T H O D S

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), including cluster-randomised trials where the data has been or can be adjusted for clustering. We will include studies reported as full text, abstract only, and unpublished data. We will not restrict studies by duration of follow-up.

Types of participants

We will include both male and female children and adolescents aged between 5 and 18 years with asthma diagnosed by a physician or as per international or national guidelines. Studies will be included irrespective of psychological symptoms at baseline. We will include participants from both inpatient and outpatient settings.

Types of interventions

We will include trials which assess all psychological interventions of any duration compared with a control. Psychological interventions must have been created or delivered by a qualified professional, and may include in-person or online formats. We will include studies with co-interventions (e.g. prescribed medications), provided they are not part of the randomised treatment. Treatments may include the following.

1. Behavioural therapies: concerned with identifying the processes by which behaviour has been learned via association, reward or observation and modifying behaviour using methods such as systematic desensitisation, selective reinforcement and positive modelling. The behaviour itself, rather than the underlying motivations, is the focus of behavioural interventions.
2. Cognitive therapy: identification and constructive management of damaging thoughts, such as perceptions of helplessness or disproportionate fear of asthma attack that can trigger respiratory symptoms and/or asthma symptoms.
3. Cognitive behavioural therapy (CBT): incorporating the key elements of both behavioural and cognitive models.
4. Relaxation techniques: designed to control stress and anxiety which, in asthma, may improve breathing and respiratory function. The following approaches are used:
    a. Progressive relaxation: systematically creating tension and release in diCerent parts of the body and/or via guided imagery.
    b. Autogenic training: focuses on attending to bodily feelings and mentally controlling them.

c. Hypnosis: deep relaxation that may be induced using mental imagery, oOen accompanied by autosuggestion to create positive thoughts and feelings.
d. Biofeedback: feedback of biological indicators which the subject must control via relaxation. May also be considered a behavioural intervention since the feedback can act as a reinforcer.

5. Psychodynamic psychotherapy: including psychoanalysis, psychosomatic therapy, and hypnosis.
6. Counselling: involves talking over problems with a health professional. In supportive counselling, the counsellor aims to

be a good listener and provide emotional support, rather than oCering a more targeted psychotherapeutic intervention.

7. Group therapy: psychotherapeutic interventions conducted in groups (e.g. group psychosomatic therapy).
8. Family therapy: works to change the relationships within families to help them better deal with a wide range of problems.

We will include trials comparing psychological interventions with usual care, active control (e.g. self-help) or wait-list control groups.

We will exclude treatments involving educational approaches, and breathing re-training techniques. These treatments have been independently reviewed previously (Haby 2001; Wolf 2003).

Types of outcome measures

The main objective will be explored through the following primary and secondary outcomes. The secondary objective(s) will be evaluated through subgroup analysis as appropriate.

Primary outcomes

1. Primary eCicacy of intervention to reduce psychological distress: change in anxiety or depression (or both), as measured by standard validated questionnaires (e.g. the State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Kessler Psychological Distress Scale (K10)).
2. Medical contacts, as measured by presentation to hospital, emergency room or GP, singly or in combination.
3. Asthma attacks, as measured by number of children with one or more asthma attack (defined as an acute increase in asthma symptom severity requiring use of corticosteroids or hospital admission) during follow-up, or rate of asthma attacks.

Secondary outcomes

1. Self-reported asthma symptoms (e.g. asthma symptom scale such as Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ)).
2. Medication use (e.g. frequency of use, dosage). Use of preventer inhalers. Use of reliever inhalers.
3. Self-reported quality of life as measured by validated questionnaires (e.g. Paediatric Asthma Quality of Life Questionnaire (PAQLQ)).
4. Adverse events/side eCects.

We will group outcomes reported at diCerent time points in the following way: less than 3 months from baseline; 3 months to less than 6 months from baseline; 6 months to less than 12 months from baseline; and 12 months and over from baseline.

Reporting one or more of the outcomes listed here in the study is not an inclusion criterion for the review.

Search methods for identification of studies

Electronic searches

We will identify trials from the Cochrane Airways Group's Specialised Register (CAGR) (Cochrane Airways 2019), which is maintained by the Cochrane Information Specialist for the Group. The Register contains trial reports identified through systematic searches of bibliographic databases including:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL), through the Cochrane Register of Studies (CRS) from inception to date;
2. weekly searches of MEDLINE Ovid SP from 1946 to date;
3. weekly searches of Embase Ovid SP from 1974 to date;
4. monthly searches of PsycINFO Ovid SP from 1967 to date;
5. monthly searches of CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature) from 1937 to date;
6. monthly searches of AMED EBSCO (Allied and Complementary Medicine) from inception to date;
7. handsearches of the proceedings of major respiratory conferences.

Studies contained in the Trials Register are identified through search strategies based on the scope of Cochrane Airways. Details of these strategies, as well as a list of handsearched conference proceedings are in Appendix 1. See Appendix 2 for search terms used to identify studies from the Trials Register for this review.

We will search all sources from their inception to the present, and we will impose no restriction on language of publication.

Searching other resources

We will check reference lists of all included studies and review articles for additional references. We will also conduct a search of the World Health Organization International Clinical Trials Registry Platform and the US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov).

We will search for errata or retractions from included studies published in full text on PubMed, and report the date this was done within the review.

Data collection and analysis

Selection of studies

A pair of review authors (from KJS, OS, KVC, KP) will independently screen titles and abstracts for inclusion of all the potential studies we identify as a result of the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve the full-text study reports/publication of all potentially eligible studies and two review authors (KJS, OS) will independently screen them for inclusion, and identify and record reasons for exclusion of ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult a third review author (KVC or KP). We will identify and exclude duplicates and collate multiple reports of the same study so that each study, rather than report, is the unit of interest in the review. We will record the

selection process in suCicient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table (Moher 2009).

Data extraction and management

We will use a data collection form for study characteristics and outcome data — which has been piloted on at least one study — in the review. A pair of review authors (from KJS, OS, KVC, KP) will extract study characteristics from included studies. We will extract the following study characteristics.

1. Methods: study design, study location, clustering adjustments and eCect, methods of analysis.

2. Participants: number, withdrawals, mean age, age range, gender, inclusion criteria and exclusion criteria, socioeconomic data, severity of condition, diagnostic criteria, psychological symptomatology at baseline, smoking history.
3. Interventions: study setting, intervention description, comparison, concomitant pharmacotherapy, duration of intervention.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: funding for studies and notable conflicts of interest of trial authors.

A pair of review authors (from KJS, OS, KVC, KP) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by involving a third person (KVC or KP). One review author (KJS) will transfer data into the Review Manager 5 file (Review Manager 2014). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (OS) will spot-check study characteristics for accuracy against the study report.

Assessment of risk of bias in included studies

A pair of review authors (from KJS, OS, KVC, KP) will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreements by discussion or by consultation with another author (KVC or KP). We will assess the risk of bias according to the following domains.

1. Random sequence generation
2. Allocation concealment
3. Blinding of participants and personnel

4. Blinding of outcome assessment
5. Incomplete outcome data
6. Selective outcome reporting
7. Other bias

We will grade each potential source of bias as high, low or unclear and provide a quote from the study report together with a justification for the judgement in the 'Risk of bias' table. We will summarise the risk of bias judgements across diCerent studies for each of the domains listed. We will consider blinding separately for diCerent key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for asthma attack may be diCerent than for a patient-reported symptom scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

When considering treatment eCects, we will take into account the risk of bias for the studies that contribute to that outcome.

Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and report any deviations from it in the 'DiCerences between protocol and review' section of the systematic review.

Measures of treatment e9ect

We will analyse dichotomous data as odds ratios (OR) and continuous data as the mean diCerence (MD). Where appropriate, we will use standardised mean diCerence (SMD) to pool results from various assessment scales. We will enter data presented as a scale with a consistent direction of eCect.

We will undertake meta-analyses only where this is meaningful; that is, if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense.

We will narratively describe skewed data reported as medians and interquartile ranges. Where multiple trial arms are reported in a single study, we will include only the relevant arms. If two comparisons (e.g. intervention A versus usual care and intervention B versus usual care) are combined in the same meta-analysis, we will either combine the active arms, or the control group will be halved to avoid double-counting.

If adjusted analyses are available (ANOVA or ANCOVA) these will be used as a preference in the meta-analyses. If both change-from- baseline and endpoint scores are available for continuous data, we will use change-from-baseline unless there is low correlation between measurements in individuals. If a study reports outcomes at multiple time points, we will use the latest recorded time point.

Intention-to-treat (ITT) or 'full analysis set' analyses will be used where they are reported (i.e. those where data have been imputed for participants who were randomly assigned but did not complete the study) instead of completer or per protocol analyses.

Unit of analysis issues

For dichotomous outcomes we will use participants, rather than events, as the unit of analysis (i.e. number of children admitted to hospital, rather than number of admissions per child). However, if rate ratios are reported in a study, we will analyse them on this basis.

We will include relevant cluster-randomised trials, but we will meta-analyse only data from cluster-RCTs that have been adjusted (or can be adjusted) to account for clustering. Based on recommendations from the *Cochrane Handbook for Systematic Reviews of Interventions*, we will adjust cluster-randomised data by inflating standard errors using a design eCect (DE) calculated with an intracluster correlation coeCicient (ICC).

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). Where this is not possible, and the missing data are thought to introduce

serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Assessment of heterogeneity

We will use the IQ statistic to measure heterogeneity among the studies in each analysis. If we identify substantial heterogeneity, we will report it and explore possible causes by prespecified subgroup analyses. Furthermore, to aid interpretation of the pooled estimates, we will construct a summary table which outlines the key features of the included studies to allow easy comparison

between trials contributing data to the review. We will explore possible clinical heterogeneity narratively in the discussion.

Assessment of reporting biases

If we are able to pool more than 10 studies, we will create and examine a funnel plot to explore possible small-study and publication biases.

Data synthesis

We will use a random-eCects model and perform a sensitivity analysis with a fixed-eCect model.

'Summary of findings' table

We will create a 'Summary of findings' table using the following outcomes at longest follow-up point (maximum 1-year post- treatment): medical contacts, rate of asthma attack, symptoms of anxiety and depression, asthma symptoms, medication use, and quality of life. We will use the five GRADE considerations (risk of bias, consistency of eCect, imprecision, indirectness, and publication bias) to assess the quality of a body of evidence as it relates to the studies that contribute data to the meta- analyses for the prespecified outcomes. We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) using GRADEpro soOware (GRADEpro GDT). We will justify all decisions to down- or up-grade the quality of studies using footnotes, and we will make comments to aid the reader's understanding of the review where necessary.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses.

1. Type of psychological interventions (e.g. behavioural intervention, cognitive behavioural therapy, psychodynamic therapy, etc.).
2. Individual vs group interventions.
3. Face-to-face vs online interventions.

4. School age (primary (ages 5 to 12) vs secondary (ages 13 to 18)). We will use the following outcomes in subgroup analyses.

1. Primary eCicacy of intervention to reduce psychological distress: change in anxiety and/or depression, as measured by standard validated questionnaires (e.g. the State-Trait Anxiety Inventory (STAI), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Kessler Psychological Distress Scale (K10)).
2. Medical contacts, as measured by presentation to hospital, emergency room visits, GP visits, alone or in combination.

3. Asthma attacks, as measured by number of children with one or more asthma attack (defined as an acute increase in asthma symptom severity requiring use of corticosteroids or hospital admission) during follow-up, or rate of asthma attacks.

We will use the formal test for subgroup interactions in Review Manager 5 (Review Manager 2014).

Sensitivity analysis

We plan to carry out the following sensitivity analyses.

1. Exclusion of trials with high risk of bias for randomisation, or allocation concealment, or both.
2. Exclusion of unpublished data/non-peer reviewed studies.
3. Investigation of the potential influence of study size on eCect size, by removing small trials (those with fewer than 20 participants in each arm) in a sensitivity analysis (Fisher 2018).
4. Exclusion of trials in which the intervention is supportive rather than providing targeted psychotherapeutic input.

The results from a fixed-eCect model will be compared with the random-eCects model.

A C K N O W L E D G E M E N T S

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Appendix 1. Sources and search methods for the Cochrane Airways Register of Trials

Electronic searches: core databases

Database	Dates searched	Frequency of search
CENTRAL (via the Cochrane Register of Studies (CRS))	From inception	Monthly
MEDLINE (Ovid)	1946 onwards	Weekly
Embase (Ovid)	1974 onwards	Weekly
PsycINFO (Ovid)	1967 onwards	Monthly
CINAHL (EBSCO)	1937 onwards	Monthly
AMED (EBSCO)	From inception	Monthly

Handsearches: core respiratory conference abstracts

Conference	Years searched
American Academy of Allergy, Asthma and Immunology (AAAAI)	2001 onwards
American Thoracic Society (ATS)	2001 onwards
Asia Pacific Society of Respirology (APSR)	2004 onwards
British Thoracic Society Winter Meeting (BTS)	2000 onwards
Chest Meeting	2003 onwards

(Continued)

European Respiratory Society (ERS) 1992, 1994, 2000 onwards

International Primary Care Respiratory Group Congress (IPCRG) 2002 onwards

Thoracic Society of Australia and New Zealand (TSANZ) 1999 onwards

MEDLINE search strategy used to identify studies for the CAGR Asthma search

1. exp Asthma/
2. asthma$.mp.
3. (antiasthma$ or anti-asthma$).mp.
4. Respiratory Sounds/
5. wheez$.mp.
6. Bronchial Spasm/
7. bronchospas$.mp.
8. (bronch$ adj3 spasm$).mp.
9. bronchoconstrict$.mp.
10. exp Bronchoconstriction/
11. (bronch$ adj3 constrict$).mp.
12. Bronchial Hyperreactivity/
13. Respiratory Hypersensitivity/
14. ((bronchial$ or respiratory or airway$ or lung$) adj3 (hypersensitiv$ or hyperreactiv$ or allerg$ or insuCiciency)).mp.
15. ((dust or mite$) adj3 (allerg$ or hypersensitiv$)).mp.
16. or/1-15

Filter to identify RCTs

1. exp "clinical trial [publication type]"/
2. (randomised or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. Animals/

10. Humans/
11. 9 not (9 and 10)
12. 8 not 11

The MEDLINE strategy and RCT filter are adapted to identify studies in other electronic databases.

Appendix 2. Search strategy to identify relevant studies from the Cochrane Airways Trials Register

Cochrane Register of Studies (CRS)

Line number	Search term	Results
#1	AST:MISC1	22828
#2	MeSH DESCRIPTOR Asthma Explode All	11942
#3	asthma*:ti,ab	40629
#4	#1 OR #2 OR #3	44112
#5	MESH DESCRIPTOR Psychotherapy EXPLODE ALL	1081
#6	MESH DESCRIPTOR Psychology EXPLODE ALL	116
#7	MESH DESCRIPTOR Psychophysiologic Disorders	23
#8	MESH DESCRIPTOR Psychoanalysis	0
#9	MESH DESCRIPTOR Psychosomatic Medicine	1
#10	(behavior* OR behaviour*) NEAR3 (treatment* OR therap* or intervention* OR acti- vat* or technique* or modif* or change*)	5312
#11	cognitiv* NEAR3 (behav* or treatment* or technique* or therap* or intervention* or restructur* or reappraisal*)	1967
#12	acceptance NEAR3 commitment	45
#13	(CBT or ACT):ti,ab	2192
#14	relaxation*	1431
#15	autogenic*	60
#16	hypnosis*	130
#17	biofeedback*	219

#18	psychotherap* or psycho-therap* or psychoanalytic* or psycho-analytic* or psycho- dynamic* or psycho-dynamic* or psychoanalysis or psycho-analysis or psychoso- matic or psycho-somatic	1959
#19	counsel* or (talk* near3 therap*)	2741
#20	(group* or family*) near3 therap*	2147
#21	MESH DESCRIPTOR Family WITH QUALIFIER PX	21
#22	anxiety or depression or panic	10308

(Continued)

#23	#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22	22345
#24	#23 AND #4	3416
#25	MESH DESCRIPTOR Asthma WITH QUALIFIER PX	275
#26	#24 OR #25	3521
#27	INREGISTER	41095
#28	#26 AND #27	1563

C O N T R I B U T I O N S O F A U T H O R S

KJS: initiating and coordinating review, production of protocol, data collection, undertaking searches, screening search results, organising retrieval of papers, screening papers against eligibility criteria, appraising quality of papers, extracting data from papers, data management for review, entering data into Review Manager 5, analysis of data, interpretation of data, write-up.

SO: providing input with protocol, data collection, screening search results, screening papers against eligibility criteria, extracting data from papers, write-up, contributing final comments to manuscript.

KVC-C: providing input with protocol, providing general advice on the review, providing advice on analysis of data, checking data, providing assistance with write-up, contributing final comments to manuscript.

KCP: providing input with protocol, providing clinical advice for the review, providing advice on analysis of data, checking data, providing assistance with write-up, contributing final comments to manuscript.

Contributions of editorial team

Rebecca Fortescue (Coordinating Editor): edited the protocol; advised on methodology; approved the protocol prior to publication. Chris Cates (Coordinating Editor): checked the planned methods.

Emma Dennett (Managing Editor): coordinated the editorial process; advised on content; edited the protocol. Emma Jackson (Assistant Managing Editor): conducted peer review; edited the references.

Elizabeth Stovold (Information Specialist): designed the search strategy.

D E C L A R A T I O N S O F I N T E R E S T

KJS: none known. SO: none known. KVC-C: none known.

KCP: I have acted as a consultant on an advisory board for Respiri for development of a symptom monitoring device for asthma.

S O U R C E S O F S U P P O R T

Internal sources

- University of South Australia, Translational Medicine and Technology Group, Australia. Income for employment.

External sources

- The authors declare that no such funding was received for this systematic review., Other.

3.2 Search strategy

Database/search platform/date of last search	**Search strategy**	**Results**
Airways Register (via Cochrane Register of Studies) Date of most recent search: 12 February 2021	#1 AST:MISC1 #2 MeSH DESCRIPTOR Asthma Explode All #3 asthma*:ti,ab #4 #1 OR #2 OR #3 #5 MESH DESCRIPTOR Psychotherapy EXPLODE ALL #6 MESH DESCRIPTOR Psychology EXPLODE ALL #7 MESH DESCRIPTOR Psychophysiologic Disorders #8 MESH DESCRIPTOR Psychoanalysis #9 MESH DESCRIPTOR Psychosomatic Medicine	August 2019=1613 March 2020=90 February 2021=118

	#10 (behavior* OR behaviour*) NEAR3 (treatment* OR therap* or intervention* OR activat* or technique* or modif* or change*) #11 cognitiv* NEAR3 (behav* or treatment* or technique* or therap* or intervention* or restructur* or reappraisal*) #12 acceptance NEAR3 commitment #13 (CBT or ACT):ti,ab #14 relaxation* #15 autogenic* #16 hypnosis* #17 biofeedback* #18 psychotherap* or psycho-therap* or psychoanalytic* or psycho-analytic* or psychodynamic* or psycho-dynamic* or psychoanalysis or psycho-analysis or psychosomatic or psycho-somatic #19 counsel* or (talk* near3 therap*) #20 (group* or family*)	

	near3 therap* #21 MESH DESCRIPTOR Family WITH QUALIFIER PX #22 anxiety or depression or panic #23 #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 #24 #23 AND #4 #25 MESH DESCRIPTOR Asthma WITH QUALIFIER PX #26 #24 OR #25 #27 INREGISTER #28 #26 AND #27	

CENTRAL (via Cochrane Register of Studies) Date of most recent search: 12 February 2021	#1 AST:MISC1 AND CENTRAL:TARGET #2 MeSH DESCRIPTOR Asthma Explode All AND CENTRAL:TARGET #3 asthma*:ti,ab AND CENTRAL:TARGET #4 #1 OR #2 OR #3 AND CENTRAL:TARGET #5 MESH DESCRIPTOR Psychotherapy EXPLODE ALL AND CENTRAL:TARGET #6 MESH DESCRIPTOR Psychology EXPLODE ALL AND CENTRAL:TARGET #7 MESH DESCRIPTOR Psychophysiologic Disorders AND CENTRAL:TARGET #8 MESH DESCRIPTOR Psychoanalysis AND CENTRAL:TARGET #9 MESH DESCRIPTOR Psychosomatic Medicine AND CENTRAL:TARGET #10 (behavior* OR behaviour*) NEAR3 (treatment* OR therap* or intervention* OR activat* or technique* or modif* or change*) AND CENTRAL:TARGET #11 cognitiv* NEAR3 (behav* or treatment* or technique* or therap* or intervention* or restructur* or reappraisal*) AND	August 2019=2452 March 2020=307 February 2021=189

	CENTRAL:TARGET #12 acceptance NEAR3 commitment AND CENTRAL:TARGET #13 (CBT or ACT):ti,ab AND CENTRAL:TARGET #14 relaxation* AND CENTRAL:TARGET #15 autogenic* AND CENTRAL:TARGET #16 hypnosis* AND CENTRAL:TARGET #17 biofeedback* AND CENTRAL:TARGET #18 psychotherap* or psycho-therap* or psychoanalytic* or psycho-analytic* or psychodynamic* or psycho-dynamic* or psychoanalysis or psycho-analysis or psychosomatic or psycho-somatic AND CENTRAL:TARGET #19 counsel* or (talk* near3 therap*) AND CENTRAL:TARGET #20 (group* or family*) near3 therap*	

	AND CENTRAL:TARGET #21 MESH DESCRIPTOR Family WITH QUALIFIER PX AND CENTRAL:TARGET #22 anxiety or depression or panic AND CENTRAL:TARGET #23 #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 AND CENTRAL:TARGET #24 #23 AND #4 AND CENTRAL:TARGET #25 MESH DESCRIPTOR Asthma WITH QUALIFIER PX AND CENTRAL:TARGET #26 #24 OR #25 AND CENTRAL:TARGET #27 CENTRAL:TARGET #28 #26 AND #27 AND CENTRAL:TARGET	

MEDLINE (Ovid) ALL Date of most recent search: 12 February 2021	1 exp asthma/ 2 asthma$.ti,ab. 3 1 or 2 4 exp Psychotherapy/ 5 exp Psychology/ 6 Psychophysiologic Disorders/ 7 Psychoanalysis/ 8 Psychosomatic Medicine/ 9 (cognitiv$ adj3 (behav$ or treatment$ or technique$ or therap$ or intervention$ or restructur$ or reappraisal$)).ti,ab. 10 ((behavior$ or behaviour$) adj3 (treatment$ or therap$ or intervention$ or activat$ or technique$ or modif$ or change$)).ti,ab. 11 (acceptance adj3 commitment).ti,ab. 12 (CBT or ACT).ti,ab. 13 relaxation$.ti,ab. 14 autogenic$.ti,ab. 15 hypnosis$.ti,ab. 16 biofeedback$.ti,ab.	August 2019=2964 March 2020=96 February 2021=164

	17 (psychotherap$ or psycho therap$ or psychoanalytic$ or psycho analytic$ or psychodynamic$ or psycho dynamic$ or psychoanalysis or psycho analysis or psychosomatic or psycho somatic).ti,ab. 18 (counsel$ or (talk$ adj3 therap$)).ti,ab. 19 ((group$ or family$) adj3 therap$).ti,ab. 20 Family/px [Psychology] 21 (anxiety or depression or panic).ti,ab. 22 or/4-21	

	23 3 and 22 24 (controlled clinical trial or randomized controlled trial).pt. 25 (randomized or randomised).ab,ti. 26 placebo.ab,ti. 27 dt.fs. 28 randomly.ab,ti. 29 trial.ab,ti. 30 groups.ab,ti. 31 or/24-30 32 Animals/ 33 Humans/ 34 32 not (32 and 33) 35 31 not 34 36 23 and 35	

Embase (Ovid) Date of most recent search: 12 February 2021	1 exp asthma/ 2 asthma$.ti,ab. 3 1 or 2 4 exp Psychotherapy/ 5 exp Psychology/ 6 Psychophysiologic Disorders/ 7 Psychoanalysis/ 8 Psychosomatic Medicine/ 9 (cognitiv$ adj3 (behav$ or treatment$ or technique$ or therap$ or intervention$ or restructur$ or reappraisal$)).ti,ab. 10 ((behavior$ or behaviour$) adj3 (treatment$ or therap$ or intervention$ or activat$ or technique$ or modif$ or change$)).ti,ab. 11 (acceptance adj3 commitment).ti,ab. 12 (CBT or ACT).ti,ab. 13 relaxation$.ti,ab. 14 autogenic$.ti,ab. 15 hypnosis$.ti,ab. 16 biofeedback$.ti,ab.	August 2019=3493 March 2020=243 February 2021=274

	17 (psychotherap$ or psycho therap$ or psychoanalytic$ or psycho analytic$ or psychodynamic$ or psycho dynamic$ or psychoanalysis or psycho analysis or psychosomatic or psycho somatic).ti,ab. 18 (counsel$ or (talk$ adj3 therap$)).ti,ab. 19 ((group$ or family$) adj3 therap$).ti,ab. 20 (anxiety or depression or panic).ti,ab. 21 family counseling/ 22 or/4-21 23 3 and 22 24 Randomized Controlled Trial/ 25 randomization/ 26 controlled clinical trial/ 27 Double Blind Procedure/ 28 Single Blind Procedure/ 29 Crossover Procedure/ 30 (clinica$ adj3 trial$).tw. 31 ((singl$ or doubl$ or trebl$ or tripl$) adj3 (mask$ or blind$ or method$)).tw. 32 exp Placebo/	

	33 placebo$.ti,ab. 34 random$.ti,ab. 35 ((control$ or prospectiv$) adj3 (trial$ or method$ or stud$)).tw. 36 (crossover$ or cross-over$).ti,ab. 37 or/24-36 38 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/ 39 human/ or normal human/ or human cell/ 40 38 and 39 41 38 not 40 42 37 not 41 43 23 and 42	

PsycINFO (Ovid) Date of most recent search: 12 February 2021	1 exp asthma/ 2 asthma$.ti,ab. 3 1 or 2 4 exp Psychotherapy/ 5 exp Psychology/ 6 Psychophysiologic Disorders/ 7 Psychoanalysis/ 8 Psychosomatic Medicine/ 9 (cognitiv$ adj3 (behav$ or treatment$ or technique$ or therap$ or intervention$ or restructur$ or reappraisal$)).ti,ab. 10 ((behavior$ or behaviour$) adj3 (treatment$ or therap$ or intervention$ or activat$ or technique$ or modif$ or change$)).ti,ab. 11 (acceptance adj3 commitment).ti,ab. 12 (CBT or ACT).ti,ab. 13 relaxation$.ti,ab. 14 autogenic$.ti,ab. 15 hypnosis$.ti,ab. 16 biofeedback$.ti,ab.	August 2019=347 March 2020=8 February

	17 (psychotherap$ or psycho therap$ or psychoanalytic$ or psycho analytic$ or psychodynamic$ or psycho dynamic$ or psychoanalysis or psycho analysis or psychosomatic or psycho somatic).ti,ab. 18 (counsel$ or (talk$ adj3 therap$)).ti,ab. 19 ((group$ or family$) adj3 therap$).ti,ab. 20 (anxiety or depression or panic).ti,ab. 21 family counseling/ 22 or/4-21 23 3 and 22 24 random$.tw. 25 (clinical adj5 trial$).tw. 26 (control$ adj5 trial$).tw. 27 ((clinical or control$ or comparativ$) adj5 (study or studies)).tw. 28 placebo$.tw. 29 (single blind$ or single-blind$).tw. 30 (double blind$ or double-blind$).tw. 31 (triple blind$ or triple-blind$).tw. 32 or/24-31	2021=16

	[33] 23 and 32	
ClinicalTrials.gov Date of most recent search: 12 February 2021	Study type: Interventional Condition: asthma Intervention: Psychotherapy OR Psychology OR Psychoanalysis OR Psychosomatic OR behavior OR cognitive OR counseling OR family therapy OR CBT OR ACT OR hypnosis OR relaxation OR biofeedback OR	August 2019=203 March 2020=2 February

	autogenic .		2021=27
	Condition: asthma .		

WHO trials portal Date of most recent search: 12 February 2021	Intervention: Psychotherapy OR Psychology OR Psychoanalysis OR Psychosomatic OR behavior OR cognitive OR counseling OR family therapy OR CBT OR ACT OR hypnosis OR relaxation OR biofeedback OR autogenic	August 2019=75 March 2020=2 February 2021=0

3.3 Characteristics of included studies

Characteristics of included studies [ordered by study ID]

Alexander 1972

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Convenience sample (method of recruitment not discussed) **Method of randomisation:** Not described
Participants	**Number eligible for study:** **Number randomised:** 44 **Number completed:** 36 **Age (mean, range):** mean=11.9, range=10-15 years **Gender (N and % female):** n=20, 45% female **Setting (country and study setting):** A residential treatment home for asthmatic children at the Children's Asthma Research Institute and Hospital (CARIH), USA **Severity of condition:** Moderate to very severe **Inclusion criteria:** Children aged 10-15, experiencing moderate to very severe asthma **Exclusion criteria:** Children with suspected mental disabilities, children with organic brain pathology, and children showing signs of serious psychopathology (e.g. psychosis)

	Any baseline differences?: Groups were matched for mean age, sex, and asthma severity	
Interventions	**Type of intervention:** Systemic Relaxation **Intervention description:** Experimental subjects received a modified Jacobsonian relaxation training procedure. The training consisted of successively tensing and relaxing muscles in the following order: hands and forearms, biceps, upper face, calves and feet. Throughout each session, the experimenter emphasized feelings of no tension, relaxation and warmth. **Control group:** Sitting quietly **Duration and intensity of intervention:** 3x 15 minute relaxation training sessions **Intervention format:** In person **Intervention delivered to patients by:** Trained experimenter	
Outcomes	PEFR	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described. "The subjects were randomly divided into experimental and control groups, with the restriction that, as near as was possible, the groups were matched for mean age, sex com- position and asthma severity. Approximate severity match- ing between groups was

		accomplished by attaining in each group an equal proportion of children who were receiving maintenance steroid medications and children who were not."
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	No method of blinding discussed
Blinding of outcome assessment (detection bias) All outcomes	High risk	No method of blinding discussed
Incomplete outcome data (attrition bias) All outcomes	High risk	20/22 vs 16/22 completed follow up 91 vs 73%
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol to compare for selective reporting
Other bias	Low risk	No other biases identified

Barikani 2021

Study characteristics	
Methods	**Study design:** RCT, parallel **Method of recruitment:** adolescents referred to the Asthma and Allergies clinic **Method of randomisation:** Randomly assigned into a control and an intervention group through block randomization. The size of the blocks was considered four. The allocation sequence was generation using the online Research Randomizer (www.randomizer.org).
Participants	**Number eligible for study:** 57 **Number randomised:** 52 **Number completed:** 46 **Age (mean, range):** 12.8 (combined mean); range 10-18 years **Gender (N and % female):** 16 (34.8%) **Setting:** Paediatric medical centre in Tehran, Iran **Severity of condition:** Moderate to severe persistent asthma **Inclusion criteria:** Age 10-18, physician diagosis of ashma in the past year, moderate to severe persistent asthma, daily use of corticosteroid prophylactic asthma medications, ability to speak Persian, and willingness to communicate with researchers.

	Exclusion criteria: Reluctance to stay in the study, hospitalization during the study and occurrence of non-asthma related stressful experiences during the study, failure to attent two consecutive sessions, participation in other educational programs, counselling during the study. **Any baseline differences?:** No statistically significant differences
Interventions	**Type of intervention:** Motivational Interviewing (MI) **Intervention description:** Session 1: determine degree of readiness for change, self-esteem, self-efficacy, implementation of techniques to promote these items. Session 2: focussed on patient's adherence, use of techniques to achieve these goals. E.g. Table of benefits and disadvantages of behaviour change. Session 3: identifies and highlights patient beliefs about medication. **Control group:** Routine standard treatment, including medical visits and medical prescription **Duration and intensity of intervention:** 3x 1-hour sessions per week **Intervention format:** In person **Intervention delivered to patients by:** "Interviewer"
Outcomes	10-item Medication Adherence Scale (MARS) (range 1-5, higher=better); CASES questionnaire for self-efficacy (range 8-40 for prevention of attacks, 6-30 for management of attacks; higher=better); BMQ for patient beliefs about medication (range 1-5 per dimension; lower=better)
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomly assigned into a control and an intervention group through block randomization. The size of the blocks was considered four. The allocation sequence was generation using the online Research Randomizer (www.randomizer.org)."
Allocation concealment (selection bias)	Low risk	"numbered opaque envelopes were used to blind the assignment process. 52 opque envelopes were used to hide the allocation. Envelopes were numbered from 1 to 52 and the name of the group (control or intervention) was provided witin each envelope according to the random sequences. After the pre-test, envelope number 1 was dedicated to the first participant and the assigned group was identified based on the content on the card in the envelope. Blinding of the assignments and sampling was performed by two independent individuals who were not involved in sampling."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind intervention to participants and personnel.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants could not be blinded to the intervention and the outcome of interest (medication adherence) is self-rated.

Incomplete outcome data (attrition bias) All outcomes	High risk	6/26 (23.1%) participants randomized to the intervention group were not included in the analysis due to distance from the clinic and absenteeism
Selective reporting (reporting bias)	Unclear risk	Not suspected but prospective trial registration or protocol not available.
Other bias	Low risk	No other biases identified

Beebe 2010

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Information provided to all students at the school, those interested identified themselves to school staff **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 22 **Number randomised:** **Number completed:** **Age (mean, range):** 7-14 years **Gender (N and % female):** **Setting:** Kunsberg School, National Jewish Health, USA

	Severity of condition: **Inclusion criteria:** **Exclusion criteria:** **Any baseline differences?:**	
Interventions	**Type of intervention:** Art therapy **Intervention description:** The sessions included an opening activity,discussion of the weekly topic and art intervention, art making, opportunity for the patients to share their feelings related to the art they created, and the closing activity. In each session, a new topic and art intervention related to chronic illness were presented **Control group:** Wait-list **Duration and intensity of intervention:**1 hour art therapy session for 7 weeks **Intervention format:** In person **Intervention delivered to patients by:**	
Outcomes	Quality of life, emotional health (as measured by BYI)	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not reported. Identity of outcome assessors not described at all.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear how many participants completed the study
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol to compare for selective reporting
Other bias	Unclear risk	Baseline demographics and differences not reported

Bruzzese 2008

Study characteristics	
Methods	**Study design:** RCT

	Method of recruitment: To identify eligible students, caregivers completed a symptom-focused case detection survey that asked questions about: (a) past diagnosis of asthma; and the frequency over the past 12 months of (b) symptoms of wheeze, persistent cough, chest tightness, and night wakening; (c) symptoms with exercise; (d) urgent use of health care; and (e) the use of medication for asthma. To maximize return rates, a multilevel case detection procedure was used with the following steps: (1) case detection surveys were sent home via students; (2) the school nurse or health aide distributed case detection surveys to students known to have asthma but who did not return the form in Step 1; and (3) case detection surveys were completed at school functions. **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 78 **Number randomised:** 24 **Number completed:** 23 **Age (mean, range):** 12.9 years **Gender (N and % female):** n=11, 45.8% female **Setting:** Students of a public middle school in New York City, USA **Severity of condition:** **Inclusion criteria:** Eligible students had an asthma diagnosis from a medical provider, and over the past 12 months exhibited asthma symptoms an average of three times per month and used asthma medication. **Exclusion criteria:** Families were excluded if (1) the child had a co-morbid disease that affects lung functioning or highly specialized developmental or learning needs, (2) the child and/or the caregiver did not speak English, or (3) the caregiver and child did not live together.

	Any baseline differences?: No significant differences on demographic or disease variables between the two groups were found.
Interventions	**Type of intervention:** School-based family therapy (Asthma: It's a Family Affair!) **Intervention description:** Based on social cognition theory, cognitive behavioral theory, and two forms of family systems theory, parenting styles, and Behavioral Family Systems Theory. Two complementary components: (1) a behavioral intervention to empower middle school students to manage their asthma; and (2) parent training to teach child-rearing skills that support the youth's growing autonomy and need to self-manage their asthma. Lesson topics included: (1) information and feelings about asthma; (2) asthma medication; (3) prevention and management of asthma symptoms; (4) problem-solving and coping with negative feelings about asthma; and (5) communicating about asthma to peers and teachers, relaxation exercises, and healthy behaviors, including smoking refusal skills and avoiding exposure to secondhand smoke **Control group:** No treatment **Duration and intensity of intervention:** 6x 75-minute group sessions held once a week for 6 weeks **Intervention format:** In person **Intervention delivered to patients by:** A developmental psychologist (first author) delivered the student sessions.
Outcomes	Asthma management, asthma symptom severity, child-caregiver interactions
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described.
Allocation concealment (selection bias)	Unclear risk	Method of randomisation not described. Randomization took place after completion of baseline surveys by all families to conceal random assignment from participants and study personnel during baseline
Blinding of participants and personnel (performance bias) All outcomes	High risk	No method of blinding discussed
Blinding of outcome assessment (detection bias) All outcomes	High risk	No method of blinding discussed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low for all outcomes with possible exception of caregivers immediate follow up 66 vs 83% follow up

Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol to compare for selective reporting
Other bias	Low risk	No other biases identified

Bruzzese 2020

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 61 **Number randomised:** 61 **Number completed:** **Age (mean, range):** 15.2 **Gender (N and % female):** 67% female **Setting:** Enrolled from two New York City public high schools (n = 37) and geographically diverse clinics, community-based organizations and third-party recruitment services (n = 24), New York City, USA **Severity of condition:** **Inclusion criteria:** Inclusion criteria included: (1) a prior asthma diagnosis; (2) use of asthma medication in the past 12 months; (3) uncontrolled asthma, defined as having in the past 12 months (a) daytime symptoms 3 or more days a week,

	(b) night awakenings 1 or more nights per week, or (c) 2 or more exacerbations [i.e., steroid bursts or asthma-related ED visits or hospitalization]; and (4) English proficient because the intervention is currently available only in English **Exclusion criteria:** To allow broad generalization of study findings, the only exclusion criterion was co-morbid diseases that affect lung functioning **Any baseline differences?:**
Interventions	**Type of intervention:** e-Health intervention **Intervention description:** The final version of CAMP Air consists of seven modules with core instructional topics and tailored sessions, embedded hands on interactive activities, personalized feedback, and dynamically generated supplemental resources geared towards adolescents with uncontrolled asthma. Grounded in social cognitive theory and motivational interviewing, each module intermixes instruction (for definition and description of concepts) with self-assessments, videos, and interactive practice opportunities (for exploration and application of learned concepts, which is needed to build asthma self-management skills) **Control group:** Adolescents randomized to the information-and-referral control intervention were given written educational materials used in our prior studies regarding asthma and stress. **Duration and intensity of intervention:** 7 modules, daily assessment but modules spaced by one week **Intervention format:** Online **Intervention delivered to patients by:** Online modules, created by motivational interviewing expert
Outcomes	Asthma knowledge, asthma control, symptom frequency, healthcare utilisation, quality of life
Notes	

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described
Allocation concealment (selection bias)	Unclear risk	Method of randomisation not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants and personnel not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Research assistants blind to treatment-control status interviewed adolescents in person for the school sample or by phone for the community sample. However, subjective self-report measures used.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition data not reported

Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol to compare for selective reporting
Other bias	Low risk	No other biases identified

Chiang 2009

Study characteristics	
Methods	**Study design:** Two-group experimental design **Method of recruitment:** Participants were recruited from patients at the asthma clinic by a well-trained research assistant **Method of randomisation:** First child was assigned by coin toss, then alternating. They were assigned based on gender, age and severity of asthma.
Participants	**Number eligible for study:** 65 **Number randomised:** 62 **Number completed:** 51 **Age (mean, range):** 6-14 years **Gender (N and % female):** 18, 37.5% female **Setting:** Patients of the pediatric asthma clinic of a medical center in Taiwan **Severity of condition:** Moderate to severe

	Inclusion criteria: (1) diagnosed with moderate-to-severe asthma by a physician at least 6 months before the study, (2) had > 5 episodes of asthma per year, with an Aas score of > 2 (Aas 1981), and (3) regularly treated with asthma medication in a pediatric clinic. **Exclusion criteria:** Children were excluded if they had participated in any other clinical trials **Any baseline differences?:**	
Interventions	**Type of intervention:** Relaxation-breathing training combined with self-management **Intervention description:** Relaxation-breathing training based on Jacobson - progressive muscle relaxation with deep breathing **Control group:** Asthma self-management program **Duration and intensity of intervention:** 12 week intervention, participants asked to practice 30 minutes at least 3 times per week **Intervention format:** Training in person, then provided CD and instruction sheet **Intervention delivered to patients by:** Researcher	
Outcomes	Anxiety, self-perceived health status, asthma signs/symptoms, PEFR, asthma medication	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	High risk	First child was assigned by coin toss, then alternating. They were assigned based on gender, age and severity of asthma.
Allocation concealment (selection bias)	Low risk	Conducted by administrator independent of study team researchers were not involved in the randomisation process
Blinding of participants and personnel (performance bias) All outcomes	High risk	No method of blinding described.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No method of blinding described.
Incomplete outcome data (attrition bias) All outcomes	High risk	22/29 vs 26/33 followed up 75% vs 79%
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol to campare for selective reporting
Other bias	Low risk	No other biases identified

Colland 1993

Study characteristics

Methods	**Study design:** RCT: pre-post **Method of recruitment:** Method of recruitment unclear **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 112 **Number randomised:** 112 **Number completed:** 112 **Age (mean, range):** 10, 8-12 years **Gender (N and % female):** 76, 39% female **Setting:** Outpatient clinics, the Netherlands **Severity of condition:** **Inclusion criteria:** (i) the child had been treated by a pediatrician for longer than 1 year, (ii) the diagnosis asthma was evident (minimum score 1 on a 9- point scale concerning the severity of asthma), (iii) the child was between 8 and 13 years of age, (iv) the child could speak Dutch fluently and (v) the child had been absent from school because of asthma more than once a year. **Exclusion criteria:** **Any baseline differences?:** There were no significant base- line differences between the experimental group (group l), the placebo group (group 2) and the normal control group (group 3) on any of the above-mentioned variables. Educational levels of the parents (on a 7-point scale) were equally represented in the group: low, moderate and high levels of education were all included.

Interventions	**Type of intervention:** Behavioural self-management program **Intervention description:** The program consisted of a combination of behavioural techniques, self-management training, developmental psychology and group therapy techniques. **Control group:** Two control groups - one received an information session, one received nothing **Duration and intensity of intervention:** Ten weekly 1-hour sessions **Intervention format:** Face-to-face in a group of 6-8 children **Intervention delivered to patients by:** One behaviour therapist, one a person with experience in working with groups of children	
Outcomes	Asthma coping, self-efficacy, asthma knowledge, compliance, anxiety	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described. "They were randomly allocated to the experimental group or one of the two control groups", but authors matched based on age, coping score and severity of asthma
Allocation concealment (selection bias)	Unclear risk	Method not described.

Blinding of participants and personnel (performance bias) All outcomes	High risk	No method of blinding described.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No method of blinding described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No numerical data provided for number of children at follow-ups. "No drop-outs during the 10-week program". "We note that there were no drop-outs at all and that all children stated that they enjoyed the program and the learning materi- als a lot"
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol to campare for selective reporting
Other bias	Low risk	No other biases identified

Dahl 1990

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Not described **Method of randomisation:** Not described

Participants	**Number eligible for study:** 20 **Number randomised:** 20 **Number completed:** 19 **Age (mean, range):** 12.2 years **Gender (N and % female):** n=8, 42% female **Setting:** Children with severe asthma at a pediatrics unit, Sweden **Severity of condition:** Severe asthma using continual B2 agonist therapy **Inclusion criteria:** Not described **Exclusion criteria:** Not described **Any baseline differences?:** Treatment group had higher average spray doses/day, school absenteeism/month, and days experiencing asthma symptoms than the control group
Interventions	**Type of intervention:** Behaviour Therapy **Intervention description:** Principles for the Behaviour Therapy BT treatment followed the problem area as revealed in the behaviour assessmentBA and were as follows: discrimination training of asthma signals, self-management techniques of breathlessness, counter-conditioning of any learned fear response, contingency management of asthma-related behavior, and compliance training **Control group:** Usual care **Duration and intensity of intervention:** 4x 1 hour sessions over 4 weeks **Intervention format:** In person **Intervention delivered to patients by:** Not reported

Outcomes		
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described - "children were randomised into two groups"
Allocation concealment (selection bias)	Unclear risk	Method not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding not described

Incomplete outcome data (attrition bias) All outcomes	High risk	"One child was dropped from the treatment group due to lack of reliable dependent measures."
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol available to detect reporting bias
Other bias	Unclear risk	Treatment group had higher average spray doses/day, school absenteeism/month, and days experiencing asthma symptoms than the control group, however we do not know if this was significant, nor if this was considered in the analysis

Gustafsson 1986

Study characteristics	
Methods	**Study design:** RCT, crossover design **Method of recruitment:** 20 most severe cases of asthma were selected from outpatient department **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 20 **Number randomised:** 17 **Number completed:** **Age (mean, range):** 9, 6-15 years **Gender (N and % female):**

	Setting: Patients from the Pediatric Outpatient Department of the University Hospital, Linkoping, Sweden **Severity of condition:** Severe, chronic cases (based on functional impact) (Asthma grade D) **Inclusion criteria:** Children with asthma who attend the Pediatric Outpatient Department of the University Hospital **Exclusion criteria:** **Any baseline differences?:**
Interventions	**Type of intervention:** Family therapy **Intervention description:** Family therapy was defined as treatment of the entire family, or parts of it, with psychological and pedagogical methods aimed at changing interpersonal relations. The therapeutics called attention to and tried to change dysfunctional patterns of family interaction, explored the role of the asthma symptoms in the family system, tried to reveal hidden conflicts, strengthened boundaries between individuals and between parents and children, and tried to enhance communication about the emotional impact of the disease on the family members. **Control group:** Conventional therapy **Duration and intensity of intervention:** Eight months of family therapy. Number of sessions were 2-21, mean = 8.8 **Intervention format:** **Intervention delivered to patients by:** Two experienced therapists
Outcomes	General pediatric assessment, clinical grading, PEF, patient compliance, emergency inpatient days and ED visits, days with functional impairment, doses of beta2-agonists, steroid treatment
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not described - "children were randomly assigned to two groups"
Allocation concealment (selection bias)	Unclear risk	Method not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Method not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"The children were clinically evaluated three times during each data collection period by a pediatric allergist who did not know whether the children and their families received family therapy or not. "
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear if any participants withdrew - total numbers not reported in results. "Two families assigned to the experimental group did not participate in therapy. They were nevertheless incuded in the experimental group in the group comparisons"
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol available to determine reporting bias

Other bias	Low risk	No other biases identified

Halterman 2021

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Study team members used school 'medical alert' forms to identify teens with asthma and called caregivers for eligibility screening. Screening procedures included a telephone survey with the caregivers, verbal consent to contact the primary care provider, and scheduling a baseline home visit. **Method of randomisation:** Randomization was stratified by school and use of a preventive medication at baseline (Y/N). The randomization scheme was independently developed by a programmer in the Biostatistics Center.
Participants	**Number eligible for study:** 545 **Number randomised:** 430 **Number completed:** 371 followed up **Age (mean, range):** 13.4 **Gender (N and % female):** n=190, 44% female **Setting:** 69 secondary schools in urban Rochester, New YorkY, USA **Severity of condition:** Persistent severity **Inclusion criteria:** Teen/caregiver dyads were eligible if the teen was between the ages of 12-16 years and had physician diagnosed asthma with persistent severity or poor control according to NHLBI asthma guideline criteria

	Exclusion criteria: Exclusion criteria included an inability to speak and understand English, a lack of access to a working phone for follow-up surveys, the presence of significant medical conditions (cystic fibrosis, congenital heart disease, chronic lung disease, and developmental or intellectual disability), or living situations in which consent could not be obtained from a legal guardian. **Any baseline differences?:** There were no differences in any of the demographic characteristics or exposure to smoke among teens in the three treatment groups.
Interventions	**Type of intervention:** School-based intervention **Intervention description:** Trial of directly observed therapy of preventive asthma medication at school combined with up to 3 school-based motivational interviewing counseling sessions. **Control group:** Directly observed therapy only group, asthma education group **Duration and intensity of intervention:** Directly observed therapy daily, 3 motivational interview sessions (1x 30-40 minute, 2x 20-30 minute) over 6 weeks **Intervention format:** In person **Intervention delivered to patients by:** Trained staff member - nurse or psychologist
Outcomes	Symptom-free days, ED visits, hospitalisations, urgent care visits, nights with asthma symptoms, days needing rescue medication, and days with limited activity, Quality of life, school absenteeism, FeNo
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomisation scheme was independently developed by a programmer in the Biostatistics Centre"
Allocation concealment (selection bias)	Unclear risk	"After baseline, the study coordinator assigned the subject's ID number and treatment group" however, no further information provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Teens and caregivers were not masked to group allocation; they were told they were randomly assigned to different methods of approaching asthma management"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Outcomes were assessed 3-, 5-, and 7-months after baseline by research assistants masked to treatment allocation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Potential participants approached and reasons for exclusion reported. However, reasons for attrition after randomisation not reported

Selective reporting (reporting bias)	Unclear risk	No pre-specified published protocol to allow detection of reporting bias
Other bias	Low risk	No other biases identified

Hock 1978

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 43 **Number randomised:** **Number completed:** **Age (mean, range):** 12.4, 10-17 years **Gender (N and % female):** 0, 0% female **Setting:** Allergy Outpatient Clinic at Cook County Hospital, Chicago, USA **Severity of condition:** **Inclusion criteria:** Male children being treated in the Allergy Outpatient Clinic at Cook County Hospital for bronchial asthma **Exclusion criteria:** **Any baseline differences?:**

Interventions	**Type of intervention:** Relaxation Training (RT), Assertive Training (AT), or Combination (RT + AT) **Intervention description:** Relaxation TrainingT: modified form of progressive relaxation (tense and relax muscles) with guided imagery to promote relaxation. Assertive TrainingT: trained to express socially appropriate feelings and rights. This included role playing and exercises in four major areas: (a) learning to say no to authority figures, (b) learning to practice the expression of positive and negative feelings, (c) learning to initiate and terminate general conversations, and (d) learning to make requests for favors. CombinationRT+AT: combination of the two training types. **Control group:** Normal medical treatment, or normal medical treatment with peer support group **Duration and intensity of intervention:** 40 minute session, once a week for 8 weeks **Intervention format:** **Intervention delivered to patients by:**	
Outcomes	Respiratory functioning and asthma-attack frequencies	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not described "The patients were randomly assigned to one of three treatment groups, or to one of two control groups"
Allocation concealment (selection bias)	Unclear risk	Method not described "The patients were randomly assigned to one of three treatment groups, or to one of two control groups"

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants and personnel not described.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"A nurse unaware of the specific group to which the child was assigned took the measurements"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Withdrawals not discussed. Numbers not listed in results.
Selective reporting (reporting bias)	Unclear risk	No pre-specified protocol available to assess reporting bias
Other bias	Low risk	No other bias identified

Khoshnavay Fomani 2013

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Method not described **Method of randomisation:** Method not described

Participants	**Number eligible for study:** **Number randomised:** 48 **Number completed:** **Age (mean, range):** **Gender (N and % female):** **Setting:** Elementary schools in Iran **Severity of condition:** **Inclusion criteria:** **Exclusion criteria:** **Any baseline differences?:**
Interventions	**Type of intervention:** Rational Emotive Behaviour Therapy (REBT) **Intervention description:** Comprehensive, active-directive, philosophically and empirically based psychotherapy which focuses on resolving emotional and behavioural problems. **Control group:** Common and similar medical treatments **Duration and intensity of intervention:** Rational Emotive Behaviour TherapyEBT conducted in 10 sessions on the experimental group **Intervention format:** **Intervention delivered to patients by:**
Outcomes	Quality of life

Notes	Abstract for conference	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not described "students were randomly assigned"
Allocation concealment (selection bias)	Unclear risk	Method not described "students were randomly assigned"
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding described
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No protocol provided
Selective reporting (reporting bias)	Unclear risk	No protocol provided

Other bias	Low risk	No other source of bias identified

Kohen 1996

Study characteristics	
Methods	**Study design:** Randomised, 4 groups **Method of recruitment:** Recruitment included letters to praciticing paediatricians, family physicians, and allergists, and descriptions of the proposed study in local publications **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 33 **Number randomised:** 33 **Number completed:** 28 **Age (mean, range):** 7-12 years **Gender (N and % female):** n=10, 30.3% female **Setting:** Minneapolis Children's Medical Centre, USA **Severity of condition:** No pre-study assessment of asthma severity was determined **Inclusion criteria:** Any child from 7-12 years with asthma, who agreed to the protocol, and had not formally been taught relaxation techniques **Exclusion criteria:** Previously taught relaxation techniques, or if they requested specific group assignment rather than agreeing to accept random assignment **Any baseline differences?:**

Interventions	**Type of intervention:** Relaxation/Mental Imagery (self-hypnosis) **Intervention description:** Experimental group patients were taught a relaxation/mental imageryRMI exercise at the first session, with attention to and flexibility for the individual needs and developmental abilities of each child. Included were a variety of direct, indirect and metaphirc suggestions for prevention and control of wheezing, and training in self-hypnosis in order to be able to practice relaxation/mental imageryRMI at home **Control group:** Waking Suggestion Group - suggestions made in matter-of-fact manner without hypnosis. Attention Placebo Control Group - equivalent time and attention in the form of age-appropriate conversation or games without discussion regarding asthma. OR Traditional Control Group - received no special attention, time or instruction **Duration and intensity of intervention:** Initial 30-40 minute session **Intervention format:** In person **Intervention delivered to patients by:** Principal Investigator	
Outcomes	Medication use, severity, relaxation/mental imageryRMI, pulmonary function tests, psychological testing	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Unclear risk	Method not described. "Patients were randomly assigned"
Allocation concealment (selection bias)	Unclear risk	Method not described. "Patients were randomly assigned"
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding - participants dropped out due to group allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Method of blinding not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for withdrawal clearly discussed. These individuals were included in the analysis. "Five subjects dropped out, either after agreeing to participate and after initial PFTs, or after assignment to their group and prior to the second PFTs. Reasons for withdrawal included changing their minds, the two-year commitment required, and dissatisfaction with the (random) group assignment. These subjects did not differ significantly from study usbjects with regard to demographic characteristics or asthma medication usage"

Selective reporting (reporting bias)	High risk	Numerical data not provided for outcomes included psychological evaluation
Other bias	Low risk	No other source of bias identified

Lask 1979

Study characteristics	
Methods	**Study design:** **Method of recruitment:** **Method of randomisation:** Method not described
Participants	**Number eligible for study:** 37 **Number randomised:** 37 **Number completed:** 29 **Age (mean, range):** 4-14 years **Gender (N and % female):** **Setting:** Asthma clinic, The Hospital for Sick Children, London, UK **Severity of condition:** Grade C or D asthma **Inclusion criteria:** Children between 4 and 14 with grade C or D asthma **Exclusion criteria:** **Any baseline differences?:** The groups were homogenous with respect to severity of asthma, age, social class, and psychological health. There were more boys than girls in group A.

Interventions	**Type of intervention:** Family therapy **Intervention description:** The family therapist would meet the whole family together and, in the case of an asthmatic child, would focus on such themes as the varying attitudes to the illness, the doctor and the medication, the fear of death, and the experiencing of painful and frightening emotions. By dealing with such themes and helping to adjust attitudes away from the extreme and towards the more realistic, he would work towards an improvement in the psychological well-being of the family. **Control group:** Seen and appropriately treated by paediatrician at 3-weekly intervals during a 4-month period **Duration and intensity of intervention:** 6x 1 hour sessions of family psychotherapy **Intervention format:** In person **Intervention delivered to patients by:** Family psychotherapist	
Outcomes	Day-wheeze and activity limitation, PEFR, FEV, TGV	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not described. "Their families were then randomly allocated to the experimental (group A) or control group (group B)."

Allocation concealment (selection bias)	Unclear risk	Method not described. "Their families were then randomly allocated to the experimental (group A) or control group (group B)."
Blinding of participants and personnel (performance bias) All outcomes	High risk	No mention of blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear reasons for withdrawals, n-values included in results and analysis "Consequently, at final follow up there were 18 children in group A and 11 in group B of whom 3 had each missed one test"
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Unclear risk	Small case numbers

Loew 1996

Study characteristics

Methods	**Study design:** Single cohort with randomised order of treatment, i.e. all children received treatments in randomised order over 3 days (each treatment was given once) **Method of recruitment:** Known patients of the Children's Hospital Outpatient Care were contacted by letter, and paediatricians were contacted by letter **Method of randomisation:** Randomised by the random principle
Participants	**Number eligible for study:** **Number randomised:** 18 **Number completed:** **Age (mean, range):** 10.6, 7-17 years **Gender (N and % female):** n=5, 27.8% female **Setting:** Outpatients care Children's Hospital, Germany **Severity of condition:** **Inclusion criteria:** Children and adolescents with asthma bronchiale **Exclusion criteria:** Not stated **Any baseline differences?:**
Interventions	**Type of intervention:** Functional Relaxation **Intervention description:** 5 minute introduction to functional relaxation **Control group:** Bronchospasmolysis with Salbutamol inhaler, or placebo relaxation technique **Duration and intensity of intervention:** 1x 5 minute session

	Intervention format: In person **Intervention delivered to patients by:**	
Outcomes	FEV1, PEF, MEF50, MEF75, ITGIGTV, RV	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method not described. "Randomised by the random principle"
Allocation concealment (selection bias)	Unclear risk	Method not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No method of blinding mentioned.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not mentioned.

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition data not reported.
Selective reporting (reporting bias)	Unclear risk	No protocol available, but all outcome measures listed in paper were reported.
Other bias	Low risk	No other risk of bias identified.

Marsland 2019

Study characteristics	
Methods	**Study design:** Parallel randomised controlled design **Method of recruitment:** School nurses identified children who (a) had a diagnosis of asthma on school medical records and/or who carried a bronchodilator inha-ler and (b) met other study inclusion criteria. **Method of randomisation:** Participants were allocated to condition by stratified randomisation (allocation ratio: 1:1:1)
Participants	**Number eligible for study:** 111 **Number randomised:** 104 **Number completed:** 93 **Age (mean, range):** 10.6, range 8-14 years **Gender (N and % female):** 46% female **Setting:** Urban public schools in Pittsburgh, PA, USA **Severity of condition:** Mild-severe

	Inclusion criteria: Children aged 8-14 in grades 3-8 at 12 participating public schools. All were eligible for free or reduced-cost school lunch program in PA, met the American Thoracic Society (ATSC) criteria for persistent asthma, as confirmed by the study physician, and had a legal parent willing to participate **Exclusion criteria:** Exclusion criteria were chronic illnesses other than asthma, developmental delay with function <age 8 years of age as assessed by the school, and inability to understand English. **Any baseline differences?:**
Interventions	**Type of intervention:** I Can Cope (ICC) a stress management intervention **Intervention description:** Manualised intervention. Each session includes 15 minutes of psycho-education, 15 minutes of related games/activities, 15 minutes of relaxation training and 5 minutes of homework assignment and review. Content focuses on: (a) the pathophysiology of asthma; (b) the biological impact of stress on the body; (c) relationships among thoughts, feelings, actions and asthma;(d) coping skills to help deal with asthma-related and day-to-day stressors and (e) training in biofeedback-assisted relaxation techniques, including guided imagery, progressive muscle relaxation,diaphragmatic breathing and mindfulness-based body awareness techniques. Children received CDs or MP3 files with the relaxation exercises and a portable CD player to enable home practice **Control group:** a) asthma education (Open Airways for Schools), b) no treatment **Duration and intensity of intervention:** 6x 50 minute sessions over a period of 2-4 months **Intervention format:** In person **Intervention delivered to patients by:** Interventionists were a doctoral level clinical psychologist, a master's level counselling psychologist and three graduate students in clinical or counselling psychology programmes

Outcomes	Intervention feasibility and acceptability, asthma coping, self-efficacy, psychological function, sleep quality, and asthma health)	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Participants were allocated to condition by stratified randomization (allocation ratio: 1:1:1)
Allocation concealment (selection bias)	Low risk	Participants were allocated to condition by stratified randomization (allocation ratio: 1:1:1). Participant ID numbers and asthma severity (mild, moderate, severe) were sent to a co-investigator who was blind to all other participant information. Within each asthma severity stratum, participants were randomized to study condition. Study staff were blinded to the randomization process.
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Study staff were blinded to the randomization process." - Unclear if blinding continued throughout study

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff who conducted assessments were blind to the participants'study condition
Incomplete outcome data (attrition bias) All outcomes	Low risk	Dropout rates were also low, with 11 children (11%) dropping out prior to the T2 evaluation. Of these 11 children, five withdrew (three from the NT group, one from ICC because they moved school and one from OAS because of missing gym class) and six were lost to follow-up (three from the NT and three from the active interventions due to moving school).
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	No other bias identified

Naar 2018

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Medical record review and direct contact with clinical staff identified 399 patients who were hospitalized or admitted to the ED twice in 1 year for asthma. Of these, 196 were contacted by research staff to further screen for eligibility. **Method of randomisation:**

Participants	**Number eligible for study:** 170 **Number randomised:** 170 **Number completed:** 147 (167 included in analysis) **Age (mean, range):** 13.48, 12-16 years **Gender (N and % female):** n=65, 38.9% female **Setting:** High-risk African American youth **Severity of condition:** Moderate to severe **Inclusion criteria:** Between 12 years 0 months and 16 years 11 months old, to be diagnosed with moderate to severe persistent asthma, to self-identify as African American, and to be residing in a home setting (e.g., not in residential treatment) with a caregiver who was willing to participate in treatment. **Exclusion criteria:** Exclusion criteria included thought disorder, suicidality, mental retardation, having another chronic health condition, or unable to complete assessments or interventions in English. **Any baseline differences?:** Significant differences between groups: single-parent households (FS), completed 6-month assessment (MST), medication adherence
Interventions	**Type of intervention:** Multi-systemic therapy **Intervention description:** Self-management treatment including: identified risk factors, empirically based clinical treatments (e.g. CBT), behavioural change interventions **Control group:** Family support: weekly, home-based, client-centered, nondirec-tive supportive family counseling.

	Duration and intensity of intervention: Based on our previous multi-systemic therapyMST-HC trials, treatment was planned to last for 6 months. Mean length of treatment, excluding dropouts, was 5.14 months (SD1.25), and mean number of sessions was 27.09 (SD12.03; range4–62 sessions). **Intervention format:** In person **Intervention delivered to patients by:** MST-HCMulti-systemic therapy was provided by four master's-level therapists withvaried backgrounds (one psychologist, three social workers).	
Outcomes	Asthma management (FAMSS), lung function	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Stratified, but no description of randomisation method in text
Allocation concealment (selection bias)	Unclear risk	Stratified, but no description of randomisation method in text
Blinding of participants and personnel (performance	High risk	No mention of blinding participants/staff.

bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All data collectors were blind to the participant's studycondition.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcomes at the follow-up were analyzed for both the intent-to-treat sample (all randomized participants) and per-protocol sample (participants who received a pre-defined minimum dose of treatment).
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	No other source of bias identified.

Pulgaron 2010

Study characteristics	
Methods	**Study design:** RCT pilot **Method of recruitment:** Participants were recruited through aflier mailed to parents before camp or in-person during on-site camper registration. **Method of randomisation:** Method of randomisation unclear
Participants	**Number eligible for study:** 63

	Number randomised: 50 **Number completed:** 41 **Age (mean, range):** 10.44, 7-14 years **Gender (N and % female):** 38% female **Setting:** Dragonfly Forest summer camp, Pennsylvania, USA **Severity of condition:** Persistent asthma (defined by the camp as being on prophylactic medication but having asthma under control to the extent that the child had not been hospitalized in the last year) **Inclusion criteria:** The inclusion criteria for this study were that the child be a camper at Dragonfly Forest, be between the ages of 7 and 14 years, and have persistent asthma (defined by the camp as being on prophylactic medication but having asthma under control to the extent that the child had not been hospitalized in the last year). **Exclusion criteria:** Campers were to be excluded if they did not speak English. **Any baseline differences?:** Kruskal–Wallis tests indicated that there were no differences among the four groups on the demographic or baseline-dependent variables.
Interventions	**Type of intervention:** Problem solving **Intervention description:** Intervention sessions and trainings were manualized based on problem-solving therapy techniques supported in the chronic illness literature. Specifically, the focus was on the four problem-solving skills domains:(1) defining and formulating problem; (2) generating alternative solutions; (3) deciding which solution to implement based on identifying consequences and conducting a cost-benefit analysis; and (4) implementing a solution and verifying whether it was successful. **Control group:** Standard cabin chat

	Duration and intensity of intervention: 4 sessions **Intervention format:** In person **Intervention delivered to patients by:** Clinical psychology graduate students trained and supervised by two pediatric psychologists (CAP, LPB) and an advanced graduate student (ERP); interventionists were not camp counselors	
Outcomes	Problem solving abilities (Cognitive-behavioural Problem-Solving subscale of the Coping Scale for Children and Youth), disease-specific knowledge, quality of life, healthcare utilisation	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Campers were assigned to the intervention or control groups using a stratified random assignment. Participants were divided into four groups accordingto gender and age (7–10 years and 11–14 years) and then randomly assigned to one of the two conditions.
Allocation concealment (selection bias)	High risk	Unable to conceal due to nature of intervention
Blinding of participants and personnel	High risk	No mention of blinding

(performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	High risk	No mention of blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	16% (8/50) attrition rate, across both arms, 7/50 (14%) lost to follow event. Unclear if data included where appropriate.
Selective reporting (reporting bias)	Unclear risk	Healthcare utilisation information collected but not reported in results, no protocol
Other bias	Low risk	No other bias identified

Taheri 2019

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Convenience sample, patients of pediatric ward of Valiasr hospital in Birjand, Iran were approached in clinic

	Method of randomisation: For random allocation of participants to either of the study groups, each of them was provided with a card labeled A (i.e. control group) and a card labeled B (i.e. intervention group) and was asked to randomly select one card. The label on the card determined the group allocation of the intended participant.
Participants	**Number eligible for study:** **Number randomised:** 64 **Number completed:** 64 **Age (mean, range):** 11.66, 10-15 **Gender (N and % female):** 25, 39% female **Setting:** Pediatric ward in hospital, Iran **Severity of condition:** **Inclusion criteria:** The eligibility criteria were an age of 10 - 15, asthma diagnosis by a specialist at least one year before the study, willingness for participation in the study, parental consent for participation, basic literacy skills, use of at least one inhaled asthma medication, and no mental disorders. **Exclusion criteria:** The exclusion criteria included more than one absence from MI sessions and withdrawal from the study due to events such as accident or death. **Any baseline differences?:** Study groups did not significantly differ from each other concerning participants' age, gender, education level, father's and mother's employment status, family income, and place of residence ($P > 0.05$)
Interventions	**Type of intervention:** Motivational Interviewing

	Intervention description: It was developed by Miller and Rollnick based on Rogers' client-centered therapy approach to psychotherapy. In the first session, the participants and the interviewer (i.e. the first author) got familiar with each other and group norms and regulations were explained. Then, group members were evaluated respecting their latitude, independence, commitment, confidence, and factors affecting their behaviors. The second session was on the assessment of participants' feelings about their asthma-related behaviors. Accordingly, a list of positive and negative feelings was provided to each participant and he/she was asked to identify his/her feelings and explain them for other group members. In the third session, brainstorming was used to assess the short- and long-term advantages and disadvantages of behaviors. The positive and negative aspects of each behavior were written in a table and behavior modification strategies were described and exercised. In the fourth session, participants' values were identified and prioritized, value-behavior gaps were identified, and strategies for filling the gaps were exercised. Finally, in the fifth session, tempting situations were identified and the content of previous sessions was reviewed. **Control group:** Participants in the control group received no specific intervention. **Duration and intensity of intervention:** 5x 60 - 80-minute weekly sessions **Intervention format:** In person, group format **Intervention delivered to patients by:** First author of paper (researcher)
Outcomes	Asthma control (ACQ)
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	For random allocation of participants to either of the study groups, each of them was provided with a card labeled A (i.e. control group) and a card labeled B (i.e. intervention group) and was asked to randomly select one card. The label on the card determined the group allocation of the intended participant.
Allocation concealment (selection bias)	High risk	For random allocation of participants to either of the study groups, each of them was provided with a card labeled A (i.e. control group) and a card labeled B (i.e. intervention group) and was asked to randomly select one card. The label on the card determined the group allocation of the intended participant.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No mention of blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	No mention of blinding

Incomplete outcome data (attrition bias) All outcomes	High risk	No description of withdrawals/lost to follow up. No final numbers for follow-ups.
Selective reporting (reporting bias)	Unclear risk	Compared with trial registration, only ACQ reported in this paper. Could not find any other published works surrounding this trial.
Other bias	Low risk	No other sources of bias identified

Tong 2002

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Recruited from in-patient admissions **Method of randomisation:**
Participants	**Number eligible for study:** 116 **Number randomised:** 116 **Number completed:** 23 **Age (mean, range):** 4-15 **Gender (N and % female):** n=40, 34.5% **Setting:** Xiaoshan Fifth Hospital, Hangzhou, Zhejiang, China **Severity of condition:**

	Inclusion criteria: Asthma medical history over 1 year; aged 5-14; parents agreed to undertake psychology treatment. **Exclusion criteria:** Not mentioned **Any baseline differences?:** No	
Interventions	**Type of intervention:** Relaxation **Intervention description:** Relaxation training, desensitization therapy for children and health education to parents **Control group:** **Duration and intensity of intervention:** (1) relaxation training: twice everyday, 20min everytime; (2) desensitization therapy: twice every week for 4-6 weeks **Intervention format:** In-person education then follow-up with in-person and/or teleconference consultantion. **Intervention delivered to patients by:** Researcher	
Outcomes	Asthma symptoms, Achenbach scale	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described

Allocation concealment (selection bias)	Unclear risk	Method of randomisation not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals were reported
Selective reporting (reporting bias)	Low risk	The author reported overall difference, as well as differences in lung function, symptoms during day and night time, utilization of beta receptor angonist.
Other bias	High risk	For the treatment group, only 23 patients continuously completed the relaxation training. 10 patients completed up to 10 months, 17 patients completed upto 6 months, 8 patients completed upto 3 months, and 2 patients completed less than 3 months.

Tseng 2020

Study characteristics

Methods	**Study design:** A two-arm, parallel-group, randomized controlled trial **Method of recruitment:** Method not described **Method of randomisation:** Randomization was undertaken using a computer-generated random number by an independent statistician. Participants were allocated to the intervention or control group in a one-to-one ratio.
Participants	**Number eligible for study:** 90 **Number randomised:** 90 **Number completed:** 83 **Age (mean, range):** 14.3 **Gender (N and % female):** n=36, 43% female **Setting:** Tertiary hospital located in Northern Taiwan **Severity of condition:** Mild to severe **Inclusion criteria:** Inclusion criteria included being diagnosed with asthma and receiving treatment, 12–18 years old, able to converse in Chinese, with access to a mobile phone. **Exclusion criteria:** Patients diagnosed with a cognitive deficiency were excluded **Any baseline differences?:**
Interventions	**Type of intervention:** Self-management intervention **Intervention description:** The content of the intervention program will be based on the four elements of the Expert Panel Report-3 (EPR-3) of the NHLBIational Heart, Lung, and Blood Institut e iin the USA (NIH 20072007). The strategies will be guided by Bandura's self-efficacy model (Bandura 19771997), and will consider adolescent

	developmental needs, including seeking support at school, and interactive communication. Bandura's self-efficacy model includes efficacy-expectation (performance accomplishment, vicarious experience, verbal persuasion, and physiological information) and outcome-expectation (what outcome people expect from engaging in a particular behaviour) **Duration and intensity of intervention:** The asthma self-management program ASMP contained three face-to-face sessions, followed by two short text messages and a telephone call. A booklet titled "Living with Asthma Together" including "My Asthma Action Plan" was provided at the first face-to-face meeting for recording participants' goals for asthma management in week 1, discussing their feeling and concerns about asthma symptoms. Week 2, in a face-to-face meeting. At week 3, the asthma self-management programASMP session was focused on problem solving skills of asthma exacerbation. Two text messages were sent weekly after each meeting for 4 weeks as reminders to encourage participants to carry out their self-management behaviours. A telephone call was made at week 4 to inquire how the participant was progressing. **Intervention format:** 3 face to face sessions, followed by 2 text messages and a phone call **Intervention delivered to patients by:** Researcher	
Outcomes	The primary outcome was asthma self-efficacy and secondary outcomes were outcome-expectancy, asthma prevention and management behaviours, and asthma symptoms.	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	Randomization was undertaken using a computer-generated random number by an independent statistician. Participants were allocated to the intervention or control group in a one-to-one ratio.
Allocation concealment (selection bias)	Low risk	Randomization was undertaken using a computer-generated random number by an independent statistician. Participants were allocated to the intervention or control group in a one-to-one ratio.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No report of blinding participants and personnel.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collection was undertaken by a trained research assistant who was blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear how many completed intervention, as flow diagram of participants differs from described text
Selective reporting (reporting bias)	Low risk	Outcomes listed in protocol paper reported in results
Other bias	Low risk	No other sources of bias identified.

Wang 2012

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Recruited from outpatient asthma clinic (method not described) **Method of randomisation:**
Participants	**Number eligible for study:** 44 **Number randomised:** 44 **Number completed:** 39 **Age (mean, range):** 10, 8-15 years **Gender (N and % female):** n=17, 38.6% female **Setting:** Patients of an outpatient asthma clinic in China **Severity of condition:** **Inclusion criteria:** Aged 8-16, receiving GINA program suggested long-term control and fast-relief drug treatment; CBCL total score or one factor score is higher than standard **Exclusion criteria:** Patient has intellectual and cognitive impairment, organic mental illness; patients and parents have mental disorder; patient not able to finish the questionnaire **Any baseline differences?:** No differences reported.
Interventions	**Type of intervention:** Counselling

	Intervention description: Members from the experimental group were provided with counseling for 3 months, once every two weeks for a total of 6 times **Control group:** During this period, the members of the control group had not received any experimental intervention. **Duration and intensity of intervention:** 6 sessions over 3 months, 90min every session/every two weeks **Intervention format:** In-person **Intervention delivered to patients by:** Psychology nurse (Masters student)	
Outcomes		
Notes	behavior problems (depression, poor communication, compulsive behavior, social withdrawal) in male patients agend 8-11 improved significantly in the intervention group; behavior problems (depression, poor communication, compulsive behavior, social withdrawal) in female patients agend 8-11 improved significantly in the intervention group;	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Children were numbered according to the order of treatment.
Allocation concealment (selection bias)	Unclear risk	Children were numbered according to the order of treatment.
Blinding of participants and personnel	High risk	No mention of blinding.

(performance bias) All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No mention of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data are complete as per pre-specified outcomes.
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.
Other bias	Unclear risk	No other sources of bias identified.

Warner 2006

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** Patients were recruited from six local asthma/allergy clinics by mailing letters, posting fliers at clinics, and approaching patients in waiting rooms. **Method of randomisation:** A random numbers table was used to randomize participants to groups separately for each gender.

Participants	**Number eligible for study:** 180 **Number randomised:** 61 **Number completed:** 50 **Age (mean, range):** 14, 12-17 years **Gender (N and % female):** n=29, 58% female **Setting:** USA **Severity of condition:** 40% had mild persistent, 52% had moderate persistent, and 8% had severe persistent asthma **Inclusion criteria:** Participants were adolescents, aged 12–17, and one parent of each adolescent (92% were mothers). Chart review or physician report indicated that all adolescents were classified with at least mild persistent asthma (i.e., asthma symptom activity at least 2 days per week and nocturnal symptoms at least twice monthly). **Exclusion criteria:** Exclusion criteria were having only seasonal or exercise-induced asthma, the presence of a serious medical condition other than asthma, and current use of psychotropic medication or participation in counseling or psychotherapy. Adolescents known to have cognitive impairment were excluded because of the intervention's reliance on verbal skills. **Any baseline differences?:** The disclosure group did not differ significantly from the control group on demographics or any of the asthma history variables (all $p > 0.25$). Also, groups did not differ at baseline on any of the outcome measures (all $p > .32$;Table I).
Interventions	**Type of intervention:** Written disclosure **Intervention description:** Adolescents were instructed to "write continuously for 15 to 20 minutes about a trauma or problem that you may be experiencing right now, or that you experienced at some other time in your life. You can write

	about anything that you want, but remember that the event you choose should be the one you consider to be the most stressful that you have ever experienced and that is the most important to you. When you write about the event, I want you to let yourself go and touch the deepest feelings and thoughts that you have. In other words, write about what happened and how you felt about it, and how you feel about it now. You should try to write about the same event for 3 consecutive days, but this is not a requirement. Again, ideally, the topic will be one that you have not talked about in detail with others." **Control group:** Writing about time management (write about your behaviours, try not to write about your feelings) **Duration and intensity of intervention:** 15 to 20 minutes, 3 days in a row **Intervention format:** Instructions and assessments were completed at the clinic when possible, although most patients who were recruited via letters were contacted only by telephone and completed all measures at home **Intervention delivered to patients by:**	
Outcomes	Asthma symptoms, affect, internalizing behavior problems, and functional disability; parents independently completed measures of the teen's internalizing behavior and functional disability. Lung function (spirometry) was tested when possible.	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	A random numbers table was used to randomize participants to groups separately for each gender.
Allocation concealment (selection bias)	Unclear risk	Suspected low, but not addressed directly." Participants were telephoned by a research assistant who reminded them to open an envelope that contained group-specific instructions, writing packets, and pre- or postwriting questions and to begin writing"
Blinding of participants and personnel (performance bias) All outcomes	High risk	No method of blinding described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The researcher was blind to group assignment during recruitment and baseline assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	"The 11 noncompleters and the 50 completers were similar on demographic, asthma history variables (presence of allergies, controller medication, and hospitalizations), and baseline levels of the outcome measures (all $p > .60$). Noncompleters came equally from both writing conditions ($p = .93$), indicating no differential group attrition. Both disclosure participants who were less than fully adherent were retained in analyses. The results on the intent-to-treat sample were identical to or slightly stronger than those on the

		50 completers, including significant group main effects on PA (p = .007) and both parent-rated (p = .02) and adolescent-rated (p = .05) internalizing behaviors."
Selective reporting (reporting bias)	High risk	Data collected at 1 month, but not included in analyses
Other bias	High risk	Sample mainly conssis of Caucasian individuals (90%) and financially well off (54%), therefore not representative

Yang 2004

Study characteristics	
Methods	**Study design:** RCT **Method of recruitment:** 578 qualified cases were selected from 1438 asthmatic children visiting the Bo'ai Hospital. 64 of these were randomly selected as subjects **Method of randomisation:** Not described
Participants	**Number eligible for study:** 578 **Number randomised:** 64 **Number completed:** 64 **Age (mean, range):** 10.35 years **Gender (N and % female):** n=26, 40.6% female

	Setting: Asthmatic children in the computer database of asthma specialist in the Department of Pediatrics, Bo'ai Hospital, Zhongshan City, China **Severity of condition:** Mild to moderate **Inclusion criteria:** Diagnosis of asthma as per GINA criteria, aged 8 to 14 years with more than one history of non-acute asthma attack period with mild to moderate course of disease, no intelligence or congnitive disorder, patients and parents willing to participate **Exclusion criteria:** Organic psychiatric diseases **Any baseline differences?:** There were no significant differences of gender, age, education background, family background, grade of asthmatic situation and the courses of disease between the two groups ($p > 0.05$), which indicated an equilibrium between data of two groups
Interventions	**Type of intervention:** Relaxation training **Intervention description:** Correct application of the recording tape with relaxation training in horizontal position was taught to the children and their parents by experts. Half an hour before sleep at night, patients quietly laid on the bed with their eyes closed to relax the 11 muscle groups of entire body in turn according to the instruction. **Control group:** No relaxation training **Duration and intensity of intervention:** 4 weeks **Intervention format:** **Intervention delivered to patients by:** Training delivered by "experts", then via instructional recording

Outcomes	Score for anxiety and depression, score of asthmatic symptoms during day and night, days without asthmatic symptoms, asthma attack and time of aggravation	
Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Participants selected from eligible patients - method of selection not described
Allocation concealment (selection bias)	Unclear risk	No method described
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding described
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding described

Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals
Selective reporting (reporting bias)	Unclear risk	N values changed between results tables (table 1, study=33, control=31. Table 2, study =31, control=33).
Other bias	Low risk	No other sources of bias identified

Study	Reason for exclusion
Aby 2020	Adult population
ACTRN12613000675729 2013	Could not recruit for study
ACTRN12615000582550 2015	Wrong intervention
ACTRN12616001253493 2016	Doesn't separate asthma data
ACTRN12617000212358	Wrong intervention
ACTRN12617000614392	Wrong intervention
Agnihotri 2013	Wrong intervention
Ainsworth 2022	Adult population
Alexander 1972a	Wrong study design
Alimohammadi 2018	Wrong intervention

Anonymous 1968	Doesn't separate asthma data
AstraZeneca 2022	Wrong intervention - education intervention aimed at pulmonologists and nurses
Austin 2021	Wrong intervention - basis not in psychological theory

3.4 Characteristics of excluded studies

Study	Reason for exclusion
Balfour 1957	Adult population
Barendregt 1957	Adult population
Ben-Zvi 1982	Wrong study design
Bosley 1995	Wrong study design
Castes 1999	Wrong study design
Celano 2012	Wrong intervention
Chadi 2019	Doesn't separate asthma data
Chernoff 2002	Doesn't separate asthma data
Cluss 1986	Wrong study design
Coen 1996	Adult population
Creer 1970	Wrong study design
Dardouri 2021	Wrong intervention
Davis 1973	Wrong intervention
Davis 2021	Wrong intervention - no explicit psychological focus, asthma self-management
Deenen 1996	Doesn't separate asthma data
Ducharme 2005	Wrong intervention
Dwinger 2013	Adult population
Ecker 2001	Wrong study design
Ecker 2009	Wrong study design
Ellis 2016	Wrong intervention
Erdogan 2020	Adult population
Ernst 1999	Wrong study design
Erskine 1979	Adult population
Ewer 1986	Adult population
Fedele 2018	Wrong intervention
Fedele 2019	Wrong study design
Fedele 2021	Wrong intervention - no explicit psychological focus, asthma self-management
Fedele 2022	Wrong intervention - no explicit psychological focus, asthma self-management
Fernandes 2012	Adult population

Fernandez 1993	Wrong study design
Field 1998	Wrong comparator
Gamble 2011	Adult population
Gardner 1968	Wrong study design
Gebert 1998	Wrong intervention
Georga 2018	Adult population
Georga 2019	Adult population
Gerald 2009	Wrong intervention
Golan 2017	Wrong intervention
Groller 1992	Wrong study design
Grover 2002	Wrong study design
Grover 2007	Adult population
Hammelehle 2022	Wrong population - not asthma
Hampel 2003	Wrong study design
Harris 2022	Wrong intervention - no explicit psychological focus, theatre intervention delivered to schools
Hockemeyer 2002	Adult population
Holley 2018	Wrong intervention
Holmes 2022	Wrong intervention - no explicit psychological focus, asthma self-management
Hoskins 2013	Adult population
IRCT20100919004775N10 2018	Adult population
IRCT20170611034471N1 2018	Wrong study design
IRCT20211102052946N 2022	Wrong intervention - no psychological focus
IRCT20220106053642N 2022	Adult population
Isik 2021	Wrong intervention - not based in psychological theory, asthma self-management
Joseph 2018	Wrong intervention
JPRN-	Wrong study design - single-arm, non-randomized. Educational intervention

UMIN000039058 2020	with counselling element.
JPRN-UMIN000046775 2022	Doesn't separate asthma data
Kahrizi 2017	Adult population
Kamps 2008	Wrong intervention
Kashaninia 2018	Wrong intervention
Kern-Buell 2000	Doesn't separate age data
Khan 1973	Wrong intervention
Khanpour 2015	Wrong study design
Kinnell 1979	Wrong study design
Kintner 2009	Wrong intervention
Kotses 1991	Wrong intervention
Larbig 1980	Doesn't separate asthma data
LaVelle 1998	Wrong intervention
Lehrer 1994	Adult population
Loewy 2020	Wrong intervention
Maher 1962	Doesn't separate age data
Maher 1969	Wrong study design
Maher-Loughnan 1970	Wrong study design
Mallouli 2022	Wrong intervention
Mancuso 2009	Adult population
Marriage 2012	Wrong study design
Martin 2020	Wrong intervention
Miklich 1977	Wrong study design
Moore 1965	Doesn't separate age data
Mosenzadeh 2019	Wrong intervention
Mosler 2020	Wrong study design
Murphy 1989	Adult population
Nasiri 2018	Wrong study design
NCT00094276	Doesn't separate age data

2004	
NCT00140439 2005	Wrong intervention
NCT00217906 2005	Wrong population - very young paediatric population
NCT00233181 2005	Wrong intervention

Study	Reason for exclusion
NCT00250588 2005	Adult population
NCT00359775 2006	Doesn't separate asthma data
NCT00384813 2006	Wrong intervention
NCT00516633 2007	Wrong intervention
NCT00910585 2009	Wrong intervention
NCT00916240 2009	Wrong intervention
NCT01079000 2010	Adult population
NCT01175369 2010	Wrong intervention
NCT01381159 2011	Adult population
NCT01675921 2012	Wrong intervention
NCT02141893 2014	Wrong intervention
NCT02293499 2014	Wrong intervention
NCT02374138 2015	Wrong intervention
NCT02405962 2015	Wrong patient population
NCT02571309 2015	Wrong intervention
NCT02575326 2015	Wrong intervention

NCT03066596 2017	Wrong intervention
NCT03446365 2018	Wrong intervention
NCT03536416 2018	Wrong intervention
NCT03938324 2019	Wrong intervention
NCT04089085 2019	Wrong study design
NCT04230369 2020	Adult population
NCT04373499 2020	Wrong intervention
NCT04442646 2020	Adult population
NCT04448002 2020	Wrong intervention
NCT04691557 2020	Wrong intervention
Nekooee 2008	Wrong intervention
Ng 2008	Wrong intervention
Nowobilski 2005	Adult population
NTR2626 2010	Adult population
Perez 1999	Wrong intervention
Perrin 1992	Wrong intervention
Pokladnikova 2013	Adult population
Pommer 2012	Adult population
Pouwer 2010	Adult population
Pringuetg, 1964	Wrong study design
Put 2003	Adult population
Rakos 1985	Wrong intervention
Rhee 2012	Wrong intervention

Rhee 2021	Wrong intervention - designed to test the impact of peer vs adult-led interventions - both education and discussion focussed not psychological theory
Rietveld 2000	Doesn't separate age data
Schaeffer 1975	Adult population
Scherr 1975	Wrong study design
Sigurdardottir 2013	Wrong study design
Smith 2021	Adult population
Sommaruga 1995	Adult population
Spurgeon 2005	Adult population
Srof 2012	Wrong intervention
Stepans 2000	Adult population
Stoop 2015	Adult population
Streisand 2018	Wrong intervention
Sun 2010	Adult population
Sutanto 2016	Adult population
Tan 2019	Adult population
Teach 2021	Wrong population - intervention aimed at parents
Thomas 2009	Adult population
Van Bragt 2014	Wrong intervention
van Es 2001	Wrong interention
Vazquez 1992	Wrong study design
Vazquez 1993	Wrong study design
Vazquez 1993a	Wrong study design
Wagaman 2000	Adult population
Walders 2003	Wrong intervention
White 2001	Adult population
Wilkening 1999	Wrong study design
Xi 2015	Adult population
Yeh 2016	Wrong intervention
Yorke 2016	Adult population
Yorkston 1979	Adult population

Zargar 2022	Adult population
Zhang 1999	Adult population
Zhang 2017	Adult population
Zhang 2017a	Adult population
Zorc 2011	Wrong intervention

3.5 Summary of direction of effect

Author year	**Final sample (analysed)**	**Longest follow-up (months)**	**Anxiety (Analysis 1.1)**	**Depression (Analysis 1.2)**	**Medical contacts (Analysis 1.3)**	**Asthma attacks (Analysis 1.4)**	**Asthma symptoms (Analysis 1.5)**	**Medication use (Analysis 1.6)**	**Quality of Life (Analysis 1.7)**
Alexander 1972	44	Post-test							
Barikani 2021	46	2						⇑	
Beebe 2010	22	6	⇑			~			~
Bruzzese 2008	23	2					~		
Bruzzese 2020	**61**	**2.6**			⇑		~		~
Chiang 2009	48	3	~				~	~	
Colland 1993	**195**	**12**	**Λ**						
Dahl 1990	19	1					Λ	⇑	
Gustafsson 1986	18	42			⇡			Λ	
Halterman 2021	***377***	***7***			~			⇗	~
Hock 1978	43	2				⇑		⇡	
Khoshnavay Fomani	48	Not reported							Λ

2013									
Kohen 1996	13	24			⇑				
Lask 1979	29	12					⇑		
Loew 1996	18	Post-test							
Marsland 2019	**104**	**2-4**	~	⇑			~	~	~
Naar 2018	**167**	**7**			~		⇑	⇑	
Pulgaron 2010	41	4-5							~
Taheri 2019	**64**	**3**					⇑		
Tong 2002	23	12							
Tseng 2020	**83**	**1**					~		
Wang 2012	39	3							
Warner 2006	**50**	**2**					~		
Yang 2004	**64**	**1**	⇑	⇑		⇑	⇑		

Section 5

5.1: Constructs of the TFA with supporting participant quotes.

TFA Construct	Example quotes	Participant
Anticipated affective attitude	*"I think certainly novel in a different way of engaging. So that's going to reach different audience or reach the same audience in a slightly different way. So, like I said, it just broadens out your options a little bit sometimes that, just that engagement, "Oh, this is different" people tune in because it's different."*	Health professional
	"I think it's really cool thing, especially if you're like going through therapy to help with your fears or something like that. I find that very cool. And, amazing."	Young person with asthma
	"If they were informative and, you know, gave the patient lots of information and alternatives and if they are really well done, then, then that would be great."	Parent of young person with asthma
Experienced affective attitude	*"Uh, I, I must admit I had kind of maybe more ridiculous expectations. Like I thought it would be a matter of just like coming up in front of me somehow as opposed to having to look through the pyramid. Yeah."*	Health professional (about holographic technology)
	"I mean an old bloke like me think's its bloody fantastic, so I don't think there's any limit really"	Parent of young person with asthma

	"Yes of course I would. These like really work, very informative and very, very calming"	Young person with asthma, when asked if they would use these tools
Anticipated effectiveness	*"Um, it's just another learning tool. But, um, one that would address so many different types of learning types being able to see, do yeah. Um, yeah. Rather than just reading on paper and things like that. Yeah. So many people are visual learners."*	Health professional
	"Um, yeah, definitely. It would help. A lot because you know a lot of people spend most of their time on their phones nowadays, having an app like that. Well, you know, it would probably help a lot and you would be more, you know, you would probably use it more."	Young person with asthma
Experienced effectiveness	*"Can't see why they wouldn't benefit any more than any other way of doing it? Again, it comes down to engagement. This is a tool that is bound to be engaging. If the content is good, then it should, should be effective."*	Health professional
	"I suppose as an adjunct to other therapies it might, it would be worth trying. Um, yeah. So it might be a different way of trying to get someone to engage in some breathing or relaxation exercises. Um, maybe they're going to be more interested than they might if it was just a audio track."	Health professional
	"Um, not really. I mean, it serves a purpose and does, does the job. Yeah. Um, yeah, it's	Parent of young person with asthma

	already bright and colourful and right there, and it's got that 3D aspect and you know, it's a good tool for kids to help understand something and see it visually. So, no, I think it's good."	
	"Yeah, it definitely would. It would like, you know, if you were in a place that, you know, that was kind of like making you, you know, you know, like very stressed and that. If you put like the headset on that was there, you'd forget that you're there. And like with the meditation, it can also like, help you calm down and then, you know, bring you to a state where you just feel calm and you're ready to go back."	Young person with asthma, when asked if delivering interventions via virtual reality would be a good idea
Ethicality	*"Uh, it's got advantages and disadvantages. – But it was a concern because that can be falsely reassuring. And some of these children were, um, uh, at risk or identified as being at risk in terms of neglect and abuse. And sometimes physically seeing a child is, is important"*	Health professional
	"Um, I think I have concerns over privacy and access to data and so on, in particular as most, um, servers seem to be based overseas. And so the question of what happens to your data is a significant one and probably one that needs to be thought through carefully with some of, some of the things that we, we do, you know, in our line of work."	Health professional
		Health professional

	"I think the only risk is around that. I don't mean this in a bad way, but around compliance and that understanding that if you give the technology intervention and then they go do it and you say, "how was that?" and they go "good". what does, and then trying to unpack. So what did they get out of it? Did they, did they have interaction with it or did they just sort of go through the motions with it? Did they understand if there's language in it? Do they understand the, sort of the language or the concepts behind this? I think the risk is around that sort of meaningful engagement as opposed to just having it." *"And what happens if your internet breaks down?"* *"I think that it's important that not everything is self-diagnosed and then self referred to sort of technology treatments, I suppose. I think probably having an element of, um, human interaction is important. I think one of the things that doesn't get discussed with, um, sort of online, um, you know, treatment programs for anxiety is just the actual benefit of connection with someone which may be the underlying issue rather than, even though someone might be saying that depressed, connection's a big part of treatment of depression or anxiety as well."*	Parent of young person with asthma Health professional

Anticipated opportunity costs	*"If it was really quality information, um, and it engaged them more than say, just chatting with me, like if they're really engaged and really taking it in and, um, the information was good, then it would be a really good use of time."*	Health professional
	"I would be unlikely to use my time to do this sort of teaching or, or, um, therapy."	Health professional
Experienced opportunity costs	*"Uh, I don't feel like they would be hard to learn how to use, so I don't feel like you'd been losing a lot of other productivity time or anything like that. I think it would have been fairly straightforward to learn how to use them, um, and then potentially become a really good use of your time because while they're watching whatever it is for however long it goes for, you can be, you know, setting up something else for them or working on something else. And they've got that information, you check back in with them to see, you know what they've gotten from it and sort of build from there, I guess."*	Health professional
	"The benefits outweigh, you know, you just, it's just, it's something else to learn, but that's fine. It's good benefits to it."	Parent of young person with asthma
	"Oh, that's, I mean, that's very simple. Um, so I think, um, I think you couldn't ask for something to be more accessible than that really. Um, with the link and, um, and, bring up the app and um, and just watch it."	Parent of young person with asthma

Anticipated burden	*"Depending on what age you were."*	Parent of young person with asthma
	"Um, no, not really. It really depends, like you know how there's like millennials and gen Z and that. I'm not really that known on those things, but yeah, like those people, like they would know a lot about technology, but the older ages, um, yeah, some people do, have learnt to develop like a known thing about technology. So I feel like it would be really easy to use. Yeah."	Young person with asthma
	"I'm assuming it's probably not difficult to use. Yeah. Technology seems to get more, more advanced and it doesn't seem to be that tricky."	Health professional
Experienced burden	*"The only thing I thought that it was obviously fiddly. That's obviously something you will work on as you develop it."*	Health professional, when asked about holographic technology
	"Yeah. I think like [child's name] and that would probably handle it quite readily and accessible. But for me, the technology side of it, I'd sort of have trouble with."	Parent of young person with asthma
	"Oh, that's, I mean, that's very simple. Um, so I think, um, I think you couldn't ask for something to be more accessible than that really. Um, with the link and, um, and, bring up the app and um, and just watch it."	Parent of young person with asthma

	"Um, it could be, yeah. It could be easy to use. I would call that one of the easier things to you, you know?"	Young person with asthma, about augmented reality technology
Self-efficacy	*"Um, yes, because if I know how to turn on an app and register information, yes."*	Health professional, when asked if they would be comfortable using apps/technology
	"Probably difficult for my age group. Um, because you know, we didn't grow up with them, but the kids it's just like, they don't find it difficult at all."	Parent of young person with asthma
	"I would personally use it. Yeah. If I was unsure about something or if I wanted to learn something, I'm like, I would definitely use this. It's good to have different resources to go to."	Young person with asthma
Intervention coherence	*"Well, young people are very visual, so I think they'll really like being able to watch that it's like it came to life. Like it was real, which I think they will like more and will engage them. And there's so much you could use that for"*	Health professional
	"Well, like if you want to be like more of a bit of an educational side, you could also, like, I guess could have been like a video, video or something of like demonstrating how asthma works and like whatnot. That'd be like really helpful to like looking at both	Young person with asthma

	like figuring out like how asthma works and how, you know, help, you know, control it." *"I'm trying to promote it cause there's a lot of, lot of kids that, you know, chronic illnesses that are quite institutionalized, that we do regular things to them that they hate. So why not try and take them off to another place and, you know, make it not as scary for them."*	Parent of young person with asthma

Key: TFA=Theoretical Framework of Acceptability, gen Z = generation Z,

Section 6

6.1 Workbook examples



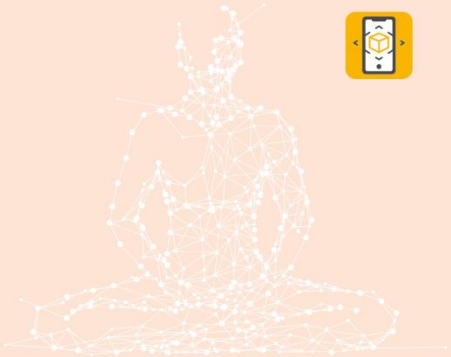


Emotions log

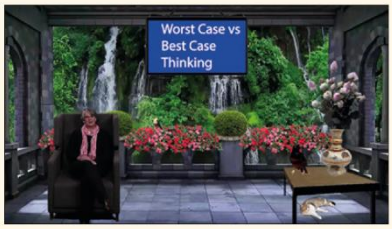
Date And Time	How Did You Feel?	How Severe Was The Feeling? (1 – 10 None — Extreme)	Where Were You?	What Happened Just Before You Felt This Way?	What Thoughts Did You Have?	Did Anything Else Contribute? (E.g. Exercise, Alcohol, Illness, Lack Of Sleep, Hunger)

Guided Meditation





Worst vs Best Case Thinking







6.2 Feasibility protocol manuscript

Title page

Title: Augmented reality technology as a delivery mechanism for psychological intervention in adolescents with asthma: a randomised controlled feasibility trial protocol.

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Abstract

Background: Australia has one of the highest rates of asthma prevalence worldwide, with almost one in 10 children affected. The mental health and wellbeing of asthmatic children is reported to be significantly more impacted than non-asthmatic peers; affecting both asthma management and their overall quality of life. The relationship between asthma and psychological distress is likely bi-directional, therefore requiring an intervention that addresses both psychological and physiological factors. Technology-based psychological interventions provide a potential solution that may increase engagement with treatment amongst adolescents. In particular, augmented reality (AR) is a novel technology that can be tailored to individual populations and has been proven effective in the management of other conditions. No evidence exists currently on the feasibility of AR in the management of psychological wellbeing within the asthmatic community.

Methods: An 80-page workbook has been developed based on best-practice asthma guidelines and through consultation with field experts in Psychology and Paediatric Respiratory Medicine, AR tools have been developed following a needs assessment, and a bespoke smartphone app has been developed by Portal Australia. Forty (n=40) young people aged 13-17 years with persistent asthma will be recruited from the Respiratory Department at the Women's and Children's Hospital. Participants will be required to download a smartphone application (YOLO de-stress) and will be encouraged to use the app for a month. Participants will be required to complete the Youth Asthma-related Anxiety Scale, Paediatric Asthma Quality of Life Questionnaire and the Asthma Control Questionnaire at baseline and one-month post-intervention. Data analysis will be descriptive, with counts and percentages for categorical data, and means and standard deviations for continuous data compared between baseline and follow-up. For continuous outcome variables mixed effects linear models will be used. For other outcome measures mixed effects generalized linear models will be used.

Discussion: This study will explore the feasibility of AR tools to aid delivery of psychological intervention to manage symptoms of elevated psychological distress among young people with asthma, and inform development of a fully powered RCT.

Trial registration: This project was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12620001109998

Keywords

Asthma, augmented reality, psychological intervention, psychological distress, adolescents

Background

Asthma in adolescence

Australia has one of the highest asthma prevalence rates in the world (1), with approximately 2.7 million adults living with the condition (2). Moreover, a 2017-18 review reports almost one in ten Australian children under 14 suffer from this chronic and debilitating condition (3). The health and mental wellbeing of young people with asthma is reportedly worse than their non-asthmatic peers, particularly anxiety and depressive symptoms. Two separate meta-analyses looking at the prevalence of anxiety disorders and depression/anxiety symptoms, reported that those with asthma display a three times increased prevalence (4) and a one in four chance of experiencing symptoms (5) respectively. Furthermore, a 2014 survey of Australian asthmatic young people (12 to 25 years), found 50% experienced symptoms of elevated psychological distress; double the general population rate (6).

Asthma and psychological distress in adolescence

The increased psychological distress experienced by young people with asthma is likely compounded by a range of social, psychological and developmental challenges traditionally experienced by adolescents (7, 8). These challenges may include social isolation, restricted independence and self-consciousness (9), which may all combine to decrease quality of life (10), increase functional impairment (11), and incur higher preventable hospital visits compared to non-asthmatic peers (12). However, it is likely the relationship is bidirectional between asthma and psychological distress (13) as psychological factors can exacerbate asthma symptoms (14-16) and potentially decrease medication adherence and proper asthma management (13). Utilising psychological interventions may assist in managing psychological distress within young people, therefore assisting in asthma management (17). One example of said interventions are ‘behaviour-based therapies’. Acceptance and Commitment Therapy (ACT) is a mindfulness-based behaviour therapy that focuses on how positives and negative thoughts and events are part of life, and encourages acceptance of thoughts and feelings (18). The goal of ACT is to build psychological flexibility to assist in building and managing a life that aligns with ones values (18). In the area of young people with symptoms of mental health conditions, an adolescent case study of a female with anorexia nervosa reported successful adoption of

ACT in practice, suggesting that despite her thoughts about body dissatisfaction, she was able to adapt her behaviour and adopt healthier eating practices (19). Furthermore, ACT has been evidenced to improve symptoms in clinically depressed individuals both immediately and 3 months post-therapy (20), and assist in the management of chronic paediatric pain as part of a behavioural medicine approach (21). Within the asthma community, ACT has been integrated into parental education and shown to be effective in decreasing parental anxiety and stress of those with children aged 3-12 (22), and improve the psychological wellbeing of adult asthmatic patients (23). While there has been evidence of ACT success with parental and adult populations, more research is needed in adolescent populations.

Technology for health interventions

The 2012-16 National Youth Mental Health Survey identified the internet as a leading source of information for youth (9), with self-help and self-reliance preferred over seeking help from professionals or family and friends (24). Unguided self-help however, varies in effectiveness due to the vast range, quality of sources available and varying retention rates (25).

To address said issues, authorities are seeking technology-based solutions to increase engagement amongst young people and tackle current barriers influencing care for both mental health (9, 10) and asthma management (9, 26). Technology-delivered psychological interventions in particular, have the means to be effective within mental health care as a low-cost, low-burden option (9). These interventions increase access and quality of care (27), preserve anonymity, and provide an alternate option to those in remote and rural locations (28). A randomised control trial combining an online ACT intervention for adults living with Fibromyalgia with their normal treatment regime increased pain acceptance significantly, which lead to a significant improvement in Fibromyalgia impact both post intervention and at 3-months follow up (29). Combining ACT interventions with normal treatments has additionally proven effective in targeting parents of, and children living with Autism Spectrum Disorder by decreasing parental stress, increasing child prosocial behaviours and decreasing hyperactive behaviours (30). Further research is needed into how best to make these online ACT interventions (similar to those aforementioned) into effective treatments for a range of other populations. One novel solution may be augmented reality (AR) technology.

Augmented reality for health interventions

AR technology superimposes digital information within the real world through a smartphone to create an interactive learning environment (31) that is able to be tailored to specific populations to promote increased user engagement (32). AR provides multiple other benefits; from improving accessibility of information and geographic reach due to its portability (33), to addressing low health literacy by utilising videos, graphics and animation rather than relying on written information (26, 31). AR has been evidenced to provide additional learning opportunities to assist in the education of school-aged children (34) and has been shown to be a feasible tool in assisting with the psychological management of phobias (35). Moreover, a 2017 pilot study reported AR as a helpful tool in education of correct inhaler techniques amongst asthmatic individuals and health professionals (36), however little evidence currently exists to support the use of AR as a delivery mechanism of psychological interventions for asthmatic individuals. To overcome previous limitations, this research will examine the feasibility of AR technology as a delivery mechanism for an ACT intervention, in order to manage symptoms of elevated psychological distress among young people with asthma.

Methods/Design

Aims

Explore the feasibility of AR tools to aid the delivery of ACT to manage symptoms of elevated psychological distress among young people with asthma, aged 13 to 17 years. This will be achieved through:

Development of a paper-based workbook and AR resources for delivery via bespoke smartphone application. These tools have been developed following a needs assessment of the biopsychosocial needs of adolescents with asthma (37), and refined based on qualitative feedback obtained in Stage 2a (38).

Evaluation of the practicality and feasibility of these ACT resources for use by youth (13-17 years), their guardians and health professionals via:

Qualitative research which has been completed and published elsewhere (38).

Randomised controlled feasibility study of AR ACT + self-help smartphone application (YOLO.de-stress) versus self-help smartphone application alone for treatment of symptoms of anxiety among young people with asthma, with one-month follow-up.

Hypothesis

Children with asthma using AR resources plus self-help smartphone app compared to children using the self-help app alone by 1-month will have:

Increased use (number of logins, total time and adherence data) of smartphone resource measured through smartphone access logs (*primary outcome*)

Secondary outcomes:

Reduced anxiety symptoms measured by the Youth Asthma-related Anxiety Scale (YAAS)

Improved quality of life measured by the Paediatric Asthma Quality of Life Questionnaire (PAQLQ)

Project Design

Stage 1: Development of workbook, AR resources + self-monitoring smartphone app

An 80-page workbook has been developed based on best-practice asthma guidelines and through consultation with field experts in Psychology and Paediatric Respiratory Medicine. Content includes educational information about asthma and/or psychological distress, and ACT strategies such as mindfulness activities (see appendix 6.1 for examples from workbook). When scanned through the YOLO_de.stress app on the participant's smartphone, printed resources will seemingly come to life with digital content via AR technology.

The AR tools have been developed following a needs assessment of the biopsychosocial needs of adolescents with asthma (This included37), and refined based on qualitative feedback obtained in Stage 2a (38). AR video content (around 1-minute duration) was filmed with a depth camera and 360^{o} digital photography using investigators from this proposal. Both real world settings and green screen backdrops were used to facilitate digital environments. AR resources have been custom-built by the investigator team using Unity software. The type of content filmed includes educational information about asthma and ACT strategies, as well as verbal and visual instruction on how to perform ACT techniques.

The self-help smartphone application has been developed by Portal Australia. It has been designed to facilitate navigation to credible online self-help websites and track self-monitoring of psychological symptoms. It will also be the access platform for AR tools. Daily symptom recordings will be displayed in four visual charts (pie, line, bar and

odometer graphs) for real-time feedback on their health management. Data from the app will be forwarded electronically to investigators and used to track app usage.

Stage 2a: Evaluation of AR resources – Qualitative research

This research has been undertaken previously (HREC/18/WCHN/172), and data has been published elsewhere (38).

Stage 2b: Evaluation of AR resources – Randomised controlled feasibility study

Aim: To determine the feasibility of undertaking a fully-powered randomised controlled trial, through a feasibility pilot study.

Participants: Forty (n=40) young people (13 to 17 years) with persistent asthma will be recruited from the Respiratory Department at the Women's and Children's Hospital. Participants will be identified through Respiratory Department inpatient and outpatient lists at the Women's and Children's Hospital, and via flyers and radio/television news stories advertising the project. Hospital staff will provide potential participants with a copy of the participant information sheet and consent form for their review. Participants recruited through hospitals will only be approached by research staff once written consent has been provided to say that they are willing to discuss the project more with research staff, in order to undertake informed consenting procedures. Participants recruited via flyers and radio/television news stories will contact research staff to begin informed consenting procedures. As this is a feasibility study, a sample size calculation is not required. A sample of n=40 participants will be sufficient based on other similar studies (39, 40) to examine the primary outcome of AR smartphone resources (process measures) between the two groups.

Inclusion criteria:

Young people will be eligible for inclusion in this study if they: are aged between 13 and 17 years; have been formally diagnosed with asthma by a health professional; have experienced or are currently experiencing heightened symptoms of anxiety determined by self-report on the K10+ questionnaire; have access to a smartphone with the owner's permission to use it; are English speaking/able to understand written English.

Exclusion criteria:

Participants with an intellectual disability or cognitive impairment that would inhibit their ability to provide informed consent and participate in the project will be ineligible to participate.

Procedure: Hospital staff will provide potential participants with a copy of the participant information sheet and consent form for their review. Participants will only be approached by research staff once written consent has been provided to say that they are willing to discuss the project more with research staff, in order to undertake informed consenting procedures. Research staff will meet with potential participants to conduct eligibility screening and informed consenting procedures in meeting spaces in the respiratory department at Women's and Children's Hospital (WCH), in meeting spaces at the South Australia Health and Medical Research Institute (SAHMRI), or online via Zoom, at the participant's convenience. Randomisation was performed in Microsoft Excel using the "=Rand()" function. Forty participant ID numbers were listed in column A, the =RAND() function was then applied in column B. A filter function was added to both rows, whereafter column B was sorted from 'Largest to Smallest'. The first 20 numbers were allocated to Cohort #1 (Control), the second lot of 20 numbers were allocated to Cohort #2 (Intervention). This randomization process was conducted by a volunteer who was not involved in the recruitment, interview, or analysis process conducted in accordance with this project. The primary researchers (KS, KVCC) were blinded to the allocation of participant IDs to cohorts. Data analysts will also be blinded to group allocation.

Following consenting, screening, and randomisation processes, baseline assessments will be conducted, including completion of the Youth Asthma-related Anxiety Scale (YAAS), the Paediatric Asthma Quality of Life Questionnaire (PAQLQ), and the Asthma Control Questionnaire (ACQ). The smartphone app (YOLO de-stress) will be downloaded onto participant smartphones, and they will be provided with a tutorial by research staff. Intervention participants will also be provided with a copy of the workbook, and shown the AR tutorial. All participants will be asked to use the app for the one-month study period, during which time they will be presented with a booster session encouraging app usage through positive affirmation via push notifications at weekly intervals post-recruitment.

At 1-month post-intervention, research staff will again meet with participants in meeting spaces at WCH, SAHMRI, or online via Zoom. Follow-up assessments include completion of the YAAS, PAQLQ, ACQ.

Data analysis

Participant flow through the trial will be displayed using a CONSORT diagram. Analysis of the questionnaire data will be descriptive, with counts and percentages for categorical data, and means and standard deviations for continuous data compared between baseline and follow-up. Missing information from quantitative scales and surveys will be accounted for through random imputation. Drop-outs or loss to follow-up will be compared between study arms, and against those remaining in the trial. For continuous outcome variables mixed effects linear models will be used. For other outcome measures mixed effects generalized linear models will be used.

Data management

Participants will be de-identified, and will be provided ID numbers as opposed to names. De-identified data will not be stored in the same place as identified data (e.g. names, contact numbers). All data collected will be stored electronically in a password protected database on the secure University of South Australia network, while all hard copies will be stored in a locked filing cabinet in the South Australia Health and Medical Research Institute building. It will be stored for seven years in accordance with responsible research guidelines.

As the developers of the smartphone application, Portal Australia will have access to all the data in the system for the purpose of providing a working system, and exporting any data needed for analysis. They will not keep any data beyond the study. They will not have access to any identifying information about participants as that lives outside the system – participants will be registered to use the app by study staff, and will use an ID number to log on.

Discussion

This randomised controlled feasibility study will explore the feasibility of AR tools to aid the delivery of ACT to manage symptoms of elevated psychological distress among young people with asthma, aged 13 to 17 years. While evidence in other areas of healthcare and education is promising, little research has been conducted to support the use of AR as a delivery mechanism of psychological interventions for asthmatic adolescents.

Participants will receive a report once the project has been completed. Additionally, where appropriate, participants will receive a copy of any subsequent publications. Upon completion of the project, data will be synthesised for use in publications and conferences.

Reports will be provided to participants and relevant consumer stakeholders, as well as funding bodies as per requirements. All ethical reporting procedures will be followed.

This study will provide essential pilot data to guide development of a grant submission for a fully powered RCT if shown to be feasible.

List of abbreviations

ACQ – Asthma Control Questionnaire

ACT – Acceptance and Commitment Therapies

AR – Augmented reality

IM – Intervention Mapping

PAQLQ – Paediatric Asthma Quality of Life Questionnaire

SAHMRI – South Australian Health and Medical Research Institute

WCH – Women's and Children's Hospital

YAAS – Youth Asthma-related Anxiety Scale

Declarations

Ethics approval and consent to participate

This project is conducted in accordance with the principles of the Declaration of Helsinki (41) and has received ethical approval by the Human Research Ethics Committee for the Women's and Children's Health Network (2021/HRE00055), and the University of South Australia Ethics Committee (Application ID: 204144).

Consent for publication

Not applicable

Availability of data and materials

All data collected will be stored electronically in a password protected database, while all hard copies will be stored in a locked filing cabinet in the South Australia Health and Medical Research Institute building.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors contributions

KCC is overseeing all aspects of the project, from design to implementation to analysis and interpretation of data; AT provided expertise and knowledge of asthma, contributed to the development of AR resources, and will assist with recruitment from hospital sites; RS provided expertise for the development of AR technology; AE provided statistical analysis guidance; IG is responsible for creative design input for AR resources; DS provided expert clinical knowledge about mental health issues, and contributed to the development of AR resources; KJS is responsible for project management and manuscript production; all authors provided feedback on the draft, and approved the final manuscript.

Acknowledgements

Not applicable.

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6.3 Example of recent grant application based on this work

Excerpt from the WCH Foundation 2023 Bloom Grant Round

Please provide a description of the proposed project, including project rationale, aims and objectives, and a brief project plan.

RATIONALE: South Australia (SA) has one of the highest rates of asthma in the world, and SA children have the highest rate of asthma hospitalisations in the entire country. Asthma is the largest chronic illness among Australian children aged 0-14-years, it can be life-threatening, yet 70% of deaths and 30% of admissions are preventable. Many 'basics' of good asthma management are not done well: 90% of asthmatics are not using their inhalers correctly, 70% do not have an asthma action plan and 55% have poor medication adherence, costing Australian hospitals $239million in 2015 alone.

FOUNDATIONAL RESEARCH: Over the past nine-years our team of clinicians (respiratory and clinical psychology), allied health professionals, researchers, policy makers, asthmatics, carers and key community stakeholders (e.g., representatives from Asthma Australia, Lung Foundation of Australia and the Thoracic Society of Australia and New Zealand), have partnered with the extended asthma community to co-design a multifaceted solution to these issues. Together, we co-designed four technology-enabled prototypes to deliver asthma self-management education, including smartphone applications capable of delivering content through augmented reality, virtual reality and holographics. We used evidence from our systematic reviews and qualitative research to co-design these prototypes, enhancing acceptability, usability, practicality, and implementation feasibility for one combined artificial intelligence (AI)-based smartphone application, called Asthma AI+.

AIMS/OBJECTIVES: To achieve our overarching objective of reducing the disproportionate burden of asthma among Australian children, families and society, our aim is to clinically validate effectiveness, safety, and feasibility of the Asthma AI+ app at 12-week follow-up. Additionally, we will continue to build evidence translation pathways with organisations such as Asthma Australia, who want to disseminate our app nation-wide to asthma patients and families contacting their call centres.

PROJECT PLAN: A randomised controlled trial of our Asthma AI+ smartphone application that includes symptom monitoring, will be compared to our symptom monitoring alone app (pilot ethics/governance already approved). A total of n=460

asthmatics aged 8-18- years presenting to WCH will be recruited over two-years. Health professionals (HPs) across respiratory, general medicine and the emergency departments will be trained by research/clinical personnel in how to recruit asthmatics/families into the trial, removing the need for direct researcher involvement. Active recruitment by HPs will be supplemented with hospital-based advertising materials (posters/flyers). Informed consent, randomisation, intervention delivery and data collection will all occur inside the app through in-app tutorials, with researcher support accessible via the app and a bespoke website. These approaches were specifically chosen to reflect standard clinical care and thus one potential evidence translation pathway for future service delivery. Just-in-time adaptive intervention (JITAI) methodology, successfully applied in other contexts by AI Mayer, an expert in AI, will ensure the right type/amount of intervention support is delivered via our app, at the right time, by adapting to individual characteristics and changing internal/contextual states. The primary outcome is change in Asthma Control Questionnaire (ACQ) at 12-week follow-up, with secondary outcomes including improved self-efficacy, knowledge, quality of life, inhaler technique, and reduced symptoms of psychological distress (anxiety/depression/stress), hospital utilisation and health care costs at 12-weeks and 12-months.